ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

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

IUPAC NAME(S): n.a.

EC NUMBER(S): n.a.

CAS NUMBER(S): n.a.

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LIST OF ABBREVIATIONS

Note: Due to the large scope of the dossier, some abbreviations in this list appear more than once, since they can have different meanings. Also, in a few cases different abbreviations can have the same meaning. In both cases, abbreviation and meaning are written in *Italics*. The abbreviations can be easily deduced from the context.

Acronym	**Explanation**
2-BTP	2-bromo-3,3,3-trifluoro-1-propene
3-D	Three-dimensional
3F	Fluorine-free foam
4:2 Cl-PFESA	4:2 Cl-polyfluorinated ether sulfonate
4:2 FTMA	4:2 Fluorotelomer methacrylate
4:2 FTO	4:2 Fluorotelomer olefin
4:2 FTSA	4:2 Fluorotelomer sulfonic acid
6:2 Cl-PFESA	6:2 Chlorinated polyfluorinated ether sulfonate
6:2 diPAP	6:2 Fluorotelomer phosphate diester
6:2 FTOH	6:2 Fluorotelomer alcohol
6:2 FTS	6:2 Fluorotelomer sulfonate

6:2 FTSA	6:2 Fluorotelomer sulfonic acid
6:2/8:2 diPAP	6:2/8:2 Fluorotelomer phosphate diester
7:3 FTCA	7:3 Fluorotelomer carboxylic acid
8:2 Cl-PFESA	8:2 Cl-polyfluorinated ether sulfonate
8:2 diPAP	Bis[2-(perfluorooctyl)ethyl] phosphate
8:2 FTOH	8:2 Fluorotelomer alcohol
8:2 FTSA	8:2 Fluorotelomer sulfonic acid
8:2 monoPAP	8:2 Fluorotelomer phosphate monoester
8:2 PTrMeOSi	8:2 Polyfluoroalkyl trimethoxysilane
8:2/10:2 diPAP	8:2/10:2 Fluorotelomer phosphate diester
9Cl-PF3ONS	9-Chlorohexadecafluoro-3-oxanonane-1-sulfonic acid
10:2 diPAP	10:2 Fluorotelomer phosphate diester
ABS	Anti-lock Braking System
AC	Airconditioning
AC	Alternating Current
ADAS	Advanced Driver Assistance Systems
ADME	(Process of) Absorption, distribution, metabolism, and excretion
ADONA	Ammonium 4,8-dioxa-3H-perfluorononanoate, 3H-perfluoro-3-[(3-methoxy-propoxy)propanoic acid]
AEC	Anion Exchange Capacity
AFFF	Aqueous Film-Forming Foam
AFT	Acrylic Foam Tape
AIX	Anion Exchange
ALK	Alkaline water electrolysis
ALP	Alkaline phosphatase
ALT	Alanine transferase
AMA	Amphibian Metamorphosis Assay (OECD TG 231)
AoA	Analysis of Alternatives
AOF	Adsorbable Organic Fluorine
AOP	Advanced Oxidation Process
APC	Air Pollution Control
APFO	Ammonium perfluorooctanoate
API	Active Pharmaceutical Ingredient
AR	Androgen Receptor
AR-AFFF	Alcohol Resistant-Aqueous Film Forming Foam
ARFF	Aircraft Rescue & Firefighting
AR-FFFP	Alcohol-Resistant Film-Forming Fluoro-Protein
ASBT	Apical Sodium-Dependent Bile Salt Transporter
AST	Aspartate transferase
ATC	Anatomical Therapeutic Chemical
ATSDR	Agency for Toxic Substances and Disease Registry
BAC	Biological Activated Carbon
BAF	Bioaccumulation Factor
BAU	Business As Usual
BCCC	Basel Coordination Centre for Africa
BCF	Bioconcentration Factor
BCF$_{SS}$	Bioconcentration Factor at steady state
BIONIC	Bioconcentration Model for Ionogenic Organic Compounds

BMF	Biomagnification Factor
BMI	Bodymass Index
BN	Boron Nitrate
BOD	Biological Oxygen Demand
BP	Biocidal Product
BPR	Biocidal Products Regulation
BREF BAT	Best Reference Best Available Technique
br-PFOS	Branched PFOS
BSA	Bovine Serum Albumine
BUN	Blood Urea Nitrogen
BW	Body Weight
C4-FN	Heptafluoroisobutyonitrile
C5-FK	1,1,1,3,4,4,4-Heptafluoro-3-(trifluoromethyl)-2-butanone
C6/C6 PFPiA	C6/C6 Perfluorophosphinic acid
C6/C8 PFPiA	C6/C8 Perfluorophosphinic acid; Perfluorohexylperfluorooctyl phosphinate
C6/C10 PFPiA	Perfluorohexylperfluorodecyl phosphinic acid
C6/C12 PFPiA	C6/C12 Perfluorophosphinic acid
C8/C8 PFPiA	C8/C8 Perfluorophosphinic acid
C8/C10 PFPiA	C8/C10 Perfluorophosphinic acid
CAA	Civil Aviation Authority
CAF	Compressed Air Foam
CAGR	Compound Annual Growth Rate
CAR	Constitutive Androstane Receptor
Carc.	Carcinogenicity
CAS	Chemical Abstracts Service
CASRN	Chemical Abstracts Service Registry Number
CBT	Closed Bottle Test
CBRN	Chemical, biological, radiological and nuclear
CCM	Catalyst-coated Membrane
C-E	Cost-effectiveness
CE marking	European Conformity Marking; French: Conformité Européenne
CEN	Chicken Embryonic Neuronal
CEPI	Confederation of European Paper Industries
CEWEP	Confederation of European Waste-to-Energy Plants
CFC	Chlorofluorocarbon
CfE	Call for Evidence
ChG	Choriogenin
CHO	Chinese Hamster Ovary
CI	Confidence Interval
CIC	Combustion Ion Chromatography
CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging
Cl-PFESA	Chlorinated Polyfluorinated Ether Sulfonate
CMR	Carcinogenic, Mutagenic and Toxic for Reproduction
COD	Chemical Oxygen Demand
COF	Coefficients of Friction
COP	Conference of the Parties

