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/[Opinion N°(same as opinion number)]

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

Draft date: [16/03/2023]

16/03/2023

RES-O-0000007226-75-01/F

[Date]

[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

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

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

Co-rapporteur, appointed by RAC: Bridget GINNITY

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **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** of all members having the right to vote.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Jean-Marc BRIGNON

Co-rapporteur, appointed by SEAC: Johanna KIISKI

The draft opinion of SEAC

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

[The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.**] [**No comments were received from interested parties during the consultation in accordance with Article 69(6)(a).**]**.

[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.**] [**No socio-economic analysis, or the information which can contribute to one, were received from interested parties during the consultation in accordance with Article 69(6)(b).**]**.

The draft opinion was published at https://echa.europa.eu/restrictions-under-consideration on **dte_2nd_public_consult_start**. Interested parties were invited to submit comments on the draft opinion by **dte_2nd_public_consult_deadline**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]]**.

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

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

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Tables

Figures

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	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.

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

Column 1	**Column 2**
or not they contain a substance falling within this column of this entry.]	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 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 should be excluded from the scope of the restriction.

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

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

PFAS have attracted regulatory scrutiny due to their ubiquitous persistence in the environment. If releases of PFAS 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. Such exposures are practically irreversible.

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

Due to the above-mentioned hazardous properties, a quantitative risk assessment is 'impracticable', but instead a 'case-by-case' risk assessment was performed in accordance with paragraph 0.10 of Annex I to REACH. 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**, rather than specific PFAS or groups of related PFAS, is appropriate to address the risks from PFAS in firefighting foams, including those arising from so called 'regrettable substitution' in the future.

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

tests for alternative foams and application methods for these scenarios[5]. To minimise the adverse socio-economic impacts associated with the phase out of PFAS-containing foams, including any potential to compromise fire safety, specific transitional arrangements (i.e., transitional periods) are proposed by the Dossier Submitter for each type of use and user sector where alternatives are not yet readily available. The restriction proposal includes an obligation for users to prepare 'PFAS-foam management plans' and apply best-practice risk management measures to continue to use PFAS-containing foams during any applicable transitional period.

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

The Dossier Submitter concluded that the risks from 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 RMO. The following five restriction options (RO) were analysed:

- RO1: Restriction on the placing on the market but use continued to be allowed until expiry date of the stocks;
- RO2: Restriction on the placing on the market and use after use/sector-specific transitional periods;
- RO3: Restriction on the formulation, placing on the market and use after use/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 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 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 grouping. RAC notes that non-persistent substances may be

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

excluded from the scope where sufficient evidence is available.

RAC concurs with the Dossier Submitter's hazard assessment. 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 considers the high persistence of PFAS in combination with other hazards present grounds for significant concern.

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 that releases should be minimised.

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. 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.

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 additional risk management measures which are more challenging to implement.
- The ban on formulation in RO3 stops the export of environmental pollution 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 resulting waste. RAC also recommends that the overlap with related restrictions be reviewed and steps taken to avoid conflicting requirements.

RAC agrees with the Dossier Submitter that targeted inspection activities by enforcement

authorities is a way to monitor the effectiveness of the additional Risk Management Measures 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 and that that SEAC could evaluate the impacts of such reporting.

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

ECHA Text

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 theoretically 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 the risks from PFAS in firefighting foams, including those arising from so called 'regrettable substitution' in the future. 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 environmental 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 uncertainties with respect to the composition of firefighting foams, the potential for regrettable substitution, and the difficulty in individual substance evaluation due to the group containing about 9 000 substances. 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). This also gives rise to the potential for so called 'regrettable substitution' in the future and on a wide scale. Consequently, a restriction covering the whole PFAS class, rather than specific PFAS or groups of related PFAS, is appropriate 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 a definition that was developed by OECD.

RAC notes that in the Ritscher-Zurich Statement of 2018, a broad group of scientific experts also proposed a grouping approach to PFAS rather than addressing individual chemicals.

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, giving rise to regrettable

substitution.

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. RAC notes that information was submitted during 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 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 very persistent properties or the very persistent properties of their terminal degradation product (arrowhead; see further below under 'Persistence'). Additional hazardous properties 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 are listed in Figure 1 and are further described below.

