

Response to comments document (RCOM)
on the Annex XV dossier
proposing restriction on
PFAS in firefighting foams

Non-confidential

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

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

Substance name	EC number	CAS number
PFAS in firefighting foams	-	-

13 January 2023

Substance: PFASs in firefighting foams

EC number: -

CAS number: -

Comments and response to comments on Annex XV restriction report submitted by **ECHA** on **14/01/2022**
Consultation on Annex XV report started on **23/03/2022**

1. General comments and answers to specific information requests

1.1. Specific information requests

In addition to providing an opportunity for interested parties to submit general comments on the proposed restriction, the Dossier Submitter and RAC/SEAC Rapporteurs posed a series of specific information requests as part of the consultation. These requests were, as follows:

1. Information on the status of PFAS firefighting foam substitution (that is not already described in the Annex XV report, annex or appendices), specifically in relation to the following applications:
 - a. Portable fire extinguishers for class B fires;
 - b. Tanks and flammable liquids in the transportation sector (rail and road);
 - c. High-temperature climate conditions within the EU (e.g. climate-change induced heatwaves);
 - d. Availability of sufficient quantities of alternatives for the replacement of stocks.
2. Are the proposed transitional periods (see Table 3 and Section 2.8.2 of the Annex XV report) appropriate to implement alternative (PFAS-free) firefighting foams (incl. any time required for additional performance testing and/or adaptation of the fire extinguishing systems/process)? If not, please:
 - a. describe the socioeconomic impacts that would occur after the end of the proposed transitional period(s). Please refer to Annex XVI of REACH for details of elements to consider in an impact assessment;
 - b. describe the socioeconomic impacts that would occur with (i) longer and (ii) shorter transitional periods;
 - c. Provide a justification for the representativeness of the information provided for a particular sector or use in the EU/EEA.
3. Paragraph 3b and 3e of the proposed restriction (see section 2.2.5) details a transitional period of 10 years after entry into force for establishments covered by Directive 2012/18/EU (Seveso III Directive; both upper and lower tiers). Are the definitions in this Directive appropriate to identify the industrial installations that require 10 years to transition to alternative (PFAS-free) firefighting foams? If not, how else could such a distinction be practically made at a European level?

4. Is the order of magnitude of the cost estimates (see Tables 4 and 5) appropriate? If not, please:

- a. justify different assumptions (see Tables 12 and 13) and cost estimations per cost category and/or industry sector/use and
- b. Provide a justification for the representativeness of the information provided for a particular sector or use in the EU/EEA.

5. Any robust, representative, data on the costs to implement operational conditions and risk management measures to minimise emissions to the environment and direct and indirect exposures to humans of PFAS in firefighting foams during the transitional periods (i.e. the requirements of paragraph 4b of the proposed restriction)?

In the absence of more specific information, the Dossier Submitter estimated these costs based on the disposal costs of PFAS-containing foams used for training and incidents (€1 000 per tonne, -50% as a lower bound and +100% as an upper bound, see also Wood et al. (2020), Table 8.14 on p. 163).

If you have more appropriate information, please

- a. justify different assumptions and cost estimations per cost category and/or industry sector/use and
- b. Provide a justification for the representativeness of the information provided for a particular sector or use in the EU/EEA.

6. Any specific information on the costs of treatment (e.g. reverse osmosis) that is effective at removing PFAS from drinking water?

7. The Dossier Submitter estimated that there are 15 million hand-held fire extinguishers containing PFAS in the EU (see 2.3.2). Are you aware of any specific information at EU or national level that would allow a refinement of this estimate? If so, please provide a justification for the representativeness of the information provided.

8. Any robust, representative, data that challenges the assumption that fire-water containing PFAS is currently sent to either on-site or urban waste water treatment plants? If so, how do they relate to Appendix 2 and 3?

9. Any robust, representative, data regarding the cost and available capacity of incinerating the retired foam stock and the PFAS-containing fire-water collected in accordance with paragraph 4d and 5 of the restriction proposal?

10. The conditions of the proposed restriction include a clause on the labelling of firefighting foam concentrates containing non-PFAS organofluorine substances (column 2, paragraph 7 of the proposed restriction) to enable enforcement without requiring targeted analysis of all potential PFAS. Would this requirement facilitate enforcement? Could it be improved?

1.2. Overview of the comments received

75 comments were received during the Annex XV consultation (see also Table 1).

Table 1 Type of stakeholders responding to consultation

Type of stakeholder	Number of comments received
Trade association	17
Industry association	16
National authority	16
Company	12
NGO	7
Individual	3
Other	3
Regional authority	1

The following themes were identified in the comments and the RCOM is structured accordingly, providing responses by theme rather than per individual comment:

- Wording of the proposed restriction text
- Substance scope and hazard assessment
- Risk and exposure assessment
- The proposed concentration limit value
- Portable fire extinguishers
- Labelling requirements
- PFAS-containing firefighting foam management plans
- Analysis of alternatives and lengths and scope of proposed transitional periods
- The assessment of cost
- The assessment of other impacts
- The assessment of benefits
- Enforcement, including analytical methods
- Disposal and treatment
- Non-foam firefighting systems

2. Response to comments

The Dossier Submitter would like to thank the many interested parties that submitted comments and information to the consultation.

In April 2022, during the consultation period, the Dossier Submitter published a 'Questions and Answers (Q&A)' document to address frequently asked questions or comments received in relation to the proposal¹. The document was updated in July 2022. This document is one element of the Dossier Submitter's response to comments. Parts of the

1

https://echa.europa.eu/documents/10162/11869254/220405_pfas_ff_webinar_qa_en.pdf/b28c7be4-01d2-dd78-835e-0e14f9b35895?t=1655226454122

Q&A document have been brought forward to the Background Document or the Annexes to the Background Document to clarify the proposal.

The Dossier Submitter notes that many of the comments received were similar in nature and concerned a limited number of common themes. Given the large number of comments received, and to improve the clarity of the Dossier Submitter's responses to them, the Dossier Submitter has prepared a set of general responses to common themes. These general responses summarise the nature of the comments received and how the Dossier Submitter has responded to them, typically by undertaking revisions to the Background Document. These general responses should be read alongside the updated version of the Background Document.

In some cases, the Dossier Submitter has responded to comments by revising the wording of the 'conditions of the restriction' (i.e. the wording of the restriction presented in Tables 2 and 6 in the Background Document). Respondents should note that the wording of the conditions of the restriction in the Background Document is intended to express the intention of the Dossier Submitter. The European Commission would ultimately decide on the precise legal wording used to update Annex XVII of REACH in the event that a restriction was adopted.

2.1. Wording of the proposed restriction text

2.1.1. Dossier Submitter response to comments

Comments were submitted by industry associations, companies, trade associations, national authorities and NGOs. These included for example comments #3543, #3544, #3548, #3549, #3550, #3552, #3555, #3556, #3561, #3566, #3596, #3607, #3612, #3614, #3627, #3633 and #3634.

Overlap with PFHxA restriction proposal:

A number of comments pointed to an overlap between the REACH restriction proposal for 'PFHxA, its salts and related substances' submitted by Germany (termed hereafter restriction of PFHxA) and the current proposal. The former also covers the use of PFHxA, its salts and related substances in firefighting foams. As decision making on this proposal is not yet concluded (i.e. the restriction is not added to Annex XVII of REACH) and it is not yet known how the decision maker will reconcile the opinions of RAC and SEAC with the Dossier Submitter's proposal), the restriction of PFHxA was not part of the Dossier Submitter's regulatory baseline i.e. the Dossier Submitter did not assume that the restriction would be added to Annex XVII and the scope of any entry. This was done intentionally to ensure that there were no gaps in the uses or substances covered by ECHA's proposal in the event that the proposed restriction of PFHxA was not adopted by the Commission. In practice, this means that there is a degree of overlap between the PFHxA proposal and the PFAS in firefighting proposal developed by ECHA and the decision maker will need to reconcile them after taking into account RAC and SEAC's opinions on the different proposals. The Dossier Submitter does not know the precise scope or timeline for the phase out of PFHxA. It could potentially be the timeline proposed by Germany or, depending on how the Commission reconcile the different proposals and opinions it could be the timeline proposed by ECHA. In general, in the event of an overlap between restrictions (i.e. where a substance is within the scope two or more restrictions) the

strictest measure would apply.

In addition, some stakeholders also pointed out that there are existing bans on certain PFAS including PFOS, PFOA and PFHxS under various regulatory regimes.

Comments #3565 and #3628 call for a harmonisation of transitional periods and thresholds for PFAS in firefighting foams, including the already existing bans on PFOA. These comments point to the time-limited derogation for the use of PFOA in firefighting foams in Annex I to Regulation (EU) 2019/1021, including the end-date to the derogation and the concentration threshold² established there.

