ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): Per- and polyfluoroalkyl substances (PFASs) in firefighting foams

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List of abbreviations

Acronym	**Explanation**
3F	Fluorine-free foam
4:2 FTMA	4:2 fluorotelomer methacrylate
4:2 FTO	fluorotelomer olefin
8:2 FTSA	8:2 fluorotelomer sulfonic acid
6:2 FTOH	6:2 fluorotelomer alcohol
6:2 FTSA	6:2 fluorotelomer sulfonic acid
7:3 FTCA	7:3 fluorotelomer carboxylic acid
8:2 Cl-PFESA	8:2 Cl-polyfluorinated ether sulfonate
8:2 PTrMeOSi	8:2 polyfluoroalkyl trimethoxysilane
9Cl-PF3ONS	9-Chlorohexadecafluoro-3-oxanonane-1-sulfonic acid
ADME	Processes of absorption, distribution, metabolism, and excretion
ADONA	Ammonium 4,8-dioxa-3H-perfluorononanoate, 3H-perfluoro-3-[(3-methoxy-propoxy)propanoic acid]
AFFF	Aqueous Film-Forming Foam
ALT	Serum alanine transferase
AOF	Total adsorbable organic fluorine
AOP	Advanced oxidation process
AR	Androgen receptors
AR-AFFF	Alcohol Resistant-Aqueous Film Forming Foam
ARFF	Aircraft Rescue & Firefighting
AR-FFFP	Alcohol-Resistant Film-Forming Fluoro-Protein
ATSDR	Agency for Toxic Substances and Disease Registry
BAC	Biological activated carbon
BAF	Bioaccumulation potential
BAU	Business as usual
BCF	Bioconcentration Factor
BOD	Biological oxygen demand
BP	Biocidal products
C	Carcinogenicity
CAA	Civil Aviation Authority
CAF	Compressed air foam
CAR	Constitutive androstane receptor
CBT	Closed Bottle Test
C-E	Cost-effectiveness
CIC	Combustion ion chromatography
CMR	Carcinogenic, mutagenic or toxic for reproduction
COP	Conference of the Parties
CSS	Chemical Strategy for Sustainability
CTD	Characteristic Travel Distance
CTVs	Chronic toxicity values
DMW	Distribution ratios for membrane–water
DoD	Department of Defense
DONA	Dodecafluoro-3H-4,8-dioxanonanoic acid
DPW	Distribution ratios for protein–water

dw	Dry weight
DWD	Drinking Water Directive
EA	Endocrine Activity
ECHA	European Chemicals Agency
EC50	Half maximal effective concentration
ECOS	Environmental Coalition on Standards
ED	Endocrine Disruption
EEA	European Economic Area
EFSA	European Food Safety Authority
EOF	Extractable organic fluorine
EPAs	Environmental Protection Agencies
EQSD	Environmental Quality Standards Directive
ER	Estrogen receptors
EtFOSAA	N-Ethyl perfluorooctane sulfonamidoacetic acid
Eurofeu	European Committee of the Manufacturers of Fire Protection Equipment and Fire Fighting Vehicles
EUREAU	European Federation of National Associations of Water Services
EURITS	European Union for Responsible Treatment of Special Waste
F-53B	6:2 Cl-polyfluorinated ether sulfonate (6:2 Cl-PFESA)
FABPs	Fatty acid binding proteins
FASAs	Perfluoroalkane sulfonamides
FASEs	Perfluoroalkyl sulfonamidoethanols
FBG	Fasting blood glucose
FCCC	US association Fire Fighting Foam Coalition
FFFC	Fire Fighting Foam Coalition
FFFP	Fluoroprotein foam concentrates and film forming fluoro-protein
FHEA	Perfluorohexyl ethanoic acid
FI	Fasting insulin
FOSA	Perfluorooctane sulfonamide
FMV	Swedish Defence Materiel Administration
FP	Fluoro Protein
FPA Australia	Fire Protection Association Australia
FRV	Fire Rescue Victoria, Australia
FPAR	Fluoro-Protein Alcohol-Resistant
FTCA	Fluorotelomer carboxylic acid
FTIs	Fluorotelomer iodides
FTSAs	Fluorotelomer sulfonic acids
FTTAoSs	Fluorotelomer thioether amido sulfonates
FTUCA	Fluorotelomer unsaturated carboxylic acid
GAC	Granular activated carbon
GDP	Gross domestic product
GFK	Glass fiber reinforced composite material
GGMs	Gaussian graphical models
GHG	Greenhouse gas
GRP	Glass-fiber reinforced plastic
GWP	Global Warming Potential
HCFCs	Hydrochlorofluorocarbons

HDL	High-density lipoprotein
HDL-C	High-density lipoprotein cholesterol
HFCs	Hydrofluorocarbons
HFEs	Hydrofluoroethers
HFOs	Hydrofluoroolefins
HFP	Hexafluoropropene
HFPO-DA	Hexafluoropropylene oxide dimer acid, 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, FRD-903, GenX
HPG	Hypothalamic–pituitary–gonadal
HPT	Hypothalamic–pituitary–thyorid
HWI	Hazardous waste incinerators
IBCs	Intermediate bulk containers
IC50	The concentration of drug required for 50% inhibition
ICAO	International Civil Aviation Organization
IED	Industrial Emissions Directive
IMO	International Maritime Organization
Intertanko	International Association of Independent Tanker Owners
IPEN	International Pollutants Elimination Network
IPCC	Intergovernmental Panel on Climate Change
ITRC	Interstate Technology and Regulatory Council
IX	Ion exchange
K_d	sediment/water distribution coefficients
kg	Kilogram
KEMI	Swedish Chemicals Agency
L	Lactation effects
LAST	Large atmospheric storage tank
LC	Lethal Concentration
LDL	Low-density lipoprotein
LDL-c	Low-density lipoprotein cholesterol
LfU	Bavarian State Ministry for the Environment and Consumer Protection
LOEC	Lowest observed effect concentration
LoQ	Limit of Quantification
LRT	Long-range transport
LRTP	Long Range Transport Potential
M	Mutagenicity
MAC Directive	Mobile Air-Conditioning Directive
MoD	Ministry of Defence
MetS	Metabolic syndrome
mg	Milligram
MFB	Victorian Metropolitan Fire and Emergency Services Board
MLB	Mobile extinguishing water treatment plant (DE)
MoA	Mode of Action
monoPAPs/diPAPs	Polyfluoroalkyl phosphoric acid mono-/diesters
MSFD	Marine Strategy Framework Directive
MWV	Mineralölwirtschaftsverband (German associations for Mineral oil Industry)
n:2 FTIs	n:2 Fluorotelomer iodides
NDAA	National Defence Authorization Act

NIVA	Norwegian Institute for Water Research
ng	Nanogram
NHANES	National Health and Nutrition Examination Survey
NK	Natural killer
NPS	Nano-sized particle fractionator
NPV	Net present value
NTCP	Na+/taurocholate co-transporting polypeptide
NTS	Non-destructive Testing System
OATs	Organic anion transporters
OATPs	Organic anion transporting polypeptides
OBS	Additional PFASs such as F-53B and p-perfluorous nonenoxybenzenesulfonate
OECD	Organisation for Economic Co-operation and Development
OF/AOF	Extractable/adsorbable organofluorine
PAC	Powdered activated carbon
PAHs	Poly aromatic Hydrocarbons
PAPs	Perfluoroalkyl phosphate esters
PASF	Perfluroalkane sulfonyl fluoride substances
PBTK	Physiologically based toxicokinetic
PBT	Persistent, bioaccumulative and toxic
PCBs	Polychlorinated biphenyls
PCTFE	Polychlorotrifluoroethylene
PEC	Predicted Environmental Concentration
PEG	Polyethylene glycol
PFA	Perfluoroalkoxy polymer
PFAAs	Polyfluoroalkyl acids
PFAEs	Perfluoroalkylethers
PFASs	Per- and Polyfluoroalkyl Substances
PFBA	Perfluorobutanoic acid
PFBPA	Perfluorobutyl phosphonic acid
PFBS	Perfluorobutane Sulfonic acid
PFCAs	Perfluoroalkyl Carboxylic acid
PFDA	Perfluorodecanoic acid
PFDoDA	Perfluorododecanoic acid
PFECAs	Perfluoroalkylether carboxylic acids
PFECHS	Perfluoroalkane sulfonate
PFESAs	Perfluorooctyl phosphonic acid
PFHpA	perfluoroheptanoic acid
PFHxA	Perfluorohexanoic acid
PFHxS	Perfluorohexane sulfonic acid
PFMOBA	Perfluoro(4-methoxybutanoic) acid
PFNA	Perfluorononanoic acid
PFOA	Perfluorooctanoic acid
PFOPA	Perfluorooctyl phosphonic acid
PFOS	Perfluorooctane sulfonic acid
PFOSA	Perfluorooctanesulfonamide
PFPAs	Perfluoroalkyl phosphonic acids

PFPE	Perfluoropolyether
PFPiAs	Perfluoroalkyl phosphinic acids
PFTeDA	Perfluorotetradecanoic acid
PFTrDA	Per-fluorotridecanoic acid
PFSAs	Perfluoroalkane sulfonic acids
PFUnDA	Perfluoroundecanoic acid
PICs	Products of incomplete combustion
PMM	Perfluoro-N-methylmorpholine
PNEC	Predicted No Effect Concentration
POP	Persistent Organic Pollutants
POPRC	POP Review Committee
PPAR	Peroxisome proliferator activated receptors
ppb	Parts per billion
PPE	Personal protective equipment
ppm	Parts per million
PPP	Plant protection products
PTFE	Polytetrafluoroethylene
PXR	Pregnane X-receptor
QSAR	Quantitative structure–activity relationship
R	Reproductive toxicity
RAC	Committee for Risk Assessment
RCF	Root concentration factor
R&D	Research and Development
RISE	Research Institute of Sweden
RIVM	The National Institute for Public Health and the Environment NL
RMM	Risk management measure
RMO	Risk management option
RO	Restriction option
SDS	Safety data sheet
SEA	Socio-economic assessment
SEAC	Committee for Socio-economic Analysis
SFPs	Side-chain fluorinated polymers
SHB	Southern Hudson Bay
SPM	Suspended particulate matter
SS	Steady state
STOT RE	Specific target organ toxicity on repeated exposure
SVHC	Substances of Very High Concern
TBG	Thyroxine-binding-glubolin
TC	Total cholesterol
TDAR	T-cell-dependent antibody responses
TERC	Toxicology & Environmental Research and Consulting, The Dow Chemical Company
TF	Total fluorine
TFA	Trifluoroacetic acid
TFE	Tetrafluoroethylene
TFMP	4-(trifluoromethyl)phenol
TG	Triglycerides

TMF	Trophic magnification factor
TRR	Total radioactive residue
TSCA	Toxic Substances Control Act (US)
TOC	Total organic carbon
TOF	Total fluorine
TOPA or TOP	Total oxidizable precursor
TTR	Thyroxine transport proteins transthyretin
TWI	Tolerable Weekly Intake
UBA	German Environment Agency
UNECE	United Nations Economic Commission for Europe
UNFCCC	United Nations Framework Convention on Climate Change
UNEP	United Nations Environment Programme
US EPA	U.S. Environmental Protection Agency
US NFPA	US National Fire Protection Agency
UWWTD	Urban Wastewater Treatment Directive
UTV	Unabhängige Tanklagerverband e.V. (German Independent tank farm association)
UV	Ultraviolet
vPvB	Very persistent and very bioaccumulative
VTG	Vitellogenin
WFBC	Woman Firefighting Biomonitoring Collaborative
WFD	Water Framework Directive
WFVD	Der Verband Bundesverband Betrieblicher Brandschutz (German Industrial Fire-Fighters Association)
WHB	Western Hudson Bay
ww	Wet weight
WWTP	Wastewater Treatment Plant

Summary

This report details a human health and environmental risk assessment of the use of per- and polyfluoroalkyl substances (PFASs) in firefighting foams and describes an assessment of the effectiveness, practicality, monitorability and socioeconomic impacts of different risk management options (RMOs), including different restriction options (ROs) under REACH, to address the identified risk. The work was conducted by ECHA at the request of the European Commission[1].

The assessment concluded that the risks to human health and the environment from the use of PFASs in firefighting foams in the EU are not adequately controlled and that a restriction under REACH is the most appropriate means to address the identified risks; a preferred restriction option is identified.

The preferred restriction option would ban the placing on the market, use and export of PFASs in firefighting foams after use/sector-specific transitional periods. The restriction is estimated to reduce emissions of PFASs in the European Union by around 13 200 tonnes over the 30-year period following its implementation (the assessment period). The societal cost of implementing the restriction over the same period is estimated to be €6.8 billion[2] with an average cost of €515 per kilogram of emission avoided. Several elements determining the costs are uncertain and therefore the costs could be as low as €3 billion or as high as €17 billion.

PFASs are a family of thousands of synthetic (i.e. man-made) chemicals that are used widely in the EU, including in firefighting foams. All PFASs contain at least one perfluorinated carbon atom (see section 1.1.1.1). A carbon-fluorine bond is one of the strongest chemical bonds in organic chemistry. All PFASs are very persistent in the environment. This is the key hazardous property common to all PFASs. Many PFASs are likely to persist in the environment longer than any other synthetic organic substance. Consequently, if releases of PFASs are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects are likely. In such an event these exposures are practically irreversible. Even if further releases of PFASs were immediately prevented, existing environmental stocks would continue to be a source of exposure for generations.

PFASs are known to have additional hazardous properties. However, due to the heterogeneity of chemical structures in the PFAS class, these additional hazardous properties vary dependent on the molecular structure of specific PFASs. Nevertheless, most PFASs are mobile in water; humans and other biota cannot avoid exposure to such PFASs. For example, contamination of groundwater, surface water (freshwater, estuarine and marine) and biota with PFASs is already widespread and -specific to firefighting foams- at many locations with intensive use of firefighting foams. Drinking water contamination is already widely reported and will become ubiquitous if releases of PFASs are not minimised. Drinking water is very difficult and costly to treat to remove PFASs, contrary to other common contaminants. Plants also accumulate PFASs. Consumption of plant material, e.g.

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[1] https://echa.europa.eu/documents/10162/17233/request_echa_pfas_fff_en.pdf/aa089887-bc27-e642-747e-b935809075cc?t=1601895611682

[2] Using 4% discount rate to the cost to the EU is estimated at €390 million per year during the assessment period. The corresponding emission reduction would be of 440 tonnes per year.

grains and vegetables either as roots or above ground plant parts, function as a source of PFASs to humans and animals.

Some PFASs are distributed to remote areas by long-range transport processes. Some PFASs are gases (fluorinated gases or F-gases[3]). These PFASs are distributed around the globe once released where they contribute substantially to climate change[4].

The most thoroughly researched PFASs (so-called 'long-chain' PFASs) are suspected carcinogens, cause harm to the developing child and trigger effects at low concentrations in organs such as the liver or in the immune system. However, for most PFASs there are insufficient data to adequately assess their effects on human health and the environment (i.e. to demonstrate that they can be used safely). As research efforts progressed beyond long-chain PFASs (e.g., to shorter chain PFASs such as 6:2 FTOH) similar adverse effects to long-chain PFASs were reported. There are also data indicating that some PFASs are potential endocrine disruptors. The environmental effects of some PFASs are sufficient to warrant classification (e.g., 6:2 FTOH). Adverse effects resulting from 'combined exposure' to complex mixtures of PFASs are likely for both humans and wildlife. However, these effects cannot be currently assessed quantitatively with sufficient certainty for regulatory purposes.

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

Whilst some PFASs are already restricted in firefighting foams either in the EU or internationally (e.g., PFOS, PFOA, PFHxS, PFHxA and related substances) or are proposed for future risk management in the EU (e.g., PFHxS and PFHxA), the risks posed by the PFAS class in firefighting foams (also termed the PFAS universe) are not adequately controlled, requiring additional risk management.

The precise identities of the PFASs currently used in firefighting foams are largely unknown due to manufacturer confidentiality. Industry report that they mostly belong to the C6 chain length category (i.e., PFHxA related substances). However, substances with shorter chain length structures have also been used in firefighting foams[5] and novel unregulated PFASs could theoretically be developed for use in firefighting foams in the future. Consequently, a restriction covering the **whole PFAS class**, rather than specific PFASs or groups of related PFASs with a common final (terminal) degradation product[6], is appropriate to address the risks from PFASs in firefighting foams, including those arising from so called 'regrettable substitution' in the future.

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[3] F-gases are subject to a phase-down administered by Regulation (EU) 517/2014 due to their high global warming potential and contribution to climate change. Hydrofluorocarbons (HFCs) are also subject to a global phase-down under the Montreal Protocol Kigali Amendment.

[4] See for example the IPCC 4th Assessment Report: https://unfccc.int/process-and-meetings/transparency-and-reporting/greenhouse-gas-data/frequently-asked-questions/global-warming-potentials-ipcc-fourth-assessment-report

[5] As per uses reported in REACH registration dossiers.

[6] Sometimes termed as an 'arrowhead' e.g., PFOA is the arrowhead structure for all PFOA-related substances.

Around 30 000 tonnes of firefighting foams are manufactured in the EU per year by around 25 manufacturers. Despite previous restrictions on specific PFASs in firefighting foams, 18 000 tonnes (60 %) of the current manufactured tonnage are PFAS-containing foams. It is estimated that €90 million of revenues are generated from the sales of firefighting foams, with 25 % of revenues assumed to be resulting from exports to non-EEA countries. Precise data on imports are not available but they are presumed to be in the same order of magnitude as the exports.

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 (consuming 59 % of the annual tonnage). Firefighting foams are used both for training and in a variety of 'live' fire incidents, ranging from small fires to large tank fires.

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[7].

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) should be applied for each type of use and user sector. During these transitional periods PFAS-containing foams may still be used. Such a differentiation is justified because the likelihood of emissions[8] to the environment from the uses, as well as progress with substitution of PFAS-containing foams, is different for each use and user sector.

Uses for training and testing, use by municipal fire services and use in civilian marine applications can be relatively quickly substituted without adverse impacts. Whereas a longer transition period of up to 10 years appears to be justified for certain applications (notably for large atmospheric storage tank fires and industries dealing with numerous different flammable liquids at the same site) where further testing is required to determine the technical feasibility of alternatives, and where potential fire-safety risks from using inappropriate alternatives may be higher.

Several stakeholders requested longer transition periods (of up to 12 years) or an exemption for defence applications. The defence sector is a relatively small user of PFAS-containing firefighting foams in the EU (around 6 % of volumes sold). Despite some notable exceptions, defence applications are able to transition to fluorine-free alternatives in a

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[7] 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 needed to ensure the effectiveness of fluorine-free firefighting foams. Since large fire incidents are rare and large fire testing is costly, limited practical experience has been gained until now 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).

[8] In this report the terms "emissions" and "releases" are used interchangeably.

similar time frame as required for civilian aviation (where rapid extinguishing times are also required). In a limited number of cases (such as currently 'in service' military ships), exemptions or longer transitional periods could be justified. However, these scenarios would appear to be relevant to only very few Member States. Therefore, a generally longer transition period or exemption is not considered justified.

Longer transition periods are justified only for the most sensitive applications within the oil(petro-)chemical sector, i.e. those installations subject to the Seveso Directive on major accident hazards[9].

For all other sectors, shorter transition periods are expected to be sufficient to ensure a transition to PFAS-free alternatives, while having limited socio-economic consequences.

Regarding an appropriate concentration limit for PFASs in foams and equipment that previously used PFAS-containing firefighting foams, stakeholder input suggests that a PFAS concentration of 1 ppm can be achieved using a relatively simple cleaning process and would avoid the majority of emissions. Lower concentration limits are achievable with more complex and costly cleaning processes. However, setting a lower concentration limit would lead to a relatively small additional reduction in PFAS emissions, compared to the overall reduction achieved by the restriction and is therefore less desirable from a cost-effectiveness perspective.

Finally, 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. This obligation would cover, among other items, foam purchase, containment, treatment, proper disposal of foams and fire water run-off, as well as use of personal protective equipment. These measures provide a relatively effective reduction in PFAS emissions and exposure of workers and professionals at a relatively low cost during the transition periods over which PFAS-containing foams could continue to be used.

The EU is not alone in phasing out PFASs in firefighting foams. Several US states, including California, New York, Washington have also done so. Various other initiatives exist also including some in Australia (see section 2.2.2.2). This global trend of substituting PFASs in firefighting foams and due to the functioning of the internal market for firefighting foam products justifies an EU-wide restriction. Moreover, firefighting foams are traded over the borders and it would not be meaningful or possible to restrict them nationally due to internal market considerations. Furthermore, due to their high mobility and persistence (at least of some PFASs), PFAS emissions could lead to cross-border pollution.

Table 1 summarises the main restriction options (RO) assessed, their emission reduction potential, cost and cost effectiveness. Recognising the uncertainties in the results, they are considered to provide robust order of magnitude estimates, and to describe the differences between different ROs. The different RO are described and analysed in Section 2.2, including some which have been considered but not assessed in detail.

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[9] 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

Table 1. Summary of main restriction option (RO) assessed, their emission reduction potential, cost and cost effectiveness

Restriction option		Emission reduction (tonnes over 30 years)	Cost to society (€billion over 30 years)	Cost-effectiveness (€/kg avoided emission)
1	Restriction on the placing on the market but use continued to be allowed until expiry date of the stocks	11 800	5.9	500
2	Restriction on the placing on the market and use after use/sector-specific transitional periods	13 000	6.8	520
3[1]	Restriction on the export, placing on the market and use after use/sector-specific transitional periods	13 200	6.8	520
4	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	12 600	5.2	415
5	Restriction on the placing on the market and use for all uses after sector or use-specific transitional periods, unless adequate risk management measures are in place to capture all the emissions to the environment	12 500	15.0	1 200

Notes: 1 - Option #3 is the Dossier Submitter's preferred restriction option

The Dossier Submitter proposes restriction option 3 as most appropriate EU-wide measure to address the identified risks from the use of PFASs in firefighting foams. The restriction option is specified in detail below "Proposed restriction". Restriction options 4 and 5 are not considered to be practical as explained in Section 2.7.

Proposed restriction

Restriction on the export, placing on the market and use of PFASs in firefighting foams.

Column 1	**Column 2**
Per- and polyfluoroalkyl substances (PFASs) 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. Shall not be placed on the market or exported as substances on their own, as a constituent in other substances or in mixtures for use in firefighting foam concentrates where the concentration of total PFASs is greater than 1 ppm[10] 10 years after entry into force. 2. Shall not be used as substances on their own, as a constituent in other substances or in mixtures in firefighting foam concentrates where the concentration of total PFASs is greater than 1 ppm. 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 Directive 2012/18/EU (Seveso III) and for use in these establishments only); c. three years after entry into force for civilian ships; d. five years after entry into force for portable fire extinguishers as defined by EN3-7; e. 10 years after entry into force for establishments covered by the Directive 2012/18/EU (Seveso III)[11] (upper and lower tiers); 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). 4. Without prejudice to paragraph 3, six months after entry into force users of firefighting foam concentrates where the concentration of total PFASs is greater than 1 ppm shall: a. ensure that firefighting foam concentrates are only used for fires involving flammable liquids (class B fires);

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

[11] 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 exposures to humans of 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 firefighting foam concentrate where the concentration of total PFASs is greater than 1 ppm (including an assessment of the technical and economic feasibility of alternatives). ii. details of the conditions of use and disposal of each PFAS containing foam used on site specifying how paragraph 4(b) is achieved (including plans for the containment, treatment and appropriate disposal of liquid and solid wastes arising in the event of foam use, routine cleaning and maintenance of equipment or in the event of accidental leakage/spillage of foam). iii. The management plan shall be reviewed at least annually and be kept available for inspection by enforcement authorities on request. d. Ensure that the collected PFAS-containing waste with a concentration of PFASs above the one mentioned in paragraph 2 shall be handled for adequate treatment. The treatment shall minimise releases of PFASs to environmental compartments as far as technically and practically possible and shall exclude municipal wastewater 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, firefighting foam concentrates containing PFASs above the threshold indicated in paragraph 1 which are held in stock and need to be disposed of shall be handled for adequate treatment. The treatment shall

Column 1	**Column 2**
	minimise releases of PFASs to environmental compartments as far as technically and practically possible and excluding any wastewater 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 firefighting foam concentrates placed on the market or used, containers of firewater runoffs or other PFAS-waste in relation with the use of firefighting foams or the cleaning of firefighting foam equipment in concentrations above the one mentioned in paragraph 1 shall be labelled indicating the presence of PFASs above this threshold with the following wording: "WARNING: Contains per- and polyfluoroalkyl substances (PFASs)". This information shall be displayed in a clear and visible manner in the official language(s) of the Member State(s) where the firefighting foam concentrate is placed on the market, unless the Member State(s) concerned provide(s) otherwise. 7. [From six months after entry into force, packaging of firefighting foam concentrates placed on the market containing organofluorine substances above 1 ppm, but where the concentration of total PFASs is not greater than 1 ppm, shall be labelled: "Contains non-PFAS organofluorine substances with a total organofluorine concentration of (*insert concentration*) ppm". This information shall be displayed in a clear and visible manner in the official language(s) of the Member State(s) where the firefighting foam concentrate is placed on the market, unless the Member State(s) concerned provide(s) otherwise.]

Explanatory notes:

(1) "Testing of the firefighting systems for their function" means testing the fire protection system in the same way as it would operate in case of emergency. Other types of testing include but are not limited to: testing of foam agents during their development phase, testing of foam agents by users to evaluate products' suitability on specific combustibles, testing of correct proportioning of firefighting foam concentrates.

(2) Municipal fire services (i.e. local authority fire and rescue services) are covered under the restriction entry 3 (b.), except if they are also in charge of industrial fires for establishments covered by the Seveso-III Directive and for use in these establishments only. In this case, the transitional period of paragraph 3(e) applies.

(3) Other uses of firefighting foams include – but are not limited to -: civilian aviation, defence, aerospace, offshore oil/gas/chemical facilities, onshore oil/gas/chemical manufacturing or processing facilities which are not coved by paragraph a. (Seveso

establishments), power plants, glass manufacturers, waste treatment facilities, food processing industry, metal processing, etc.

(4) The use of PFAS-containing foam agents in portable fire extinguishers are covered by paragraph 3(d), with a proposed transitional period of five years, irrespective of the sector of use, i.e. their use would be continued to be allowed during this period even if the sector where they are used is subject to a shorter transitional periods (e.g. ships).

(5) "Civilian ships" refers to marine and non-marine civilian ships.

(6) Foam concentrates are the foam formulations purchased by the users and which are further mixed with water at the moment of the use. Water-added foams are the foam concentrates mixed with water at the moment of the use. Fire run-off waters (or "firewater runoff") are the run-off waters containing the firefighting foam concentrate mixed with water and all other elements mixed with them during the use of the firefighting foam during a fire incident, training or other use (e.g. flammable liquids, dirt, etc).

(7) The labelling of the containers containing PFASs above the threshold indicated in paragraph 1 aims at facilitating the identification and handling of the PFAS-containing foam concentrates, firewater runoff and waste.

(8) Placing on the market after 10 years is banned as the use is not allowed in any of the sectors or uses anymore at that time.

(9) The ancillary requirement detailed in paragraph 7 is intended to facilitate the enforcement of the proposed restriction by means of 'total fluorine' analytical methods, rather than targeted analysis of specific PFAS. The utility of this requirement shall be reviewed after the consultation on the Annex XV report.

1. Problem identification

PFASs are a family of thousands of synthetic chemicals that are used widely in the EU, including in firefighting foams. All PFASs are very persistent in the environment. Consequently, if releases of PFASs are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects are likely. In such an event these exposures are practically irreversible.

Most PFASs are mobile in water; humans and other biota cannot avoid exposure to such PFASs. For example, contamination of groundwater, surface water (freshwater, estuarine and marine) and biota with PFASs is already widespread and -specific to firefighting foams- at many locations with intensive use of firefighting foams. Drinking water contamination is already widely reported and it is very difficult and costly to treat to remove PFASs. Plants also accumulate PFASs. Consumption of plant material, e.g. grains and vegetables either as roots or above ground plant parts, function as a source of PFASs to humans and animals.

Some PFASs are distributed to remote areas by long-range transport processes. Some PFASs are gases (fluorinated gases or F-gases). These PFASs are distributed around the globe once released where they contribute substantially to climate change.