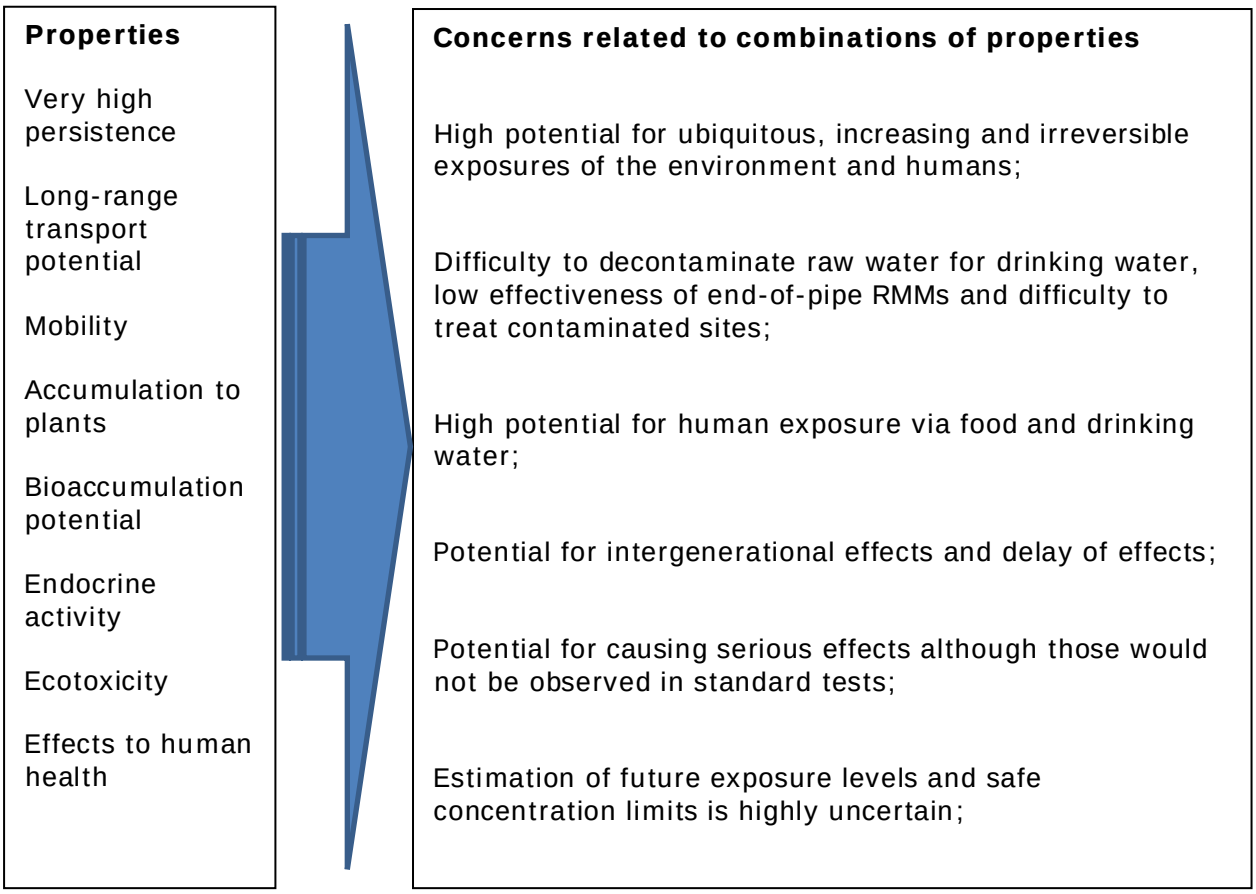

Figure 1. PFAS properties and property-related concerns resulting from combinations of the properties.

Case-by-case assessment

In cases where quantitative risk characterisation or PBT/vPvB assessment are not practicable, under REACH Annex I, paragraph 0.10[6], 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). On this basis, risk characterisation may be considered in terms of when, rather than if. 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.

[6] "*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….*".

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

Persistence

PFAS are among the most stable organic compounds. Common for all the 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 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

Based on increasing lines of evidence from modelling, laboratory and field monitoring studies, there is a justified concern for a subset of PFAS 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.

It should nonetheless be pointed out that, by now, C11-C14 PFCAs[7] and C6-PFSA[8] have been shown to fulfil the vB-criterion and C8[9]-C9[10]-C10[11]-PFCA the B criterion (vB not assessed) under REACH.

Studies with mammalian species show that PFAS are readily absorbed and distributed across various tissues and that some PFAS (particularly the long-chain PFAS) 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 not follow typical accumulation patterns, i.e. partitioning into adipose tissue, but rather bind and accumulate

[7] MSC Decision ED/169/2012

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

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

[10] MSC Decision ED/79/2015

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

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 silico, *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 all PFAS. There is however evidence for a subset of PFAS 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 effects 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 concurs with the Dossier Submitter's hazard assessment of PFAS acknowledging that the latter subgroups 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 precursors have ceased. The longer the stock is allowed to increase, the less effective the emission reduction will become. 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 breach planetary boundaries.