Section 1.3.1 and 2.2.1.1 and 2.2.1.2 of the Background Document were revised to better explain how the proposal at hand relates to previous and ongoing regulatory action on PFOS, PFOA, PFHxS and PFHxA.

Legality of proposal

A number of comments related to the legal basis for the restriction proposal, in particular comment #3612.

According to Article 67 of the REACH Regulation³, a new restriction can be introduced “when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis [...]”.

The risk assessment included in the Annex XV report explains why persistence in combination with other supporting hazard properties is associated with a risk that is not adequately controlled and why risks are not hypothetical based on the properties of the substances within the scope.

It should be noted that the Dossier Submitter does not have to demonstrate that there is an unacceptable risk (Article 68 REACH) per se but that there is a non-adequately controlled risk (Article 69 REACH) and this justification is an essential part of the proposal. According to Article 69 of the REACH Regulation, a Member State has the mandate to suggest restrictions which could address a substance on its own, in a mixture or in an article posing a risk to human health or the environment that is not adequately controlled and needs to be addressed on a Union-wide basis. The proposal therefore falls within this legal basis in so far as it follows a substance approach.

The Dossier Submitter is further of the view that it is possible to restrict PFAS in firefighting foams on the basis of a broad definition of “PFAS” without listing the specific PFAS substances that are proposed to be restricted. Group entries in Annex XVII to the REACH

² Column 4, paragraph 1 establishes a concentration threshold of 0.025 mg/kg for PFOA or any of its salts present in substances, mixtures or articles. This applies to PFOA in firefighting foams after the time-limited derogation for this use ends on 4 July 2025 (subject to conditions).

³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Regulation are common and this possibility is referred to in the heading of the same Annex, (Column 1) as well as in Chapter 4.2.3 of ECHA's Guidance on restriction. For example, the guidance refers to cases where 'the key property in combination with the exposure that causes the risk leading to the proposal of a restriction is shared by several related substances'. The restriction proposal is based on the persistence of all PFAS containing at least one fully fluorinated carbon which leads to increasing concentrations in the environment and exposure to humans. Human exposures occur efficiently via all environmental exposure routes and cannot be avoided or mitigated.

The risk assessment of PFAS contained in this proposal applies the 'case-by-case' approach described in paragraph 0.10 of Annex I to the REACH Regulation⁴, i.e. where a standard risk assessment is not considered to be appropriate. The Background Document of the restriction proposal has provided justifications why a conventional quantitative risk assessment approach has not been applied. A REACH restriction is not limited to substances having legally set hazard properties, such as those underpinning SVHC or CLH. Other hazards and risks can be considered where justified.

Comment #3612 further questions the proportionality of the proposal with reference to societal costs and Article 68.1 of REACH. The Dossier Submitter would like to point out that SEAC will consider this aspect. Our initial view is that the proposal is proportionate and will be enforceable.

Definitions

Various comments pointed to missing or unclear definitions in the restriction proposal.

Reference to the REACH definition of "placing on the market" (Article 3(12)) has been added to the Background Document in section 2.3.1.

The term "use" has been further clarified in the Background Document and consumer uses of portable fire extinguishers in particular are now treated separately by the proposed restriction entry text (see also section 2.3.1 for a rationale).

Descriptions of use sectors have been added to the Background Document in section 1.3.3.

The Dossier Submitter recognises that the term "use" is defined by Article 3 of REACH and includes formulation. The targeting of both "use" and "formulation" by the proposed restriction was nonetheless maintained to ensure that the difference between the different restriction options was expressed clearly in order that their different impacts could be considered.

Contaminated equipment

Comment #3561 referred to the fact that the proposed entry text in the Annex XV report does not refer explicitly to the applicability of the concentration limit value to equipment

⁴ Paragraph 0.10 of Annex I to REACH: "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 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and shall be summarised in the safety data sheet."

previously used with PFAS-containing foams.

Section 2.3.1 of the Background Document now clarifies that paragraph 2 of the proposed restriction entry text also applies to the use of mixtures for firefighting with equipment previously potentially filled with PFAS-containing foams and therefore potentially contaminated with PFAS.

2.1.2. RAC Rapporteurs comments

RAC agrees with the Dossier Submitter's response regarding the legality of the proposal.

Aspects concerning the 'case-by-case' approach are discussed by RAC under 2.3.2, below.

RAC notes that the Background Document clarifies the meaning of 'contaminated equipment'.

2.1.3. SEAC Rapporteurs comments

SEAC generally agrees with the Dossier Submitter's answers as far as the issues are within SEAC's remit.

The issue of contaminated equipment is addressed in the reply related to comments on limit values (part 2.4.1 of this document).

In relation to the claim that the proposed restriction would be disproportionate, notably as regards societal costs (comment #3612), SEAC has evaluated the information on costs provided in the Background Document and submitted in the consultation on the Annex XV Dossier and assessed the cost-effectiveness of the proposed restriction. Also considering the expected benefits of the restriction. SEAC finds that the proposed restriction appears to be proportionate.

2.2. Substance scope and hazard assessment

Comments were submitted by industry associations, companies, trade associations, national authorities, individuals and NGOs. These included for example comments #3544, #3549, #3554, #3558, #3559, #3560, #3561, 3562, #3566, #3567, #3568, #3571, #3572, #3582, #3596, #3606, #3612, #3613, #3617, #3618, #3620, #3622, #3623, #3624, #3629, #3633, #3634. Some of these comments have been handled as confidential as per the respondent's request.

2.2.1. Dossier Submitter response to comments

Substance scope

(#3544, #3546, #3549, #3558, #3559, #3560, #3566, #3567, #3568, #3571, #3582, #3612, #3617, #3629, #3633, #3634)

Provided comments questioned the Dossier Submitter's approach to address all PFAS under the OECD definitions as one group including fluoropolymers and F-gases which they claim are not used in firefighting foam and therefore are not supposed to be covered by the restriction proposal.

The firefighting foam restriction aims to minimise emissions of PFAS in general as well as

to prevent future potential regrettable substitutions. In addition, the specific PFAS that are used in firefighting foams are not always known. Hence, a broad scope was determined for the restriction proposal, including all PFAS under the OECD definition and not only the ones that are currently known to be used in firefighting foams. That is also the reason why fluoropolymers, fluorinated gases and PFAS with only one trifluorinated or difluorinated carbon moiety present in the substance are within the scope as long as they fulfil the PFAS definition in the dossier, irrespective of the use of these substances in firefighting foams

For most PFAS which could serve as substitutes for already restricted or soon to be restricted PFAS, there are currently not sufficient data available to document, e.g., toxic effects on human health or the environment. Nevertheless, the DS sees the necessity to cover the current knowledge around toxic effects of all PFAS, also the ones already regulated. Additionally, for most PFAS in the scope of this restriction, besides persistence (including degradation to persistent substances) also at least one other supporting hazard has been identified or at least indicated (e.g., long-range transport potential, mobility accumulation in plants, bioaccumulation, endocrine activity/disruption, ecotoxicity, effects on human health).

Besides persistence and bioaccumulation, also other hazards like long-range transport potential, mobility, accumulation in plants, endocrine activity/disruption, ecotoxicity, effects on human health are considered as well in the restriction proposal. For example, in the case of PFHxA, persistence and mobility alone likely explain the frequent occurrence of PFHxA in bottled drinking water and tap water (e.g. Kaboré et al. 2018, see Annex B – section on “Mobility as a concern”).

The DS agrees that PFHxA does not fulfil the bioaccumulation criteria of Annex XIII to REACH. However, as stated in the PFHxA restriction proposal, “independent of the half-lives and regardless of the half-life in mammals the non-reversible environmental background concentrations lead to long-term continuous human exposure. Substances that have a low bioaccumulation potential could potentially reach similar levels in biota to substances that are known to bioaccumulate, provided that they are sufficiently persistent and mobile in the environment”.

Unlike Anderson et al. (2022), which addresses human health risks and stated that all PFAS should not be grouped together, persistence alone is not sufficient for grouping PFAS for the purposes of assessing human health risk, and that the definition of appropriate subgroups can only be defined on a case-by-case manner, the restriction proposal is based on an environmental concern with human health concerns as a support. Please also note that there is a disclaimer in Anderson et al. (2022) that not all authors share the same view on the mentioned conclusion.