The most thoroughly researched PFASs (so-called ‘long-chain’ PFASs) are suspected carcinogens, cause harm to the developing child and trigger effects at low concentrations in organs such as the liver or in the immune system. However, for most PFASs there are insufficient data to adequately assess their effects on human health and the environment. As research efforts progressed beyond long-chain PFASs similar adverse effects to long chain PFASs were reported. There are also data indicating that some PFASs are potential endocrine disruptors. The environmental effects of some PFASs are sufficient to warrant classification (e.g., 6:2 FTOH). Adverse effects resulting from ‘combined exposure’ to complex mixtures of PFASs are likely for both humans and wildlife. However, these effects cannot be currently assessed quantitatively with sufficient certainty for regulatory purposes.

This chapter defines per- and polyfluoroalkyl substances (PFASs) and presents a human health and environmental hazard and risk assessment of the use of per- and polyfluoroalkyl substances (PFASs) in firefighting foams.

1.1. Hazard, exposure/emissions and risk

1.1.1. Identity of the substance(s), and physical and chemical properties

1.1.1.1. Substance identity restriction scope

For the purpose of this restriction proposal, PFASs are defined as substances that contain at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom, without any H/Cl/Br/I attached to it. This definition is equal to the OECD definition, derived in 2021, which reads as: “PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few exceptions, any chemical with at least a perfluorinated methyl group (–CF_3) or a perfluorinated methylene group (–CF_2–) is a PFASs.” (OECD, 2021b).

For the purpose of the Annex XVII restriction entry, we propose to use the following phrasing:

> Per- and polyfluoroalkyl substances (PFASs) 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).

This restriction proposal covers all PFASs as defined above as substances on their own, as a constituent (including as impurity or additive)[12] as well as in mixtures.

The substance scope includes PFASs (as defined above) irrespective of their market status. Hence substances on the EU market and other than those currently on the EU market are included to avoid regrettable substitution to substances that would have the same identified risks. Some of the substances in the scope, which are neither registered under REACH or CLP-notified, may be or may have been on the market outside of the EU. The substance scope also includes theoretical substances that are likely never to have been on the market.

Figure 1 shows the main PFAS subgroups as defined by (OECD, 2021b)

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[12] As defined in the ECHA Guidance for identification and naming of substances under REACH and CLP (May, 2017, Version 2.1).

Figure 1. Main PFAS subgroups, including the subgroup of stable substances (PFAAs) or 'arrowheads' and the precursors to the PFAAs. Figure adapted from OECD (2021b) – see figure 9 therein for more details on the grouping and nomenclature. The terms 'arrowhead' and 'precursor' are described in Section 1.1.2.

PFASs are a large group of organic chemicals that have been used since the 1950s, i.e., as ingredients for or intermediates of surfactants and surface protectors for assorted industrial and consumer applications. PFASs used in firefighting foams are discussed in section 1.1.1.2.

In perfluoroalkyl substances all C-H bonds have been replaced by C-F, while in polyfluoroalkyl substances one or more C-H bond(s) have been replaced by C-F but some C-H bonds still remain in the molecular structure. Polyfluoroalkyl substances containing at least one perfluorinated moiety are included in the scope of the proposal.

PFASs can be divided into subgroups in several ways. Figure 1 provides one way to differentiate, where the subgrouping is based on main chemical moieties present. Further ways to differentiate are for example carbon chain length and non-polymeric vs polymeric structures. The non-polymeric PFASs comprise a range of diverse molecules and include, inter alia, perfluoroalkyl carboxylic acids (PFCAs e.g., PFOA), perfluoroalkane sulfonic acids (PFSAs e.g., PFOS)[13], fluorotelomer-based compounds (e.g., 6:2 FTOH), per- and polyfluoroalkanes (e.g., perfluorooctance), perfluorotrialkylamines and per- and polyfluoroalkyl ether compounds, such as perfluoroalkyl ether carboxylic acids (PFECAs, e.g., HFPO-DA). Within the polymeric PFAS group, fluoropolymers (polymers consisting of a polymeric fluorinated carbon backbone) and side-chain fluorinated polymers (polymers consisting of non-fluorinated polymer backbones with per- or polyfluoroalkyl side-chains attached) are differentiated from one another. Please, see section B.1.1 for examples of these groups.

A distinct PFAS subgroup are the trifluoroacetic acid (TFA) precursors. They are a special subclass of PFASs often containing only a single $–CF_3$ group. Most of these occur – in addition to TFA itself- in gaseous form. Such fluorinated gases or "F-gases" are treated as a distinct group in this report due to their distinct properties.

A recent study by the OECD/UNEP Global PFC Group identified 4 730 CAS-numbers associated with individual PFASs or PFAS mixtures (OECD/UNEP, 2018). A comparison of REACH registered and/or CLP notified PFASs in 2019 with the OCED/UNEP list revealed that there may be more than 9 000 different individual PFASs. Of these, 6 257 were notified only to the ECHA classification and labelling database and there were 508 substances with active registrations, 257 of these were full and the remainder intermediate. In addition, The US EPA have assembled a consolidated 'master list' of 6 330 PFASs by combining information from several existing lists (U.S. EPA, 2020).

The scope of the proposed restriction is harmonised with the OECD definition (OECD, 2021b) for practical reasons. The OECD definition of PFASs is based solely on chemical structure and does not take into account hazardous properties or risks. Irrespective of this, as described in Section 0, the substance scope is considered to be a concern -based scope (with the exception of the excluded substances. For these no rationale was presented by OECD for their exclusion and these have not been elaborated in this report either).

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[13] A frequently used division is based on alkyl chain length where perfluoroalkyl carboxylic acids (PFCAs) with seven or more perfluorinated carbons and PFSAs with six or more perfluorinated carbons are considered as "long-chain" PFCAs and PFSAs, respectively, and those with shorter perfluoroalkyl chains "short-chain" PFCAs and PFSAs (OECD, 2021). It is noted that this definition has not been extended to other PFAAs nor to other PFASs. In this document, alkyl chain length of PFCAs and PFSAs is indicated as C[number of carbons].

1.1.1.2. Overview of PFASs used in firefighting foams

Long-chain PFASs were used as surfactants specifically because of their potent water and oil repellence at low concentrations . However, short-chain PFASs are nowadays used due to the phase out of long-chain PFASs.

Firefighting foam concentrates usually contain general classes of compounds, such as surfactants, solvents, stabilisers and thickeners. However, each foam formulation is unique and even foams with the same name differ over time in the combination of specific ingredients.

The main function of PFASs in firefighting foams is to act as a surfactant, that is 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 from reigniting.

Different types of PFAS-containing foams are available on the market, mainly:

- "Aqueous Film Forming Foam" (AFFF) which form an aqueous film on the surface of the flammable liquid by the foam solution as it drains from the foam blanket;
- "Alcohol Resistant-Aqueous Film Forming Foam" (AR-AFFF) which are resistant to polar solvent and alcohol liquids;
- "Fluoro Protein" foams (FP) and
- "Film Forming Fluoro-Protein" foams (FFFP)[14] .

However, other types of PFAS-containing foams also exist, such as "Alcohol-Resistant Film-Forming Fluoro-Protein" foams (AR-FFFP) and "Fluoro-Protein Alcohol-Resistant" foams (FPAR)[15].

Thanks to their properties, PFAS-containing foams are therefore used in fires involving flammable liquids (Class B fires[16]) across a range of sectors. The quantities of foam used by different sectors are discussed in section 1.1.5 and annex A.2.2. PFAS-containing firefighting foams are used for fires in many different applications involving flammable liquids and are used in equipment ranging from small fire extinguishers up to large tank fires. They can be applied with both mobile and stationary equipment and are also used in training and testing of equipment.

Firefighting foams are made up of water, air and a foam concentrate mixed together during use.

ECHA's substance database was searched for structures covered by the substance scope of this proposal. A large number of highly diverse PFAS substances were identified as potentially being used in firefighting foams with carbon chain length from C2 to ≥C8. No PFAS-substance with only a single -CF_3 moiety has been identified for this use. Briefly, PFAS classes found to be used in firefighting are:

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[14] https://www.chemguard.com/about-us/documents-library/foam-info/general.htm

[15] https://pfas-1.itrcweb.org/3-firefighting-foams/#3_1

[16] The European Standard Classification of Fires distinguishes between the following fires:
Class A – fires involving combustible solid materials (e.g. wood, paper or textiles);
Class B - fires involving flammable liquids (e.g. petrol, diesel or oils);
Class C - fires involving gases;
Class D - fires involving metals;
Class K - fires involving live electrical apparatus;
Class F - fires involving cooking oils.

- Unsubstituted long-chain PFASs
- Unsubstituted short-chain PFASs
- Substituted short- and long-chain PFASs
- Fluorotelomers
- Others

See Annex B.1.1 for details on the PFASs used in firefighting foams.

According to the European Committee of the Manufacturers of Fire Protection Equipment and Fire Fighting Vehicles (Eurofeu) as well as the US association Fire Fighting Foam Coalition (FCCC), PFASs used in firefighting foam technology in the EU are presently exclusively of PFHxS, PFHxA and related substances. FFFC further indicates that PFASs based on <C6-chemistry have never been used as an active ingredient for firefighting foams as the chemistry is not suitable. These would be unintended by-products of the synthesis process (telomerisation process).

Eurofeu further commented that PFOS, PFOA and related substances-based foams are solely legacy foams and that there has been no use of C8 beyond impurities in the C6-surfactant production since 2010. Eurofeu has not received any information about fluoro-compounds with chain lengths of less than C6 being used in firefighting foam technology today. According to the information received by their members, sales for fluorine-containing foams for aviation and municipal fire brigades applications are declining rapidly (Eurofeu, 2021).

1.1.2. Justification for grouping

PFASs are considered as a group because all members of the group share a common hazard and risk (described in Sections 1.1.4 and 1.1.6). This is, in essence, the result of the very persistent property of the perfluorinated part(s) of PFAS molecules.

Specific PFASs have previously been assessed (and in some cases have been subject to risk management) on the basis of the PFAS moieties that they contain (see section B.1.4). For example, PFOA is a very persistent (vP) substance that is the common final (terminal) product of the environmental (bio)degradation of various different PFASs which all contain the perfluorooctanoate moiety. PFASs have been allocated to subgroups based on their respective terminal degradation product (respective common perfluorinated moiety) (see Figure 1). The terminal degradation products are often referred to as **arrowhead substances**, while the parent substances degrading to the arrowheads are referred to as **precursors** (e.g., 6:2 FTOH is a precursor of PFHxA). Term **related substance(s)** is used interchangeably with the term precursor. Over sufficient time horizons all precursor substances will contribute to environmental stocks of their corresponding arrowhead substances (see Section 1.1.4 for further details). This grouping approach is acknowledged as a basis for risk assessment also by several scientists (see, e.g., Cousins et al., 2020a).

Based on the experience with European regulatory activities on PFASs since 2014, it is expected that PFASs restricted individually or per arrowhead group (e.g., PFOA and related substances) might simply be replaced with slightly different non-restricted PFASs (e.g., ADONA or HFPO-DA) with the same risks. This observation provides the main motivation to include all PFASs having equivalent hazard and risk in a single restriction, to avoid regrettable substitution by other PFASs.

Some PFASs included in the scope of the proposed restriction may have a negligible or indeed no current use. However, such PFASs would need to be included in the scope, either because their use may increase as a result of becoming an alternative for another, restricted PFASs, or due to new uses/applications.

To summarise, 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. However, the grouping is also justified by the desire to avoid regrettable substitution and prevention of future exposures of those PFASs which are not currently in use.

It is noted that there are various other fluorinated substances on the market which appear related to PFASs and which may have similar hazards. These are further discussed in section B.1.1.

1.1.3. Classification and labelling

Over 6 000 PFASs have a classification (mostly a self-classification) for at least one environmental, human health and/or physicochemical endpoint in the ECHA classification and labelling notifications database.

The following human health endpoints are considered of most concern following long-term exposure of humans: carcinogenicity (C), mutagenicity (M), reproductive toxicity (R) including lactation effects (L), and specific target organ toxicity (STOT RE). 388 PFASs have a classification for at least one of these five endpoints, of which 44 are harmonised classifications. See Annex B.3 for more information. Note that it was not assessed whether the effects leading to the classification are due to the PFAS-moieties or due to some other structures in the substance.

With regard to the environmental hazards, 1 129 PFASs have a self-classification. For more detail see Annex B.3.

1.1.4. Hazard assessment

1.1.4.1. Overview

PFASs is a broad term used to cover approximately 4 700 specific chemical species[17] which have a wide range of uses. These uses are principally based around the carbon-fluorine bond which is particularly strong and offers physical properties that include high water and oil repellence[18]. The same properties mean that many PFAS substances are also highly mobile (within the natural environment) and highly persistent (see below the sections on hazard assessment, and Appendix 3 of the underlying study[19]). This can create issues where PFAS substances emitted to the environment reach and contaminate important

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[17] OECD, 2018, PFAS database, toward a new comprehensive global database of per and polyfluoroalkyl substances.

[18] Buck et al, 2011, 'Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification and origins', Integrated environmental assessment and management vol 7 issue 4.

[19] Wood, Ramboll, COWI: "The use of PFAS and fluorine-free alternatives in fire-fighting foams - Final report". Report for the European Commission DG Environment and European Chemicals Agency (ECHA) under specific contracts No 07.0203/2018/791749/ENV.B.2 and ECHA/2018/561.

resources such as groundwater, on which abundant literature is available, including from the use of firefighting foams[20].

The Nordic Council of Ministers[21] indicates that the contamination may be poorly reversible or even irreversible, and may reach levels that could render natural resources such as soil and water unusable far into the future, resulting in continuous exposure and unavoidable harmful health effects, particularly for vulnerable populations, such as children. The example of PFOS in firefighting foams applied during the explosion in 2005 of the Buncefield oil storage facility is cited, which contaminated an aquifer that is an important public drinking water source for the Greater London area, so that it is no longer available as a water supply.

There is evidence to suggest that exposure to PFASs can lead to adverse health effects in humans (by eating or drinking food or water contaminated by PFASs). In particular the US EPA[22] highlight studies that indicate the long-chain (chain length of 8 or more) species PFOS and PFOA can cause reproductive and developmental, liver and kidney, and immunological effects on laboratory animals. Furthermore, both chemicals have caused tumours in animal studies. Their use is already restricted in the EU and elsewhere. Some short-chain PFASs (PFHxS, PFBS, HFPO-DA) have also been listed as SVHCs, based on there being an equivalent level of concern to the named groups of chemicals under the authorisation provisions under REACH (carcinogens, mutagens and reprotoxicants (CMRs) and persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs) chemicals).

The Nordic Council of Ministers[23] commented that the annual health-impacts within an EEA exposure study (from all uses of PFASs, not only firefighting foams) was estimated at €52-84 billion. This gives an indication of the scale of the issue and magnitude of the potential impacts from the environmental build-up of PFASs. The same study describes remediation costs associated with contamination from PFASs at European sites ranging from several hundred thousand up to €40 million with one high-cost example for the Dusseldorf Airport, Germany estimating a total remediation cost of up to €100 million.

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[20] See e.g.

- Dauchy et al., 2017, Per- and polyfluoroalkyl substances in firefighting foam concentrates and water samples collected near sites impacted by the use of these foams, Chemosphere, Vol. 183, 2017, Pages 53-61, https://doi.org/10.1016/j.chemosphere.2017.05.056.
- EFSA, 2012. Perfluoroalkylated substances in food: occurrence and dietary exposure. EFSA J. 10, 2743. Available at: https://www.efsa.europa.eu/efsajournal/pub/2743;
- Hu et al. 2016 Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Defence Fire Training Areas, and Wastewater Treatment Plants, Environ. Sci. Technol. Lett. 2016, 3, 10, 344–350;
- Hurley et al, 2016 Preliminary Associations between the Detection of Perfluoroalkyl Acids (PFAAs) in Drinking Water and Serum Concentrations in a Sample of California Women, Environ. Sci. Technol. Lett. 2016, 3, 7, 264–269;
- Ingelido et al, 2018, Environment International, Volume 110, January 2018, Pages 149-159

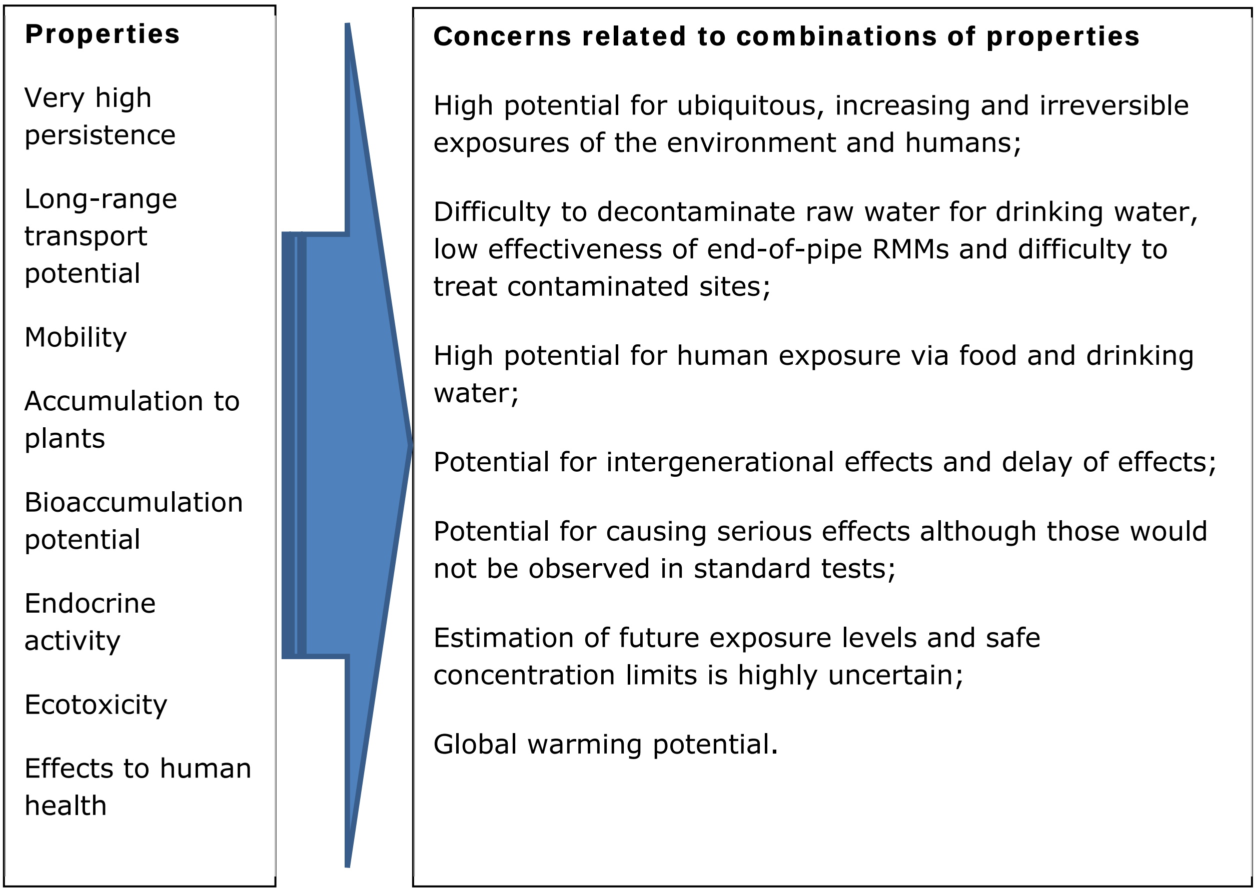
[21] Nordic Council of Ministers, 2019, 'The Cost of Inaction – A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS', *http://norden.diva-portal.org/smash/get/diva2:1295959/FULLTEXT01.pdf*

[22] US EPA, 2019, 'Basic information on PFAS', https://www.epa.gov/pfas/basic-information-pfas

[23] Nordic Council of Ministers, 2019, 'The Cost of Inaction – A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS', *http://norden.diva-portal.org/smash/get/diva2:1295959/FULLTEXT01.pdf*

Based on the physical properties of PFASs (particularly mobility and persistence) along with identified health effects for some PFASs, PFASs represent a challenging environmental and human health hazard issue.

All PFASs 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). Additional hazardous properties depend on the specific structure of a PFASs. Properties of concern identified in investigated PFASs as well as concerns resulting from specific combinations of properties are listed in Figure 2 and further described below.



Properties

Very high persistence

Long-range transport potential

Mobility

Accumulation to plants

Bioaccumulation potential

Endocrine activity

Ecotoxicity

Effects to human health

Concerns related to combinations of properties

High potential for ubiquitous, increasing and irreversible exposures of the environment and humans;

Difficulty to decontaminate raw water for drinking water, low effectiveness of end-of-pipe RMMs and difficulty to treat contaminated sites;

High potential for human exposure via food and drinking water;

Potential for intergenerational effects and delay of effects;

Potential for causing serious effects although those would not be observed in standard tests;

Estimation of future exposure levels and safe concentration limits is highly uncertain;

Global warming potential.

Figure 2. PFAS properties and property-related concerns resulting from combinations of the properties.

1.1.4.2. Persistence

As detailed in Annex B.4.1., PFASs are among the most stable organic compounds. Common for all the PFASs is that they have perfluoroalkyl moieties present. These moieties resist environmental and metabolic degradation due to the very stable C-F bonds. As presented in

Figure 1 and introduced in section 1.1.1.1, PFASs can be divided with regard to the hazard assessment into "precursors" and "arrowheads". The precursors are known or expected based on modelling to degrade on a timescale from hours to years to the arrowheads, such as PFCAs, PFECAs and PFSAs. There is a common understanding about grouping PFASs according to their stable degradation end-products (e.g., Cousins et al. (2020)).

After gradual degradation of the non-fluorinated part, the degradation stops when only perfluorinated carbons, and in some cases other moieties at their highest oxidation state and with high persistence, are left in the substance (see more in Annex B.4.1).

Environmental degradation of the non-fluorinated moieties in PFAS precursors often leads to the formation of PFAS intermediate and ultimate degradation products with increased mobility in water and/or air via oxidative chemical and biochemical degradation processes in the environment. See description of the precursor degradation in Annex B.4.1.3.

Lifetimes of the arrowhead PFASs in the environment exceed the criteria for very persistent substances in Annex XIII to REACH by far. For example, PFAAs are key arrowheads in the environment, and if PFAAs degrade, they do it so slowly that it is not observable in standard tests.

The high persistence of PFASs is their main concern, for the following reasons:

The continuous use and release of these very persistent substances leads to sustained exposure and increasing stocks in the environment. The high persistence in the environment will lead, inevitably, after release to distribution of PFASs from one environmental compartment to another e.g., from soil to freshwater to marine environment). Even if releases of PFASs are minimised now, PFASs will remain in the environment for very long time (see further details in section B.4.1). Furthermore, the combined historic releases of precursor PFASs form arrowhead PFASs over time. Therefore, the 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 the emission reduction will become.

The increasing stock pollution will result in increasing likelihood that known and unknown effects occur, be it by a single chemical and/or in a mixture with other substances (e.g. Bil 2021).

The persistence as the core concern of PFASs has also been pointed out by scientists for instance in the Helsingør Statement on PFASs (Scheringer et al., 2014) as well as the follow up Madrid statement (Blum et al., 2015). (Cousins et al., 2019) suggested to regulate PFASs on the basis of their very high persistence only and has named this the "P-sufficient approach" to regulatory action. Persistence alone was the justification for the regulation of PFASs as a class in California (Balan et al., 2021).

Further papers have discussed the role of persistence in decision making as the most important criterion or only property to justify regulation (Stephenson, 1977; Klöpffer, 1994; Mackay, D. 2014 Persson et al., 2013). See also section B.4.1.3.

1.1.4.3. Long range transport potential (LRTP)

The LRTP is assessed and discussed in section B.4.2.5. PFASs may concentrate in the respective compartment into which PFASs partition according to their specific properties (e.g., water-soluble substances concentrate in water, while volatile substances partition to air). PFASs 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 PFASs 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 PFASs, 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-PFASs complex due to the change of the fate properties along the degradation.

As provided by monitoring data (see Annex B.4.2.4/Appendix 10) PFAS contamination is not geographically limited but PFASs are found ubiquitously in the environment. This is due to their wide dispersive uses and distribution in a global market but also due to their global distribution in long-range environmental transport from source regions to the entire global environment including remote areas.

1.1.4.4. Mobility

Generally substances with a moderate to high solubility in water combined with a low adsorption potential can be considered to have a high mobility in the aqueous environment. Such substances tend to stay in the water phase, rather than bind to organic material and sediments.

Water solubility of PFASs varies from very soluble to almost insoluble (see examples in Annex B.1.3). For example, the water solubility of PFCAs and PFSAs is high with carbon chain length below 8 but with increasing carbon chain length the solubility tends to decrease.

The adsorption potential of PFASs is also subject to variation depending on the PFAS (see details in Annex B.4.2.1). Data for PFCAs, PFSAs and perfluoroalkylphosphonic acids indicate that there is a trend of increasing Koc values with increasing chain length (e.g., PFCAs logKoc 0.437-3.3, PFSA 0.352-3.675). Perfluorinated olefins which lack a functional group have higher K_{OC} values than the PFAAs with the same chain length. It is expected that PFASs lacking a functional group will be more adsorptive than a PFASs with a functional group of the same chain length.

It should however be noted that up to a chain length of 4 carbons perfluoroalkanes have boiling points below 0 C°. It is more likely that these short-chain perfluoroalkanes evaporate into the air when released to the environment. The same applies to the short-chain perfluoroalkylethers without further functional groups (see Annex B.1.3).

Ding et al. (2018) measured the partitioning behaviour of PFASs between the dissolved phase, surface sediment and suspended particulate matter in the Dalian Bay, China. PFOA, PFBA, and PFBS were the predominant PFASs in the water dissolved phase, while PFBS, PFOS and PFOA were the most prevalent compounds in suspended particulate matter. A log Kd for PFBS of 3.4 was reported, and it was concluded that PFSAs (including PFBS) and the long-chain PFCAs were more inclined to prefer the suspended particulate matter phase.

Generally, short-chain PFAAs and many long-chain PFAAs can be considered mobile in water (see section B.2.1 for details). Degradation of precursor -PFASs in the environment to PFAAs also render the precursors mobile in water at some point of time. For example, fluorinated olefins, which are not necessarily all mobile themselves, degrade into PFCAs (see Annex B.4.1.3) hence becoming mobile. Same occurs, e.g., to side-chain fluorinated polymers.

Measured data illustrating the distribution of PFASs in the environment is provided in section B.4.2.4/Appendix 10. These support the findings based on property data on the mobility of PFASs.

Mobility of PFASs in water contributes to their long-range transport potential, drinking water contamination potential, uptake in plants and in combination with high persistency to increase of internal exposures in biota. See further discussion on mobility as a concern in section B.4.2.1 and the subsection "Combination of…" below.

For those PFASs, which are volatile (see Annex B.4.2.2), distribution in the environment occurs mainly via air.

1.1.4.5. Accumulation in plants

Studies on accumulation of PFASs in plants are lacking for the majority of PFASs. However, several studies provide evidence that plants accumulate many PFASs to levels which exceed the expected levels based on equilibrium partitioning (see further details in Annex B.4.4). According to the review by Li et al. (2022), the reported average log BAF values range between 0 and 1 (or even exceed 1 for PFBA), indicating potential of PFASs to transfer from contaminated soil to plants. High accumulation of some PFASs is also indicated for instance by the study Blaine et al. (2013), where the accumulation of PFCAs (C5-C10) and PFSAs (C4, C6, C7, C8, C10) was investigated in lettuce and tomato grown on biosolid-amended soils. The reported BAFs for lettuce in this study ranged between 0.19 – 28.4 (municipal soil), and between 0.52 – 56.8 (industrially impacted soil) (C10 PFDS < LOQ). The greatest accumulation was seen for C4 PFCA. Another study with plants from biosolid-amended fields (Yoo et al., 2011) reports the highest accumulation factor among all measured PFASs (PFCAs, PFSAs, FTOHs) for PFHxA, with a grass/soil accumulation factor of 3.8. Accumulation potential (BAF) decreased logarithmically with increasing chain length. It is noted that all the studied PFASs are arrowhead PFASs, hence also very persistent.

A recent review article on exposure routes, bioaccumulation and toxic effects of PFASs on plants shows that bioaccumulation processes of PFASs in plants highly vary because of the complexity of PFAS chemistry (Li et al., 2022).