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 an adverse impact. 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.

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 the input during consultation on the Annex XV restriction dossier (referred to also in 3.1.1) that indicates 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[12]; HPFO-DA[13]; PFHxA[14].

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.

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

[12] 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.

[13] See footnote 12

[14] 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.

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 enrich 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 wheatgrass 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 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.

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)[15], 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 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

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

10 800 tonnes are estimated to be employed in fixed systems and about 7 200 in mobile systems. The oil/(petro-)chemical industry is by far the largest user sector of foams (59 %), but municipal fire brigades (13 %), marine applications (12 %), airports (9 %) and defence applications (6 %) also account for significant volumes. Ready for use products only account for a very small share of PFAS-containing foams (1 %[16]), 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 3 for a breakdown by sector). This represents a total of around 14 100 tonnes of cumulative emissions of PFAS over 30 years.

Table 3. Total emissions of PFAS to the environment under the baseline per sector or use*

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

*Note: Rounded figures. These are approximate values

Using a source-flow model and the assumptions outlined in 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.

[16] 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.

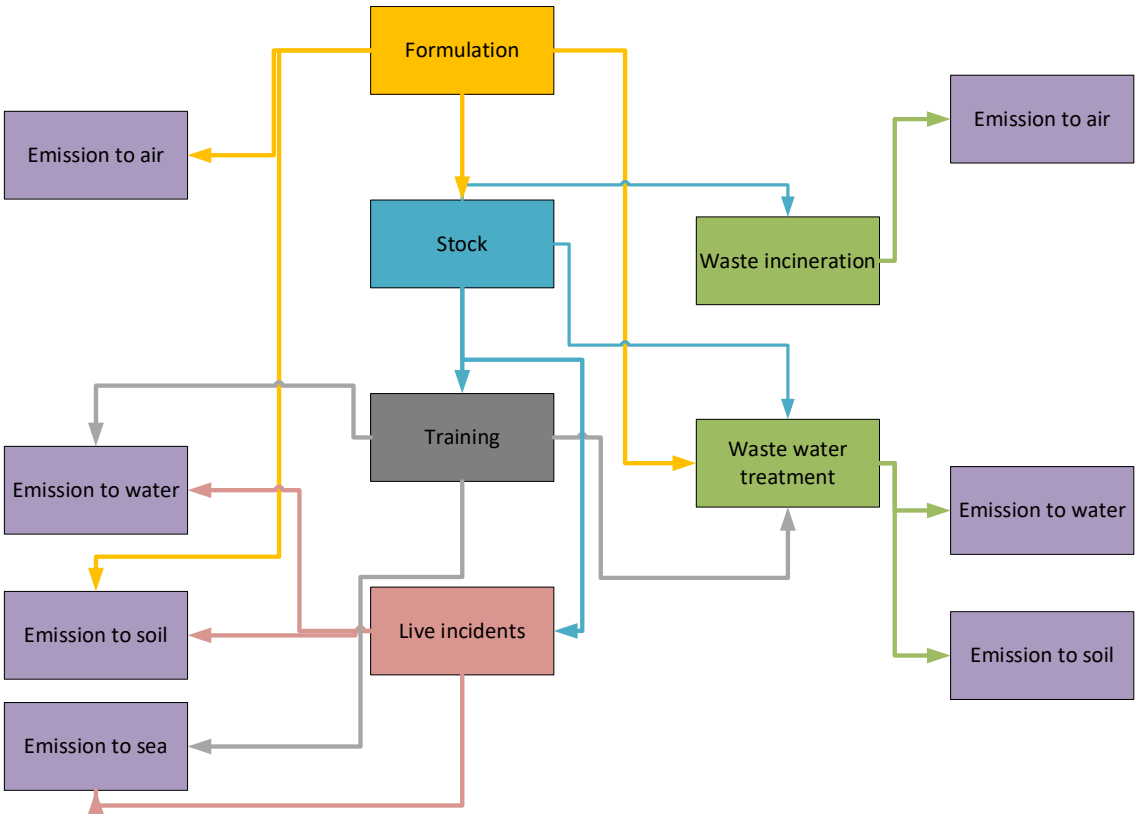

Figure 2. Material flow diagram showing the connection between the different life cycles stages of formulation, in-use, stock and waste treatment for PFAS in firefighting foams under the baseline scenario.