Substance by substance assessment and regulation are not manageable for a group of substances that contains more thousands of substances. Therefore, PFAS are addressed at a group level, while assessments of the different properties are assessed at subgroup and individual substance level in the dossier. The DS considers persistence to be the main concern with PFAS, while other properties such as bioaccumulation, aqueous mobility and toxicity represent supporting concerns. In combination, it is likely that these may lead to health and environmental effects if the concentration of the substances in the environment are allowed to increase. The DS sees the substances as non-threshold substances for which a classical risk assessment is not justified.

Thank you for comments (#3568, 3629, 3633, 3634) providing data on degradation of some trifluorinated and difluorinated compounds stating those PFAS as not persistent. However, the provided information was not sufficient to carry out the necessary assessment to judge whether some PFAS should be excluded out of the substance scope of this dossier. For the purpose of such an assessment data on degradation rates/half-lives should be available and representative for degradation in all environmental

compartments (water, soil, sediment, air) for relevant conditions. Neither sole hydrolysis data nor fast degradation in air are sufficient to render a substance automatically as non-persistent. Initial results provided by one stakeholder (comment #3568) for a trifluoromethyl derivative on a soil degradation simulation test (BRI/22/LO/35973) can be considered initially worthwhile following up but the data provided were not sufficient to derive half-lives for the trifluoromethyl fragment neither to transpose the results to the relevant temperature of 12 degrees of Celsius or to other compartments.

It is noted that based on the available information on the substances used in firefighting foams, it is strongly indicated that PFAS with only one trifluorinated or difluorinated carbon moiety present in the substance are not relevant for firefighting foams. Further assessment of potentially non-persistent PFAS is therefore not further explored in this proposal.

Hazard assessment

Persistence as a sole risk

(#3544, #3558, #3559, #3560, #3571, #3596, #3606, #3612, #3633)

All PFAS within the scope of this restriction are either very persistent themselves or degrade to very persistent PFAS. However, the restriction is not solely justified by the persistence of these substances or their degradation products. For most PFAS in the scope of this restriction, besides persistence (including degradation to persistent substances) also at least one other supporting hazard has been identified or at least indicated (e.g., long-range transport potential, mobility, accumulation in plants, bioaccumulation, endocrine activity/disruption, ecotoxicity, effects on human health).

In addition to persistence, global PFAS contamination is practically irreversible since no current means are available to recover PFAS from water, soil, and air on a large scale. For many PFAS, the hazard profile remains unknown, and the Dossier submitter considers the combination of these three points (persistence, irreversibility of contamination, and additional known and unknown hazards) to justify an unacceptable risk.

The suggestion to use “degradation half-life” instead of “lifetime” when referring to Annex XIII criteria was adopted and the wording of the proposal has been amended accordingly.

Fluoropolymers

(#3558, #3559, #3560, #3582, #3612, #3617, #3623)

Several stakeholders expressed their concerns that fluoropolymers are within the scope of the restriction proposal regardless of lack of bioavailability and bioaccumulation or other negative properties related to human health.

Please see the new section B.7.5. on Hazard and occurrence of fluoropolymers.

It should be noted that the whole lifecycle of fluoropolymers should be considered. Degradation may not (only) take place during use phase of the fluoropolymers, but also in end-of-life phase (waste stage), where PFAAs can be formed. Therefore, fluoropolymers do degrade to PFAAs.

The discussion on fluoropolymers polymer low concern criteria is ongoing in the EU and not finalised yet, therefore no response can be given yet.

It is expected that non-bioavailable polymeric PFAS, such as fluoropolymers/fluoroplastics, may end up in bioavailable particles or chemicals at the end of their life cycle. Given that at any point in their lifecycle fluoropolymers may generate and/or release non-polymeric PFAS, e.g., PFAAs, in particular at end-of life, fluoropolymers contribute to the overall exposure to and hazards of non-polymeric PFAS (Lohmann et al. 2020).

Additionally, as stated in the Annex B.5.1.5 of the dossier, "Lohmann et al. (2020) argue that mass-based cut-off for fluoropolymers, as suggested by Henry et al. (2018) is not supported by the scientific literature related to bioavailability of similarly sized micro- and nanoplastics of fluorine free polymers."

The polymer fume fever is addressed in Annex B of the dossier, p. 206. These effects demonstrate a toxicological relevance of polymeric PFAS and their degradation products in acute inhalation exposure scenarios, which are however not the main focus of this restriction proposal. For this reason, the DS avoided adding more details to this hazard.

The DS appreciates the provided data on fluoropolymers (comment #3582), which mainly covers endpoints such as acute toxicity, genotoxicity, skin sens. and skin irrit. as well as in vitro cytotoxicity, and implantation hemocompatibility. However, the subchronic and chronic endpoints relevant in the dossier are not covered by these studies with fluoropolymers. The DS is mainly interested in reviewing study reports or summaries of subchronic and chronic repeated dose toxicity studies considering the most appropriate exposure routes (during the different life-cycle phases of fluoropolymers) of humans (oral, inhalation and/or dermal) with environmental PFAS and according or at least comparable to OECD TGs 407 up to OECD 413, as well as toxicity to reproduction and carcinogenicity studies.

In the environmental and human health hazard description, no incorrect statements for PVDF or other fluoropolymers could be identified. From a human health perspective, PVDF and other fluoropolymers are not necessarily directly of concern during the use phase (applied in accordance with the terms of use), but two indirect concerns remain from a human health perspective. Firstly, PVDF that is still produced with PFAS processing aid can lead to PFAS emissions to the environment from the production and impurities in PVDF products are possible, which could at some point lead to exposure of PFAS processing aids to humans through the environment. Secondly, incomplete decomposition of PVDF (irrespective of processing aids) at regular municipal incineration temperatures may lead to emissions of low molecular weight PFAS which may be of concern.

The DS agrees that PTFE or fluoropolymer is a more appropriate wording. The term Teflon was replaced by PTFE.

The DS is fully aware that TFE is not a processing aid, but a monomer used in the polymerisation to PTFE. This will be amended accordingly. Processing aid was replaced by monomer in the sentence referring to Zapp (1962).

TFA and fluorinated gases

(#3559, #3560, #3571, #3624, #3629, #3633)

The scope of the restriction proposal is limited to the use of substances in mixtures for firefighting.

The purpose of the description of available toxicological studies and effects is to give an overview on possible effects of PFAS (including F-gases) at any concentration, not including risk assessment for specific uses. In Annex B.5. the hazards of PFAS are documented and not their risks.

Regarding the persistence of F-gases, the primary concern is chemical degradation in the atmosphere to TFA (and similar substances) which precipitates with rain and snow and ends up in the aqueous environment as persistent substances. Although there are currently no formal criteria for M and vM substances, mobility in the environment of a substance represents a concern and is described for PFAS in the dossier.

The DS is of the opinion that the term "[F-gases] contribute substantially to climate change" is precise and correct. Furthermore, it is explained in the dossier that there are low-GWP F-gases alongside the high-GWP F-gases.

In the assessment of the dossier, PFAS are regarded as non-threshold substances on the basis of their properties, and a classical quantitative risk assessment is therefore not justified.

Regarding the formation of TFA from trifluoroacetaldehyde, the DS refers to the WMO (2018) report which says that "Trifluoroacetic acid (TFA; CF₃COOH) is produced as the result of the breakdown in the atmosphere of several HCFCs and HFCs, such as HCFC-123 and HCFC-124, HFC-134a, HFC-143a, HFC-1234yf, and possibly HFC-1234ze". Hence, the corresponding 2014 report should not be regarded as evidence that no TFA is formed from the relevant F-gases.

The Zhai et al. (2015) paper shows strong increase in TFA concentrations from 2002 to 2012 in landscape waters in Qingnian Lake, The Summer Palace (south and central), Beihai Park and Chaoyang Park.

The Holland et al. (2021) paper estimates the relative increase in TFA concentrations when switching from HFC-134a to HFO-1234yf (as 33-fold and 250-fold etc.) which will be independent of any small variation in the base numbers.

The comments made on the MAC directive is recognized and the text changed accordingly.

Regarding toxicity of TFA, a new study on TFA (OECD TG 414) indicates developmental toxicity in rabbits with major malformations (ECHA dissemination site, 2021: <https://echa.europa.eu/registration-dossier/-/registered-dossier/5203/7/9/3/?documentUUID=bbe1c0df-91db-4cef-a965-89ded98a88c8>). The DS is aware of the ongoing work regarding the developmental toxicity of TFA in NZW rabbits, but for now, the available information is used and the texts on TFA developmental toxicity will not be edited.

Overall, human health effects have a supporting role to the main concern of persistence and other supporting concerns like mobility (TFA) or ozone-depleting potential (fluorinated gases).