Whereas short-chain PFASs typically accumulate in above-ground plant parts, long-chain PFASs accumulate in 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 PFASs. Studies also indicate that the short-chain PFCA are more effectively taken up by plants compared to the long-chain PFCA (Felizeter et al., 2014, Yoo et al., 2011).

Consumption of plant material, e.g. grains and vegetables either as roots or above ground plant parts, function as a source of PFASs to humans and animals. Accumulation of many arrowhead PFASs in plants increases the relevance of this route of exposure. Accumulation in plants is of additional relevance when agricultural soil is contaminated with PFASs, leading to the contamination of agricultural plants (see Annex B.4.2.4/Appendix 10 and B.4.5 for an example case).

1.1.4.6. Bioaccumulation

The assessment of bioaccumulation is provided in Annex B.4.3 and B.5.1. Annex B.4.2.4/Appendix 10 on monitoring data also provide information on bioaccumulation in the field. By now, C11-C14 PFCAs and C6-PFSA have been shown to fulfil the vB-criterion and C8-C10-PFCA the B criterion (vB not assessed) under REACH.

Studies with mammalian species show that PFASs are readily absorbed and distributed across various tissues and that some PFASs (particularly the long-chain PFASs) have a long half-life in organisms. Data for PFCAs and PFSAs and some PFECAs indicate that PFASs partition into proteins. Binding to albumin and transporter proteins, which are classes of proteins ubiquitously expressed, efficiently distributes PFASs into different tissues, and enhance passage across brain, placental barriers, and transfer via milk. Accordingly, PFASs do not follow typical accumulation patterns, i.e. partitioning into adipose tissue, but rather bind and accumulate in protein-rich organs like liver.

Generally, BCF measurements have been focused on PFHxS, PFOS, PFOA, PFNA, and PFDA. Accordingly, in general, carbonyl and sulfonyl PFAS classes are relatively data rich, whereas phosphate, fluorotelomer, and ether PFAS classes are data -limited for fish and lack data for most other taxonomic classes. Among the 43 PFAS compounds for which mean BCF and BAF studies are available in different aquatic species 62 % (27 compounds) have a BCF and/or BAF values above the REACH threshold for B. For example, additional PFASs such as F-53B and p-perfluorous nonenoxybenzenesulfonate (OBS) were recently shown to significantly accumulate in common carp (Shi et al. 2015; 2020). The existing studies suggest that PFPiAs and PFPAs follow similar pattern with PFCAs where the total number of perfluoroalkyl carbons correlate with the BCF. In a BCF study of Chen et al. (2016) the long-chain PFPiAs (total carbon ranged C12 to C18) would appear to exceed BCF of 5 000 in fish (whole-body log BCFs ranged between 4.6 and 9.2), while the log BCF values of the PFPAs (C6-C10) ranged between 1.2 and 2.3 (see further details in Annex B.4.3).

Furthermore, PFASs, particularly the PFAAs as arrowheads, accumulate more in air-breathing organisms as compared to gill breathing organisms, because unlike the latter, air-breathers cannot readily eliminate PFASs by passive diffusion. Elimination to water via gills is facilitated by the appropriate solubility of most PFASs, while air-breathing organisms are not able to excrete PFASs by ventilation via the lungs to air. Thus, established assessment methods of bioaccumulation based on bioconcentration testing in aquatic organisms do not function as methodology for estimating the bioaccumulation behaviour of PFASs (see Annex B.4.5) in general. Unfortunately, in comparison with freshwater species, laboratory bioaccumulation data are very limited for air-breathers. Further discussion on toxicokinetic behaviour from experimental studies in laboratory mammals, is provided in Annex B.5.1 and B.4.3 (under subsection "Toxicokinetics in animals").

Short-chain PFASs are generally more hydrophilic and mobile in aqueous systems than long-chain PFASs. Short-chain PFASs are also more readily excreted by urinary excretion in air-breathing organisms and tend to be less bioaccumulative, while the strength of bioaccumulation potential usually increases with perfluoroalkyl chain length. In general, BCFs and BAFs of PFASs with 8 or more carbons increase uniformly with increasing number of carbons in the alkyl chain, with highest bioaccumulation potential of compounds with 12 to 14 carbon-chain length. Available laboratory bioconcentration studies in freshwater fish indicate that PFASs with a shorter alkyl chain, i.e. HFPO-DA, EEA-NTH, ADONA, are generally less bioaccumulative in fish. However, the relationship between chemical structure, affinity to proteins and accumulation pattern is complex though and still a matter of research. For example, a comparison of laboratory BCFs with field BAFs revealed that 60% (26 of 43 comparisons) of the BAFs are greater than their corresponding BCFs (Burkhard 2021), possibly due to multiple exposure routes taking place in field conditions (e.g. exposure via food in addition to exposure from the water phase only).

Due to the aforementioned properties, many PFASs accumulate in air-breathers, and long-chain PFASs biomagnify in marine and fresh-water food webs, reaching high levels in top predators including humans and vulnerable species (see monitoring Annex B 4.2.4). It is noted that as a consequence this may negatively affect the recommendations related to consumption of meat and/or entrails of certain animals (e.g., deer, fish for PFOS and PFOA in EFSA, 2018).

Field studies on long- and short-chain PFASs that can be analytically distinguished demonstrate that PFASs (primarily PFBA, PFBS, PFHpA, PFHxA, PFHxS, PFOS, FOSA, 6:2 FTOH, F-53B, 6:2 Cl-PFESA, TFA, and C9-C11 PFCAs) are found in all environmental compartments in mammals, birds, fish or other vertebrates throughout Europe and globally. Notable is that not just arrowheads but also precursors (e.g., 6:2 FTOH, F-53B, 6:2 Cl-PFESA) are found in biota, even though only very few studies focus on their detection. Given the fact that for the majority of PFASs no or insufficient data are available on bioaccumulation behaviour, substantial and large uncertainties remain. In conclusion and considering the increasing lines of evidence from modelling, laboratory and monitoring studies, there is a justified concern for a subset of PFASs of being bioaccumulative while large uncertainties remain for the majority of compounds due to lack of data.

It is noted that routine target analysis of food items and wildlife usually includes only the most commonly used and/or identified C4–C15 PFCAs and C4–C10 PFSAs, missing a large fraction of other PFASs. Hence the actual combined exposures of all PFASs, also considering the expected specific bioaccumulation behaviour as described above, may be even higher than the one observed in the monitoring programs.

Overall, the data on the bioaccumulation potential of PFASs, which are currently available, are not sufficient to substantiate bioaccumulation in the environment for all PFASs.

1.1.4.7. Endocrine Activity / Endocrine Disruption

Collected evidence of EA/ED of several PFASs indicates that adverse effects through interaction of PFASs with the hormone system as well as cross generational exposure cannot be excluded (see details in Annex B.7.4). In summary, the *in silico*, *in vitro* and *in vivo* data listed in Annex B.7.4 provide indications of interactions of various PFASs with the endocrine system of environmental species.

1.1.4.8. Ecotoxicity

There is evidence for a subset of PFASs that adverse effects occur (see Annex B.7). The large amount of different substances in the group of PFASs with heterogenous properties (e.g. due to different functional groups) makes the assessment of their ecotoxicity very complex. It is noted, that most recently, 6:2 FTOH was evaluated by RAC to warrant a classification of Aquatic Chronic 1 (ECHA, 2021).

Considering the effective uptake and even accumulation of many PFASs by plants, consideration of plant toxicity is also relevant. However, environmentally relevant concentrations of PFASs rarely lead to obvious phenotypic/physiological damages in plants, but markedly perturb some biological activities at biochemical and molecular scales. PFASs exposure induces the over-generated reactive oxygen species and further damages plant cell structure and organelle functions.

Overall, the data on the ecotoxicity of PFASs, which are currently available, are not sufficient to substantiate adverse effects in the environment for all PFASs.

1.1.4.9. Effects on human health

Available scientific literature on PFASs that have been investigated in animal and epidemiological studies clearly show human health hazards and concerns for many PFASs (for details, see Annex B.5).

There is a vast amount of literature published on the health effects of PFASs, mostly on the PFAA arrowheads PFCAs and PFSAs, especially on PFOA and PFOS. Other PFASs have been less well-studied, but attention of the research and available 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 (see Annex B.4.1 for details) and hence, also add to the concern. Below the human health effects as reported for PFASs are summarized, per main PFAS category.

PFAAs (arrowheads/precursors)
In humans, many PFAAs are readily absorbed after oral exposure, while less is known regarding absorption after inhalation and dermal exposure (details in Annex B.5.1.). Many PFAAs bind to proteins and are thus distributed to protein-rich tissues including liver, kidneys, and blood. PFAA precursors are metabolised in humans to arrowhead PFAAs, which are not further metabolised. Estimated human elimination half-lives for PFAAs range from a few days (such as PFBA) and a month (PFHxA, PFBS) to a couple of years (such as PFOA, PFNA, PFDA, PFHxS or PFOS) or >10 years (e.g. PFUnDA). Half-lives are much shorter in rodents than in humans and a difference in half-lives between sexes is often observed. Consequently, the observed toxicity in rodents underestimates the toxicity to humans. PFAAs are mainly excreted via urine and faeces and are released to the environment. PFAAs have a strong potential for bioaccumulation in humans as shown by the long half-lives (details in Annex B.5.1) due to the protein-binding properties (details in Annex B.4.3).

EFSA extensively reviewed the epidemiological evidence for association between PFAS exposure and adverse effects in humans (EFSA, 2018; EFSA, 2020). Most data were on PFOS and PFOA, but information was available also for some other PFCAs and PFSAs. EFSA inferred that there is sufficient evidence to conclude that there is association between increased serum levels of various PFCAs and PFSAs and reduction in vaccine antibodies, increased propensity of infections, increased serum cholesterol, increased serum alanine transferase (ALT) and reduced birth weight. EFSA also identified some evidence of increased propensity of infections (Annex B.5.3). The association with immune effects was considered the most sensitive endpoint in humans (supported by data from experimental animals) and based on this EFSA has established a Tolerable Weekly Intake (TWI) of 4.4 ng/kg bw/week for the sum of PFOA, PFOS, PFNA and PFHxS (EFSA, 2020). Epidemiological studies published after the EFSA opinion generally support or strengthen conclusions on the above-mentioned associations and some more data on other PFAAs than PFOS and PFOA have become available. Furthermore, additional data for the PFOS alternative 6:2 Cl-PFESA (F-53B), which were not evaluated by EFSA, indicate similar associations with these health outcomes.

Experimental animal studies across different groups of PFASs demonstrate that liver, kidney, thyroid, immune system, and reproduction are main targets of PFAAs' toxicity, as outlined in Annex B.5. In rodent studies, the most consistent effects included enlarged liver, hepatocellular hypertrophy, increased serum ALT, increased kidney weight, toxicity to reproduction, effects on lymphoid organs, and decreased serum thyroid hormone levels. In particular liver effects have been observed for most PFAAs for which animal studies are available (Annex B.5.2). 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), see Annex B.3. Harmonized classifications for PFHpA (Repr. 1 and STOT RE 1) and 6:2 FTOH (STOT RE 2) have been agreed by RAC but are not yet officially included in Annex VI of CLP.

Data available for less well-studied PFAA arrowheads and some PFAA precursors indicate that these PFASs can have similar effects as the well-studied ones mentioned above (see Annex B.5). For example, PFBA exposure of experimental animals resulted in similar effects on liver (enlarged liver, hepatocellular hypertrophy and partially necrosis) as well as thyroid hypertrophy and full litter resorption, although effects occur at higher concentrations compared to PFOS/PFOA. Another example is HFPO-DA (GenX), which was initially introduced as a safer alternative to PFOA but showed comparable concerns as PFOA (Blake et al., 2020) and for which US EPA recently proposed an even lower reference dose than for PFOA and PFOS (EPA US, 2021).

As supporting evidence for similar toxicity concerns, a number of other PFAAs and PFAA precursors have self-classifications for Carc., Repr., Lact. and/or STOT RE. These self-classifications cover, for example, the following PFAS categories: the side chain aromatics (part of which are TFA precursors), the fluoro-telomers (e.g. fluorotelomer alcohols, epoxides, (meth)acrylates, sulfonic acids, etc.), and other PFAA-precursors (e.g., perfluoroalkyl iodides, sulfonamides, carbonyl amides etc.; details in Annex B.3). Exemplarily of note, HFPO-DA, PFOS, 6:2 FTSA and 8:2 FTSA have self- classifications for STOT RE, and PFOS as well for reproductive toxicity. Even though there is still a large number of PFASs that have no (self-)classification for the properties of concern, the absence of classification does not mean that these PFASs do not have these properties. It is more likely that for the vast majority of these substances, no study data are available to serve as a basis for classification. In the absence of evidence to the contrary, it can therefore be assumed that some of the less well studied PFAAs and PFAA precursors also exhibit one or more of the properties of concern.

Many PFASs contain only a single $-CF_3$ group and are considered TFA precursors as a special subclass of PFAAs. This group is heterogeneous with various types of effects and mechanisms of actions. The effects of these substances measurable in standard tests can often be attributed to the non-fluorinated parts of the substances. However, as these substances will ultimately degrade in the environment to TFA (see Annex B.4.1.3), they will contribute to the overall exposure to and risks of PFAAs. Concerns for human health by TFA itself are limited to effects at high doses in experimental animals: liver effects (increased liver weight, hepatocellular hypertrophy, increased ALT), increased kidney weight, decreased white blood cells, reduced weight of reproductive organs, litter loss, reduced body weight of offspring, and malformations.

Polymeric PFASs

Polymeric PFASs cover fluoropolymers (incl. fluoroelastomers), side-chain fluorinated polymers as well as per- and polyfluoropolyethers. For fluoropolymers, it is often assumed that they are non-toxic due to their alleged size- and chemically inertness- related non-bioavailability (Henry et al., 2018). The non-bioavailability has been questioned by Lohmann et al. (2020), summarising variability of airborne fluoropolymer particle size as well as membrane crossing capabilities of macromolecules, such as polymers and corresponding nanoparticles (details in Annex B.5.1). Furthermore, polymer molecules, e.g. from plastics or resins, are not all of the same large size and that especially the low molecular weight fraction is small enough to be diffusible. Additionally, the polymer-specific chemical diversity (e.g. size, reactive groups, polymerization aids, additives, unintentional

PFAS by-products, impurities, etc.) determine their potential toxicity (more details in Annex B.5.2). Blood and liver concentrations of polychlorotrifluoroethylene (PCTFE) trimer and tetramer oligomers as well as PCTFE 3.1 oils of different compositions were reported after oral exposure in monkeys (Jones et al., 1991), which indicates systemic distribution of polymers with low molecular weight.

Excessive inhalation of aerosolized fluoropolymer-containing products and pyrolysis products of fluoropolymers in humans and experimental animals is reported to cause respiratory illness, such as acute chemical pneumonitis, and reactive airway dysfunction syndrome, occasionally accompanied by nonspecific systemic symptoms, such as fever, chills, malaise, arthralgias, and nausea (REFs: Strøm and Alexandersen 1990; Hays and Spiller 2014; Johnson et al. 2018). These effects are of unclear etiology but demonstrate a potential toxicological relevance of fluoropolymers and their degradation products in acute inhalation exposure scenarios. However, toxicological relevance was also shown in continuous inhalation rodent exposure studies.

Repeated oral animal studies (mainly with rodents) with polytetrafluorethylene (PTFE) and polychlorotrifluoroethylene (PCTFE) trimer and tetramer oligomers, reported adverse health effects, such as loss of body weight and/or liver effects, which would generally fit the typical effects observed for PFASs (details in B.5.2). However, insufficiently reported study details weaken the power of the available effect data for PTFE and PCTFE. Clarity on effects after repeated oral exposure of the highly diverse group of fluoropolymers cannot be given on the basis of available data. However, at any point in their lifecycle fluoropolymers may generate PFAAs, e.g. during incomplete incineration at end-of-life (Lohmann et al., 2020), and as such contribute to the overall exposure to and risks of PFAAs.

The structures of side-chain-fluorinated polymers and polyfluoropolyethers are different from that of fluoropolymers. Little to no data is available on the toxicity of these two groups of polymeric PFASs. However, for side-chain fluorinated polymers it is expected that they release PFAAs at any point in their lifecycle, and will thus contribute to the overall exposure to and risks of PFAAs (Wood, 2020, OECD, 2021a).

F-gases

For various HFCs, HFOs, and HFEs, some effects are similar to those observed for PFCAs and other PFAA arrowheads, in particular effects on liver and lymphoid organs (see Annex B.5). Data available indicate that most of the F-gases have lower potencies compared to the arrowheads. Moreover exemplarily, some F-gases (e.g. some HFOs) ultimately degrade to PFAAs, e.g. TFA or PFBA (Annex B.4.1.3). Hence, also F-gases will contribute to the overall exposure to and risks of PFAAs.

Cumulative effects of co-occurring PFASs

Many different PFASs co-occur in the environment, drinking water, food, and in human blood (see section B.4.2.4). Many PFASs exhibit similar effects, such as effects on the liver, kidney, thyroid, serum lipids, and immune system. Accordingly, an assessment of hazards and risks taking into account such combined exposure would reflect exposure conditions more realistically than single compound assessments.

The similarity of the effects of most PFAS groups raises concerns about cumulative effects of PFASs. The lack of toxicity data for most PFASs precludes precise modelling of combined effects of all PFASs but concentration addition has been suggested as a precautious first tier, irrespective of the modes/mechanisms of action of the mixture components (Backhaus and Faust, 2012). This might give a realistic worst-case estimation of combined toxicities for risk assessment procedures even if similarity of components is unknown (Backhaus et al., 2000, Martin et al., 2021). Dose addition has also been adopted as the default assessment approach in EFSA's "Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals" (EFSA, 2019).

However, due to the immense number of PFASs and the lack of toxicological data for the vast majority of them, a combined assessment for all PFASs is unattainable within the scope of this restriction. In conclusion, it is emphasized at this point that combined exposure to different PFASs affecting the same target organs may result in combined additive effects rendering exceedance of effect thresholds or limit values more likely than assessment of individual substances.

Cumulative effects are considered in further detail in Annex B.5.4.

1.1.4.10. Concerns triggered by combinations of properties

Most of the PFASs manufactured, used and released to the environment can be expected (and are in case of investigated PFASs known) to have several of the above listed properties, depending on the specific identity of the PFASs. A combination of at least two or more properties is expected in particular for the arrowhead PFASs (see more details in Annex B.1.3, B.4., B.5 and B.7). As explained above, all arrowhead PFASs are very persistent, and their precursors will contribute to the environmental concentrations of the arrowheads as well through degradation in the environment. The presence of some of the additional properties is expected to correlate with each other: these are mobility in water with enrichment in plants and LRTP, volatility with global warming, volatility with LRTP.

In the following sections the concerns triggered by certain combinations of PFAS properties are discussed.

High potential for ubiquitous, increasing and irreversible exposure of the environment and humans

Although exceptions may occur, the overall expectation is, using the general knowledge on degradation pathways and, more specifically, the observations from monitoring data, model data, degradation testing (see Annex B.4.1. for details) and information on mobility (Annex B.4.2.1 and volatility (see Annex B.4.2.2) that the more time that passes after the release of PFASs into the environment, the more the environment is exposed to those PFASs which are the most mobile in water and/or the most volatile (F-gases) and most persistent among the PFASs.

Very persistent properties in combination with mobility in the aquatic environment results in a scenario where none of the environmental compartments act as a potential removal pathway (i.e. a sink). In this scenario, mobility increases the already high potential of very persistent substances to result in exposures of biota and humans. Marine surface water is an important compartment for very persistent and mobile PFASs and facilitates their distribution by advection (Cai et al., 2012b). Occurrence of elevated concentrations of PFASs in waters near the points of releases are problematic, because mobile substances are also bioavailable for efficient uptake in the food chain. Cai et al. (2012b) discusses this for coastal waters as an intermittent storage before PFASs are further diluted in the marine environment.

The very persistent PFASs have time to be distributed in and between environmental compartments, such as aquatic and atmospheric media. Combined with mobility, the distribution and transport via aqueous media is efficient and faster than for non-mobile substances. PFASs therefore reach effectively all media, including groundwater aquifers which function as drinking water reservoirs. This is illustrated by monitoring data showing that measured PFASs are already ubiquitously present in the environment (see section B.4.2.4).

Furthermore, PFASs are subject to long-range transport. Long-range transport in combination with very high persistence means that even the most remote sites of the globe and most vulnerable environments cannot be protected from PFAS exposures.

For the very persistent PFAS environmental concentrations increase as a result of releases until reaching a steady state at a far point of time. In consequence also PFASs having less or no bioaccumulative properties can show elevated levels in biota as illustrated by monitoring data (B 2.4.2). Recent models demonstrate that mobile and persistent PFASs will ultimately reach over time -unless the exposure is removed- such high levels in organisms that will affect both ecosystems and human health widely (Crookes and Fisk 2018). The report by Crookes and Fisk (2018) indicates that also substances which have bioconcentration factors below 2000 L/kg could potentially reach similar levels in biota compared to substances that are known to bioaccumulate, provided that they are sufficiently persistent and mobile in the environment. For example, calculations in the study show that a substance with a half-life of 365 days and a BCF of 800 l/kg may reach comparable concentrations in a system as a substance with a half-life of 60 days and a BCF of 5000 l/kg, if time allows for steady-state to be reached. See Annex B.4.3. "Persistence compensating for low bioaccumulation potential" for further details.

As a case study applying the model of Crookes and Fisk (2018), the nominal biota concentration calculations were repeated for PFBS and compared with some relevant model substances (ECHA, 2019). A degradation half-life in water of 10 years for PFBS was assumed, representing a best-guess estimate in the absence of any measured degradation half-life, and the calculations were performed with the following bioaccumulation values: BCF Fish: 23.5 (Chen et al., 2016); BAF crab 110 (Naile et al., 2013) and BAF fish 1736 (Campo et al., 2015). The outcome of the modelling of development of biota concentrations for PFBS over time is shown in Figure 3. The model substances (A, B, C and D) have combinations of half-life and BCF as shown in Figure 3. An assumption in the model is that the substance is mobile and not removed from the aqueous phase so that the concentration, and therefore the exposure, is maintained unchanged over time.

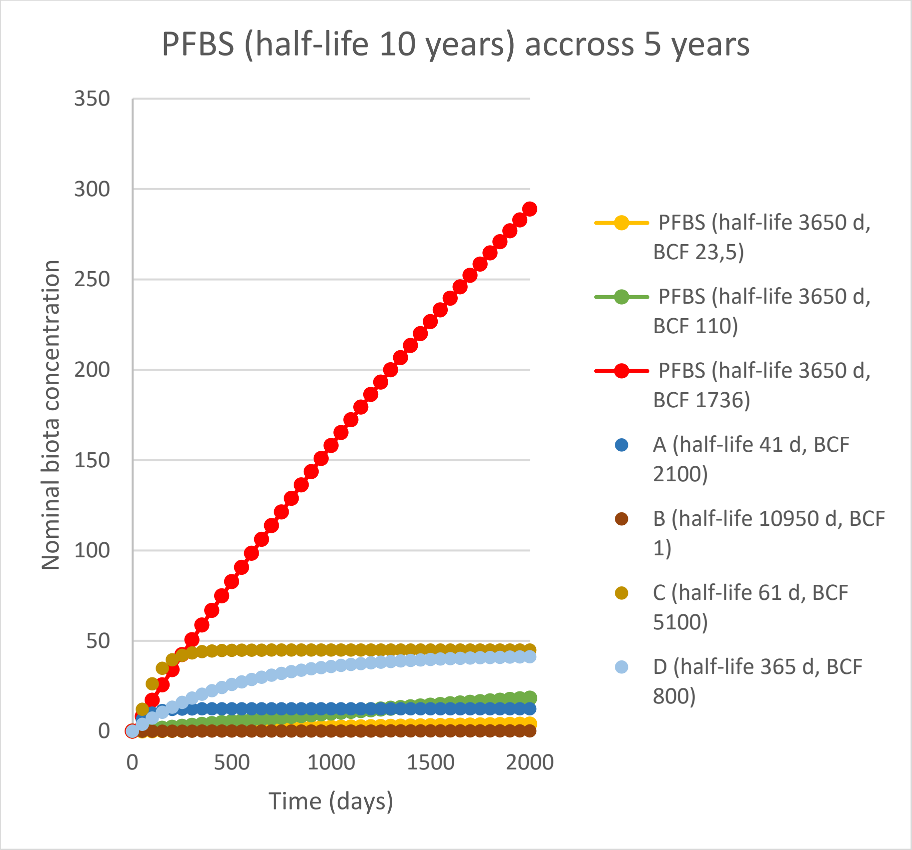


Figure 3. Modelling of development of nominal biota concentrations for PFBS over time.

Figure 3 demonstrates in a simplified way that when considering an appropriate long time scale, e.g., few decades (note figure X shows only 5.5 years), a long degradation half-life for a substance may lead to high steady-state concentrations in biota, even when the BCF is only moderate. The red line represents a BCF of 1736 for PFBS reported in fish (Campo et al., 2015) and demonstrates the effect of a long half-life in combination with a relatively high BCF. However, as is outlined in (ECHA 2019a), this BCF is an outlier and may be an overestimate, and the red line is disregarded in this evaluation. The green line represents a BAF of 110 measured in crab (Naile et al., 2013). The graph shows that this moderate BAF in combination with a half-life of 10 years, may lead to very high concentrations in biota over time. The green line even crosses the dark blue line, representing a substance with half-life in water of 41 days and a BCF of 2100, i.e. a substance just exceeding the P and B criteria in REACH Annex XIII. For the substance B combination of BCF of 1 and half-life of 30 years the high steady state would be reached very slowly far beyond the time-scale of the simulation. When the model from the Crookes and Fisk (2018) report is used for PFAS, concentrations of very persistent and mobile subgroups in biota may be expected to exceed the biota concentrations for a persistent and bioaccumulative substance over time. The steady state in biota would only be reached for PFASs in the model in far future.

Bioaccumulation and mobility can be seen as properties facilitating exposure and enhancing the likelihood of adverse effects in particular when combined with the very persistent property. With regard to bioaccumulation this is due to the slowly reversible internal exposure caused by a slow elimination kinetics in organisms and therefore elevated internal levels. Exposure to very persistent and mobile PFASs occurs continuously via drinking water and food crops. Finally, some PFASs (e.g., PFOA) can be both, mobile and bioaccumulative and distinguishing between the impact of each of the properties to the observed levels is not always possible.

To conclude, mobility in combination with very high persistence cause a high potential for increasing contamination of surface waters and aquifers. This contamination is very difficult to reverse. Even if releases are ceased, the exposure levels of the arrowhead PFASs continue to increase until the precursor PFASs have gradually all vanished from the environment. The environmental stock of the arrowhead PFASs formed is expected to prevail in the environment for decades if not centuries and is readily available for uptake by biota and humans.

Difficulty to decontaminate raw water and to reduce emissions with site-specific risk management

The combination of the very high persistence of PFASs and mobility and for many PFASs also of surface activity trigger specific challenges to wastewater treatment and decontamination of, e.g., raw water used for drinking water and contaminated sites (e.g., groundwater contamination around airports, see Annex B.4.5).

Municipal sewage treatment plants are not able to remove very persistent and mobile PFASs as they remain in the water phase and cannot be degraded within the retention time by the available micro-organisms. The available chemical removal methods are expected to reach removal of only a small fraction from the aqueous phase. The suspended PFASs, however, cannot be not degraded in sludge, or are in an ideal case merely degraded from precursor forms towards arrowhead forms. The monitoring data in influents and effluents of municipal sewage treatment plants supports this pattern (see Annex B.4.2.4).

Conventional and advanced raw water treatment methods applied to produce process water for industry and drinking water are neither able to remove PFASs effectively due to their persistence and inertness to chemical and thermal reaction. Thermolysis and sonolysis might achieve complete mineralization but come with a high process cost. Other treatment processes cannot remove PFCAs and PFSAs. The same applies to PFECAs. Conventional adsorption, ion-exchange, and membrane filtration can remove long-chain PFASs, but are less effective for the more hydrophilic short-chain PFASs. See Annex B 4.5 for details.