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. RAC considers 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 is concerned 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 imported and exported amount 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 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[17] and ECHA guidance R16[18]. 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 Cost of Inaction) and an air base in Sweden (Jakobsson 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).

[17] "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

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

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 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). This also supports the conclusion that waste water treatment is ineffective.

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 factors for hazardous waste incineration in ECHA guidance is 99.9 %[19]. 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 demonstrate 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 release estimates for 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 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 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 3.3.2.

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

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

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 as part of this restriction process 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, increasing and irreversible exposures 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 high potential for human exposure via food and drinking water. These together, in addition with the intergenerational transfer mechanisms, lead to a potential for intergenerational effects and delay of effects. Due to the complex co-occurrence of PFAS in the environment and the very long-term exposures, standard tests do not provide sufficient understanding of possible effects. Furthermore, due to the exposure to mixture 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 known to cause effects 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.

It is obvious that 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 minimise the likelihood of 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 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 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):

Assessment methodology

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 PFAS are being addressed as a group in this restriction proposal because of the common property of persistence combined with other hazards and DNEL/DMELs cannot be assigned. 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[20]. The releases are then used as a surrogate for risk.

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

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 properties of concern regarding human health and the environment associated with many PFAS give rise to a significant hazard when combined with the common property of persistence, particularly when also combined with mobility.

The continuous and irreversible 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. It has been hypothesised that environmental contamination by PFAS defines a separate planetary boundary and that this boundary has been exceeded (Cousins)[21].

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.

RAC compared the release quantities estimated here with estimates for other restrictions

[21] *Environ. Sci. Technol.* 2022, 56, 16, Outside the Safe Operating Space of a New Planetary Boundary for Per- and Polyfluoroalkyl Substances (PFAS)

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[22]. 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 from PFAS in firefighting foams, including those arising from so called 'regrettable

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

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.

There are also efforts on the Member State level. 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 and proposed restrictions have limited the use of specific PFAS in firefighting foam such as PFOA, PFHxS and PFHxA. However, 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 PFAS foams currently on the market although 11 were identified from stakeholder consultation (Annex B1.1.2.5). It is reasonable to assume that these substances, and/or their degradation products, are likely to pose a 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 the national borders within the EU, different restrictions in different Member States could make it very challenging to make firefighting foam products available for sale across the Member States. The principle of the internal market foresees that goods can move freely within the European Economic Area, enabling an open and competitive economic environment. It would therefore not be in the meaning of this principle to restrict PFAS-containing firefighting foams nationally. Moreover, due to their persistence and other supporting hazard concerns such as mobility, it is likely that 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 the risks posed by PFAS will still be observed Union-wide 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 regulatory risk management action 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):

Text

Key elements underpinning the SEAC conclusion(s):

Text

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 the Commission's choice to address the risks of PFAS, including in firefighting foams, by means of a restriction under the REACH regulation was part of the Chemical Strategy for Sustainability (CSS). As a REACH restriction is envisaged to deliver the objectives of the CSS, the assessment of alternative **novel** Union-wide legislative RMOs was not specifically considered by the Dossier Submitter. The CSS also commits the European Commission to address PFAS via a group approach to prevent regrettable substitution, improve reporting of PFAS releases into the environment (via the Industrial Emission Directive and the European Pollutant Release and Transfer Register), address PFAS via international fora such as the Stockholm Convention and establish financial support for research and innovation of PFAS alternatives as well as remediation practices.

Aside from the above-mentioned considerations on novel RMOs, the Dossier Submitter compared the relative merits of the proposed restriction with risk management via **existing** Union-wide legislation, such as the POPs Regulation (and by extension the Stockholm Convention), the Water Framework Directive, the Groundwater Directive, the Drinking Water Directive, the Marine Strategy Framework Directive, the Industrial Emissions Directive, the SEVESO Directive, and the Urban Wastewater Treatment Directive. Other analysed risk management options include voluntary industry agreements, taxation of 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 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.

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.

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

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

RAC conclusion(s):

RAC agrees that an EU-wide restriction under REACH that treat 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.

Key elements underpinning the RAC conclusion(s):

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

Control at source is the optimal approach. 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. The Stockholm Convention on POP takes a similar approach to restriction and RAC would welcome this as a global measure.