Knowledge on the degradation of various fluorinated gases is summarised in the restriction dossier. Moreover, the study indicating 2% formation of TFA from trifluoroacetaldehyde in the atmosphere is already included. Different assessments come to different conclusions

on this. However, under REACH, substances that degrade to more than 0.1% of a persistent substance is to be considered persistent themselves (ECHA Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.11: PBT/vPvB assessment).

QSAR/degradation

(#3544, #3633, #3634)

Regarding the assessment of applicability and reliability of the QSAR models, a separate Appendix 13 has been added that elaborates more on the basis for the modelling exercise.

The results from the BIOWIN 4 predictions of primary biodegradation show unexpected trends which are not in line with the knowledge from experimental studies for these substances. Hence, these results are regarded as indication that the model has limited suitability for these kinds of compounds. Assessment added to Section B.4.1.2. The unexpected outlier result for BIOWIN 5 (PFBA) is discussed under the assessment of perfluoroalkylcarboxylic acids.

Haloperfluoroalkanes are within the scope as long as they fulfil the PFAS definition in the dossier. It is relevant for the assessment of persistence how the non-F halogen affects the degradation of an otherwise perfluorinated carbon-chain. However, the example compound chosen was, as noted in consultations comments, not within the PFAS definition and has been changed.

Reference to new appendix with information on fragments included in training sets added for clarification of the prediction reliability of BIOWIN 1-4.

The 'not assignable study', which shows that co-metabolic degradation in anaerobic conditions can happen, refers to a statement in the registration dossier which is not explained any further. However, the statement was included for completion and transparency.

Distribution

(#3633, #3634)

Koc values used to assess the mobility of PFAS. This is in accordance with the proposed mobility criteria as suggested in (Neumann and Schliebner, 2017, Protecting the sources of our drinking water - A revised proposal for implementing criteria and an assessment procedure to identify Persistent, Mobile and Toxic (PMT) and very Persistent, very Mobile (vPvM) substances registered under REACH, ISSN 2363-8273). The advantage of Koc values compared to a Kd is that the Koc values are normalised to organic carbon content in the soil. This allows to compare different values and to show pattern and trends.

log Kow in bioaccumulation assessment

(#3633, #3634)

A review of recent peer-reviewed articles and scientific reports was carried out. The section on bioaccumulation does not make a bioaccumulation assessment based on log Kow. Several aspects governing the accumulation potential of PFAS are discussed in the bioaccumulation section. This includes toxicokinetics and characteristics influencing

bioaccumulation and toxicokinetic behaviour such as protein binding, chain length and chemical structure. Partitioning and bioaccumulation behaviour is discussed regarding various distribution coefficients such as membrane–water distribution, albumin–water distribution and muscle protein–water distribution. The reach of Equilibrium in protein binding is an aspect in enzyme kinetics (as it has been studied approximately 120 years ago). However, it needs to be noted that proteins do not solely function as catalyst (enzymes) but as transporter proteins (influence on toxicokinetic) and as structural proteins.

Trophic transfer of PFAS along food webs

(#3633, #3634)

Indeed, there seems to be a trend that shorter chained substances exhibit lower biomagnification or bioaccumulation factors (see e.g. De Silva et al. 2020). There might be a seasonal change when plants become scarce. It should also be noted that water is another potential source for shorter chain substances, which could lead to additional exposure levels in organisms. This is of particular concern when chemicals persist in the environment as many PFAS do leading to high environmental concentrations in the long-term.

Toxicokinetics

(#3633, #3634)

The sentence on distribution of PFBS to the liver has been corrected in section B.4.3.2.

For instance, PFOA, PFOS, and PFBS preferentially distribute to the liver in most species; PFBA and PFHxS appear to preferentially distribute to the serum and, to a lesser extent, to the liver in animals.

Contrary to the statement in the comments, the section on toxicokinetic does not conclude that all serum elimination half-lives of PFAS are all similar. Several transporters are addressed in this paragraph sodium-dependent and a sodium-independent manner by Na⁺/taurocholate co-transporting polypeptide (NTCP) as well as organic anion transporting polypeptides (OATPs) are addressed. Furthermore, characteristics influencing toxicokinetics are addressed in an extra section.

The Dossier Submitter notes that Kudo (2015) only concludes that PFCAs are not metabolised. The section B.4.3.2. also mentions studies that certain precursors have in rodents been shown to transform, to various extents, into e.g. their perfluorinated carboxylate “backbone structures”, such as 8:2 FTOH that is metabolised into e.g. PFOA and C9-PFCA.

Please note that that steric hindrance of longer- chained PFAAS is also mentioned in the section describing binding to BSA (Bischel et al., 2011).

Physicochemical data

(#3633, #3634)

With regard to the wide range of individual compounds of PFAS only a few measured physicochemical property data are available. Additionally, experimental determination of property data for the PFAS can be challenging because the property values lie near the limits of applicability of many methods. For the assessment of the environmental partitioning and fate of PFAS physical/chemical properties are however crucial. Therefore, also modelled data are additionally used. For instance, some of the data given in the table

summarising physical chemical properties (section B.1.3.) was derived with the quantum-chemical model which has been conducted for 130 individual PFAS. The quantum chemistry-based method requires no specific calibration, and thus is expected to be adaptable to estimating properties for PFAS, for which only few calibration data are available. In support of this view, properties estimated showed good agreement with the experimental data for a limited number of PFAS (see also Wang Z., et al., (2011) *Environmental Chemistry*, 8 (4), pp. 389 – 398 and Arp H.P.H. et al (2006) *Environmental Science and Technology*, 40 (23), pp. 7298 – 7304).

Endocrine effects

(#3633, #3634)

As discussed in section B 4.2.3.3, protein binding is governed by several factors. Table B.37. list data for 32 individual PFAS which have been investigated for their ED properties. PFAS as a group are not characterized as all being endocrine disrupting substances in section B 7.4. though there is a large knowledge gap on the whole group of PFAS. Nevertheless, for clarity the summary of the restriction proposal was adjusted to “some PFAS”.

Anaerobic degradation

(#3633, #3634)

Data from anaerobic degradation studies are considered in the dossier. Nevertheless, they cannot be used on their own within persistence assessment but should be considered as a part of a Weight-of-Evidence approach. Please note that for persistence assessment results of tests are decisive that offer aerobic or at least partially aerobic conditions. It is thus not sufficient that PFAS in principle can be converted under anaerobic conditions. For example, in sediment or soil, substances will usually need to cross an aerobic zone before reaching the anaerobic zone.

Combined toxicity of PFAS

(#3633, #3634)

Equal toxicities or potencies of PFAS have not been assumed in the dossier.

A mixture risk assessment approach has not been applied as stated in the dossier because a “modelling of combined effects of all PFAS in the scope of this restriction is realistically not achievable due to lack of data on toxicodynamics, toxicokinetics, slope of dose response curves as well as limited knowledge of the mode-of action” (see section B.5.4 in the dossier). Additionally, “The immense number of PFAS in addition to the fact that appropriate toxicological data are not available for the vast majority of them, renders approaches for combined risk assessments [such as mixture risk assessment approaches or relative potency approaches] unattainable for all the PFAS within the scope of this restriction.” However, it is emphasized in the dossier that combined exposure to different PFAS affecting the same target organs may result in combined effects, rendering exceedance of effect thresholds or limit values more likely than single compound assessments.

Epidemiology

(#3633, #3634)

Many issues and comments raised on the epidemiological data have been addressed by EFSA in their responses to comments on the EFSA Opinion. The DS refers to this document: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1931>, in particular p.124-163.

Editorial remarks

(#3633, #3634)

Regarding analytical problems in the PFAS measurements of lung autopsies by Perez et al. (2013), the DS is aware of the analytical difficulties of this study and these problems are addressed already later in another section of the dossier (B.5.1.2.). To avoid misunderstandings, the DS added a note to the paragraph in B.4.3.3: "Note that PFBA levels in lung and kidney tissues are likely overestimated by Perez et al. (2013)." Please note that the analytical difficulties in this study apply to one substance, namely PFBA.

Regarding partitioning to blood and liver instead of fatty tissue, the fact that not all PFAAs accumulate in the liver had already been mentioned in the first paragraph of the section B.4.3.2.

The statement on serum half-lives that there are distinct differences in serum elimination half-lives of PFAS in mammalian species, including humans which was commented to be based on outdated information, refers to the decisions made by the Member State Committee. This is brought in the context of bioaccumulation assessment and which PFAS have already been considered bioaccumulative. The section "B.5.1 Toxicokinetics/ADME (absorption, metabolism, distribution and elimination)" of non-polymeric PFAS refers to updated reports and scientific papers on toxicokinetics.

Additional comments

(#3561, 3562, 3566, 3572, 3613, 3618, 3620, 3622)

The Dossier Submitter would like to thank those supporting the hazard assessment and scope of the restriction proposal.