Raw water used for drinking water is obtained either from groundwater, bank filtration or surface waters. Monitoring data already reveal a contamination of either drinking water itself or raw water, ground water and river bank filtrates used for the preparation of drinking water (see Annex B.4.2.4). A recent review paper from (Li et al., 2020) on drinking water treatment concludes that short-chain PFAS are more widely detected, also persistent and even more mobile in aquatic systems, and thus may pose broader risks on the human and ecosystem health as compared to their long-chain counterparts. Routine target analysis, however, usually only addresses very few PFASs missing a large fraction. Furthermore, due to an analytical gap in the past the problem of persistent and mobile organic compounds and their impact on drinking water quality has been underestimated (Reemtsma et al., 2016), making older monitoring data possibly giving too optimistic views of the presence of PFASs in the environment.

The challenges are further elaborated in Annex B.4.5. To conclude, there are significant limitations to remove the PFASs from raw water and wastewater or sludge. In general, it seems that releases to water cannot be mitigated with on-site removal techniques, although some specific exceptions may apply. Exposure of humans via drinking water cannot be prevented effectively. Removal or remediation might only be feasible for contamination hotspots in few specific cases, but not for the majority of the environment, such as large aquifers, surface waters and the world's oceans.

High potential for human exposure via food and drinking water

Accumulation of many PFASs in edible plants, the bioaccumulation potential observed in some PFASs in a.o. fishery products and the very high persistence and mobility as discussed above mean that human exposure via food can be expected to be transmitted broadly by many routes of nutrition. Furthermore, drinking water is also a source of PFAS exposures due to the difficulty to decontaminate raw water prepared for drinking water. The exposure via drinking water and via food is expected to increase in future due to expected increasing concentrations of the arrowhead PFASs in the environment unless releases of PFASs are ceased. Even then it will take a very long time until the environmental concentrations are considerably reduced due to the high persistence if the substances. To conclude, the abovementioned combined properties of PFASs induce a high potential for exposure of the human population at large. Current exposure of the general population can be observed for several PFASs from the available biomonitoring data (see section B.4.2.4).

Potential for intergenerational effects and delay of effects

Several PFASs are transferred to the offspring (see Annex B.4.2.4 and B.5). The high potential for human exposures and the expected increasing and irreversible exposures, as discussed above, in combination with the intergenerational transfer of PFASs indicate that none of the stages of human life and wildlife can be effectively protected from exposure to PFASs. The very long-term exposures, continuing over decades or even centuries increase the likelihood for intergenerational effects. Furthermore, although effects would not be yet observed, the expected increase of exposures to the arrowhead PFASs even after releases have been ceased together with the above discussed results from tests on human health toxicity and endocrine disruptive effects raise the likelihood of effects to be observed at a later stage. At such point of time the effects would be very difficult to reverse.

Considering the increasing lines of evidence for effects of well-studied PFASs occurring at lower levels than previously anticipated (EFSA, 2020), combined with increasing findings of hazardous properties of less studied PFASs (e.g., (ECHA, 2021)) and the increasing stock pollution and the expected irreversible ubiquitous environmental contamination as outlined above indicates a threat of irreversible damage for future generations. The findings from studies investigating endocrine effects add to the concern. If yet unidentified adverse effects do occur these cannot be reversed.

Potential for causing serious effects although those would not be observed in standard tests

Already only the arrowhead PFASs constitute a diverse mixture of exposure whereas all the released PFASs in combination with the arrowhead PFASs form a very complex cocktail in the environment. As concluded in Annex B.5.4, combined effects should not be excluded but rather expected in this situation. There are no standard tests available which could simulate the exposure of PFASs taking place in the real environment. Additionally, potential effects arising from low-dose long-term exposure, as well as multigenerational exposures cannot be appropriately addressed by standard tests.

Additionally, the fact that exposures may take place at a different location than where releases occurred, and at a different moment in time due to the persistence, impedes the understanding of potential effects taking place.

Estimation of future exposure levels and safe concentration limits is highly uncertain

Currently no appropriate tools exist to estimate exposures reliably far in future. The prediction is further complicated for PFASs by the degradation of the precursors to the arrowhead PFASs. Number of PFASs in total yet higher than the number of PFASs manufactured and used can be expected to be simultaneously present in the environment. Environment is also exposed to intermittent degradation products. In example, side-chain fluorinated polymers (SFPs) which degrade in the environment at a very slow rate are a long-lasting constant source especially if long timeframes are investigated for emissions and exposures over centuries. This applies particularly to the end of service-life where surface soils and landfills constitute a major global reservoir for PFASs (Washington et al., 2019).

Currently it is also not possible to reliably assess (eco)toxcity of all PFASs. This is on the one hand reflected by the increasing lines of evidence for effects of well-studied PFASs occurring at lower levels than previously anticipated (EFSA, 2020) and findings for less studied PFASs (ECHA, 2020). On the other hand, the prediction of safe levels is more challenging, if not impossible, due to the complex mixture of used PFASs actually prevailing in the environment over long-term. The simultaneous exposure to the transient degradation products of the precursors impedes such a prediction before they finally form their respective arrowhead substances. As pointed out in sections B.5 and B.7 on effects to human health and ecotoxicity, both similar effects and different types of effects have been observed in available data across the PFASs. Combined effects can be expected over the long-term increasing exposure periods, as described in section B.5.11. This furthermore complicates the derivation of safe levels.

Global warming potential

Some of the PFASs are persistent and volatile and will partition to the atmosphere where they will stay for a very long time. These PFASs may have a considerable global warming potential which could contribute to the greenhouse effect and global warming. In fact, some of the strongest greenhouse gases known are PFASs. For details, see Annex B.7.2.

One of the most relevant subclasses of PFASs that contribute to global warming are the F-gases, e.g. hydrofluorocarbons (HFCs), hydrofluoroolefins (HFOs) and hydrofluoroethers (HFEs). Emitted F-gases reside in the atmosphere. The Environmental Coalition on Standards (ECOS) notes in a recent report that even though F-gases ‘only’ account for approximately 2% of the greenhouse gas (GHG) emissions in the European Union by weight, their contribution to the radiative forcing is about 20%, thus being a major contributor to global warming (ECOS, 2021). F-gases in the atmosphere will degrade over a shorter or longer timeframe and the contribution to global warming will be removed, e.g., via formation of TFA that precipitates with rain or other species like HF and CO_2.

1.1.5. Exposure assessment

Based on an extrapolation of data provided by Eurofeu (see Annex A for more details) it is estimated that **about 18 000 tonnes of PFAS-containing firefighting foam concentrates are sold in the EU per year,** fluctuating between 14 000 to 20 000 tonnes. Of the total (central estimate), about 10 800 tonnes are estimated to be employed in fixed systems and about 7 200 in mobile systems[24]. The split by sector is detailed in Figure 4 below. This shows that chemical/petrochemical is by far the largest user sector of foams (59 %), but municipal fire brigades, marine applications, airports and defence applications also account for significant volumes. Ready for use products only account for a very small share of PFAS-containing foams, the vast majority of this category are fire extinguishers.

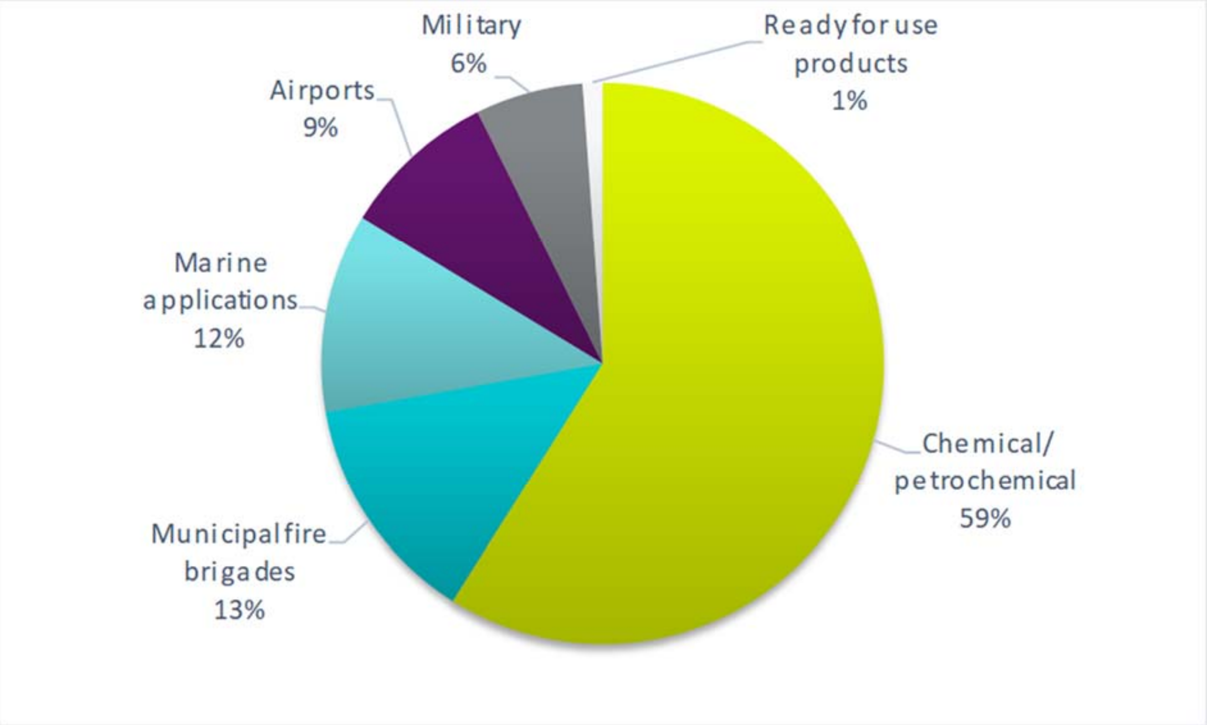


Figure 4. Split of PFAS-containing firefighting foams by sector. Source: (Wood et al., 2020) based on data provided to the authors by Eurofeu.

The use of these PFAS-containing firefighting foams accounts for an annual consumption of around 480-560 tonnes of fluorosurfactants per year in the EU, based on data provided by Eurofeu.

According to the model calculations under the baseline scenario[25], a total annual emission of around 470 tons of PFASs across the environmental compartments would occur[26]. This represents a total of around **14 100 tonnes of cumulative emissions of PFASs over 30 years.**

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[24] All these figures have been extrapolated from the original values provided by Eurofeu, which covered approximately 70 % of the market. The number of companies that provided a response on whether the foams are used in fixed or mobile systems is lower than those that provided a response for the sectoral overview, therefore in the original data the total tonnage of the former is lower than the latter. To fill this gap, the tonnages for both fixed and mobile systems have been inflated so that their total matches the total in the sectoral split

[25] Using the central scenario (i.e. best estimates input parameters)

[26] With the same sectoral breakdown as the sales data.

The emission estimates are based on data and assumptions from Wood et al. (2020) and further refined based on additional stakeholder input, ECHA Guidance R.16 (ECHA 2016b) and, where no data are available, based on expert judgement (see list of input parameters in Section 3 "Assumptions, uncertainties and sensitivities").

Eight sectors/use categories were considered[27]:

- Oil/(petro-)chemical industry
- Other industries[28]
- Civilian aviation
- Defence
- Municipal fire services
- Ready-to-use applications
- Marine applications
- Training and testing (for all the above categories except Ready-to-use applications)[29].

Using a source-flow model and the assumptions outlined in Section 3 "Assumptions, uncertainties and sensitivities" and Annex B.9., F.5.2 and Appendix 8 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 5.

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)[30]. During training exercises, aside from marine applications, it is assumed that the efficacy of bunding[31] and/or other control measures is relatively good[32]. 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[33] is considered to be less effective and variable among sectors and, under the baseline scenario, the collected fire waters are mainly sent to WWTPs[34]. It is noted that municipal WWTPs are not effective in removing/eliminating PFASs (see section B.4.5 and B.4.2.4).

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[27] See Annex E.2.5 on technical feasibility of alternatives for details on the sectors/use categories.

[28] Assumed to represents 2% of the PFAS-containing foams sales to the oil/(petro-)chemical industry indicated by Eurofeu, the remaining 98% assumed to be used by Seveso establishments. See section A.2.3.1 in Annex for more details.

[29] "Training and testing" has been segregated as a separate type of use, across all sectors of use, to better assess the impact of a shorter transitional period compared to longer transitional periods for uses for real fire incidents.

[30] See Annex B.9 for details

[31] The use of retaining walls to contain fire water run-off.

[32] Assumed to be 97% (see assumptions and input parameters in section 3. "Assumptions, uncertainties and sensitivities").

[33] Fire runoff waters (or "fire water runoff") are the run-off waters containing the firefighting foam concentrate mixed with water and all other elements mixed with them during the use of the firefighting foam during a fire incident, training or other use (e.g. flammable liquids, dirt, etc).

[34] In absence of more specific and representative data, the Dossier Submitter assumes for a conservative assessment that the typical treatment method of collected fire waters containing PFASs is wastewater treatment plant (see Annex B.9 for more details).

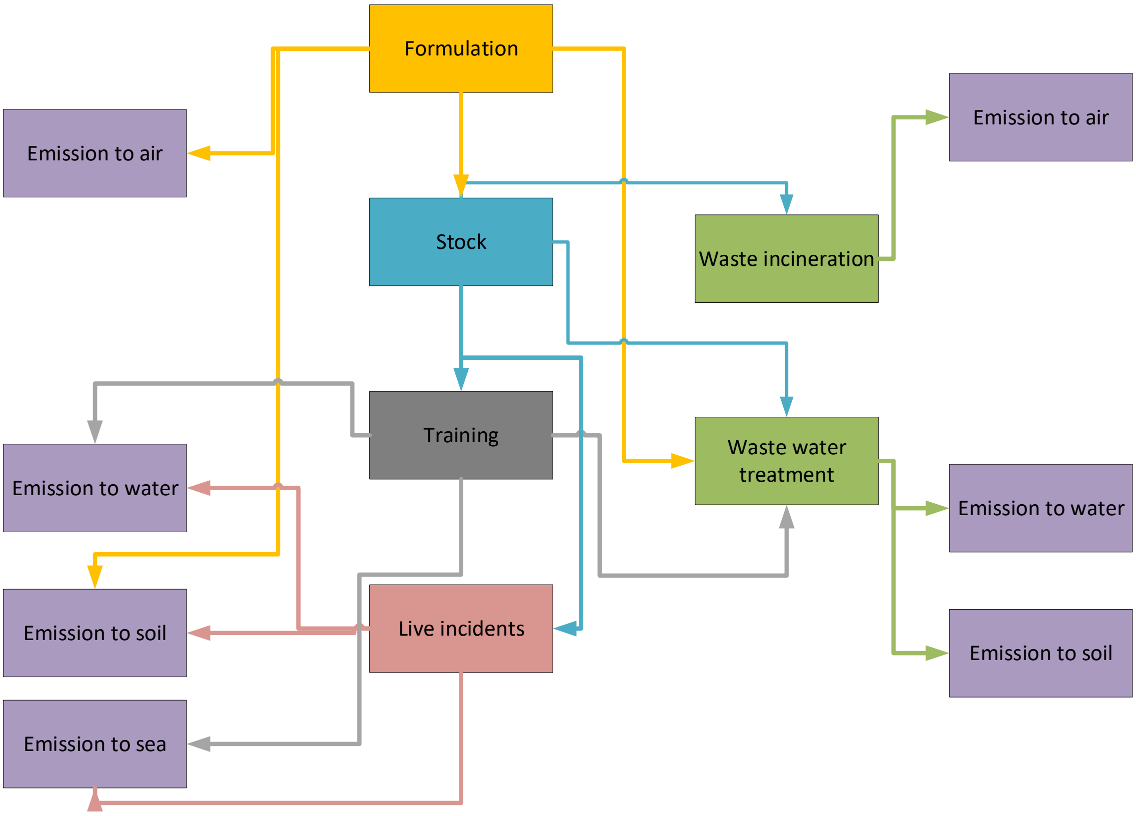

Figure 5. Material flow diagram showing the connection between the different life cycles stages of formulation, in-use, stock and waste treatment for PFASs in firefighting foams under the baseline scenario.

Table 2 describes the calculated total emissions of PFASs in the environment under the baseline per sector or use.

Table 2. total emissions of PFASs 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

Regarding the emissions to the environment, it should be noted that while the non-fluorinated firefighting foams make up approximately one third of the market, the volumes of alternative surfactants can be greater than their PFAS counterparts due to greater concentrations within the product itself, potentially leading to higher emissions of the non-fluorinated alternatives. However, it is important to recognise that emission alone is not an indicator of impact, and the degradation rates, potential for bioaccumulation, and harmful effects also need to be considered (as discussed in section 0 and in more detail in Annex B.5).

For the non-fluorinated alternatives, the effectiveness of wastewater treatment is considered to be relatively good[35], minimising the emission which is split between surface water and soil. In contrast, wastewater treatment is expected to be ineffective at treating PFASs, meaning direct release to surface water or soil depending on the partition coefficient.

1.1.6. Risk characterisation

All PFASs exceed the vP criteria, either themselves (arrowheads) or by degrading to arrowhead PFASs. The half-lives of the most stable PFASs (e.g., PFAAs) are known to be in the order of years, by far exceeding the vP criteria. Due to the high diversity of the PFASs the bioaccumulation potential and ecotoxicity are expected to largely vary among the substances. Therefore, no conclusion on B/vB and T criteria was derived for each substance/subgroup. The very high persistence is not sufficient to identify the PFASs as PBT or vPvB substances. However, the additional properties described above combined with the very high persistence add substantially to the overall concern which are very similar to those of the PBT/vPvB substances. Therefore the case-by-case approach has been investigated below.

Case by case assessment according to para 0.10 of Annex I to REACH

As summarised in section 1.1.4 on the properties, PFASs 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 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 PFASs 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 PFASs in the environment, complex degradation patterns of precursor PFASs to arrowheads and 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 PFASs. Combined effects may be expected for PFASs. The significant global warming potential of many volatile PFASs adds yet another category of effects to the picture.

Because of the persistence of PFASs, its mobility and long range transport potential, concerns have been expressed about whether their releases into the environment might ultimately reach concentration levels that could breach so-called ‘planetary boundaries’ – a point at which the earth is no longer able to assimilate or degrade a human-released chemical which is discovered only too late to have a disruptive effect on a vital earth system, and the effects of the pollutant cannot be readily reversed (Persson et al., 2013; Diamond et al., 2015). At the time when notable effects from PFAS exposure occur in the environment it will be difficult, if not impossible, to remove the contamination. Due to the ubiquitous occurrence of PFASs this may ultimately lead to an impairment or total loss of

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[35] Calculation of emissions of non-fluorinated alternatives has not been undertaken under this report. However, Wood et al. (2020) made a basic assessment for several alternative substances.

important natural resources, as well as increased overall pressure on human health and the ecosystems (Goldenman 2017). Examples could be a loss in biodiversity or impaired ecosystem services (e.g. regulating or provisioning services).

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

It is obvious that PFASs 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 PFASs as underpinned by the available information on their high persistence in the environment in combination with the additional properties summarised above.

Section 1.1.5 summarises the information on the current releases of PFASs from firefighting foams to the environment. Manufacture, placing on the market and use of some PFASs have already been restricted in the EU (e.g. PFOA, PFOS and, as of February 2023, C9-C14 PFCAs and their salts and related substances) or are in the process of being restricted (e.g. PFHxS and PFHxA and their salts and related substances), however most of the PFASs need to be still addressed by regulatory risk management. Monitoring data for some PFASs show that PFASs are ubiquitously distributed in the environment. It should be noted that so far only a limited subset of PFASs are addressed in monitoring programs and therefore current monitoring results are expected to provide only a partial picture of the overall exposures to PFASs.

In conclusion, 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.

It is noted that RAC supported the proposal to restrict microplastics based on a closely similar case-by-case hazard and risk assessment approach (ECHA, 2020). Analogously, a specific case for excluding a PFAS from the scope of the proposed restriction could be made if sufficient evidence is provided that the specific PFASs is not very persistent itself and does not degrade into a very persistent PFASs.

1.2. Justification for an EU wide restriction measure

Section 0 has illustrated the hazards and combined concerns associated with PFASs. In section 1.1.5 an overview of the current releases and exposures due to the use of PFASs in firefighting foams was provided. Section 1.1.6 summarises that due to the non-threshold nature of the hazards, the risks cannot be quantified and that current releases of PFASs should be minimised. Any release should be considered a proxy for risk. Due to the ongoing releases, the risks are currently not adequately controlled.

While in some user sectors PFAS-based foams have been increasingly replaced by fluorine-free alternatives and industry best practice guidance recommends not using PFAS-containing foams in training and testing, 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 PFASs were shown to be ubiquitous contaminants, for instance in arctic wildlife (Muir et al., 2019).

The use of certain long-chain PFAS substances has been regulated in the past. This has led to the replacement of these regulated PFASs with fluorine-free alternatives in some cases, but also with other PFASs substances (e.g. short-chain PFASs), as illustrated by the fact that a high share of firefighting foams used still contain PFASs.

Some national regulations exist that require the containment of firewater run-off, but the consultation suggested that containment is rarely 100 % effective, that the collected fire water is usually sent to WWTP (unless prescribed differently by local/national legislation) and the effectiveness of WWTP in the degradation of PFASs is known to be poor. Industry best practice measures aim 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 stakeholders consultation suggested that these are not being fully implemented (e.g. the use of PFAS-containing foams in training and testing has been reported). Stakeholder input did not allow to conclude on their relative effectiveness.

In conclusion, it has been demonstrated that the use of PFASs in firefighting foams is associated with risk to the environment - and human health via the environment - that is not adequately addressed by the current measures in place (current measures are discussed in more detail in Section 1.3). 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). This has implications not only for the degree to which the environment is protected, but also in terms of ensuring the functioning of the internal market. Firefighting foams being traded over the borders, different restrictions in different Member States could make it very challenging to market firefighting foam products available for sale in all Member States. It would therefore not be meaningful or possible to restrict them nationally due to internal market considerations. Moreover, due to their mobility and persistence PFAS emissions lead to cross-border pollution. Therefore, potential further regulatory management on EU-level is likely required.

1.3. Baseline

1.3.1. Overview

The baseline presented here comprises an overview of the current use of PFAS-containing firefighting foams based on the market analysis (used in particular as baseline economic activity for the assessment of economic impacts). Resulting baseline exposure has already been presented in Section 1.1.5 and are not repeated here. Note that an overview of the current regulatory and voluntary industry measures to control the risk are presented in sections 2.2.1 and 2.2.2, respectively. It should be noted that the baseline only took adopted EU regulations into account.

1.3.2. Definition of the baseline scenario for the assessment of economic impacts

The baseline scenario describes the situation in the absence of any further risk management. It was used to compare restriction scenarios (defined in the next sub-section), to ensure that the socio-economic assessment (SEA) evaluates the impacts of the RMOs being assessed.

More details are provided in the market analysis (see Annex A), but the key points are below.

- It is estimated that currently some 14 000 – 20 000 tonnes (likely closer to the upper end of the range; 18 000 tonnes have been taken as best estimate in the calculations) of PFAS-containing firefighting foams are sold per year in the EU and used in various sectors including chemicals/petrochemicals, municipal firefighting, marine, airports, defence, railways and fire extinguishers. Their use is particularly important and widespread where there is a risk of Class B fires, i.e. where flammable liquids are present. They are used for firefighting, but in some cases also for training and testing of equipment.

- Around 9 000 tonnes per year of fluorine-free foams are already used in most of the same applications, although the split by sector varies from that of PFAS-containing foams. Several stakeholders, including manufacturers of firefighting foams, have indicated that the use of fluorine-free foams has been increasing, particularly in applications where PFAS-containing foams can be very easily replaced (e.g. training). This trend is expected to continue in the future to some extent (even in the absence of any restriction on PFAS-containing foams). Some stakeholders also noted containment of fire water run-off, particularly from training. However, these run-offs seem to be mostly sent to WWTP which are considered not effective in preventing releases of PFASs to the environment, therefore the impact of this measure in terms of reduced emissions of PFASs is considered to be close to zero.

- In addition, there are significant existing stocks of PFAS-containing foams which have been already purchased. These may need to be disposed of and replaced. The total quantity of these stocks is uncertain, but are estimated as follows:
    - Annual sales of PFAS-containing foams are estimated at between 14 000 – 20 000 tonnes per year.
    - Current annual sales of fluorine-free foams are estimated at 7 000 – 9 000 tonnes per year. Historically, this demand would have been served by PFASs containing foams, hence the total annual sales of PFAS-containing foams could have been some 21 000 - 29 000 tonnes.
    - The shelf life of PFAS-containing foams is reported to be typically between 10 and 20 years (and up to a maximum of 30 years)[36]. Given that foams may be used before the end of their shelf life, the actual lifetime of foams could be shorter. Bipro (2011) suggests that the average lifespan of firefighting foams is 15 years, which appears consistent with the information above and the stakeholder’s consultations.

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[36] Proposal for a restriction: Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related substances https://echa.europa.eu/documents/10162/a22da803-0749-81d8-bc6d-ef551fc24e19

- No reliable information is available regarding the stock of PFAS-foam at EU level. In this report, the total stock has been calculated as a function of the annual sales and the annual usage rates. Under the best estimate scenario, the value of 148 500 tonnes has been calculated[37].

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[37] (Wood et al., 2020) estimated a stock between 210 000 and 435 000 tonnes. Comments from stakeholders on the PFHxA restriction proposal indicate that the figure of 62 500 tonnes would be a more realistic figure (e.g. (FFFC, 2020). However, the Dossier Submitted decided to derive the estimated stock based on the sales figures of PFAS-containing FAS foams (which are more accurately known) and the average annual usage rates indicated by industry stakeholders. See details on the calculations in Appendix 8.

2. Impact assessment

2.1. Introduction

The Annex XV restriction dossier on the use of per- and polyfluoroalkyl substances (PFASs) in firefighting foams was prepared at the request of the European Commission. As identified in section 1.1.6, uses of PFASs in firefighting foams are considered to pose a risk to the environment and humans via the environment that is not adequately controlled.

This impact assessment is prepared to assess whether restriction is the most appropriate Risk Management Option (RMO) to control the risks; and to justify which of several Restriction Options (RO) is identified as the preferred option.

The impact assessment estimates the costs and benefits of different ROs. The environmental benefits are described in a qualitative manner including quantified elements on emissions and cost-effectiveness (cost of reducing 1 kg of emission). For sensitivity analysis low, best and high estimates on emissions, costs and cost-effectiveness are reported complemented with one parameter sensitivity analysis. These low and high estimates are also used to present the estimated costs per sector and cost category as ranges, to avoid false impression of accuracy in the results.

The assessment horizon is set to 30 years to allow full substitution of existing stocks after the longest sectoral transition period and shelf lives of the firefighting foams. During a shorter time horizon (such as 20 years), some PFAS-containing foams in use would still not be affected by the restriction. It is assumed that there is no trend in the quantities used or other input parameters. The geographical boundary of the assessment is the EEA, and potential impacts occurring outside the EEA are described qualitatively only.

The proposed restriction comprises the following elements:

- Ban on placing on the market of PFAS-containing firefighting foams
- Ban on use of PFAS-containing firefighting foams
- Ban on export of PFAS-containing firefighting foams
- Transition periods for different sectors and uses
- Concentration limit for PFASs content (including contamination) in foams
- Requirement to implement a PFAS-containing firefighting foams management plan and best practice risk management measures

The first three points (ban on placing on the market, use and export) are covered by the main quantitative impact assessment in this section. The justification for the proposed transition periods is provided qualitatively in Section 2.8.2 and the justification for the proposed concentration threshold is provided in Section 2.8.3. Additional risk management measures (implementation of management plan and best practice RMMs) are described in Section 2.2.5 and justified in Section 2.8.5.

2.2. Analysis of risk management options (RMOs)

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

The Dossier Submitter notes that the Commission's choice to address the risks of PFASs, including in firefighting foams, by means of a restriction under the REACH regulation was part of the recently published 'The EU's chemical strategy for sustainability towards a toxic-free environment'[38] (generally referred to as Chemical Strategy for Sustainability or CSS), that included a draft of both legislative and non-legislative initiatives to protect citizens and the environment from harmful chemicals while boosting innovation for safe and sustainable chemicals in Europe. It is part of the EU's zero pollution ambition, which is a key commitment of the European Green Deal.