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. RAC is of the opinion that they are not sufficient in themselves to address the risk posed by all PFAS that are potential ingredients of firefighting foams, and that a wider restriction complements existing regulatory controls.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3.2. Effectiveness in reducing the identified risk(s)

Summary of Dossier Submitter's assessment:

All PFAS are 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. In such an event the exposures are practically irreversible. 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 avoided released quantities 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.

The Dossier Submitter proposed five Restriction Options (RO1 to RO5) as follows:

- RO 1: Restriction on the placing on the market of PFAS-containing firefighting foams with different transitional periods per type of use. The use of legacy foams, i.e. foams already in stock at producers' or users' sites, is still permitted.
- RO 2: Restriction on the placing on the market and the use of PFAS-containing firefighting foams with different transitional periods per type of use.
- RO 3: Restriction on the formulation, placing on the market and use of PFAS-containing firefighting foams with different transitional periods per type of use. This restriction option is similar to RO 2, but covers the additional ban on formulation (with an impact on exports) of PFAS-containing firefighting foams at the end of the longest transitional period applicable for the placing on the market in the EU.

- RO 4: Restriction on the placing on the market and use of PFAS-containing firefighting foams with different transitional periods per type of use and a derogation mechanism via a local environmental permit system to which Seveso establishments and defence sites would be eligible. This restriction option is similar to RO 2, however, Seveso establishments and defence sites would not be granted a specific transitional period but the use on these sites would be subject to the temporary approval by the relevant local/national competent authorities in charge of delivering the operating permit to the operator, based on an assessment of the risks to human health, the environment and other risks such as fire risks and the efforts made to transition to safer alternatives.
- RO 5: Restriction on all the uses of PFAS-containing firefighting foams after a transitional period per type of use, unless measures to ensure full recovery and safe disposal of all fire run-off waters and are implemented.

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

Table 4. 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[23]
Ready-to-use applications	Placing on the market: 6 months Use: 5 years
Seveso establishments	10 years[24]
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 5). 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 5. Total avoided PFAS emissions over 30 years, compared to the baseline, using the best estimate scenarios (low and high scenario in brackets), with and without (t PFAS, figures rounded)

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

[24] See footnote 15.

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.

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 disposal method to estimate the emissions to the environment from disposal. 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 and 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 environmental pollution 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, 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.

<u>General considerations</u>

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 a significant adverse environmental impact, and that any restriction that reduces or eliminates release of PFAS from firefighting use will reduce the adverse impact of PFAS on the environment and human health.

RAC evaluated the effectiveness of the proposed restriction options by evaluating and 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.

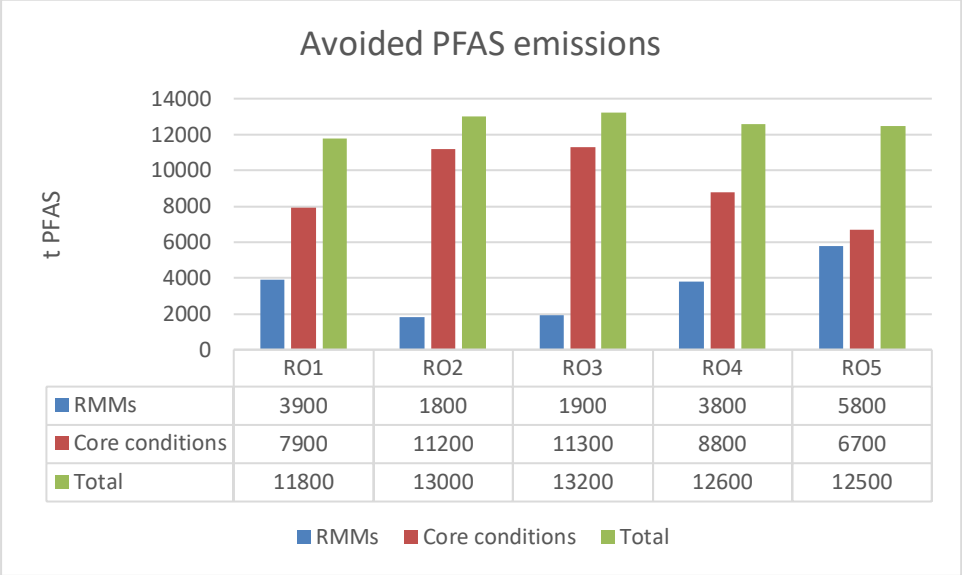

Figure 3. Avoided PFAS emissions per restriction option, and contribution of RMMs and core conditions to this reduction

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.