2.2.2. RAC Rapporteurs comments

Substance Scope

RAC considers it is important to stress that, according to the available information on substances used in firefighting foams, PFAS containing only one trifluorinated or difluorinated carbon moiety are not found in any records for their use. Therefore, the concerns raised about single moieties in comment (#3568) are deemed irrelevant for the use in firefighting foams.

Hazard assessment

Persistence as a sole risk

RAC endorses the Dossier Submitter's viewpoint.

Fluoropolymers

RAC concurs with the Dossier Submitter that fluoropolymers need to be considered within the scope.

Epidemiology

RAC acknowledges that EFSA has already addressed comparable concerns and comments regarding the epidemiological data on PFAS. The Dossier Submitter has cited an EFSA reference on this matter.

2.2.3. SEAC Rapporteurs comments

SEAC has no further comment.

2.3. Risk and exposure assessment (including waste lifecycle stage)

Comments were submitted by industry associations, trade associations, national authorities, individuals and NGOs. These included for example comments #3544, #3546, #3561, #3562, #3600, #3601, #3611, #3613, #3622, #3626. Some of these comments have been handled as confidential as per the respondent's request.

2.3.1. Dossier Submitter response to comments

A justification for the case-by-case approach is provided in the Annex XV under section 1.1.6.

The Dossier Submitter assessed all information submitted during the consultation and concluded that no significant new information was provided to warrant fundamental changes to the exposure assessment. Comment #3544 received corroborated the Dossier Submitter's assumption that PFAS-containing firefighting foams have a long service life and that destruction of expired stocks is not a common occurrence. The comment also suggested that the Dossier Submitter's assumption regarding the PFAS content in foams of 2.5% is reasonable. The same comment also offered information corroborating the assumption that in the order of 18 000 tonnes of concentrate are used annually. The Dossier Submitter would like to clarify that the total amount of releases calculated during the lifecycle stage adds up to approximately 18 000 tonnes of foam concentrate per annum. Bearing in mind a PFAS content of 2.5%, this equals to PFAS releases of 450 tonnes per annum. The Dossier Submitter noted comments providing information that PFAS-containing firefighting foams reaching shelf-life in refineries are transferred to waste disposal companies guaranteeing incineration but the information was limited to one EU Member State and cannot be extrapolated to whole EU/EEA.

The continuous use and release of PFAS leads to sustained exposure and increasing stocks in the environment. While there are clear declining trends for PFOS and PFOA in humans as mentioned in the comments (#3633, #3634), the trends in biota are mixed and often not significant according to a review by Land et al. (2018) (DOI 10.1186/s13750-017-0114-y). Regarding time trends of PFAS in abiotic matrices, the review by Land et al. (2018) (DOI 10.1186/s13750-017-0114-y) found declining trends for PFOS and PFOA in surface waters, whereas most studies on sediment cores reported increasing concentrations. The authors concluded that the PFOS and PFOA restrictions resulted in decreasing concentrations especially in surface waters with high water exchange, whereas remote areas might have a delayed response to regulatory measures.

Additional information received regarding worker exposure has been acknowledged in Annex B.9.3.5 to the Background Document.

The Dossier Submitter noted comments (#3546, #3596) proposing the disposal of PFAS containing foams through Wastewater Treatment Plants (WWTP). Taking into consideration the wide dispersed use of foams and the need to apply advance filtration methods to separate PFAS from water, the Dossier Submitter does not consider this option as an efficient way to prevent emissions to the environment. Section B 4.5 discusses

several PFAS removal technics as mentioned in the comments. Furthermore, Section B 4.5 summarises several studies also including studies on the effectiveness of removal technics in WWTP. Though some techniques may remove shorter and more mobile PFAS, and complete mineralization may be possible, technics are often not efficient enough to allowing emission to the environment and/or come with high process costs. Furthermore, the required technics are not necessarily installed in WWTPs. For instance, several studies have concluded that Municipal WWTPs are not able to effectively remove shorter or longer chained-PFAAs and the discharge of municipal sewage water is a significant source of PFAAs to the aquatic environment. Additionally, monitoring data show a ubiquitous occurrence of PFAS and there are no current means and end of pipe solutions available to recover PFAS from water and soil on a large scale. The proposal to allow the disposal of PFAS containing foams through Wastewater Treatment Plants does not take in consideration fire incidents happening in places where firewater cannot be collected.

The Dossier Submitter provided additional information on the efficiency of disposal technics, alternative disposal technics as well as on storage and landfill disposal. For more information, please see revised/new Appendixes 2-5.

The monitoring data received has been incorporated into Appendix 10.2.5 and Appendix 10.4 to the Background Document and referred to in the hazard assessment in Section 1.1.4 of the Background Document.

2.3.2. RAC Rapporteurs comments

RAC agrees with the Dossier Submitter that PFAS should be treated as non-threshold substances in a risk assessment, similar to PBT/vPvB substances, where releases are considered as a proxy for risk, and should be minimised. RAC supports the Dossier Submitter's argument that all PFAS used in firefighting foams are likely to be released into the environment, either directly through use or indirectly through inadequate waste treatment. The Dossier Submitter estimated an annual release of 470 t/y, and RAC concurs that this release poses a risk to humans and the environment. Furthermore, the risk will increase with continued use due to the persistence of PFAS and a resulting accumulation in environmental stocks over time.

RAC recognises the concerns regarding worker exposure to PFAS. While information on exposure from firefighting and formulation would be helpful, RAC believes that further analysis is unnecessary as part of this restriction process. This is because the existing information on risk to humans via the environment is sufficient. However, RAC believes that incorporating information on worker exposure would enhance the comprehensiveness of the dossier.

2.3.3. SEAC Rapporteurs comments

SEAC has no further comment.

2.4. The proposed concentration limit value (including cleaning of equipment)

Comments were submitted by industry associations, trade associations and national authorities. These included for example comments #3543, #3544, #3549, #3550, #3552, #3553, #3560, #3561, #3563, #3565, #3570, #3579, #3600, #3607, #3614, #3615,

#3616, #3628. Some of these comments have been handled as confidential as per the respondent's request.

2.4.1. Dossier Submitter response to comments

Feasibility to achieve concentration limit values though the cleaning of PFAS-contaminated equipment

The effectiveness of removing residual PFAS from equipment (i.e. through different cleaning methods) and the proposed concentration limit value are inherently linked topics and the impacts of the former could be considered to largely determine the proportionality of the latter. There are also links to the availability of appropriate analytical methods, which will be treated separately below.

No significant new information regarding cleaning methods and the PFAS concentration reduction in re-filled equipment achievable has been submitted. The Dossier Submitter proposal for the concentration limit has therefore remained unchanged. Some stakeholders confirmed information that reaching concentration of PFAS below 1ppm limit requires extensive cleaning which may require draining, washing with chemicals, flushing, monitoring, and potentially dismantling or even replacement of some equipment. Several stakeholders commented that setting higher concentration limits (3ppm, 10ppm, 50ppm) will improve the cost effectiveness of the restriction.

Risks associated with the proposed 1 mg/L concentration limit value

Several stakeholders pointed that reduction of concentration of PFAS below the limit of 1 mg/L may not completely exclude emission of PFAS to the environment. It may result in contamination of the soil and water and lead to local exceedance of Drinking Water Directive limit values but those cannot easily be calculated on an EU scale. The possibility of this happening as a result of releases of PFAS from firefighting foam use with a PFAS concentration up to 1mg/L are acknowledged in the BD in section E.5.3.

Concentration limit value

Following several comments on the units used in the dossier, the Dossier Submitter changed all units from ppm to mg/L. Non-cleaning as suggested by some stakeholders was considered during the development of the proposal but discarded given the availability of cleaning agents. The Dossier submitter is also aware that in some installations reaching the concentration limit will require partial change of elements of installations. The Dossier Submitter believes that the proposed transitional periods will allow to schedule changes of firefighting foams, and necessary cleaning or changes in the installation during the standard technical maintenance breaks. The 1mg/L limit is the result of these considerations and no new information was submitted in the consultation that would justify a change in this concentration limit value.

Associated costs are already taken into account in the cost -effectiveness analysis in section 2.9.3 of the Background Document.

2.4.2. RAC Rapporteurs comments

RAC notes no significant new information regarding cleaning methods to reach a concentration of PFAS below 1mg/l has been submitted. RAC however considers that the

proposed concentration limit of 1mg/L is well below the lowest concentration of 0.1% that can be considered to provide functionality for PFAS in concentrates and ready-to-use firefighting foams.