As a REACH restriction is envisaged to deliver the objectives of the CSS[39], the assessment of alternative **novel** Union-wide legislative risk management options (RMOs) was not specifically considered by the Dossier Submitter. Instead, it was presumed that during the development of the CSS due consideration was given to the most appropriate means to effectively achieve the strategy's objectives; resulting in the conclusion that a REACH restriction was most appropriate.

The CSS also commits the European Commission to address PFASs via a group approach to prevent regrettable substitution, improve reporting of PFASs releases into the environment (via the Industrial Emission Directive and the European Pollutant Release and Transfer Register), address PFASs via international fora such as the Stockholm Convention and establish financial support for research and innovation of PFASs alternatives as well as remediation practices.

In addition, 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 (WFD), Marine Strategy Framework Directive (MSFD), and the Urban Wastewater Treatment Directive (UWWTD).

The possibility to address the risks posed by PFASs in firefighting foams with other REACH regulatory measures and existing Union-wide legislation and other possible Union-wide RMOs was examined (see section 2.2.1). Measures already taken by Member States and in other jurisdictions are also briefly described below for completeness, as are industry initiatives on PFASs in firefighting foams (see section 2.2.2). Whilst it was recognised - and taken into account when developing the scope of the proposed restriction - that some existing EU legislation or other measures could have an impact on the risk management of certain sectors, approaches other than a REACH restriction were deemed inappropriate to address the uses identified to be contributing to risk that is not adequately controlled.

Annex E.1.3 describes the risk management options other than restriction considered, as well as the reasons for their rejection.

Therefore, the option to use a restriction under REACH to address the identified risks was investigated further (see section 2.2.3).

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[38] https://ec.europa.eu/environment/strategy/chemicals-strategy_en

[39] The Annex to the CSS indicates the following measure: "Proposal to restrict PFAS under REACH for all non-essential uses including in consumer products" via REACH (Comitology) with a timeline of 2022-24.

2.2.1. Overview of current regulatory measures

2.2.1.1. Stockholm Convention

The Stockholm Convention on Persistent Organic Pollutants (POPs) restricts at international level the production and use of a number of specific PFASs, namely perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds and perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF). The Convention includes a specific exemption for the use of firefighting foams containing PFOA, its salts and PFOA related compounds and perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride.

PFOS, its salts and PFOSF are listed under Annex B of the Stockholm Convention, which restricts production and use to specified acceptable purposes and specific exemptions. Upon its initial listing in 2009, an acceptable purpose was included under the Convention allowing the use PFOS in firefighting foams[40]. At the POP Review Committee (POPRC) meeting in 2018, the committee recommended, based on the findings of an assessment of alternatives to PFOS[41] , that the acceptable purposes for the production and use of PFOS, its salts and PFOSF for firefighting foam be amended to a specific exemption for the use of firefighting foam for liquid fuel vapour suppression and liquid fuel fires (Class B fires) already in installed systems, including both mobile and fixed systems, and with the same conditions put in place for PFOA (see below). This exemption was agreed accordingly at the Ninth Meeting of the Conference of the Parties (COP) to the Stockholm Convention in 2019[42].

At their 14th meeting in September 2018, POPRC recommended listing PFOA, its salts and PFOA-related compounds in Annex A to the Convention[43], including a specific exemption for the use of firefighting foams containing PFOA already installed in systems including both mobile and fixed systems subject to specific conditions. Parties to the Convention can register for this exemption if they: i) ensure that FFFs that contain or may contain PFOA shall not be exported or imported except for the purpose of environmentally sound disposal; ii) do not use firefighting foams that contain or may contain PFOA for training or testing purposes (unless all releases are contained); iii) by the end of 2022 if possible, but no later than 2025, restrict uses of firefighting foams that contain or may contain PFOA, to sites where all releases can be contained; iv) ensure all fire water, waste water, run-off, foam and other wastes are managed. This exemption was also agreed accordingly at the 9th COP meeting in 2019[44] when listing the PFOA, its salts and related substances in the Annex A to the Convention.

At its fifteenth meeting, the POPRC adopted the risk management evaluation on perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds and recommended to the Conference of the Parties that it consider listing the chemicals in

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[40] SC-4/17 :

[41] UNEP/POPS/POPRC.14/INF/8: http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC14/Overview/tabid/7398/Default.aspx

[42] SC-9/4: http://www.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP9/tabid/7521/Default.aspx

[43] POPRC-14/2:

[44] SC-9/12 http://www.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP9/tabid/7521/Default.aspx

Annex A to the Convention without specific exemptions[45]. The COP will decide on the listing of the substance at its 10th meeting in June 2022. The eventual listing under the Convention would enter into force one year after the date of the communication of its adoption by the depositary for the Convention.

2.2.1.2. EU Regulation

The provisions of the Stockholm Convention and the Aarhus Protocol are implemented in the European Union by the POPs Regulation (EC 2019/1021)[46]. Once the COP adopts a decision to amend the Annex(es) to the Stockholm Convention to list a new substance, the decision needs to be transposed in Union law by amending Annex I, II and/or III of the POPs Regulation. These amendments are done by delegated acts

PFOS, its salts and PFOS related substances were originally restricted in the EU under REACH Annex XVII (entry 53). However, following the addition of PFOS, its salts and PFOSF to the Stockholm Convention in 2009, the entry 53 in Annex XVII to REACH was removed[47] and the substances were included under the Annex I to the POPs Regulation in 2010[48]. PFOS, its salts and its derivatives are currently listed under Annex I of the POPs Regulation.

The production, placing on the market and use of PFOS, its salts and PFOS-derivatives[49] on their own, in mixtures or in articles is severely restricted under the POPs Regulation, with no exemptions allowing for the use of the substance in firefighting foams[50].

PFOA and its ammonium salt have been identified under REACH as a SVHCs and included in the Candidate List in 2013 (ED/69/2013). PFOA, its salts and related substances were initially restricted under entry 68 of Annex XVII to REACH. However, following the addition of PFOA to the Stockholm Convention in 2019, the entry 68 in Annex XVII to REACH was removed[51] and the substances were included under the Annex I to the POPs Regulation[52]. The production, placing on the market and use of PFOA, its salts and derivatives[53] on their

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[45] POPRC-15/1 : http://www.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC15/Overview/tabid/8052/Default.aspx

[46] http://data.europa.eu/eli/reg/2019/1021/2021-03-15

[47] http://data.europa.eu/eli/reg/2011/207/oj

[48] http://data.europa.eu/eli/reg/2010/757/oj

[49] Covering substances with the formula: $C_8F_{17}SO_2X$ (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)

[50] Substances and mixtures containing PFOS, its salts and related substances as unintentional trace contaminant equal to or below 10 mg/kg are allowed to be used and placed on the market.

[51] http://data.europa.eu/eli/reg/2020/2096/oj

[52] http://data.europa.eu/eli/reg_del/2020/784/oj

[53] 'Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds' means the following:
(i) perfluorooctanoic acid, including any of its branched isomers;
(ii) its salts;
(iii) PFOA-related compounds which, for the purposes of the Convention, are any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety (C7F15)C as one of the structural elements.
The following compounds are not included as PFOA-related compounds:
(i) C8F17-X, where X = F, Cl, Br;
(ii) fluoropolymers that are covered by CF3[CF2]n-R', where R'=any group, n> 16;
(iii) perfluoroalkyl carboxylic acids (including their salts, esters, halides and anhydrides) with ≥ 8 perfluorinated carbons;

own, in mixtures or in articles is severely restricted, but a number of exemptions are included in the POPs Regulation, including a derogation allowing the use of PFOA, its salts and PFOA-related compounds in firefighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems by 4 July 2020, including both mobile and fixed systems, until 4 July 2025, subject to the following conditions:

> (a) firefighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall not be used for training;
>
> (b) firefighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall not be used for testing unless all releases are contained;
>
> (c) as from 1 January 2023, uses of firefighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall only be allowed in sites where all releases can be contained;
>
> (d) firefighting foam stockpiles that contain or may contain PFOA, its salts and/or PFOA-related compounds shall be managed in accordance with Article 5 to the POPs Regulation.

Perfluorohexane-1-sulphonic acid (PFHxS) and its salts, have been identified as SVHCs and included in the Candidate List in June 2017 (ED/30/2017). There is an ongoing restriction proposal for PFHxS, its salts and PFHxS-related substances[54]. The final RAC and SEAC opinion on the restriction proposal was published on 11 June 2020, which includes an exemption allowing the use of concentrated firefighting foam mixtures that are placed on the market 18 months after the entry into force of the restriction. It is expected that PFHxS, its salts and PFHxS-related substances will ultimately also be regulated at EU-level under the POPs Regulation, when its listing to the Stockholm Convention is finalised (see above).

In December 2019, a proposal for a restriction under REACH on PFHxA was published[55]. 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 proposed restriction will not interfere with any adopted EU regulation (i.e. REACH restriction or bans under the POPs Regulation). Even 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), the stricter

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(iv) perfluoroalkane sulfonic acids and perfluoro phosphonic acids (including their salts, esters, halides and anhydrides) with ≥ 9 perfluorinated carbons;
(v) perfluorooctane sulfonic acid and its derivatives (PFOS), as listed in Annex I to POPs

[54] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1827f87da
[55] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d

measure applies. The proposed restriction is therefore complimentary to other existing and future regulation of PFASs in the EU.

See also Annex E.1.3 for additional information on EU legislation in relation with PFASs.

2.2.1.3. Controls in Member States and other jurisdictions

In 2016, The Swedish Chemicals Agency (KEMI) published its strategy for reducing the use of PFASs (KEMI, 2016) beyond solely the implementation of EU legislation. This included specific measures to tackle PFASs in firefighting foams, including a proposal for national regulations covering, for example:

- legal requirement for the collection and destruction of fluorine-based firefighting foam
- imposing reporting requirements
- review of exemptions - with the aim of reducing the number of exemptions as much as possible

In some non-EU countries, there are also regulations in place, specifically targeting PFASs in firefighting foams. For example, in Norway[56], there are regulations in place that focus on the following:

- The monitoring and screening of PFASs in the environment in general
- The monitoring and clean-up of PFAS polluted soil caused by airport fire drills
- A requirement for airports to monitor levels of PFASs at their fire drill sites and propose measures to reduce pollution
- A requirement for airports to screen and report levels of PFASs in their soil, and must propose measures to reduce pollution

In the USA, at federal level, the US EPA has developed and launched a PFAS Action Plan (US-EPA, 2019) to evaluate whether and how to regulate PFAS compounds under various federal environmental programmes (including TSCA). The primary focus of this plan is to reduce environmental and public health concerns when PFASs are released into the environment (e.g., through setting safe drinking water limits and remediation criteria). While the plan specifically references the use of firefighting foams as a key source of PFAS contamination and exposure, it does not set limits or actions specifically at national level for use of PFASs in foams.

Additionally, the Fiscal Year 2020 National Defence Authorization Act (NDAA) enacted the phase out of the US Department of Defence's use of PFAS-containing firefighting foam by October 2024 (with an exception for shipboard use). However, the Secretary of Defence may waive the prohibition for one year (renewable once for another year until 2026) if duly justified, such as the protection of life and safety or because no agent or equipment solutions are available that meet the military specifications. The NDAA also immediately prohibits the uncontrolled release of aqueous film-forming foam (AFFF) in testing and training, but allows emergency use or non-emergency use if completely contained (US-NDAA, 2020).

It should be noted that several individual US States also implement their own legislation, and there is a wide variety of approaches, measures, and timescales adopted. The Fire

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[56] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/norway.htm

Fighting Foam Coalition summarised in July 2021 the main provisions of several states (Smith, 2021). As an example of some of the States with the strictest approaches[57]:

- Washington bans the sale and the use for training purposes of PFAS-containing firefighting foams from 1 July 2020, except for terminals, oil refineries and chemical plants which can use them until 1st January 2024 with a possibility to apply for waivers that could extend until 1st January 2028. Uses required by federal law such as Federal Aviation Administration airports and military uses remain allowed. (US-WA, 2018), (US-WA, 2020).
- In California, a law was adopted in September 2020 restricting the manufacture, sale or use of PFAS-containing firefighting foams from 1 January 2022 except when required by federal law. Additional transition periods apply for certain uses, including for terminal and oil refineries under certain conditions (1st January 2028, with the possibility to apply for waivers that could extend the use until 1st January 2032) (US-CA, 2020).

In Australia, the biggest source of concentrated emissions of PFASs is from historical use of PFAS-containing firefighting foams, particularly at firefighting training grounds. The Industrial Chemicals (Notification and Assessment) Act (ICNA Act), requires industry to provide toxicity data for new substances (including PFASs) or products containing new PFASs being introduced into Australia. Based on the level of toxicity and environmental persistence, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) recommends restrictions on how these substances can and cannot be used[58].

The Australian Department of Defence commenced phasing out its use of PFOS and PFOA-containing firefighting foams. Furthermore, PFASs use is also limited by Air Services Australia, a government-owned corporation that provides air traffic control management, which has transitioned away from fluorinated firefighting foam to non-fluorinated firefighting foam including the destruction of remaining stockpiles[59].

2.2.2. Industry measures

2.2.2.1. Substitution and phase-out

As noted in several documents under the Stockholm Convention, for over a decade, a number of alternatives to the use of C8-based fluoro-surfactants (containing PFASs) in firefighting foams have been developed and are now widely available. These include short-chain (C6) fluoro-surfactants, as well as fluorine-free firefighting foams; and other developing firefighting foam technologies that avoid the use of fluorine.

The use of C8-based AFFF has been largely phased out in favour of these alternatives. For example, it is reported that the volume of AFFF-containing PFOS used in the USA declined from around 21 million litres in 2004 to less than 9 million litres in 2011 (Darwin, 2011).

The POPRC officially recognises that a transition to the use of short-chain per- and polyfluoroalkyl substances (PFASs) for dispersive applications such as firefighting foam is

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[57] See also e.g. https://www.saferstates.com/

[58] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/australia.htm

[59] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/australia.htm

not a suitable option from an environmental and human health point of view and that some time may be needed for a transition to alternatives without PFASs (POPRC-14/3).

In the USA, in 2006, the US EPA launched the PFOA Stewardship Program following concerns raised about the impact of PFOA and long-chain PFASs on human health and the environment, including concerns about their persistence and presence in the environment[60]. The programme involved eight major companies[61] committing to reducing PFOA from facility emissions and product content by 95 percent no later than 2010, and to work toward eliminating PFOA from emissions and product content no later than 2015. All participating companies state in the most recent progress reports, that they met the PFOA Stewardship Program goals[62].

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 needed to ensure the effectiveness of fluorine-free firefighting foams. Since large fire incidents are rare and large fire testing is costly, limited practical experience has been gained until now 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).

See also Annex section E.2 for information on analysis of alternatives and Table E.23. in Annexes which describes a comparison of the use of fluorine-free alternatives in key sectors of use.

2.2.2.2. Containment and control

In Germany[63], the regulatory authorities and firefighting associations have compiled a leaflet on PFASs in firefighting, which has reportedly resulted in an increased awareness of the risks associated with certain PFASs by industry, NGOs and the public.

In Norway[64] fluorine-containing firefighting foam has been substituted with fluorine-free alternatives in most civilian airports and fluorine-containing foam is no longer in use at firefighting training sites with the Norwegian defence forces. Furthermore, it is reported that PFASs are being gradually substituted with fluorine free-alternatives in the offshore sector, and the volumes of fluorine-containing foam used in this sector are decreasing.

One respondent to the consultation questionnaire conducted by Wood (Wood et al., 2020) reported that the Swedish Petroleum and Biofuels Institute has previously (2011) provided guidance on how to plan and implement the prevention of spillage and secondary containment embankments, methods for emergency response, and for the assessment and

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[60] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program

[61] Arkema, Asahi, BASF, Clariant, Daikin, 3M/Dyneon, DuPont, Solvay Solexis

[62] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/20102015-pfoa-stewardship-program-2014-annual-progress

[63] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/germany.htm

[64] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/norway.htm

preventing product tanks to lift off inside water filled bunds/embankments. It was estimated that ~80 % of the member companies were in compliance with this guidance.

The trade association, the Fire Fighting Foam Coalition (FFFC) has published a best practice guidance document for the safe use of firefighting foams for Class B fires[65], with the aim to "foster use of foam in an environmentally responsible manner so as to minimize risk from its use" (FFFC, 2016).

The guidance covers the following aspects of Class B firefighting foam use:

- **Foam Selection** – specifying situations where the use of Class B foams is, and is not, recommended, e.g. limiting the use of Class B foams to situations that present 'a significant flammable liquid hazard'.
- **Eliminating Foam Discharge** – noting that this is not always possible in emergency situations, but emphasising the possibility to achieve this in training and the testing of foam systems and equipment.
- **Training** – providing guidance on the formulation of training foams, the design, construction and operation of training facilities.
- **Foam System Testing** – including guidance on acceptance tests, conducted pursuant to installation of the system; and maintenance tests (i.e. of firefighting vehicles).
- **Containing Foam Discharge** – guidance to prevent discharge to the environment, both for manual and fixed systems**.**
- **Firewater and foam concentrate disposal –** with an emphasis on incineration but also covering coagulation, flocculation, electro-flocculation, reverse osmosis, and adsorption on granular activated carbon (GAC).

Similarly, the Fire Protection Association Australia (FPA Australia) has published a guidance document on the selection and use of firefighting foams (FPA-AUS, 2020). This covers, for example,

- **Factors impacting on selection and use** – including firefighting performance, environmental impact, system and equipment compatibility
- **Environmental and firefighting performance indicators**
- **Fluorinated and fluorine-free firefighting foams**
- **Environmental best practice -** including training and system testing and commissioning, fire water effluent, remediation of contaminated soil and water, cleaning/change out of existing foams

The consultation did not yield information on the extent to which these best practice measures outlined by the likes of the FFFC and FPA Australia are being implemented, or their effectiveness.

2.2.3. Main restriction options assessed

The following five main REACH restriction options (ROs) have been assessed and are summarised below:

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[65] Covering aqueous film-forming foam (AFFF), alcohol resistant aqueous filmforming foam (AR-AFFF), film-forming fluoroprotein foam (FFFP), alcohol resistant film-forming fluoroprotein foam (AR-FFFP), and fluoroprotein foam (FP, FPAR). Document available here: https://b744dc51-ddb0-4c4a-897d-1466c1ae1265.filesusr.com/ugd/331cad_188bf72c523c46adac082278ac019a7b.pdf

RO 1: Restriction (ban) 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 (ban) 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 export, 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 with the additional ban of 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 the provision for a derogation mechanism via the 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 of 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.

Additional details on the ROs are provided in Annex E.1.1.

In addition, for all the restriction options described above, additional risk management measures during the transitional periods have been considered, which are described in section 2.2.5.

2.2.4. Other risk management options not assessed in detail

Additional regulatory risk management options have also been considered but not assessed in detail for the reasons described below:

a. *Restriction of a few uses only, others derogated until suitable alternatives are found (based on reporting and restriction review) and full containment of releases*

The restriction would entail:

- A ban on the use of PFAS-containing firefighting foams in training, testing and municipal fire services only, after a short transitional period;
- the other uses would be allowed (derogated) until suitable alternatives are found
- an annual reporting requirement would apply to the derogated firefighting foam users (reporting to ECHA) about their use of PFAS-containing firefighting foams and availability of alternatives

- a periodic review of the restriction by the Commission would be implemented for the update of the derogations
- the mandatory collection of all PFAS-containing waste and their adequate treatment, minimising releases of PFASs to environmental compartments.

This RO is a derivative from RO 5 described above and has not been taken forward for the same reasons. Even though the uses where suitable alternative already exist would be banned, the derogated uses are likely to continue for an extensive period of time due to a much weaker incentive for substitution than a clearly indicated ban date.

The requirement for the complete collection of firewater (i.e. also for incidents management) is unlikely to be technically or economically implementable in practice for most sectors in case of small or large fire incidents due to the type of terrain and infrastructures. 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 sites such as intervention sites of municipal brigades, offshore oil platform and marine ships are all types of use of firefighting foams where a full capture of fire waters in case of a fire incident are highly unlikely.

Regarding the annual reporting requirement of users to ECHA, this would entail the need for significant additional resource for ECHA in terms of IT development and staff time to process and analyse the data (these resource needs have not been quantified). The Commission would also have additional resource needs to make use of the collected information and regularly assess the need for ending the derogations. The required additional resources have not been quantified.

b. *Restriction of a few uses only, other uses would be subject to authorisation under REACH Title VII*

This risk management option would entail:

- A ban on the use of PFAS-containing foams in training, testing and municipal fire services only, after a short transitional period;
- The other uses would also be banned unless they are applied for an authorisation under REACH Title VII Chapter 2 and the authorisation granted.

This risk management option has not been taken forward in the assessment for the following reasons: it would require the identification of all PFASs as Substances of Very High Concern (many as substances of equivalent concern), inclusion in the Candidate List and Authorisation List which would be a cumbersome, uncertain and unlikely and would encompass all uses of PFASs (covered by the Authorisation title), i.e. not only the use in firefighting foams. In addition, the fire safety aspects for major accidents are already dealt with under the Seveso Directive.

2.2.5. Proposed restriction option

The proposed restriction option is RO 3:

Restriction on the export, placing on the market and use of PFAS-containing firefighting foams with different transitional periods per type of use. The ban on export would apply at the end of the longest transitional period applicable for the placing on the market in the EU (i.e. ten years after entry into force of the restriction). During the transitional periods corresponding to each type of use, additional risk management measures described in section 2.8.5. would apply to minimise the emissions of PFASs in the environment as long as technically and economically feasible.

This RO is considered to be the most effective in reducing the emissions of PFASs in the environment while providing clearly defined deadlines for transitioning to alternatives without compromising fire safety. The transitional periods are adapted to each type or sector of use based on the availability of suitable alternatives and provide a clear signal to manufacturers to invest in the development of alternatives for all types of uses and a clear signal to users in starting to implement the transition by testing the alternatives and – where needed- making the technical and organisational adaptations.

The ban on exports after the longest transitional period would allow a further reduction of emissions from the foam formulation and storage taking place in the EU. In addition, this approach is in line with the EU Chemicals Strategy for Sustainability which states that "*The EU will […] lead by example, and, in line with international commitments, ensure that hazardous chemicals banned in the European Union are not produced for export, including by amending relevant legislation if and as needed*"[66]. This approach is particularly relevant for PFAS considering their persistence and their potential for long range transport.

The detailed restriction conditions are the following:

Restriction on the export, placing on the market and use of PFASs in firefighting foams.

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[66] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment - COM(2020) 667 final, 2020, available at https://eur-lex.europa.eu/resource.html?uri=cellar:f815479a-0f01-11eb-bc07-01aa75ed71a1.0003.02/DOC_1&format=PDF

Column 1	**Column 2**
Per- and polyfluoroalkyl substances (PFASs) 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. Shall not be placed on the market or exported as substances on their own, as a constituent in other substances or in mixtures for use in firefighting foam concentrates where the concentration of total PFASs is greater than 1 ppm[67] 10 years after entry into force. 2. Shall not be used as substances on their own, as a constituent in other substances or in mixtures in firefighting foam concentrates where the concentration of total PFASs is greater than 1 ppm. 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 Directive 2012/18/EU (Seveso III) and for use in these establishments only); c. three years after entry into force for civilian ships; d. five years after entry into force for portable fire extinguishers as defined by EN3-7; e. 10 years after entry into force for establishments covered by the Directive 2012/18/EU (Seveso III)[68] (upper and lower tiers); 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). 4. Without prejudice to paragraph 3, six months after entry into force users of firefighting foam concentrates where the concentration of total PFASs is greater than 1 ppm shall: a. ensure that firefighting foam concentrates are only used for fires involving flammable liquids (class B fires); b. minimise emissions to the environment and direct and indirect exposures to humans of firefighting foams to the extent that is technically and economically feasible.

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

[68] 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**
	c. establish a site-specific ‘PFAS-containing firefighting foams management plan’ which shall include: i. a justification for the use of each firefighting foam concentrate where the concentration of total PFASs is greater than 1 ppm (including an assessment of the technical and economic feasibility of alternatives). ii. details of the conditions of use and disposal of each PFAS-containing foam used on site specifying how paragraph 4(b) is achieved (including plans for the containment, treatment and appropriate disposal of liquid and solid wastes arising in the event of foam use, routine cleaning and maintenance of equipment or in the event of accidental leakage/spillage of foam). iii. The management plan shall be reviewed at least annually and be kept available for inspection by enforcement authorities on request. d. Ensure that the collected PFAS-containing waste with a concentration of PFASs above the one mentioned in paragraph 2 shall be handled for adequate treatment. The treatment shall minimise releases of PFASs to environmental compartments as far as technically and practically possible and shall exclude municipal wastewater 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, firefighting foam concentrates containing PFASs above the threshold indicated in paragraph 1 which are held in stock and need to be disposed of shall be handled for adequate treatment. The treatment shall minimise releases of PFASs to environmental compartments as far as technically and practically possible and excluding any wastewater treatment, irrespective of any pre-treatment. Proof of

Column 1	**Column 2**
	appropriate disposal shall be documented and kept available for enforcement authorities. 6. From six months after entry into force, packaging of firefighting foam concentrates placed on the market or used, containers of firewater runoffs or other PFAS-waste in relation with the use of firefighting foams or the cleaning of firefighting foam equipment in concentrations above the one mentioned in paragraph 1 shall be labelled indicating the presence of PFASs above this threshold with the following wording: "WARNING: Contains per and polyfluoroalkyl substances (PFASs)". This information shall be displayed in a clear and visible manner in the official language(s) of the Member State(s) where the firefighting foam concentrate is placed on the market, unless the Member State(s) concerned provide(s) otherwise. 7. [From six months after entry into force, packaging of firefighting foam concentrates placed on the market containing organofluorine substances above 1 ppm, but where the concentration of total PFASs is not greater than 1 ppm, shall be labelled: "Contains non-PFAS organofluorine substances with a total organofluorine concentration of (*insert concentration*) ppm". This information shall be displayed in a clear and visible manner in the official language(s) of the Member State(s) where the firefighting foam concentrate is placed on the market, unless the Member State(s) concerned provide(s) otherwise.]

The restriction entry does not prescribe any specific disposal method. Based on the collected information, the disposal of PFAS-containing waste in hazardous waste incinerator and cement kilns are currently considered as best available techniques. However, the Dossier Submitter underlines the fact that few field studies on the fate and emissions of PFASs resulting from these disposal techniques are available and calls for more research in the field to confirm the effectiveness of the destruction of PFASs. Other, new disposal techniques are also being developed but their effectiveness and applicability at industrial scale needs to be demonstrated.

Explanatory notes:

(1) "Testing of the firefighting systems for their function" means testing the fire protection system in the same way as it would operate in case of emergency. Other types of testing include but are not limited to: testing of foam agents during their development phase, testing of foam agents by users to evaluate products' suitability on specific combustibles, testing of correct proportioning of firefighting foam concentrates.

(2) Municipal fire services (i.e. local authority fire and rescue services) are covered under the restriction entry 3 (b.), except if they are also in charge of industrial fires for establishments covered by the Seveso-III Directive and for use in these establishments only. In this case, the transitional period of paragraph 3(e) applies.

(3) Other uses of firefighting foams include – but are not limited to -: civilian aviation, defence, aerospace, offshore oil/gas/chemical facilities, onshore oil/gas/chemical manufacturing or processing facilities which are not coved by paragraph a. (Seveso establishments), power plants, glass manufacturers, waste treatment facilities, food processing industry, metal processing, etc.

(4) The use of PFAS-containing foam agents in portable fire extinguishers are covered by paragraph 3(d), with a proposed transitional period of five years, irrespective of the sector of use, i.e. their use would be continued to be allowed during this period even if the sector where they are used is subject to a shorter transitional periods (e.g. ships).

(5) "Civilian ships" refers to marine and non-marine civilian ships.

(6) Foam concentrates are the foam formulations purchased by the users and which are further mixed with water at the moment of the use. Water-added foams are the foam concentrates mixed with water at the moment of the use. Fire run-off waters (or "firewater runoff") are the run-off waters containing the firefighting foam concentrate mixed with water and all other elements mixed with them during the use of the firefighting foam during a fire incident, training or other use (e.g. flammable liquids, dirt, etc).

(7) The labelling of the containers containing PFASs above the threshold indicated in paragraph 1 aims at facilitating the identification and handling of the PFAS-containing foam concentrates, firewater runoff and waste.