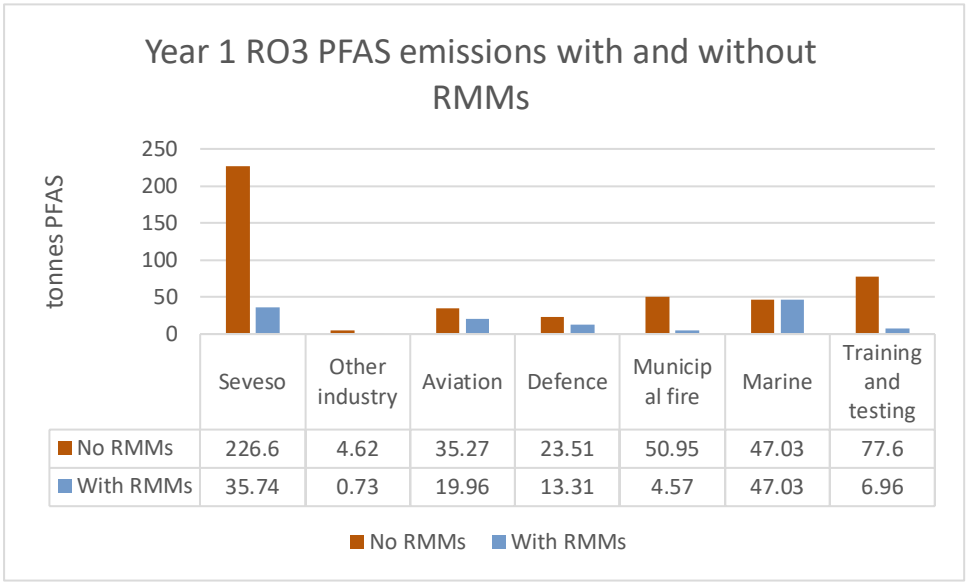

Figure 4. Estimated PFAS emissions in year 1 for RO3, indicating the impact of RMMs applicable 6 months after entry into force

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 application and 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 Documents.

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 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 exclusion. 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 current 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 GHGs. The global warming potential of 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. Input during consultation (#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 GHG 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 GHG 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 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 their identification is 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 until 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. RAC supports the inclusion of a formulation ban as it bans export 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. Input from stakeholders indicates that this is a reasonable duration in which to identify and/or 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. RAC concluded however 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 PFAS eradication under this restriction option are unwieldy. There will be many sites with differing transition periods as agreed by local permit, and the scatter 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 end 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 end 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:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3.3.2. Benefits

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3.3.3. Other impacts

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3.3.4. Proportionality

Summary of Dossier Submitter's assessment:

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

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

Sector / type of use	RO1 (€ 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.

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

Table 7. Cost-effectiveness of recent REACH restrictions

Restriction under REACH	€/kg, central value
Lead in shot in wetlands	9
D4, D5 in wash-off cosmetics	415
DecaBDE	464
Phenylmercury compounds	649
PFOA-related substances	734
PFOA	1 649

(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):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3.3.5. Uncertainties in the socioeconomic analysis

Text

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.
- that the overlap with related restrictions be reviewed and steps taken to avoid conflicting requirements.

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):

<u>Analysis</u>

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 analysis however as there is currently no standardised test for total PFAS, as identified also during consultation.

Although there is no standardised test for total PFAS, information provided in the Background Document and during 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 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.

<u>Concentration Limit</u>

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[25] 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.

RAC notes comment #3570 which includes a proposal to elevate the concentration limit for PFAS in firefighting foams for the offshore oil and gas sector regarding the concentration limit referred to in para 1 and 2. They propose this be increased 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

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 obviates the need for analysis of the runoff water and it removes 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.

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

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

In particular, 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.

<u>Use Sectors</u>

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 that they could still be placed on the market. Similar concerns were also identified by Forum and other stakeholders during the opinion forming stage.

The Dossier Submitter made substantive amendments to the proposed restriction made during opinion 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.

Legislative considerations

RAC notes that other restrictions also address the risk of specified PFAS in fire-fighting foams, a concern raised in consultation and by Forum. RAC recommends that related existing and proposed restrictions are reviewed by the Commission to ensure that conflict and confusion are avoided.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

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 is a way 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 monitorability considerations that relate to 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 have declined.

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 agrees 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 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):

Text

Key elements underpinning the SEAC conclusion(s):

Text

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 are subject to a range of 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 additional proposed 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 accepted by RAC in the opinion on the restriction proposal for 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 input 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 in the environmental compartment and considers that distribution to the air compartment 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:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

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.