2.4.3. SEAC Rapporteurs comments

Regarding **contaminated equipment**, SEAC notes the increasing costs as a lower remaining contamination level is pursued. SEAC agrees that at some point adding further cleaning rounds may become disproportionately expensive. Based on information received (comment #3570 in particular) SEAC agrees that setting a **higher limit value** for the use of already contaminated systems could be appropriate, at least for the **offshore sector**. It is to be noted that the increase of the limit value would only apply to foam exiting the contaminated equipment, not to filling the equipment or placing firefighting foams (concentrates) on the market for this type of use.

SEAC notes the claims made in the consultation that the **concentration of PFAS in new fluorine-free foam** concentrates could be higher than 1mg/l and that the limit value should therefore be raised (comments #3607, #3614). SEAC recalls that PFAS are not naturally occurring substances and infer that therefore they must have been introduced to the foam at some point (even if unintentionally). No information is available in the comments on the origins of this PFAS content. Contamination of equipment (potentially at the manufacturer's site) appears a plausible explanation. If that is the case, then the issue could be relatively easy to handle. Furthermore, considering that it is not clear whether this issue might concern only one product, SEAC does not consider the comments as a sufficient basis for revising the limit value.

2.5. Portable fire extinguishers

Comments were submitted by industry associations, companies, trade associations, national authorities and NGOs. These included for example comments #3543, #3544, #3549, #3553, #3556, #3557, #3579, #3595, #3621. Some of these comments have been handled as confidential as per the respondent's request.

2.5.1. Dossier Submitter response to comments

Portable fire extinguishers emerged as a topic for which a significant amount of new information was received. This relates to the number of units in use in the EU, existing regulations impacting the use (e.g. building codes and health and safety regulations), performance of alternatives, the cleaning and disposal of existing PFAS-containing fire extinguishers, current manufacturing, servicing and disposal capacities in the EU, training requirements and cost of phasing out PFAS-containing fire extinguishers.

Significant effort of the analysis for the ready-to-use sector was focused on information relating to the availability and feasibility of alternatives as well as other arguments relevant to the derivation of the transitional period.

Based on the received comments, the DS also decided to reassess the cost of the proposed restriction of PFAS in the ready-to-use sector to check whether the increased annual use tonnage affects the aggregated costs of the different ROs. While the share of PFAS foams used in the ready-to-use sector is comparatively small, potentially important impacts on the conclusions of the restriction proposal were not excluded because the variable of the annual use tonnage feeds into several cost categories.

The new information about the use tonnage was, however, not expected to have an impact on the emissions assessment, which is why the emissions assessment was not updated.

Although, the Dossier Submitter assumes that 100% of foams sold are released during their service life in the baseline scenario, effectively the emissions may be expected lower as stakeholders indicate that only 1-5% of extinguishers are actually used during their service life.

The analysis of the Dossier Submitter also takes into account the comments received on other topics, which indicated that the proposed conditions of the restriction would have different impacts with respect to consumer uses versus professional and industrial uses (see e.g. 2.1 above and 2.5 below).

In conclusion, several sections in the Background Document are affected by the Dossier Submitter's analysis of the received comments. The updated number of fire extinguishers assumed to be in use in the EU is discussed in detail in Annex A.2.3.2 to the Background Document. Annex E.2.5.4 to the Background Document contains additional information received on alternatives, testing standards and variety of regulations affecting the use of fire extinguishers in the EU. Changes resulting for the proposed transitional period are presented in Annex E.2.8. An additional subsection on cleaning and disposal of portable fire extinguishers has been added into Annex E.4.3.8 to the Background Document. The capacities for manufacturing, servicing and disposing of portable fire extinguishers are assessed in Annex E.4.3.9 and the outcome of the revised cost assessment can be found in Annex E.4.3.10. Additional arguments regarding training requirements have been added to Annex E.4.4.2 to the Background Document.

2.5.2. RAC Rapporteurs comments

RAC has taken note of the information provided during the consultation regarding portable fire extinguishers. RAC also acknowledges the revised estimate by the Dossier Submitter, which suggests that there are 40 million units of portable fire extinguishers in use in the EU. Additionally, RAC recognises that of the 18 000 tonnes of PFAS-containing firefighting foam concentrates sold in the EU annually, only 1% of PFAS content is found in portable fire extinguishers. Further sectoral breakdown shows that portable fire extinguishers account for less than 1% of the annual sales and existing stock. Therefore, RAC agrees to keep the emission assessment unchanged, as the concerns related to portable fire extinguishers are related to their widespread use rather than their potential for PFAS release. Compared to other uses, the release of PFAS from fire extinguishers is insignificant.

2.5.3. SEAC Rapporteurs comments

SEAC thanks the commenters for the underpinned estimations of the **number of extinguishers** to be potentially replaced in the EU. These estimates are important contributions to the data basis based on which the length of the transition periods are evaluated.

SEAC notes the statements that PFEs containing fluorine-free foam agents achieve a lower **performance rating** compared to PFEs containing PFAS-based foam agents, and that therefore more units of PFAS-free devices have to be installed to achieve the same protective performance or to comply with building regulations.

Some industry stakeholders claimed that a **5-year transition period** is too short, while some others found it achievable. Based on the available data SEAC considers that a 5-year transition period for the use of PFEs should be feasible. However, SEAC welcomes any further information vindicating the alleged infeasibility of procuring a sufficient number of alternative PFEs (manufacturing, imports, stocks) in the consultation on the SEAC draft

opinion and SEAC would re-evaluate the issue should relevant additional information, potentially with a thoroughly justified proposal of an alternative length, be submitted.

SEAC notes the concern raised by stakeholders that based on the original approach in the Dossier (use limited to **Class B fires** only), it would be necessary to replace practically all PFAS-containing PFEs in 6 months after entry into force in practice. SEAC welcomes that the Dossier Submitter expanded the 5-year derogation of use to cover all PFEs regardless of type of fire and sector of use.

A **staged substitution plan** (shorter transition period for placing on the market, longer transition period for use) was proposed in some comments. SEAC agrees that such an approach would be useful in the case of PFEs. However, SEAC considers that a 6-month transition timeline for **placing on the market** may be too short considering the availability of alternatives for some uses and the necessary actions in the supply chains to make the transition happen in practice (communicating, (re)negotiating contracts, etc.). The information available does not clearly support any other specific period such that SEAC could make another proposal. As to the time limit for **use**, as discussed above, SEAC does not think that requests to extend the transition timeline above 5 years are currently sufficiently justified.

2.6. Labelling requirements

Comments were submitted by industry associations, trade associations, individuals and NGOs #3544, #3546, #3552, #3566, #3572, #3631.

2.6.1. Dossier Submitter response to comments

Paragraph 6 requirement to label packaging of mixtures for firefighting as well as containers of firewater run-off or other PFAS waste with a warning of the PFAS content

Comment #3552 received supported the labelling requirement for packaging of firefighting foam concentrates and PFAS waste containers but that inclusion of the warning in the Safety Data Sheet should be sufficient due to the industrial and professional uses concerned. Comment #3546 asked for similar labelling requirements for all firefighting foams, regardless of their PFAS content, arguing that non-PFAS firefighting foams may also be harmful.

The Dossier Submitter did not implement any changes to the proposal regarding the labelling requirement in paragraph 6 itself. Changes elsewhere however mean that the requirement does not apply to portable fire extinguishers (defined by EN3-7, EN-1866 and EN-16856; see 2.5).

The labelling of alternative firefighting foam mixtures proposed by comment #3546 is not in scope of the restriction proposal at hand and can therefore not be required. The Dossier Submitter would however like to draw the stakeholder's attention to the labelling requirements for hazardous substances in the CLP Regulation.

The Dossier Submitter assessed a label on the packaging as an effective means to create awareness among those handling firefighting foam mixtures and wastes and thus more certainty that appropriate risk management measures are implemented to minimise the

risks including at the waste stage during the transitional periods. PFAS would only require identification in the Safety Data Sheet if they are classified as hazardous according to the Classification, Labelling and Packaging of Substances Regulation and the Dossier Submitter considers this to be insufficient for the intended purpose.

Paragraph 7 requirement to label packaging of mixtures for firefighting containing non-PFAS organofluorine substances above the 1ppm threshold

A number of comments provided have questioned the need for the labelling requirement in paragraph 7 of the proposed restriction entry text.

The Dossier Submitter considers this requirement necessary to facilitate the practicality including the enforceability of the proposed restriction using total fluorine analytical methods. This is deemed necessary to enable enforcement activities even when targeted analytical methods are not available. This issue was clarified in section 2.3.1 of the Background Document. The Dossier Submitter acknowledges that the cost of this labelling requirement has not been assessed as pointed out by comment #3566. This is based on the assumption that such labelling will only be required in rare circumstances.