(8) Placing on the market after 10 years is banned as the use is not allowed in any of the sectors or uses anymore at that time.

(9) The ancillary requirement detailed in paragraph 7 is intended to facilitate the enforcement of the proposed restriction by means of 'total fluorine' analytical methods, rather than targeted analysis of specific PFASs. The utility of this requirement shall be reviewed after the consultation on the Annex XV report.

2.3. Overview of impacts

Under RO 1, manufacturers and importers will be allowed to place PFAS-containing foam concentrates on the market for specific types of uses and sectors until the end of the specific transitional periods. The manufacture for export would still be allowed without time limit. Users of PFAS-containing foams will be allowed to use the PFAS-containing foams concentrates as long as they have them in stock but will not be able to make additional purchases after the end of the transitional period corresponding to the use concerned. A progressive reduction in the use of PFAS-containing foams is expected with a concomitant progressive increase of the use of the fluorine-free alternatives. Since continued use is allowed, the restriction would not lead to early disposal of PFAS-containing foam concentrates (i.e. the PFAS-containing foams would be used until the end of their shelf life). Users would benefit from extended periods to transition to alternatives. Six months after the entry into force of the restriction, additional risk management measures would apply that aim to reduce the amounts of PFAS-containing foams used and at collecting the firewater runoff and other PFAS waste to the extent that is technically and economically feasible.

Under RO 2, manufacturers and importers will be allowed to place PFAS-containing foam concentrates on the market during ten years and users will be allowed to use these foams until the end of the transitional periods corresponding to their sector/type of use, after which the safe disposal of the remaining PFAS-foam stocks will be required. The manufacture for export would still be allowed without time limit. During the transitional periods, the required further testing of alternatives and adaptation of firefighting foam equipment will take place progressively to ensure transition by the end of the transitional period. Similarly to RO 1, six months after the entry into force of the restriction, additional risk management measures would apply that aim to reduce the amounts of PFAS-containing foams used and at collecting the firewater runoff and other PFAS waste to the extent that is technically and economically feasible.

RO 3 is similar to RO 2 but with an additional ban of the manufacture for export after ten years (longest transitional period of the use/sector-specific transitional periods). Emissions of PFASs from the formulation stage in the EU would stop after the ban manufacturers would incur surplus losses.

RO 4 bans the use in a similar way as RO 2 with the exception that use of PFAS-containing foams at Seveso establishments and defence sites would not be assigned a transitional period. Instead, to be able to continue using PFAS-containing foams after the entry into force of the restriction, these establishments and sites would be required to apply for it via the local/national competent authorities that deliver operating permits. The Dossier Submitters considers that the incentive for substitution for these sectors is much weaker under this RO and assumes that most of these users would apply for a continued use and be granted an authorisation for a total period of ten years (expected time for a transition to alternatives for the Seveso establishments), and that the progressive transition would actually only take place after this period of ten years. In other words, a relative steady-state use of PFAS-containing foams in these sectors would be observed during ten years, followed by a linear decline until a full transition 20 years after the entry into force of the restriction. Users other than at Seveso establishments and defence sites would follow the same transition pattern as envisaged under RO 2. The same requirement for risk management measures as in RO 2 would apply for all types of uses and exports would similarly be allowed without time limit.

RO 5 bans the use in a similar way as RO 2 with use/sector-specific transitional periods, however, users able to demonstrate a minimisation of the emissions of PFASs would be allowed to continue using PFAS-containing foams without time limit. In practice, the Dossier Submitter assumes that only Seveso establishments would possibly be able to meet this requirement and that most of them would take advantage of this allowed continued use for at least the assessment period considered in this restriction proposal (30 years after entry into force). This would result in lower but continued emissions of PFASs since risk management measures in the context of firefighting are unlikely to be 100% effective. The users not being able to meet the requirement for a minimisation of the emissions of PFASs would need to transition to fluorine-free alternatives in the same pattern as RMO 2 and with the same requirement during the transitional period to apply the risk management measures to the extent technically and economically feasible. Exports would be allowed without time limit.

The two figures below summarise the main effects (i.e. anticipated responses from the supply chains along with associated impacts) resulting from the different risk management options.

The impacts of these ROs are analysed in detail in Annex E, Sections E.4, E.5 and E.6.

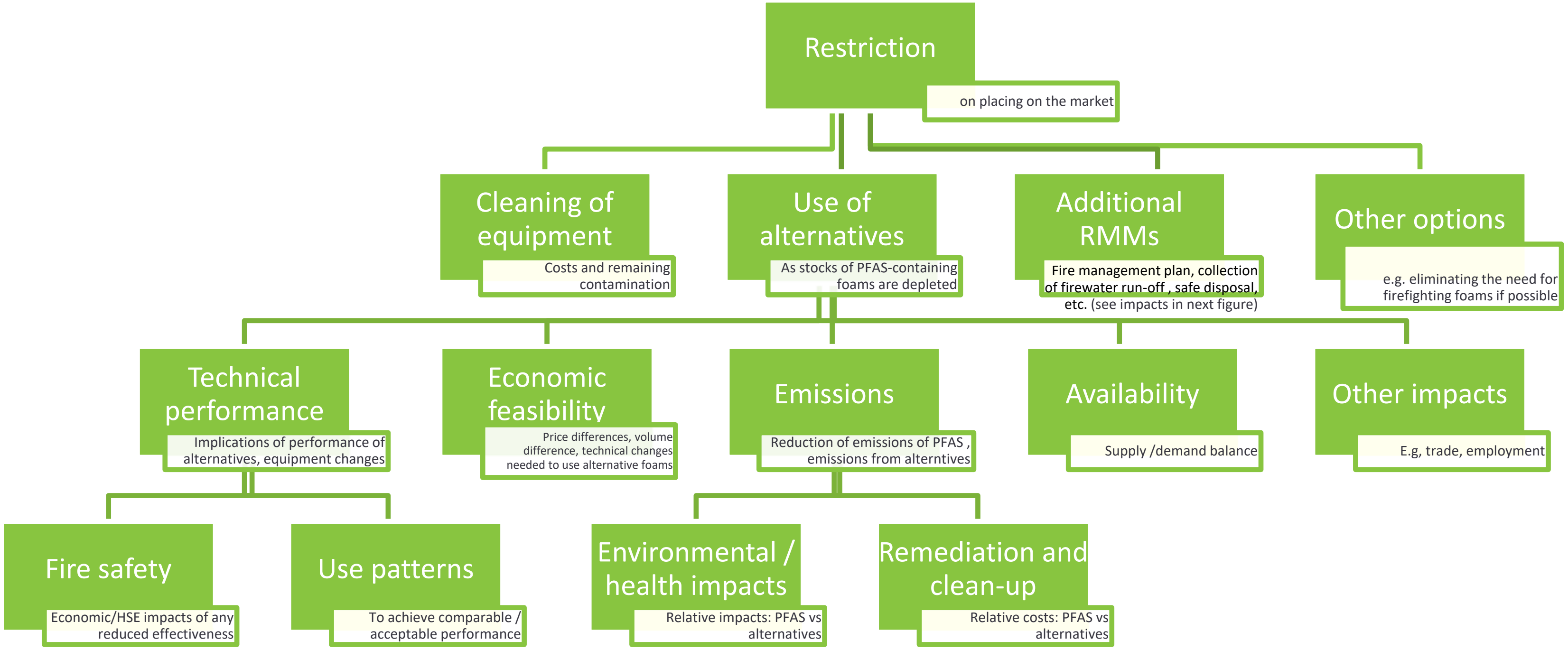

Figure 6. Schematic summarising potential effects of a restriction on the placing on the market of PFAS-containing firefighting foams (RO 1)

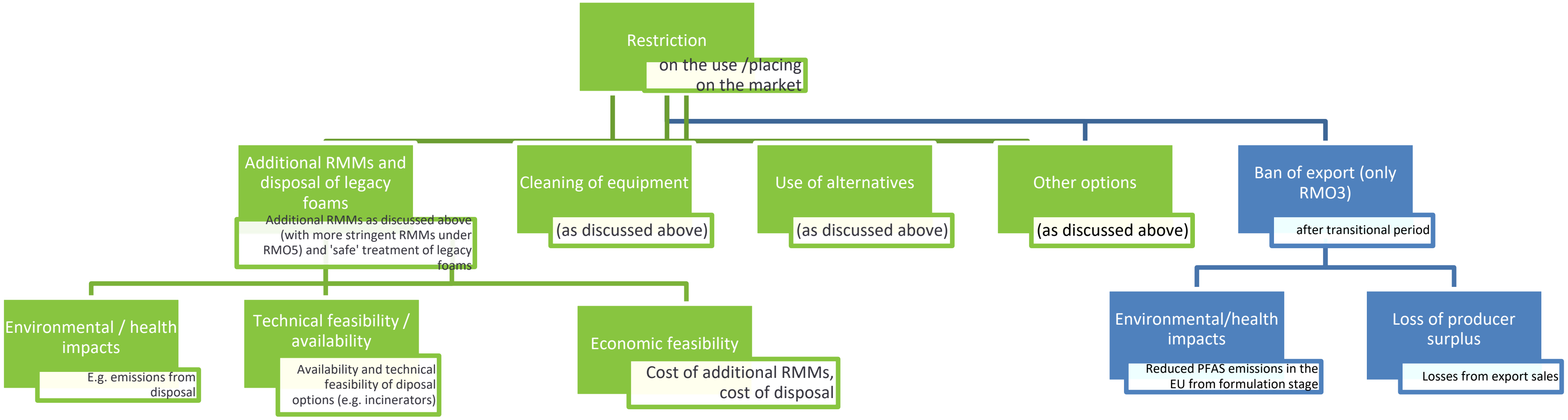

Figure 7. Schematic summarising potential effects of a restriction on the use /placing on the market of PFAS-containing firefighting foams (RO 2, 3, 4 and 5)

2.4. Economic impacts

The proposed transitional periods are set to allow the development of fluorine-free firefighting foams and the adaptation of existing firefighting systems while providing a similar level of fire protection as under the use of PFAS-containing foams. For this reason, specific transition periods by application and use sector are proposed (see Table 3 and justifications in section 2.8.2) and these are reflected in the estimated costs for each use/sector.

Table 3. 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**
Seveso establishments	10 years
Other industries	5 years
Civilian aviation	5 years
Defence	5 years
Municipal fire services	18 months
Ready-to-use applications	5 years
Marine applications	3 years
Training and testing	18 months
Export	10 years

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

- Cost of using alternative foams:

  This cost element considers the difference in prices between PFAS-containing and fluorine-free foams, and additional volumes of fluorine-free foams needed to achieve the same level of fire protection.

- Depreciation of existing stocks:

  For ROs restricting the use of firefighting foams already in stock, the lost value of the foams is estimated.

- Cost of technical changes needed to adapt equipment for the use of alternative foams:

  Technical changes are needed to use fluorine-free foams, e.g. changes in firefighting nozzles, heavy duty applicators, specialist equipment and mobile foam units.

- Incineration/disposal costs of PFAS-containing foams:

  This category could potentially represent both costs and savings. If use of existing foams is banned, these foams would have to be disposed of safely introducing costs to the industry. On the contrary, alternative foams do not require incineration if they expire. As the assumptions made in the analysis imply that existing foam would be used before it expires (in 15 years), only the cost of incinerating existing foam stocks (for ROs with use ban) is considered.

- Savings resulting from avoided clean-up:

  Savings for some users may occur in the case of avoided clean-up of contaminated land after a fire incident. Clean-up is considered to result from recent activity which is often still ongoing at the site. This is different from remediation which is carried out due to historical activities (see Annex E.4.3 for further information on clean-up and remediation).

- Cost of cleaning equipment to comply with the proposed concentration threshold:

  To comply with the proposed concentration limits, firefighting equipment needs to be cleaned to avoid residual amounts of PFASs in the fluorine-free foams.

- Cost of additional RMMs for training/testing and incidents:

  The ROs contain a requirement to safely use PFAS-containing foams during the transitional periods. This could include collection and disposal of fire water run-off.

- Producer surplus loss due to export ban (only for RO3):

  Producers of PFAS-containing foams lose profits if not being allowed to sell their products to non-EEA countries. No producer surplus changes are calculated for the sales within the EEA. This is because quantities of alternative foams produced and sold in the EEA are considered to increase due to the need to maintain the same level of fire protection. Furthermore, possible changes in production costs are already covered by the price element in the calculation of cost of using alternative foams.

- Cost of full containment of the foams (only for RO5):

  RO 5 allows continued use of PFAS-containing foams if the releases are minimised. This would require technical adaptations to achieve full containment.

A more detailed description of the cost categories and how they have been estimated is provided in Annex E.4. Sector-specific unit costs are used for monetising technical changes needed to use alternative foams and the cleaning of existing equipment.

There are also significant savings in terms of reduced remediation of contaminated sites. However, these have been considered as part of the benefits of the proposed restriction as described in the benefit and proportionality assessment in section 2.8.

Furthermore, large savings resulting from avoided contamination of drinking water resources can also be expected to benefit drinking water suppliers. Based on section 1.1.4, release reduction would avoid extensive drinking water contamination and thereby considerable costs of development and implementation of efficient drinking water purification techniques. These (unquantified) savings are also considered as part of the benefits assessment (section 2.8).

Table 4 summarises the estimated economic impacts for each RO and each cost category.

Table 4. Estimated economic impacts for each RO and cost category

Cost category	**RO1** (NPV € over 30 years)	**RO2** (NPV € over 30 years)	**RO3** (NPV € over 30 years)	**RO4** (NPV € over 30 years)	**RO5** (NPV € over 30 years)
Cleaning of equipment	2.0 billion (1 to 4 billion)	2.5 billion (1 to 5 billion)	2.5 billion (1 to 5 billion)	2.1 billion (1 to 4 billion)	1.2 billion (0.6 to 2.4 billion)
Technical changes needed	3.5 billion (2 to 11 billion)	3.5 billion (2 to 11 billion)	3.5 billion (2 to 11 billion)	2.6 billion (1 to 8 billion)	300 million (150 to 900 million)
Disposal / incineration of foams	0	110 million (100 to 140 million)	110 million (100 to 150 million)	61 million (55 to 80 million)	67 million (60 to 80 million)
Depreciation of stocks disposed	0	170 million (150 to 200 million)	170 million (150 to 200 million)	92 million (80 to 120 million)	100 million (90 to 130 million)
Cost of alternative foams	260 million (-60 to 700 million)	480 million (-0.1 to 1 billion)	480 million (-0.1 to 1 billion)	330 million (-80 to 900 million)	300 million (-70 to 800 million)
Savings due to avoided clean-up	73 million (100 to 40 million)	120 million (240 to 60 million)	120 million (240 to 60 million)	91 million (50 to 180 million)	78 million (40 to 150 million)
Cost of export ban (producer surplus)	not applicable	not applicable	8 million (4 to 24 million)	not applicable	not applicable
Cost of additional RMMs for training/testing and incidents	96 million (60 to 200 million)	60 million (30 to 120 million)	60 million (30 to 120 million)	105 million (50 to 200 million)	59 million (30 to 120 million)
Cost of full containment	not applicable	not applicable	not applicable	not applicable	13 billion (6 to 40 billion)
SUM	**5.9 billion (3 to 16 billion)**	**6.8 billion (3 to 17 billion)**	**6.8 billion (3 to 17 billion)**	**5.2 billion (2 to 13 billion)**	**15 billion (7 to 40 billion)**

The proposed restriction includes a requirement to use PFAS-containing foams safely during the transition periods by applying sector-specific best practices to the extent that these are technically and economically feasible. In the absence of information on the actual measures that are feasible in different sectors and for different users, the Dossier Submitter estimated these costs based on the disposal costs of PFAS-containing foams used for training and incidents. The additional cost of this requirement is presented in Table 4 under the cost category 'Cost of additional RMMs for training/testing and incidents'. This requirement is estimated to cost €30 to €200 million (NPV over 30 years).

The results suggest that the most significant cost categories are related to technical changes needed to use alternative foams followed by the costs of cleaning equipment. These are also the cost elements that are based on sector-specific assumptions about unit costs (see section 3 on assumptions and Annex E.4).

Table 5 presents the impacts per affected industrial sector.

Table 5. Estimated economic impacts for each RO and industrial sector

Sector / type of use	**RO1** (NPV € over 30 years)	**RO2** (NPV € over 30 years)	**RO3** (NPV € over 30 years)	**RO4** (NPV € over 30 years)	**RO5** (NPV € over 30 years)
Seveso establishments	4.5 billion 2 to 12 billion	4.9 billion (2 to 13 billion)	4.9 billion (2 to 13 billion)	3.3 billion (2 to 9 billion)	13 billion (7 to 40 billion)
Other industries	20 million 6 to 50 million	27 million (9 to 60 million)	27 million (9 to 60 million)	27 million (9 to 60 million)	27 million (9 to 60 million)
Civilian aviation	38 million 0* to 100 million	70 million (6 to 160 million)	70 million (6 to 160 million)	70 million (6 to 160 million)	70 million (6 to 160 million)
Defence	25 million 0* to 65 million	45 million (3 to 100 million)	45 million (3 to 100 million)	15 million (0.4 to 40 million)	45 million (3 to 100 million)
Municipal fire services	980 million 0.5 to 2 billion	1.2 billion (0.6 to 3 billion)	1.2 billion (0.6 to 3 billion)	1.2 billion (0.6 to 3 billion)	1.2 billion (0.6 to 3 billion)
Ready-to-use applications	2.5 million 0* to 8 million	7 million (0* to 15 million)	7 million (0* to 15 million)	7 million (0* to 15 million)	7 million (0* to 15 million)
Marine applications	300 million 100 to 700 million	390 million (150 to 900 million)	390 million (150 to 900 million)	390 million (150 to 900 million)	390 million (150 to 900 million)
Training and testing	35 million 0* to 100 million	130 million (0* to 310 million)	130 million (0* to 310 million)	130 million (0* to 310 million)	130 million (0* to 310 million)
SUM	**5.9 billion (3 to 16 billion)**	**6.8 billion (3 to 17 billion)**	**6.8 billion (3 to 17 billion)**	**5.2 billion (2 to 13 billion)**	**15 billion (7 to 40 billion)**

* For some sectors the analysis suggests negative costs based on lower bound estimates. This is because of the assumption made for the prices of PFAS-containing and PFAS-free foams and the potential savings from avoided clean-up. This does not seem to be a plausible outcome and for these sectors the lower bound costs are reported as zero in the table.

The costs presented in Table 5 show that the highest economic impacts are expected for Seveso establishments. This is due to high quantities of firefighting foams used in this sector as well as more expensive technical changes needed to maintain the same level of fire safety when using alternative foams.

The cost analysis results in the following key results. RO1 describes a ban on placing on the market of PFAS-containing foams with an estimated cost of €5.9 billion (ranging between €3 and €16 billion) (NPV over 30 years). RO2 additionally bans the use of foams already placed on the market but not yet used. In comparison to RO1, the additional cost to cover this use is estimated to be €0.9 billion (ranging between €0.4 and €1.7 billion) (NPV over 30 years). RO3 further bans the export of PFAS-containing foams after a transition period of 10 years.

The additional cost to cover exports as compared to RO2 is estimated to be €8 million (ranging between €4 and to €24 million) (NPV over 30 years). As expected, the total costs for RO4 are lower than for RO3 because some industry sectors (Seveso establishments and defence) would benefit from a permit system and could continue using PFAS-containing foams for a longer time. The significantly higher estimated costs for RO5 reflect the technical challenges necessary to achieve full containment.

2.5. Human health and environmental impacts

All PFASs are very persistent in the environment. Many PFASs are likely to persist in the environment longer than any other man-made organic substance. As a consequence, if releases are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects are likely. In such an event the exposures are practically irreversible. Even if further releases of PFASs were immediately prevented, existing environmental stocks would continue to be a source of exposure for generations. There are several additional concerns arising from the use of PFASs, e.g., that a ubiquitous contamination of drinking water resources is unavoidable unless releases are minimised. Human exposures occur efficiently via all environmental exposure routes and cannot be avoided or mitigated. Some PFASs can accumulate in plants, others have bioaccumulation potential in biota and humans. Exposures are also transmitted effectively to unborn and breastfeeding children. Humans and biota are exposed to a complex mixture of PFASs and combined effects are likely. For further details, see section 1.1.4 and section 1.1.6.

Use of PFASs in firefighting foams is substantially contributing to long-term general human and environmental exposures of PFASs besides other uses. The proposed restriction is providing a partial solution to the need to prevent the increase of general PFAS-exposures. However, specific to the use of PFASs in firefighting foams, the potential to contaminate local environments, where firefighting, equipment maintenance and training take place, is high (see Annex C.4.3). The proposed restriction directly prevents such contaminated sites to be formed in future.

The environmental persistence of the assessed non-fluorinated alternatives is considerably lower than that of PFAS compounds.

It is not possible to quantify the human health and environmental impacts of avoided releases. Following the SEAC approach for evaluating PBT and vPvB cases, the avoided released quantities of PFASs are used as a proxy of the environmental and human health risks, and thus of human health and environmental impacts of the proposed restriction.

The evolution of emissions of PFASs to the environment over a 30-year assessment period was estimated in Excel for each of the five RO scenarios, maintaining the following main assumptions:

- RO1: ban on placing on the market after a transitional period per type of use or sector but use allowed until depletion of stocks;
- RO2: ban on placing on the market after ten years and use banned after transitional periods per type of use or sector;
- RO3: same as RMO2 but in addition, taking into account the emissions from formulation for export which are banned after a transitional period of ten years;

- RO4: ban on use after sector/use-specific transitional periods, considering a progressive decline of oil/chemical (Seveso establishments) and defence uses after ten years to simulate the effect of a gradual substitution in these sectors due to the pressure induced by the permit system;
- RO5: ban on use after sector/use-specific transitional periods, considering that only the Seveso establishments would be able to meet the requirement for full containment after the transitional periods, i.e. considering that all uses would stop after their respective transitional period, except Seveso establishment which would continue using PFAS-containing foams at the same level during the entire assessment period of 30 years.

The risk management measures described in the proposed restriction entry have been considered in the emission modelling for all ROs.

As for the baseline, using a source-flow model and several assumptions that are outlined in section 3, in Annex E.5.2 and in Appendix 8 the material flow and emissions per environmental compartments occurring at the different life cycle steps have been calculated for each RO.

In addition, as sensitivity analysis, "Best", "Low" and "High" estimates scenarios were calculated for each ROs using different values for several input parameters (see section 3).

Compared to the baseline, additional risk management measures are proposed in the five ROs to reduce the emissions of PFASs from the continued used during the transitional periods. Among them, all ROs foresee the collection of all PFAS releases, especially those originating from the use of the firefighting foam in training, testing and live incidents. The safe disposal of remaining stock of firefighting foam concentrates after the end of the transitional periods is also foreseen under certain ROs. Figure 8 schematically describes the emissions expected from the in-use phase under the five RMOs. The emission modelling takes these emission sources into account.

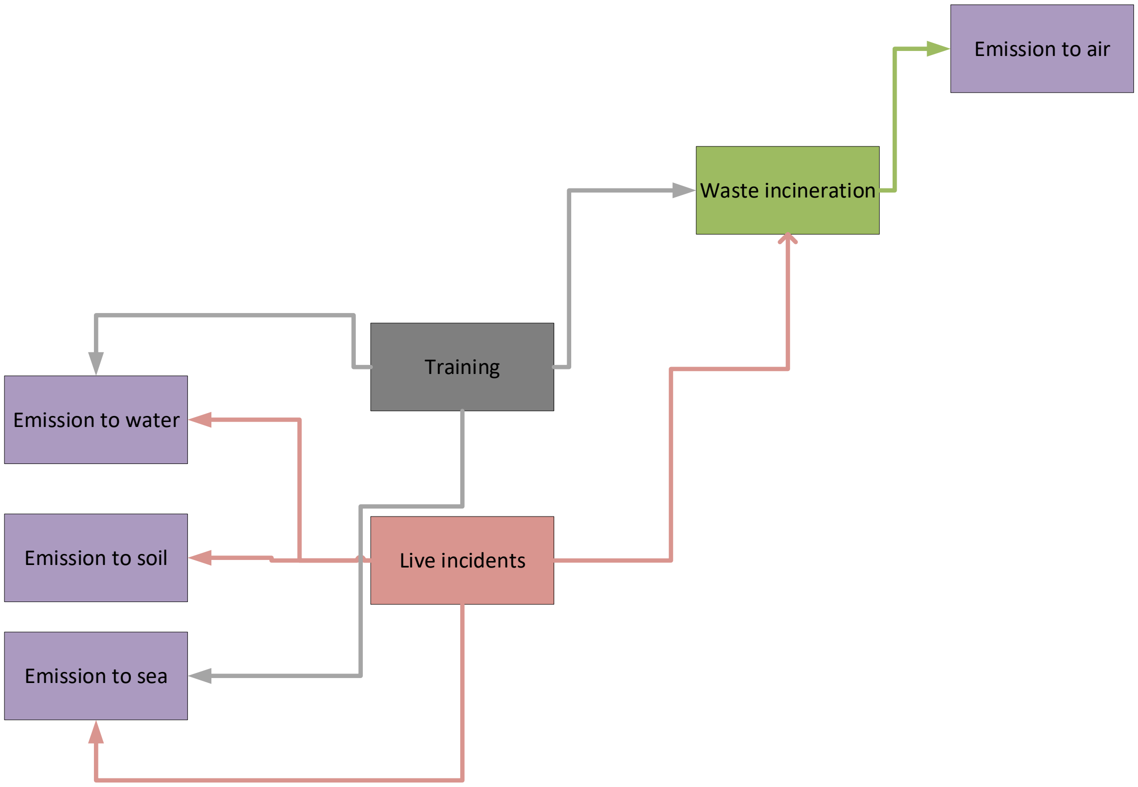

Figure 8. Material flow diagram for the life cycle stages training and incidents, including RMMs as foreseen in all the ROs.

Avoided emissions under the different ROs

For each RO, total avoided emissions of PFASs in the environment over 30 years, compared to the baseline have been calculated. To illustrate the impact of the additional risk management measures proposed under each RO (reduction of emissions as technically and economically feasible, i.e. maximisation of collection and safe disposal for training/testing and incidents), in additional to the progressive phase out, simulations have also been done with and without these risk management measures. These are summarised in Table 6 below and documented in Annex section B.9.

Table 6. 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 PFASs, figures rounded)

RO	Total avoided PFAS emissions over 30 years, **with** risk management measures (t PFASs)	Total avoided PFAS emissions over 30 years, **without** risk management measures (t PFASs)
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 PFASs over 30 years are estimated at 14 100 tonnes in the EU.

RO3 is the RO which is calculated to lead to the greatest PFAS emissions reduction, up to 13 200 tonnes over 30 years. In contrast, RO1 is the RO which leads to the smallest emissions reduction with around 11 800 tonnes. The calculations also show the large impact of the proposed additional risk management measures on the emission reductions.

The evolution of the emissions over the assessment period for each RO with and without RMMs, for each sector/type of use has been modelled and the results presented in Annex E.5.2 and in Appendix 8.

Table 7 summarises the best estimates of the avoided emissions for each RO per sector/type of use. These are used to estimate the cost-effectiveness ratios in the proportionality section. Estimations of the low and high emissions scenarios and the evolution of annual and cumulative emissions (over the assessment period) of PFASs in the environment under the main ROs and with different transitional periods per type of use are presented in annex section F.5.2 and in Appendix 8. Estimates of cumulative emissions to the environment should not be interpreted strictly as equivalent to environmental stocks. This is due to the large uncertainties in predicting future exposures for PFASs, as concluded in section 0.

Table 7. Estimated avoided emissions of PFASs (best estimate) for each RO and sector or type of use, compared to the baseline

Sector / type of use	**RO1** (tonnes over 30 years)	**RO2** (tonnes over 30 years)	**RO3** (tonnes over 30 years)	**RO4** (tonnes over 30 years)	**RO5** (tonnes over 30 years)
Seveso establishments	6087	6232	6281	5966	5653
Other industries	128	131	132	131	131
Civilian aviation	810	940	950	940	940
Defence	540	627	633	440	627
Municipal fire services	1095	1473	1489	1473	1473
Ready-to-use applications	84	117	118	117	117
Marine applications	939	1266	1280	1266	1266
Training and testing	2129	2244	2269	2244	2244
All sectors (rounded numbers)	**11 800**	**13 000**	**13 200**	**12 600**	**12 500**

Notes:

(1) Baseline emissions of PFASs over 30 years are estimated at 14 100 tonnes in the EU.

(2) Except where indicated, the results are not rounded to show the difference in the risk reduction capacity of different restriction options (i.e. avoided emissions). This should not be interpreted as suggesting accuracy in the results.

The modelling used suggests that RO1 results in reduced emissions of around 11 800 tonnes over 30 years. By restricting the use of the foams already placed on the market (RO 2) additional releases of around 1 200 tonnes could be avoided. RO3 would also restrict the export of foams and provide additional release reduction of around 120 tonnes (based on more exact figures that reported above in the table). As could be expected, the avoided releases estimated for RO4 and RO5 are lower than for the proposed RO3 as industry would continue using the PFAS-containing foams for longer. The highest release reduction is achieved in the sector with highest use volumes, i.e. in the SEVESO establishments. As all the quantities used for training/testing and fire incidents are assumed in the emission calculations to be ultimately released in the environment, the only difference in release profile between the industrial sectors or type of use is related to the efficiency of the RMMs when using PFAS-containing foams during the transition periods.

The proposed transitional periods are set to allow the development of fluorine-free firefighting foams, their testing by the users and the adaptation of the existing firefighting systems to provide similar level of fire protection as PFAS-containing foams. This is to exclude the possibility for fire safety risks that could have human health or environmental impacts. This is an important starting point as the Dossier Submitter has not estimated the human health and environmental costs of increased fire damage.

During the transition periods, additional risk management measures are proposed to minimise the emissions of PFASs in the environment. These RMMs are estimated to reduce releases by around 2 000 to 6 000 tonnes over 30 years depending on the RO. The higher end estimate is for the RO allowing the use of PFAS-containing foams for longer, i.e. RO5.

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 PFASs 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.

The human health and environmental risks of fluorine-free foams are considered lower than when using PFAS-containing foams, even if required quantities are greater. The Clean Production Action organisation developed hazard assessment standards for firefighting foams under the GreenScreen® methodology[69] and several foam products assessed have been attributed bronze and silver level scores[70]. Besides these, alternatives based on siloxanes have been identified to be available on the market. However, it should be highlighted that there are concerns related to the PBT and/or vPvB properties of some siloxanes: cyclic D4, D5, D6 have been identified as substances of very high concern under REACH based on these endpoints and others (linear) are currently undergoing PBT-assessment (e.g. octamethyltrisiloxane). Furthermore, D4, D5, D6 are subject to an ongoing restriction process that would not allow their use in firefighting foams if adopted. The restriction is subject to decision making. For this reason, alternatives based on siloxanes have not been assessed further in this report (see Annex E.2 on risks and technical feasibility of alternatives).

The Dossier Submitter highlights the importance for manufacturers of alternatives to PFAS-containing foams to assess the overall human health and environmental safety profile of their products according to recognised methodologies.

As noted in section 2.4 and 2.8, one expected impact of the reduced releases will be the avoided need for developing and implementing more appropriate drinking water purification techniques across the European drinking water suppliers. Although some of the current high-end techniques may clean PFASs from raw water to some extent (see section B.4.5 for details and a briefing note of EUREAU (2021), costs of implementation would be expected to be very large in case releases and hence increase of drinking water resource contamination would not be prevented. It should be noted, however, that for such costs PFAS-containing firefighting foams are only one substantial use among several (see, e.g., for preliminary proportions the restriction proposal of PFHxA, its salts and related substances; (ECHA, 2021).

Similar to above, but directly targetable to the use of PFASs in firefighting foams is the avoided need to change drinking water supply in future. It is currently expected that the immediate clean-up methods would not be sufficiently effective to clean up or remediate soil/groundwater contamination after firefighting in non-bunded areas (see discussion in Annex B.4.5 (see also the example in Table F.14 in Annexes to the proposal and Annex E.4.3.5).

2.6. Other impacts

The Dossier Submitter has not identified any other significant impacts (e.g. on employment or trade) resulting from the proposed restriction. This is because many producers of firefighting foams manufacture both PFAS-containing and PFAS-free foams, sufficient time is provided to develop suitable alternatives (if not available already), and because export is

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[69] https://www.greenscreenchemicals.org/certified/fff-standard
[70] https://www.greenscreenchemicals.org/certified/products

proposed to be allowed until alternatives are available for all uses and industrial sectors. See Annex E.6 for a brief analysis.

2.7. Practicality and monitorability

ROs 1-3 are considered to be practical (in terms of implementability, enforceability and manageability) and monitorable.

In terms of implementability, there are already other regulations in place controlling the placing on the market and use of PFAS-containing firefighting foams. In most of the sectors (all others than tank farms), some users have already substituted to PFAS-free foams. Sufficient transitional periods are proposed to allow the practical implementation of alternatives.

RO4 is not considered to be practical due to the need to adapt national or sub-national legislation to include the derogation system for the continued use of PFAS-containing foams on the site operating with permits.

RO5 is not considered to be practical for industry to implement as full containment of foam fire run-off including for large fire accidents is in practice unlikely to be technically and economically feasible.

Enforcement authorities can set up efficient supervision mechanisms to monitor industry compliance with the proposed restriction (RO3). Methods can be adapted based on those used to analyse PFOA and long-chain PFASs. Several types of analytical methods exist.

Targeted PFAS analysis is used to quantify individual specific PFASs, for example for the comparison with a limit value for a specific PFASs in a product. To quantify a specific PFAS reliably (e.g., for enforcement), an analytical reference standard for the particular PFASs must be available. Laboratories can currently quantify around 40 different PFASs, but this number is increasing as more reference standards become available. In addition to specific analysis methods, the total oxidizable precursor (TOP) assay has been used by several laboratories in recent years to analyse PFASs (usually PFCAs) in firefighting foam concentrates and foam container rinse water. This method simulates accelerated environmental degradation and reveals the presence of arrowhead precursors in a sample e.g., both PFOA and PFOA-related substances. These methods are typically able to quantify PFASs at concentrations well below the threshold of 1 ppm proposed by the Dossier Submitter.

Furthermore, 'total fluorine' methods measure the overall amount of (organic) fluorine in a sample: total fluorine (TF), total extractable organic fluorine (EOF) and total adsorbable organic fluorine (AOF). These methods do not identify/differentiate between different kinds of fluorine-containing organic substances. Therefore, the total fluorine methods will detect and quantify both PFAS and non-PFAS organofluorine substances if they present in the same sample. However, the advantage of total fluorine methods, compared to targeted PFAS analysis or TOP (see directly above), is that they detect and quantify PFASs for which no reference standards exist, including fluoropolymers. In this respect, using total fluorine methods to quantify PFASs in firefighting foams (e.g. for compliance and enforcement purposes) is more practical than using targeted or precursor analysis as they are more compatible with the scope of the restriction proposal (which encompasses all PFASs). However, a disadvantage of total fluorine methods is that they would also detect and quantify, where they are present, organic fluorine from non-PFAS (i.e. not restricted) organofluorine substances in firefighting foams that are outside of the scope of the proposed restriction. Therefore, and to facilitate the practicality and enforceability of the proposed restriction using total fluorine analytical methods, an additional ancillary requirement[71] for labelling the presence (and concentration) of non-PFAS organochlorine at concentrations greater than 1 ppm in firefighting foams is included in the conditions of the restriction (paragraph 7). This condition would allow the restriction to be enforced without requiring targeted analysis of all PFASs. The utility and appropriateness of this ancillary requirement shall be re-assessed by the Dossier Submitter based on comments received in the consultation on the Annex XV report. As such, it is presented in the proposed conditions of the restriction in square brackets [].

Based on the above, the absence of a European (or internationally) standardised analytical method for PFASs in firefighting foams is not considered as a hindrance to the enforceability of the proposed restriction, even though the importance of developing such a standard method at EU level is recognised by the Dossier Submitter. Therefore, considering the availability of analytical methods on the market to measure the content of various PFASs in firefighting foams, the ROs are concluded to be enforceable as regards analytical methods. Besides the availability of analytical methods, a sampling strategy is needed to monitor the restriction in the environment and humans. Analytical methods are further described in Annex E.7.

Nevertheless, the enforceability of the additional RMMs required by the proposed restriction (RO3) may be challenging for enforcement authorities. This is because the Dossier Submitter cannot define them in detail due to sector/use and site-specific differences. This is especially relevant for the techniques to collect PFAS emissions. However, best practices exist in some sectors and countries and they can be used as a basis for developing additional guidance for the industry (see e.g. section 2.2.2.2 for examples). Therefore, enforceability of ROs as regards the additional RMMs is considered feasible. In any case, enforcement can be based on the presence of the 'PFAS-containing firefighting foams management plan' required under paragraph 4c of the conditions of the proposed restriction.

To monitor the effectiveness of the proposed restriction (RO3), 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 deduction of PFAS emissions to the environment (and human exposures) resulting from this restriction should result in a decreasing PFAS concentration in such a trend monitoring.

2.8. Proportionality to the risk (including comparison of options)

The starting point for comparing the appropriateness of the five ROs is the balance between their potential to reduce PFAS emissions and their socio-economic impacts. As the environmental/health benefits of reduced PFAS emissions could not be quantified, it is not possible to use cost-benefit analysis to directly assess whether any of the proposed restriction options is proportionate. In such cases, ECHA's approach to the "Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC" requests Dossier Submitters to report the cost per unit (e.g. kilogram) of emissions reduced as the starting point for the proportionality assessment.

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[71] A similar ancillary requirement is included in Entry 75 of Annex XVII of REACH (restricted substances for tattooing)

Therefore, the approach adopted is to identify the uses/applications and restriction conditions (transition periods, concentration thresholds, other risk management measures) that would achieve high levels of effectiveness (i.e. large reductions of PFAS emissions) with relatively small socio-economic impacts. As discussed above, the proposed transitional periods are considered sufficient to develop alternatives and for the users to test alternatives and adapt the fire extinguishing systems to allow the same level of fire protection as in the baseline.

There are **potentially significant benefits in terms of the reduced remediation costs that will arise by using PFAS-free foams**. As a very high-level estimate for illustration, the order of magnitude of avoided remediation cost could be hundreds of millions of euros (assuming tens of sites across the EU requiring remediation at the cost of tens of millions of € per site) to billions of euros (assuming hundreds of sites across the EU requiring remediation at the cost of tens of millions of € per site) (see Annex E.4 for details). Better information, e.g. on the total number of sites, on the use of PFAS-containing foams per site or on the implementation and effectiveness of best practices in terms of containment and immediate clean-up would be required to assess to which extent remediation is likely to be required in the future as a result of current uses of PFAS-containing firefighting foams (and could therefore be avoided because of the restriction). It is not possible to provide estimates per RO, but any such benefits would be higher in RO3 (which results in the highest avoided emissions) than in the other ROs, given the quicker abatement of PFAS emissions.

These remediation costs are not included as savings in the assessment of economic impacts as they are considered to be covered by the quantitative estimate for reduced releases which is used as proxy of human health and environmental impacts. It could be argued that also clean-up savings should be reported as benefits. However, they are considered as economic impacts in this report as they are carried out as part of the actual use of the firefighting foams. It is not clear to what extent remediation or clean-up eventually removes PFASs from circulation, or simply reduces the risk by removing a site-specific concern. The baseline release estimates used in this report assume that all PFASs used will be eventually released to the environment and no adaptations have been done due to possible clean-up or remediation.

Same applies at larger scale for savings resulting from avoided drinking water purification costs. Use of PFASs in firefighting foams contributes to the general PFAS exposure to relevant extent. Due to their properties, most PFASs are difficult to remove from drinking water with current techniques in a manner which would be feasible for normal drinking water purification facilities. To avoid exposure via drinking water it would be necessary to develop feasible purification techniques for use in normal drinking water preparation facilities in case the releases would not be minimised. Otherwise new local water resources/aquifers would need to be taken into drinking water use. Either of these options can be expected to be costly to society. These avoided costs have not been quantified due to lack of data.

The SEAC PBT/vPvB approach recognises that while weighting on the basis of (expected) damage is currently not possible in a systematic way using quantitative approaches, it is often feasible to describe factors or situations where the properties of a particular PBT or vPvB would be likely to cause damage. The following discusses the factors that are considered particularly relevant for this case to support the proportionality assessment.

- The size and dynamics of the stock of PFASs in the environment is one of the main factors. PFASs are very persistent and many of them are expected to stay in the environment for decades and even centuries. Exposure to PFASs is hardly reversible once effects are encountered (see further discussion on consequences of persistence in section 1.1.4 and 1.1.6).

- The environmental stock of PFASs consists of a highly complex, variable mixture of PFASs. This complexity of exposure hampers (in addition to the very persistent property) both the exposure assessment and the identification of effects (see section 1.1.4 for more details).
- PFASs have a high potential for long-range transport.
- PFAS exposure via drinking water and food cannot be avoided by any parts of the human population if releases are continued (see section 1.1.4 and 1.1.6 for details). Effects are highly likely to be triggered over time when the PFAS levels increase.
- General drinking water purification of PFASs as a consequence of widespread PFAS contamination in groundwater and surface water is currently technically and economically not feasible and is expected to be challenging also in future due to the properties of PFASs (see section 1.1.4 for details and the discussion above on the potential costs).
- Wastewater treatment plants are not effective in removing PFASs (see Annex B.4.2.4. and B.4.5).
- Releases from firefighting uses substantially contribute to the overall environmental concentrations of PFASs.
- Use of PFASs in firefighting foams causes locally contaminated sites. Current remediation and clean-up methods are not fully effective to remove PFASs from contaminated sites.

To propose the most appropriate RO, the following aspects are discussed in this section:

- **Comparison of different users** or industrial sectors to describe the possibilities to substitute PFAS-containing foams with alternatives
- Based on this comparison, the sectoral **transition periods** are derived
- Derivation of **concentration thresholds**
- **Cost-effectiveness estimates** to discuss proportionality.

2.8.1. Comparison of different users

The analysis of alternatives (see Annex E.2) has concluded that alternatives are generally considered to be technically feasible in most applications. Further testing is required to confirm the technical feasibility of alternatives for some specific applications, particularly large atmospheric storage tanks and sites using different types of flammable liquids.

The various use sectors and applications of firefighting foams vary significantly in terms of the potential for a restriction to reduce PFAS emissions to the environment ('PFAS risk reduction potential'), the current feasibility of transitioning to fluorine-free alternatives ('substitution potential') and the resulting potential socio-economic impacts of that transition. Therefore, it is appropriate to set different conditions for the different sectors and applications, to balance the effectiveness of the measure with considerations around feasibility of alternatives and socio-economic impacts.

A table summarising and comparing substitution potential, socio-economic impacts and risk profile across the main identified user sectors is provided below (Table 8). The comparison in the table suggests that training and testing should be the highest priority for a quick transition to fluorine-free foams, because the use of alternatives is well established and already recommended as industry best practice. According to the stakeholder survey conducted in preparation of this Annex XV report, many users have already transitioned to fluorine-free alternatives for training and testing and the potential for adverse socio-economic impacts is very low for these types of uses.

The oil/(petro-)chemical industry is by far the largest use sector. The costs of transitioning, but also the current emissions of PFASs, are higher than in other sectors. A longer transition period for this sector is needed due to the specific applications (notably large tank fires and installations using different types of flammable liquids) where further testing is required to determine the technical feasibility of alternatives and potential fire-safety risks resulting from using alternatives. In order to cover all the sites that are likely to face such particularly hazardous fire scenarios, the Dossier Submitter suggests defining them as the establishments subject to the Seveso III Directive (upper and lower tier) instead of using a threshold based on e.g. tank size or bund area size, which might be too restrictive and could omit several relevant industries and sites.

A rapid transition in marine applications should be a high priority due to the low potential for retention of run-off and clean-up after incidents, and established alternatives (e.g. two of the alternatives shortlisted in the analysis of alternatives were reported to be used in the marine sector) and no particular issues have been raised during the stakeholder surveys. The assessment conducted in this report relates to marine ships which are understood to be the most relevant types of civilian ships using PFAS-containing foams (no information has been received from stakeholders on non-marine ships). However, by extension, the restriction entry refers to ships in general (marine and non-marine civilian ships) since the substitution considerations are assumed to be similar.

Municipal fire services should also be prioritised for a quick transition because alternatives are well established and this sector is typically involved in fire incidents outside of specific industrial sites where retention of run-off and clean-up after incidents is more difficult.

Alternatives are less well established in the defence sector. They are considered by some stakeholders to be feasible, having been adopted in Europe by the Danish and Norwegian armed forces (IPEN, 2018). However, even though some of the applications are similar to those of other sectors (e.g. civilian aviation) where substitution has taken place, the defence sector entails specificities such as the storage and transportation of explosives and ammunition, leading to increased security risks and requiring the highest level of efficiency when extinguishing and preventing re-ignition. Transition to an acceptable alternative is likely possible in some cases but requires extra care because if the use of alternatives causes any fire-safety risks, the potential damages could be significant and could include danger to human life. During the stakeholder survey conducted in 2021, several Member State Ministries of Defence have called for longer transitional periods – from a minimum of six years up to twelve years – to ensure a transition without compromising fire safety, or even requesting an exemption. According to REACH Article 2(3), Member States may allow for exemptions from the REACH Regulation in the interests of defence. The European Defence Agency has published guidelines to follow in case an exemption needs to be applied for. However, stakeholders have highlighted potential problems associated with national exemptions in the consultations of the PFHxA restriction proposal. According to industry, the national approval of an exemption is associated with extensive effort and a legal act of the Union ensures more legitimacy and acceptance because of its transparency and legal certainty.

Likewise, in civilian aviation there is a concern that, if the use of alternatives caused any fire-safety risks, the potential damages could be significant and would likely include danger to human life. However, alternatives are considered feasible and have successfully been implemented by many users (e.g. the airports of Dubai, Dortmund, Stuttgart, London Heathrow, Manchester, Copenhagen, Schiphol, Australia and Auckland) and a relatively quick transition should be sought. The 2021 stakeholder survey – to which several airports responded – did not indicate that a transition within five years would not be possible.

Some alternatives to PFAS-containing portable fire extinguishers for class B fires already exist and are in use but suitable alternatives are not available yet for all types of extinguishers. Additional time is needed to develop such suitable alternatives and make them available to the entire market.

2.8.2. Transition periods

The starting assumption adopted for this restriction proposal is to allow sufficient transition time to allow for the testing and selection of the most appropriate foam product and the adaptation or replacement of the fire extinguishing system to ensure the same level of fire protection as that achieved currently with the PFAS-containing foams. Based on this assumption, the Dossier Submitter has not quantified or monetised the impacts of any reduced fire protection capacity related to the use of alternative foams, as there should be no difference in performance.

Based on the analysis of alternatives (see Annex E.2), their applicability to specific sectors, and the input provided by a range of stakeholders on their implementation, different transition periods have been considered appropriate for different uses.

Successful transition to fluorine-free foams for **training and testing** has been reported by stakeholders across sectors and is already recommended as industry best practice. Therefore, a short transition period should be sufficient for training and most testing currently performed with PFAS-containing foams. However, there are some specific types of testing that differ in terms of their substitution potential. According to (Eurofeu, 2020), the following types of testing can be distinguished:

- testing of foam agents during their development phase,
- testing of foam agents by users to evaluate product suitability on specific combustibles,
- testing of the correct proportioning of firefighting foam concentrates, and
- testing of firefighting systems for their function (i.e. testing the fire protection system in the same way as it would operate in case of emergency).

According to Eurofeu, all types of testing can be implemented with PFAS-foam surrogates (i.e. alternatives products) except the latter one as also the properties of the foam generated by the system are subject to a pass/fail criterion. Therefore, if training and testing activities could quickly transition to fluorine-free alternatives, testing of the firefighting systems for their function should remain possible with PFAS-containing foams as long as the industry sector may use PFAS-containing foams for fire incident management. The Dossier Submitter considers that the transition in training and testing applications to fluorine-free foams should be feasible in 18 months (with the exception for testing the function of firefighting systems mentioned above).

The Dossier Submitter concludes that technically feasible alternatives to PFAS-containing foams are available on the market for **municipal fire services** and that a quick transition should be feasible. An exception to this would be municipal fire services that also have responsibility for industrial fires at establishments covered by the Seveso-III Directive. In this specific case, the same transitional period as applicable for the Seveso establishments themselves would be warranted but limited to the use in these establishments only. The Dossier Submitter considers that the transition of municipal fire services to fluorine-free foams should be feasible in 18 months (with the exception mentioned above).

Ready-for-use applications include ready-for-use firefighting agents which are predominantly used in handheld portable extinguishers but also as pre-fill of so-called "wet systems" (firefighting systems where the pipework from the extinguishing agent feed stock to the actual applicator is pre-filled with an extinguishant). Based on the information collected, the Dossier Submitter considers that a transition of five years would be necessary for developing, certifying and supplying the whole market with suitable alternatives to PFAS-containing ready-for-use agents. To allow the availability of PFAS-containing portable fire extinguishers for five years also for sectors of use with shorter transitional periods (e.g. ships: three years), the restriction entry specifies that the transitional period for portable fire extinguishers is valid irrespective of the sector of use.

The oil/(petro-)chemical industry is the sector where users have argued that a longer transition period of up to 10 or 12 years is required to ensure that fire safety is not compromised. This time would be required to conduct further testing of the feasibility of alternatives for large atmospheric storage tanks[72] (LAST) and for other types of challenging fire scenarios such as those involving different types of flammable liquids. This is broadly consistent with the reported duration of the transition by the Norwegian oil and gas company Equinor (see case study in Annex E.2.6), which took about eight years from development and testing to full operation of fluorine-free alternatives.

The collected information indicates that, even though fluorine-free foams seem to perform well against different types of fuels overall, different application rates and methods may be needed to achieve the desired effect, resulting in the need to implement several technical adaptations to the overall fire extinguishing system of a site, including foam storage tanks and bunds. Sufficient time would therefore be needed to finalise the testing of different foams, application methods and fuels as well as to allow users to implement the necessary technical adaptations (mainly to fixed systems) for the transition to PFAS-free alternatives while maintaining equivalent fire safety levels. Most stakeholders from the oil/(petro-)chemical industry having contributed to the surveys or the consultations related to the PFHxA restriction proposal called for transitional periods of 10 to 12 years to allow the development and testing of fluorine-free alternatives and to implement the necessary technical changes at their sites. To cover all the sites likely to face such hazardous fire scenarios, the Dossier Submitter suggest defining them as the establishments subject to the Seveso III Directive (tier 1 and tier 2) instead of using a threshold based on e.g. tank size or bund area size,

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[72] These are large-diameter (greater than 40m), open-top floating-roof storage tanks of flammable liquids.

which might be too restrictive and could omit several relevant industries and sites. A transition period of ten years seems appropriate for the implementation of the transition to fluorine-free alternatives for this sector of use defined as establishments subject to the Seveso III Directive.

Regarding the **defence sector**, the Dossier Submitter considers that, based on the information received so far, in most cases the transition to fluorine-free alternatives in the defence sector should not be significantly different from a technical point of view compared to other sectors like the civilian aviation sector where quick extinguishment is also required. Contrary to the downstream petrochemical sector, major equipment adaptations are not expected. Exceptions might apply for ships already built or ships under construction in countries where ship equipment adaptation would not be possible. However, this case has only been mentioned by one Ministry of Defence, therefore, a general exemption does not seem warranted. If necessary, each Ministry of Defence has the possibility to call for a national defence exemption under Article 2(3) of REACH. Therefore, the same transitional period as for civilian aviation is proposed for the defence sector (see below).

The **civilian marine sector** (and by extension all civilian ships) shows limited capability to contain foams during use. In addition, fluorine-fee alternatives are technically feasible and available for this sector. On this basis, the Dossier Submitter considers that a short transition period should be considered for this use and that three years should be sufficient to implement the necessary changes[73].

For all **other sectors** (e.g., civilian aviation, offshore oil extraction platforms, etc.), shorter transition periods, between three and six years, have been suggested by stakeholders and are considered sufficient to allow an orderly substitution towards fluorine-free foams. Regarding airports, the stakeholder survey undertaken by the Dossier Submitter in Spring 2021 – to which several airports responded – did not indicate that a transition within five years would not be possible. The Dossier Submitter therefore concludes that technically feasible alternatives to PFAS-containing foams are available on the market for the use in civilian aviation and that a complete transition within five years should be feasible. In regard to offshore oil extraction platforms, the Dossier Submitter concludes that technically feasible alternatives to PFAS-containing foams are available on the market. Considering the low potential of containment of firefighting foams during their use and the experience likely gained on the market since the transition by Equinor, the Dossier Submitter considers that a transition within five years should be feasible for offshore platforms. In general, the Dossier Submitter considers that a transition within five years should be feasible for these other sectors.

Table 8 below summarises the substitution potential, socio-economic impacts and PFAS-related risk reduction potential across the identified main user sectors and the transitional periods proposed by the Dossier Submitter for this restriction proposal.

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[73] It should be noted that certain uses of firefighting foams in the civilian marine sector are regulated by International Maritime Organisation rules and fall under Directive 2014/90/EU on marine equipment. This directive itself transposes IMO requirements and makes them applicable on vessels flying the flag of an EU Member State. For applying the restriction under REACH on firefighting foams to all sea-going ships calling at EU ports, a similar measure at IMO level would be needed.

Table 8. Substitution potential, socio-economic impacts and PFAS-replated risk reduction potential across the main identified user sector and proposed transitional periods

Use / application	Substitution potential	Potential socio-economic impacts	PFAS-replated risk reduction potential	Transitional periods proposed by the Dossier Submitter (1)
Oil/(petro-) chemical industry	**Low for some applications, medium/high for others:** Sector includes many different and complex scenarios. Alternatives have successfully been implemented for some applications but may not be readily available for others. In particular, additional testing required to confirm feasibility of alternatives for large atmospheric storage tanks and fires with different types of flammable liquids.	**High:** By far the largest user (59 % of annual sales), so transition is large scale. Highest potential fire-safety risks from using alternatives, although relatively low risk of danger to human life.	**High:** By far the largest user (59 % of annual sales), average potential for retention of run-off and clean-up after incidents.	**10 years**
Civilian marine Applications (civilian ships)	**High:** Feasible alternatives considered to be available and have successfully been implemented by many users.	**Medium:** Average user (12 % of annual sales), average potential for fire-safety risks from using alternatives.	**Very high:** Average user (12 % of annual sales), likely lowest potential for retention of run-off and clean-up after incidents.	**3 years**
Defence	**Low for some specific applications/Medium for others:** Feasible alternatives considered to be available by some users but not by others. Not many alternatives have been certified or implemented by users yet.	**Medium/High:** Relatively small user (6 % of annual sales), so relatively small scale of transition. Average potential of fire-safety risks from using alternatives, which could result in a relatively high potential of danger to human life.	**Medium:** Relatively small user (6 % of annual sales), average potential for retention of run-off and clean-up after incidents.	**5 years**
Civilian Aviation	**High:** Feasible alternatives considered to be available and have successfully been implemented by many users.	**Medium/High:** Relatively small user (9 % of annual sales), so relatively small scale of transition. Average potential of fire-safety risks from using alternatives, but any risks would result in a relatively high potential of danger to human life.	**Medium:** Relatively small user (9 % of annual sales), average potential for retention of run-off and clean-up after incidents.	**5 years**
Municipal Fire Services	**High:** Feasible alternatives considered to be available and have successfully been implemented by many users.	**Low:** Average user (12 % of annual sales), so average scale of transition. Low potential of fire-safety risks from using alternatives.	**High:** Average user (12 % of annual sales), likely lower potential for retention of run-off and clean-up after incidents because	**18 months**

Use / application	Substitution potential	Potential socio-economic impacts	PFAS-replated risk reduction potential	Transitional periods proposed by the Dossier Submitter (1)
			not restricted to specific industrial sites.	
Ready to use applications	**Medium/High:** Feasible alternatives considered to be available for some applications but not all (R&D, certification needed, staggered supply of the market to cope with manufacturing capacity).	**Low/Medium:** Relatively small user in terms of quantities (1 % of annual sales according to Eurofeu data) but large number of devices affected (15 million PFAS-containing fire extinguishers estimated). Medium potential of fire-safety risks from using alternatives.	**Medium/High:** Relatively small user, likely lower potential for retention of run-off and clean-up after incidents because not restricted to specific industrial sites.	**5 years**
Testing	**Very high:** Feasible alternatives considered to be available and have successfully been implemented by many users. No need for high performance foams.	**Very low:** Likely very small share of use across sectors of use, not the most expensive high-performance foams required. Very low risk of damages resulting from performance of alternatives.	**Low:** Likely very small share of use across sectors of use, relatively high potential for retention but collected waste are not necessarily treated adequately.	**18 months**
Training	**Very high:** Feasible alternatives considered to be available and have successfully been implemented by many users. Little need for high performance foams.	**Low:** Limited share of use. Likely not the most expensive high-performance foams required. Low risk of damages resulting from performance of alternatives.	**Low/Medium:** Limited share of use, relatively high potential for retention but collected waste are not necessarily treated adequately.	**18 months**
Other sectors or types of uses not listed above	Considered similar as the aviation sector			**5 years**

(1) Alternative transitional periods are proposed for specific cases within some of these categories. See the restriction entry and explanatory notes in section 2.2.5 for details.