2.6.2. RAC Rapporteurs comments

RAC has no further comment.

2.6.3. SEAC Rapporteurs comments

SEAC finds a labelling requirement useful to enable parties coming across with packaging of PFAS-containing materials to handle it appropriately.

SEAC notes some complications specifically related to the proposed labelling requirement of paragraph 7a, including related to availability and verifiability of information. However, SEAC considers it as a pragmatic way of addressing any non-PFAS fluorine content in the foam and finds that it improves enforceability.

SEAC notes the concern expressed by stakeholders related to the difficulties in labelling existing extinguishers. SEAC welcomes that the Dossier Submitter changed their proposal in the way that the labelling requirement does not apply to PFES.

Related to the references made to the SEAC outcome on labelling in the PFHxA case (SEAC found that they could not evaluate whether the costs and benefits of a labelling requirement would be well balanced due to lacking information) (comment #3566), SEAC considers that, noting the well-defined and limited scope of applications covered this time, there are much less uncertainties and SEAC does not have specific concern on the proportionality of the labelling requirement in this case.

2.7. PFAS-containing firefighting foam management plans

Comments were submitted by industry associations, companies, trade associations and NGOs. These included for example comments #3552, #3556, #3565, #3575, #3595, #3611, #3620, #3622, #3625.

2.7.1. Dossier Submitter response to comments

Stakeholders have provided a number of comments that touch upon the PFAS-containing firefighting foam management plans proposed in paragraph 4.(c) of the restriction proposal. The comments generally supported these PFAS-containing firefighting foam management plans. One comment argued for 18 months to develop these plans rather than the 6 months proposed without providing significant supporting information. One comment asked for clarification regarding the type of justification required for continued use during the transitional period. A number of comments drew parallels to the reporting requirement put forward by the restriction proposal on PFHxA and related substances, which proposed to require annual reporting of use amounts, stocks and substitution efforts to ECHA albeit only for continued use during the transitional period proposed for large tanks.

The Dossier Submitter adapted the proposal and users of portable fire extinguishers are no longer required to draw up PFAS-containing firefighting foam management plans during the transitional period (see section 2.3 of the Background Document).

A reporting requirement for Seveso sites subject to the proposed 10-year transitional period was already considered during the development of the proposal. Such a condition was discarded given that the proposal foresees a complete phase out of PFAS-containing firefighting foams via a clear timeline for bans on formulation, placing on the market and use. Reporting on remaining uses until then was assessed not to reduce the risk further or improve the practicality significantly while instead creating an administrative burden for industry and authorities.

More detail regarding the justification required for continued use was added to the Background Document in section 2.3.1 and 2.3.2.

The Dossier Submitter notes that many industrial sites where PFAS-foams will continue to be used during the transitional periods will already have emergency plans drawn up that include a consideration of fire events. This is in many cases required by local, national and EU-level legislation, most notably by Directive 2012/18/EU (Seveso III Directive). The proposal to require PFAS-containing firefighting foam management plans within 6 months is therefore considered feasible.

2.7.2. RAC Rapporteurs comments

RAC considers (Section 3.3.4 RAC Opinion) that the proposed PFAS-containing firefighting foams management plans are an essential element of the proposed restriction and are likely to be an effective deterrent to continuing unnecessary use. RAC acknowledges 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 and regulatory authorities in some countries.

2.7.3. SEAC Rapporteurs comments

SEAC notes the claims that the timeframe of 6 months is short considering the effort that

is necessary to compile and implement the plan. In the absence of further description of and information on the issues making a longer transition period (allegedly) necessary SEAC cannot make further evaluation on the issue and agrees with the Dossier Submitter's description above. Generally, a transition period of 6 months for establishing the management plans appears appropriate to SEAC.

2.8. The analysis of alternatives and length and scope of proposed transitional periods

Comments were submitted by industry associations, companies, trade associations, national authorities, individuals and NGOs. These included for example comments #3542, #3543, #3544, #3545, #3546, #3548, #3549, #3551, #3552, #3553, #3556, #3564, #3565, #3566, #3569, #3570, #3572, #3574, #3575, #3580, #3583, #3593, #3595, #3596, #3599, #3600, #3606, #3607, #3614, #3619, #3620, #3621, #3626, #3627, #3628, #3631, #3632, #3635, #3636. Some of these comments have been handled as confidential as per the respondent's request.

2.8.1. Dossier Submitter response to comments

The received information relates to the availability, hazardousness and performance of alternative foams (incl. points on performance criteria, standards and testing, foam properties and resulting application difficulties as well as specific issues of fuel and temperature sensitivity). The comments further cover the topic of required adaptations of equipment and firefighting strategies. The Dossier Submitter described and evaluated this information before addressing the related topic of the lengths of transitional periods proposed. In this analysis it was considered whether new information on the analysis of alternatives and other relevant factors can justify the adoption of requested changes to the transitional periods that were submitted by the stakeholders.

Based on the submitted comments, the Dossier Submitter amended the analysis in Annex E.2 to the Background Document (with most of the content presented in the sub-sections of E.2.8).

2.8.2. RAC Rapporteurs comments

RAC has considered alternatives under Section 3.3.2 of the Opinion.

2.8.3. SEAC Rapporteurs comments

SEAC thanks commenters for the information submitted on the **availability and performance** of fluorine-free alternatives. SEAC notes that suitable alternatives are already available for many sectors and that their availability in the sectors with the highest performance demands improves constantly.

SEAC also notes the statements that **PFAS-containing agents provide some properties** not matched by fluorine-free alternatives (such as film-forming ability). SEAC notes this in the opinion and considers that this is a reason why developing fully appropriate fluorine-free alternatives and techniques for the most demanding scenarios may take time and the exact timing of full transition cannot be predicted yet.

SEAC also thanks the commenters for the information on the impacts of **high and low temperature** on firefighting foams and specifically fluorine-free alternatives.

SEAC considers that the availability of suitable alternatives for the most demanding

scenarios (involving either large amounts of flammable liquids or multiple types of flammable liquids) should be ensured before a full transition is required, either by carrying out a **review** before the transition period expires or via implementing a user-specific evaluation from the start (such as a **permitting system**).

Transition periods:

SEAC thanks the commenters for the further underpinning of the necessary lengths of transition periods and for the confirmations that the proposed transition periods appear appropriate as per application/user.

Generally, SEAC supports the transition periods proposed by the Dossier Submitter (but considers a review or a permitting system related to the most demanding applications necessary as pointed out above). For some applications (civilian ships, defence applications, applications expressly excluded from the application of the Seveso directive, PFEs) further information from the consultation on the SEAC draft opinion would be useful.

SEAC agrees that in **defence uses** there are scenarios with specific requirements for the fuels and systems used. Dedicated evaluation at the Member State level may be appropriate in those cases. SEAC expects that exemptions according to article 2(3) of the REACH Regulation may be necessary for some scenarios irrespective of the length of transition period set in the restriction. Information on the expected magnitude of the difference in impacts under a 5-year or a 10-year transition period in the restriction (e.g., relating to uses where full substitution would be possible in 10 but not in 5 years) allowing further evaluation would be welcome in the consultation on the SEAC draft opinion.

Issues related to **portable fire extinguishers** are discussed in a dedicated paragraph above.

2.9. The assessment of cost

Comments were submitted by industry associations, companies, trade associations, national authorities and individuals. These included for example comments #3542, #3543, #3544, #3545, #3546, #3548, # 3561, #3564, 3570, #3593, #3599, #3600, #3621, #3628. Some of these comments have been handled as confidential as per the respondent's request.

2.9.1. Dossier Submitter response to comments

Input relevant for the cost assessment in the ready-to-use sector have already been covered in section 2.5 above. Received comments that are relevant for other sectors cover stakeholders' views on costs that are considered higher than presented by the Dossier Submitter, costs that are perceived accurate by stakeholders and costs that are considered to be missing by respondents to the consultation. The Dossier Submitter described and evaluated this information before addressing providing responses.

Based on the submitted comments, the Dossier Submitter amended the analysis in Annex E.4.3.11 to the Background Document.

2.9.2. RAC Rapporteurs comments

RAC defers to SEAC on cost assessment.

2.9.3. SEAC Rapporteurs comments

SEAC agrees in general with the Dossier Submitter that for several comments there were not enough information provided to modify the cost assessment, but also makes the following specific comments.

Regarding comment #3570 on the cost of downtime during replacement of the firefighting system at some Seveso sites, SEAC notes that the comment comes from a stakeholder with extensive experience of such replacement (one of stakeholders in the EU having already almost fully transitioned to alternative foams). Therefore, SEAC thinks the fact that downtime costs could be taken into account would deserve further consideration .