2.8.3. Concentration thresholds

There are three main considerations to choose appropriate concentration thresholds for remaining PFAS-contamination in firefighting foam systems: residual releases from contaminated firefighting foams/systems, the costs of cleaning (or replacement) of equipment, and detection limits of testing methods. The first two points are discussed here and the last one in section 2.7 (practicality including enforceability).

Considering these elements, the Dossier Submitter proposes a concentration threshold of 1 ppm.

Remaining PFAS-contamination

It is not clear what impurity levels would be in the contaminated alternative foams without a clean-up of the equipment already used for PFAS-containing foams. After transition from C8-based foam to C6-based foam without a cleaning, 'high' concentration (no quantitative information) of PFOS has been reported by a stakeholder. Another stakeholder stated that after substitution from PFAS-containing to non-fluorine foam, follow-up measurements showed that PFASs were still detectable.

When adopting a certain threshold there is a trade-off between the amount of PFAS emissions remaining and the costs of cleaning to achieve that threshold. For example, if the concentration of PFASs in the foam concentrate is on average 2.5 %, i.e. 25 000 ppm or 25 000 000 ppb, a threshold of 1 ppm would lead to a minimum reduction of concentration (and hence emissions considering a similar use and RMM pattern) of 99.99 %, whereas a threshold of 50 000 ppb would represent a reduction in concentration and emissions of 99.80 %. A threshold of 1 ppm is 25 000 times lower than the average concentration of PFASs in the firefighting foams in use (2.5 %) and 1 000 times below the lowest concentration (0.1 %) that can be considered as providing any functionality, therefore the proposed limit would impede any intentional use of PFASs in the foam concentrate.

Cost of cleaning equipment

According to industry, the cleaning cost heavily depends on the thresholds to achieve. The lowest cost reported for cleaning of equipment (foam concentrate tank) is €4 000. For large, fixed installations cleaning is more complex and therefore more expensive. The lowest cost method is reported to result in low ppb concentrations for each of 13 standard PFASs measured in the final rinse water. Other methods are reported to cost between €20 000 and €200 000 per equipment. Available information suggests that they could achieve lower concentrations (see Annex E.4.3.6 for details).

Based on the available information, the Dossier Submitter assumes that the cost of reaching the proposed 1 ppm level varies between €20 000 and €200 000 per site depending on the sector of use. This estimate accounts for the need to clean-up several equipment/systems per site, and also the possibility that higher impurity levels in the foam are reached during their storage. This could happen due to remaining PFASs, adhering to the surface of the equipment and being released via the foam over time[74].

It is not possible to derive robust cost estimates for different concentration limits. However, it can be calculated that reducing the remaining PFAS concentration in possibly contaminated fluorine-free foams from 1 ppm to 1 ppb, would reduce the quantity of PFASs released in the EU by around 150 kg[75] per year (other parameters remaining constant).

If the cleaning methods needed for reaching the lower thresholds are more expensive (e.g., 10 times) than those described above, the cost of achieving each additional kg of emission reduction would become very high. Even if there is high uncertainty in the data, the Dossier Submitter considers it sufficient to conclude that a lower threshold would not be appropriate based on its limited risk reduction capacity of less than 150 kg. However, it is recognised that

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[74] See Annex E.4 on cost of cleaning equipment to comply with the proposed concentration threshold for more details.

[75] (Stock of foams x concentration^{high}) - (Stock of foams x concentration^{low}) = (150 000 t x 0.0001 %) – (150 000 t x 0.0000001 %) < 150 kg.

some cleaning methods seem to be able to reach lower concentrations than the proposed 1 ppm. If these are preferred by the users of the substance, the lower concentrations are achieved in practice, regardless of the concentration threshold in the restriction proposal.

More detailed information on the available techniques and associated costs for cleaning procedures is available in Annex E.4.3.6 and in Appendix 1.

2.8.4. Cost-effectiveness estimates

Table 9 summarises the cost-effectiveness estimates for different ROs and industry sectors or types of use.

Table 9. Estimated C-E ratios for each RO and sector or type of use

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: 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.

Table 10 reports the incremental cost and incremental reduction in releases for RO2 compared to RO1, and RO3 compared to RO2, to allow for a comparison of the restriction options against each other (rather than against the baseline). RO4 and RO5 are not covered in this table as they are not building on the other options and not considered to be practical by the Dossier Submitter.

Table 10. Incremental cost-effectiveness (C/E) of RO1, RO2 and RO3

Restriction option	**Total costs** (€ over 30 years)	**Emission reduction** (tonnes over 30 years)	**C/E-ratio** (€ per kg)	**Incremental cost** (€ over 30 years)	**Incremental release reduction** (tonnes over 30 years)	**Incremental C/E-ratio** (€ per kg)
RO1	5.9 billion	11 800	498	5.9 billion	11 800	498
RO2	6.8 billion	13 000	520	900 million	1 200	734
RO3	6.8 billion	13 200	515	8 million	120	67

Note: These results are based on best estimate scenario

The results in Table 9 and Table 10 are derived for scenarios with additional RMMs during the transitional periods. Results without these additional RMMs are reported in section F.4 of the Annex. Recognising that the information on the effectiveness of these RMMs to reduce emissions and their costs is uncertain, the results suggest that the C/E ratio of requiring these RMMs independently from the ban on placing on the market, use or export would be €15-100 per kg of release avoided.

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

Table 11. 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 PFASs in firefighting foams is supported by the cost-effectiveness estimates as they are similar to other recent restrictions adopted by the Commission.

The Dossier Submitter considers RO3 to be the most appropriate restriction option. Even though regulating the use of existing stocks (covered by RO2 and RO3) is more expensive per kg of emissions reduced than regulating placing on the market (which is not covered by RO1), 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.

2.8.5. Additional risk management measures

The proposed restriction includes the requirement for the implementation of additional risk management measures during the transition periods by means of a mandatory 'PFAS-containing firefighting foams management plan' and the use of best practice risk management measures during the whole life cycle of PFAS-containing foams.

Current practices by foam users vary and are not always appropriate to minimise emissions to the environment. Therefore, additional risk management measures are proposed as part of the restriction.

The cost of the requirement to minimise emissions to the environment as well as direct and indirect exposure of humans to firefighting foams is monetised in this report by using the incineration cost of the foams as a proxy for the cost. Recognising that this does not completely cover the requirement, it is considered sufficient by the Dossier Submitter in the absence of more accurate cost estimates as the requirement is to minimise the emissions to the extent that is technically and economically feasible for the industry. The cost of establishing a site-specific 'PFAS-containing firefighting foams management plan' is also covered by this cost estimate. The total cost of the requirement is estimated to be €60 million (NPV) over the 30 years assessment period.

The emission reduction of the additional RMM requirement is estimated to be around 1 900 tonnes over the 30-year assessment period for RO3 in the best-case scenario. This is relatively high due to the fact that the Dossier Submitter assumes that these measures are currently not implemented, and the effectiveness of these measures is assumed to be relatively high[76].

Even though there is high uncertainty related to the cost and release reduction estimates, leading to possible overestimation of the cost-effectiveness of the requirement, the Dossier Submitter considers the information sufficient to conclude that additional risk management measures during the transition periods are justified.

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[76] See section 3. "Assumptions, uncertainties and sensitivities" for input parameters.

3. Assumptions, uncertainties and sensitivities

The following are the main assumptions made in this restriction proposal:

- There is no trend in the amounts of PFAS-containing foams used, i.e. same amounts would be used each and every year during the 30 years assessment period without regulation. An increase could be justified due to an increase in GDP, and on the other hand, a decrease could be justified because alternative foams are under development. The latter seems more plausible and thus, we may overestimate the emissions and thus the costs of the restriction. Even though a trend is not accounted for in the quantitative calculations, the assumptions about foam stocks and annual sales are varied in the sensitivity analysis.

- Environmental/health benefits of the reduction of PFAS emissions cannot be quantified, primarily due to a lack of knowledge about the effects of PFASs to human health and the environment. The avoided releases are used as a proxy of the environmental and human health impacts. Possible avoided remediation costs and avoided drinking water purification costs are not counted as savings but described qualitatively as a benefit of the avoided releases.

- In the baseline, all the PFASs in firefighting foams will be released during the service life of the foam. No effective collection and safe disposal are assumed. Only if foams expire before their use (which takes place only in some sensitivity scenarios), safe disposal is assumed.

- The proposed sectoral transition periods allow the transition to fluorine-free alternatives without compromising fire safety.

The input parameters taken for the quantitative emissions and cost calculations are summarised in Table 12 and Table 13. These also report the sources of the data, level of uncertainty and the values used for the calculations in the so-called low, best and high scenarios. For the emissions estimates in the baseline, the same input parameters as in Table 12 for the best scenario have been applied, with the exception of the parameter for "Effectiveness of additional RMMs imposed by the ROs" which is not relevant in the baseline scenario.

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.

Table 12. Input parameters for the calculation of the emissions in the five scenarios RO1 – RO5 ("Low", "Best" and "High" estimates).

Parameter	**Source of best estimate**	**How parameters have been derived**	**Level of uncertainty (low, medium, high)**	**Values used**		
				Low estimate "Low scenario"	**Best estimate "Best scenario"**	**High estimate "High scenario"**
Foam stock and annual sales	The foam stock in year 0 should be derived from the Excel sheet so that the annual use, based on (Wood et al., 2020) is obtained.	See description of mass balance calculation in Appendix 8.	Medium	Mass balance to obtain 14 000 t/y of annual sales	Mass balance to obtain 18 000 t/y of annual sales	Mass balance to obtain 20 000 t/y of annual sales
Concentration of PFAS-containing surfactants in foam	(Wood et al., 2020)	Wood's stakeholders' consultation	Low	2 %	2.5 %	3 %
Average foam life span	(Wood et al., 2020)	Literature and confirmed by stakeholders (note: the PFAS-containing foams normally do not have an indicated expiry date and in practice samples are taken from time to time and validity confirmed by lab. Can actually be used beyond 20 y)	Low	15 y	15 y	15 y
Sectoral breakdown (shares of industry sectors)	(Wood et al., 2020)	Based on Eurofeu's data	Low (only the share of Seveso vs non-Seveso ("other industries") of the oil/petrochemicals category is more uncertain, based on expert's assumption)	Defence: 6 % Civilian Aviation: 9 % Municipal Fire Services: 13 % Chemical / Petrochemical: 59 % Marine Applications: 12 % Ready to use applications: 1 %	Defence: 6 % Civilian Aviation: 9 % Municipal Fire Services: 13 % Chemical / Petrochemical: 59 % Marine Applications: 12 % Ready to use applications: 1 %	Defence: 6 % Civilian Aviation: 9 % Municipal Fire Services: 13 % Chemical / Petrochemical: 59 % Marine Applications: 12 % Ready to use applications: 1 %

				Share of Seveso versus non-Seveso (“other industries”) of the oil/petrochemicals category: 98 % versus 2 %	Share of Seveso versus non-Seveso (“other industries”) of the oil/petrochemicals category: 98 % versus 2 %	Share of Seveso versus non-Seveso (“other industries”) of the oil/petrochemicals category: 98 % versus 2 %
Sectoral transition period	Expert judgement		Not applicable	Defence:5 y Civilian Aviation: 5 y Municipal Fire Services: 1.5 y Chemical / Petrochemical Seveso: 10 y Other industries: 5 y Marine Applications: 3 y Ready to use applications: 5 y Training and testing: 1.5 y	Defence:5 y Civilian Aviation: 5 y Municipal Fire Services: 1.5 y Chemical / Petrochemical Seveso: 10 y Other industries: 5 y Marine Applications: 3 y Ready to use applications: 5 y Training and testing: 1.5 y	Defence:5 y Civilian Aviation: 5 y Municipal Fire Services: 1.5 y Chemical / Petrochemical Seveso: 10 y Other industries: 5 y Marine Applications: 3 y Ready to use applications: 5 y Training and testing: 1.5 y
Use type breakdown (training / testing and fire incidents management): annual use (compared to stock)	Eurofeu and other stakeholders’ consultation	Eurofeu’s data and other stakeholders’ consultation	Medium	13 % for fire incidents management 5 % for training and testing Except ready to use applications: only live incidents	10 % for fire incidents management 2 % for training and testing Except ready to use applications: only live incidents	5 % for fire incidents management 1 % for training and testing Except ready to use applications: only live incidents
Emissions parameters: • leakage during storage • emission formulation to WWT • emission formulation to air	Best scenario: Wood emission scenario spreadsheet High and low scenarios: leakage: OECD emission scenario document 10 for lubricants and	Best: Wood emission scenario spreadsheet (for formulation, equal to REACH default values for formulation) Low= best/2 in accordance with low and best for leakage	Medium	leakage during storage: 0.5 % emission formulation to WWT: 1 % emission formulation to air: 1.25 %	leakage during storage: 1 % emission formulation to WWT: 2 % emission formulation to air: 2.5 %	leakage during storage: 2 % emission formulation to WWT: 2 % emission formulation to air: 2.5 %

• emission formulation to soil • emission during incineration • share WWT to effluent • share WWT to soil/sludge • partitioning coefficient	additives: range, referenced in REACH guidance R16 page 78 Low= expert judgement	High = best *2 (leakage during storage)		emission formulation to soil: 0.005 % emission during incineration: 1 % share WWT to effluent: 0.375 share WWT to soil/sludge: 0.625 partitioning coefficient: 2.67	emission formulation to soil: 0.01 % emission during incineration: 1 % share WWT to effluent: 0.375 share WWT to soil/sludge: 0.625 partitioning coefficient: 2.67	emission formulation to soil: 0.01 % emission during incineration: 1 % share WWT to effluent: 0.375 share WWT to soil/sludge: 0.625 partitioning coefficient: 2.67
Releases to surface water, soil and sea during incidents (in absence of RMMs)	(Wood et al., 2020), based on PFOA Annex XV dossier		Medium	100 % releases: 50 %/50 %/0 % for all sectors of use except marine (0 %/0 %/100 %)	100 % releases: 50 %/50 %/0 % for all sectors of use except marine (0 %/0 %/100 %)	100 % releases: 50 %/50 %/0 % for all sectors of use except marine (0 %/0 %/100 %)
Effectiveness of bunding measures for training	(Wood et al., 2020)	Based on expert's judgment	Medium	97 % for all sectors except marine (0 %)	97 % for all sectors except marine (0 %)	97 % for all sectors except marine (0 %)
Effectiveness of WWTP for PFASs	(Wood et al., 2020) Low estimate: expert judgment	Based on expert's judgment	Medium	5 %	0 %	0 %
Effectiveness of additional RMMs imposed by the ROs: • collection to the extent feasible of the firewater from fire incidents and their incineration • incineration of all collected firewater from training/testing (collection already considered in place under the baseline scenario) • Only RO5: after 10 years for Seveso sites "full" collection and incineration of firewater from fire incidents (before that: collection to the extent feasible)	Ramboll's expert judgement		Medium	collection of firewater during incidents 97 % for all sectors except marine, ready to use and municipal fire services (0 %) 100 % incineration of all collected firewater from training	collection of firewater during incidents 50 % for all sectors except marine, ready to use and municipal fire services (0 %) Chemical / Petrochemical Seveso: 97 % 100 % incineration of all collected firewater from training	collection of firewater during incidents 0 % for all sectors Chemical / Petrochemical Seveso: 97 % 100 % incineration of all collected firewater from training

Table 13. Input parameters for the calculation of the transition costs, sources and use (low, best and high scenarios)

Parameter		Source of best estimate	How parameters have been derived	Level of uncertainty (low, medium, high)	Values used in different cost scenarios			Calculations for which parameters have been used
					Low	Best	High	
Incineration/disposal costs €/tonne		(Wood et al., 2020) Table 8.14 p. 163	Range confirmed by stakeholders	Low	-10 %	€1 000/tonne	+25 %	Early disposal of legacy foams when replaced
Cost of using alternative foams	Average price €/tonne of PFAS-containing foam	(Wood et al., 2020) Table 8.4 p. 148	Range confirmed by stakeholders	Low	+25 %	€3 000/tonne	-10 %	Depreciation of stocks to be disposed of Additional costs of alternative foams due to price and/or volume differences
	Average price €/tonne of fluorine-free foam	(Wood et al., 2020) Table 8.4 p. 148	Range confirmed by stakeholders	Low	-10 %	€3 000/tonne	+25 %	Additional costs of alternative foams due to price and/or volume differences
	Additional volumes required % increase over PFAS-containing foams	(Wood et al., 2020) Table 8.4 p. 148	Range confirmed by stakeholders	Low	+25 % required	+50% required	+75 % required	Additional costs of alternative foams due to price and/or volume differences
Savings from avoided clean-up		(Wood et al., 2020) Section "Clean-up" pp. 155-156	Wood et al. (2020) estimate cost of €100 000 to a few million € per incident requiring clean-up. Assuming several tens of incidents per year requiring clean-up due to PFAS content of foam gives around €10 million per year. Average clean-up costs per PFAS-containing foams in use (€ per tonne)	Medium	+100 %	Gradually increasing to €10 million per year for the sum of all sectors	-50 %	Clean-up (after use, training, leakage, spill) savings

			derived to come to the results of the Wood study.					
Additional producer surplus due to exports excepted from the ban (only for RM3)	Tonnage of exports	FFFC (FFFC-Interview, 2021) and Eurofeu (Eurofeu, 2021)	25% of annual sales, i.e. 25% of 18 000 t/y = 4 500 t/y	Medium	10 % of revenues for five years	10% of revenues for two years	10 % of revenues for one year	Producer surplus due to exports excepted from the ban (RO3)
	Years with profit losses due to export ban (or additional profits due to exports exempted from the ban)	(Ramboll, 2021)	Profits assumed as 10% of the value of sales revenue Two years profit loss (best cost scenario) as a proxy of the changes in producer surplus					
Costs per site for implementation of RMMs to meet full containment (only for RO5 and Seveso sector)		ECHA survey 2021	Information from industry	Medium	-50 %	€2 000 000 per site	+200 %	Costs for the implementation of RMMs to meet full containment within the total site (RO5, Seveso sector)
Costs of technical means to contain releases and disposal of PFAS-contaminated water from the fire-water run-off from testing/training		(Wood et al., 2020) Table 8.14 p. 163	Incineration/ disposal costs used as a proxy to cover the whole requirement	Medium	-50 %	€1 000/tonne	+100 %	Cost of additional RMMs for training/testing
Costs of technical means to contain releases and disposal of PFAS-contaminated water from the fire-water run-off from incidents		(Wood et al., 2020) Table 8.14 p. 163	Incineration/ disposal costs used as a proxy to cover the whole requirement*	Medium	-50 %	€1 000/tonne	+100 %	Cost of additional RMMs for incidents
Sector-specific parameters								
Cleaning cost to comply with the proposed concentration threshold	Cleaning costs per site	(Ramboll, 2021), derived from estimations from stakeholders: Vehicles: WFVD (WFVD and Peltzer, 2021) (Plant Fire Brigade Association Germany), LfU (LfU-Gierig-Interview, 2021) (Bavarian	Dependent on vehicles versus installed systems and remaining PFAS levels	Medium	-50 % in total cleaning costs	SEVESO: €200 000 per site. Civilian aviation and military: €50 000 per site Other sectors: €20 000 per site. Training and testing and ready to use applications: not	+100 % in total cleaning costs	Costs for cleaning of equipment

		State Ministry for the Environment and Consumer Protection); Cornelsen (Cornelsen-Interview, 2021) (supplier of PerfluorAd process) Installed systems: one large German chemical/Seveso company)				relevant (see footnote*)		
	Number of sites per sector(s)	(Wood et al., 2020) (A.2.3.4, p. 389).	One unit per site as an average that has to be cleaned	Medium	Same as for the best scenario (the total costs of cleaning are considered in the sensitivity analysis by varying the unit cost.	Seveso: 10 000 Other industries: 1 000 (not reported by Wood) Civilian aviation: 401 Military: 239 Municipal fire services: 50 000 marine applications: 15 000 (sea-going ships) Training and testing and ready to use applications: not relevant	Same as for the best scenario (the total costs of cleaning are considered in the sensitivity analysis by varying the unit cost.	Costs for cleaning of equipment Cost of technical changes needed to use alternative foams Costs for the implementation of RMMs to meet full containment within the total site (RO5, Seveso sector)
Cost of technical changes needed to use alternative foams	Cost of technical change per site	See Section F.4.3. (Cost of technical changes needed) in the Annex.	€500 000 assumed for Seveso sites who provided information on significant costs. For other sectors no information suggesting significant costs is available.	High	-50 %	Seveso: €500 000 Training and testing: €0 Ready-to-use applications: not relevant** Other sectors: €5 000	+200 %	Cost of technical changes needed to use alternative foams

* In the absence of better information, the incineration cost of the PFAS-containing foams is used to approximate the cost of the requirement. This may significantly underestimate the cost of the requirement considering that there are currently tens of thousands of users of PFAS-containing firefighting foams.

** The estimated total cost of €7 million over 30 years for ready-to-use applications does not consider the possible need for early replacement of the exiting fire extinguishers. According to industry, replacement of the device may be needed. In this case, the cost for this sector could be significantly higher as there are around 15 million PFAS-containing extinguishers in use in the EU. However, the five-year transition period proposed for this sector is indicated to be sufficient by the industry to replace also the devices when necessary (see Annex E.4.3 for further details).

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. The most uncertain parameters used in the cost assessment are related to the cost of technical changes needed to use alternative foams. 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. As mentioned in section 2.8, potential savings from avoided clean-up could further be described as benefits of restriction (instead of savings as done in this report). Even if this assumption would be changed, the overall results would not change significantly as this cost element represents only less than 2% of the total cost of the proposed restriction. Only for some cost categories a sector/use-specific assessment was considered necessary based on available data. This simplifies the assessment but does not mean that other sector-specific issues could not exist.

The full results of the sensitivity analysis are reported in Appendix 8 and 9.

4. Conclusion

All PFASs are very persistent in the environment. Many PFASs are likely to persist in the environment longer than any other man-made organic substance. As a consequence, if releases are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects are likely. In such an event the exposures are practically irreversible. Even if further releases of PFASs were immediately prevented, existing environmental stocks would continue to be a source of exposure for generations. There are several additional concerns arising from the use of PFASs, e.g., that a ubiquitous contamination of drinking water resources is unavoidable unless releases are minimised. Human exposures occur efficiently via all exposure routes via environment and cannot be avoided or mitigated. Some PFASs can accumulate in plants, others have bioaccumulation potential in biota and humans. Exposures are also transmitted effectively to unborn and breastfeeding children.

Use of PFASs in firefighting foams is substantially contributing to long-term general human and environmental exposures of PFASs aside other uses. The proposed restriction is providing a partial solution to the need to prevent the increase of general PFAS exposures. However, specific to the use of PFASs in firefighting foams, the potential to contaminate local environments, where firefighting, equipment maintenance and training take place, is high. The proposed restriction directly prevents such contaminated sites to be formed in future.

Five Member States are in the process of preparing a restriction that would cover all uses of PFASs. Concurrently, the Commission requested ECHA on 20 July 2020 to prepare a restriction proposal on the use PFASs in firefighting foams, as there are many technically and economically feasible alternatives available with the same function. Furthermore, initiatives have been taken in non-EU countries such as in Australia and restrictions on use in several US states and Australia. This global trend of moving away from PFASs in firefighting foams also helps the implementation of the proposed EU-wide restriction.

Based on five main options considered, a restriction covering placing on the market, use and export is proposed in the EU with specific transitional periods. The assessment of risk reduction capacity, costs and cost-effectiveness ratios supports this conclusion. The results are associated with significant uncertainties and ranges have been estimated.

The need for the restriction of PFASs in firefighting foams is based on the following considerations:

- Risks of PFASs are of the non-threshold nature.
- PFASs are very persistent. PFAS exposures are therefore likely to increase to such levels that effects are triggered. At that point of time, the exposures are hardly reversible.
- Many PFASs are mobile in water, and their potential for long-range transport is high. This in combination with high persistence mean that PFAS exposures cannot be avoided by humans.
- Humans and environmental organisms are exposed to a complex mixture of PFASs, many of which have so far not been subject of regular targeted monitoring. Combined effects are likely within the group.
- The continued use of PFAS-containing firefighting foams is estimated to result in about 14 000 tonnes of emissions to the environment in the EU in the next 30 years unless action is taken. The proposed restriction option would lead to an estimated reduction

of emissions of 13 200 tonnes over 30 years, which corresponds to an emission reduction of PFAS of 440 tonnes per year.

A restriction under REACH on the placing on the market, use and export of PFAS-containing firefighting foams is justified because:

- Suitable alternatives are available for most applications (all except sites or sectors which could face with particularly challenging fire scenarios such as establishments subject to the Seveso Directive).
- Transition periods are proposed for each type of use or industrial sector. In this manner it will be possible to select and test the most appropriate alternative firefighting product and to adapt the fire extinguishing system if necessary, without jeopardising the fire safety.
- Risk management measures that could reduce the emissions of PFASs in the environment are available and may to unknown extent be applied, however, in absence of additional regulatory measures these appear unlikely to significantly reduce the emissions of PFASs from the use of firefighting foams. To minimise the emissions of PFASs in the environment and the exposure of humans during the transition periods, the restriction needs to include additional mandatory risk management measures.
- The net-present value of the cost related to the restriction was estimated at €6.8 billion for the assessment period of 30 years. The cost-effectiveness of emission reduction was estimated at €515 per kg. This is comparable to other restriction proposals adopted by the Commission on PBT and PBT-like substances.
- The concern should be addressed at EU-level due to the functioning of the internal market for firefighting foam products. Firefighting foams are traded over the borders and it would not be meaningful or possible to restrict them nationally due to internal market considerations. Furthermore, due to their high mobility and persistence (at least of some PFASs), PFAS emissions could lead to cross-border pollution.

Fluorine-free foams have characteristics which differ from PFAS-containing foams. Therefore, for each user, testing of the alternative foam product in conjunction with the foam application method and adaptation of the fire extinguishing installation and equipment will be required. For certain types of uses this transition is expected to be implementable in a relatively short term. For other uses, a longer time is likely to be needed. In addition, the potential for emission reduction depends on the type of use. For these reasons, different transitional periods are considered per type of use and described below.

The proposed transitional periods are based the information collected during the preparation of this restriction proposal, including several stakeholder consultations. They are based on the assumption that suitable alternatives are implementable for each type of use by the end of the corresponding transitional period, i.e. that the transition to alternative would not compromise the fire safety.

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

Regarding **concentration thresholds**, a balance would need to be struck between the amount of PFAS emissions remaining if a given threshold is adopted, versus the costs of cleaning imposed to achieve that threshold. Stakeholder input suggests that 1 ppm can be achieved with a relatively simple cleaning. Lower thresholds are achievable with more complex and costly processes. However, setting a lower concentration threshold would only lead to a small additional reduction in PFAS emissions, compared to the overall reduction achieved by the restriction.

Finally, the proposed restriction would oblige the users to prepare and implement a **PFAS-containing firefighting foams management plan** and **best practice risk management measures** during and after the use of PFAS- containing firefighting foam. This covers among others foam purchase, containment, treatment, proper disposal of PFAS-containing foams and fire water run-off, use of personal protective equipment. These measures provide relatively effective reduction of PFAS emissions and exposure of workers and professionals at relatively low cost during the transition periods when PFAS-containing foams continue to be used.

In conclusion, in response to the request made by the Commission on 20 July 2020, the restriction on the placing on the market, use and export of PFASs in firefighting foams is proposed. The proposed entry for the restriction is presented in section 2.2.5.

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