Regarding comment #3546 on the underestimation of the cost to re-train firefighters, SEAC notes in its opinion that, alternatives being more specific and requiring specific practice and training (as also noted in other comments), this could imply training and organisational costs additional to the baseline situation, that are not taken into account by the Dossier Submitter.

Regarding the cleaning costs to reach the 1 mg/l level, SEAC took account of the comment within its assessment of the cleaning costs assessment by the Dossier Submitter and reported in its opinion that the calculation by the Dossier Submitter is uncertain and the cost could be underestimated.

2.10. Regarding the costs for the offshore sector, SEAC notes that this could have been compared in more detail to the default cost assessment for this sector carried out by the Dossier Submitter. The assessment of other impacts

Comments were submitted by industry associations and NGOs. These included for example comment #3595).

2.10.1. Dossier Submitter response to comments

The topic covered by these comments is related to the climate impacts of the proposed restriction.

The Dossier Submitter did not address this aspect in the Background Document.

2.10.2. RAC Rapporteurs comments

Comment (#3595) queried the climate CO₂ impact of fire water incineration which RAC has considered in its opinion.

2.10.3. SEAC Rapporteurs comments

SEAC noted comment #3595 in which estimates of the positive climate impact of the restriction were calculated. SEAC notes that the proposed restriction will introduce a new obligation to treat (most likely by incineration) firefighting water containing PFAS or unused PFAS foams and this will likely have a negative impact on the climate. However, considering that destructing PFAS would in any case be necessary, SEAC agrees that restricting use and keeping transition times short would limit the amount of PFAS to be destroyed over time and therefore the energy used for this purpose. SEAC provided an

overview of possible negative and positive climate impacts of the proposed restriction in its opinion but did not have the information to carry out further assessments.

2.11. The assessment of benefits

Comments were submitted by industry associations, national authorities and NGOs. These included for example comments #3561, #3562, #3566, #3572, #3595, #3622, #3626 and #3631.

2.11.1. Dossier Submitter response to comments

The received comments report on specific cases of pollution management and the avoided cost of measures that may have to be taken in order to manage the impact of increased PFAS pollution in the absence of effective regulatory action. The kinds of avoided costs include, for example, investment costs of measures to purify drinking water or to treat contaminated water before it can be discharged to receiving water bodies, investment costs for making available new sources of drinking water/groundwater or for realising alternative solutions where construction projects are hindered by existing PFAS contamination, or cost of remediating contaminated soil and sediments. Most of this information comes from specific smaller-scale case studies, often with local character. Other, more general submissions address the topics of estimated limit values for PFAS contamination, ongoing efforts to map contamination and develop benchmarks for PBT/vPvB substances, costs related to assessments of health effects, or greenhouse gas emissions related to contamination treatment measures.

Even though it was not possible to monetise the benefits of restricting the use of PFAS-containing firefighting foams, the Dossier Submitter complemented the Background Document in section 2.9 and Annex E.8.5 with contextual information on the cost of PFAS contamination.

2.11.2. RAC Rapporteurs comments

RAC supports the assumption that firefighting incidents using PFAS foam cause extensive PFAS release to soil and water.

2.11.3. SEAC Rapporteurs comments

Underground water contamination, necessity of drinking water treatment, avoided decontamination and lost agricultural revenue, are all impacts that are recognized in the SEAC draft opinion as being potentially avoided to some extent by the proposed restriction.

Comments also mentioned avoided healthcare costs related to the proposed restriction, but no specific information was provided.

2.12. Enforcement, including analytical methods

Comments were submitted by industry associations, companies, trade associations and individuals. These included for example comments #3542, #3543, #3544, #3549, #3550, #3560, #3600, #3607, #3614, #3621. Some of these comments have been handled as confidential as per the respondent's request.

2.12.1. Dossier Submitter response to comments

The Dossier Submitter noted the stakeholders' concerns related to the lack of standardised analytical methods to measure concentrations of PFAS in firefighting foams and the issues

around proving compliance. Nevertheless, it is not a prerequisite that standardised analytical methods are available when a restriction proposal is submitted. However, the current state of science available in the field today is summarised in the dossier, and possible solutions and methods for verification of compliance with the proposed restriction have been suggested. No changes have been introduced into the Background Document in this regard.

2.12.2. RAC Rapporteurs comments

RAC has no further comment.

2.12.3. SEAC Rapporteurs comments

SEAC thanks the commenters for the information on the availability of commercial service of analytical methods submitted in the consultation.

2.13. Disposal and treatment

Comments were submitted by industry associations, companies, trade associations, national authorities, individuals and NGOs. These included for example comments #3543, #3544, #3546, #3548, #3551, #3552, #3559, #3572, #3595, #3596, #3600, #3601, #3608, #3610, #3611, #3622, #3623 #3630, #3636. Some of these comments have been handled as confidential as per the respondent's request.

2.13.1. Dossier Submitter response to comments

Thank you for all comments concerning disposal and treatment of PFAS. The Dossier Submitter is of the opinion that the incineration in proper conditions is an efficient method to destroy PFAS in firefighting foams and fire waters. That was also confirmed by comments providing information on legal regulations concerning the waste incineration efficiency in some Members States. The Dossier Submitter is aware of the US DoD moratorium on incineration of firefighting foams containing PFAS but the Dossier Submitter is not aware of any scientific publications questioning the efficiency of hazardous waste incinerators to destroy PFAS. Moreover, the Dossiers Submitter provided information on additional methods of disposal firefighting foams containing PFAS i.e. Supercritical water oxidation. Detailed information is available in new Appendixes 2.3.1-2.3.3.

Some comments questioned sufficient capacity of the hazardous incinerators in EU/EEA while other comments provided calculations justifying sufficient capacity of hazardous waste incinerators. The Dossier Submitter is aware that availability of hazardous waste incinerators is not equal in the in EU/EEA area and the proper disposal will require storage and transport. A new Appendix 11 Transport and interim storage of the PFAS-containing firefighting foams has been added to the dossier.

The Dossier Submitter added a new Appendix 12. Analysis of possibilities of disposal of PFAS containing firefighting foams on hazardous waste landfills and geological storage to discuss other options if the incineration of other disposal methods are not available.

Concerning comments proposing to allow the disposal of PFAS containing foams through Wastewater Treatment Plants please consult section 2.3.

2.13.2. RAC Rapporteurs comments

RAC are appreciative of the information that was shared during the consultation pertaining to the disposal and treatment of PFAS in firefighting foam. RAC considers the new Appendix 11 Transport and Interim Storage for PFAS-containing firefighting foams, is a useful addition to the dossier.

2.13.3. SEAC Rapporteurs comments

SEAC noted RAC's concern that destroying PFAS via incineration is related to challenges and under sub-optimal conditions can result in incomplete destruction and lower release reductions than calculated by the Dossier Submitter. SEAC noted the Dossier Submitter carried out a review of the technical and market maturity of alternative PFAS-contaminated waste end-of-life treatment and found still uncertain if and when they could significantly contribute to PFAS destruction capacity during the transition periods, in case incineration performance or capacity would be an issue.

SEAC agrees in principle with the claim made in some comments that a transition period of 6 months for handling foam concentrates to be disposed of for adequate treatment seems quite long. SEAC notes though that some transition time may be necessary for parties not yet oriented to transition. Finding a suitable approach is important and this might have a positive effect on the benefits of the restriction. SEAC also finds that other actions stipulated in entry point 4 may necessitate substantial changes in the practices and facilities. SEAC considers that if one prefers to set only one transition period for entry 4 obligations, 6 months appears a practical solution.

2.14. Non-foam firefighting systems

2.14.1. Dossier Submitter response to comments

Comments were submitted by industry associations and national authorities. These included for example comments #3581 and #3626. Some of these comments have been handled as confidential as per the respondent's request.

The proposal includes a restriction on the use of PFAS in firefighting foams only and therefore does not cover firefighting systems relying on other methods. Fire suppressing systems and other non-foam systems such as gaseous firefighting products in sprinkler systems used e.g. in data centres are therefore not covered by the proposed restriction. This has been further clarified in section 2.3.1 of the Background Document.

Note that the use of PFAS in non-foam systems may be covered by the forthcoming restriction proposal on PFAS prepared by the Netherlands, Germany, Denmark, Sweden and Norway.

2.14.2. RAC Rapporteurs comments

RAC has taken note of the approach adopted by the Dossier Submitter regarding this matter. However, it is important to clarify that RAC's scope of work is limited to the regulation of PFAS usage in firefighting foams exclusively.

2.14.3. SEAC Rapporteurs comments

SEAC has no further comments.