COVID-19	Coronavirus Disease 2019
CR	Neoprene Rubber (Chloroprene Rubber)
CRT	Cathode-Ray Tube
CSS	Chemicals Strategy for Sustainability
CTD	Characteristic Travel Distance
CTFE	Chlorotrifluoroethylene
CTV	Chronic Toxicity Value
CYP4a	Cytochrome P4504a
CYP19	Cytochrome P-19
d	Days
Da	Dalton
DC	Direct Current
DE	Germany
DHT	5 Alpha-Androstan-17-beta-ol-3-one
DIN	German Institute for Standardisation
DIY	Do It Yourself
DK	Denmark
DMEL	Derived Minimal Effect Level
DMSO	Dimethylsulphoxide
DMW	Distribution Ratios for Membrane–water
DNEL	Derived No-Effect Level
DOC	Dissolved Organic Carbon
DoD	Department of Defense
DONA	Dodecafluoro-3H-4,8-dioxanonanoic acid
dpf	*Days Post Fertilization*
DPF	*Diesel Particulate Filter*
DPW	Distribution Ratios for Protein–water
DS	Dossier Submitter
dw	Dry Weight
DWD	Drinking Water Directive
DWR	Durable Water Repellent
E2	Estrogen/17-beta-estradiol
EA	Endocrine Activity
EbC50	Effect Concentration Algal Biomass
EC	European Commission
EC50	Effect Concentration
ECF	*Edible Part Concentration Factor*
ECF	*Electrochemical Fluorination*
ECHA	European Chemicals Agency
ECNI-MS	Electron Capture Negative Ion Mass Spectrometry
ECOS	Environmental Coalition on Standards
ECTFE	Ethylenechlorotrifluoroethylene
ED	Endocrine Disruption
EDA	Electronic Design Automation
ED EG	Endocrin Disruptor Expert Group (ECHA advisory panel)
ED-RIA	Direct Equilibrium Dialysis Followed By Radioimmunoassay
EEA	European Economic Area

EEA-NH4	Ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate
EEE	Electrical and Electronic Equipment
EEIT	Electrical Engineering and Information Technology
EFCTC	The European Fluorocarbons Technical Committee
EFSA	European Food Safety Authority
EFSA CONTAM	European Food Safety Authority- Panel on Contaminants in the Food Chain
EFTC	European Fluorocarbons Technical Committee
EGR	Exhaust gas recirculation
EIF	Entry Into Force
ELISA	Enzyme-Linked Immunosorbent Assay
ELV	End of Life of Vehicles
EMDN	European Medical Device Nomenclature
EMEA	Europe, Middle East and Africa
EO	Ethylene oxide
EOF	Extractable Organic Fluorine
EOL	End of Life
EPA	*Environmental Protection Agency*
EPA	*Efficiency Particulate Air*
EPDM	Ethylene propylene diene monomer
EPR	Extended Producer Responsibility
ePTFE	Expanded PTFE
EQSD	Environmental Quality Standards Directive
ER	Estrogen Receptor(s)
ERC	Environmental Release Category
ErC50	Effect Concentration Algal Growth
ESD	OECD Emission Scenario Document
ESI	Electrospray Ionisation
ESP	Electronic Stability Program
EtFASAs	N-ethyl perfluoroalkane sulfonamides
ETFBO	4-Ethoxy-1,1,1-trifluoro-3-buten-2-one
ETFE	Ethylene tetrafluoroethylene
EtFOSA	N-ethyl perfluorooctane sulfonamide
EtFOSAA	N-ethyl perfluorooctane sulfonamidoacetic acid
EtFOSE	N-ethyl perfluorooctanesulfonamidoethanol
ETSA	European Textile Services Association
EU	European Union
EU-27	European Union: 27 countries
EU-28	European Union: 28 countries
EUDAMED	European Database on Medical Devices
EUREAU	European Federation of National Associations of Water Services
Eurofeu	European Committee of the Manufacturers of Fire Protection Equipment and Fire Fighting Vehicles
EURITS	European Union for Responsible Treatment of Special Waste
EV	Electric Vehicle
EVA	Ethylene vinyl acetate
f	Females

F0	Parental Generation
FABP	Fatty acid binding protein
FASA	Perfluoroalkane sulphonamide
FASE	Perfluoroalkyl sulfonamidoethanol
FBG	Fasting Blood Glucose
FCCC	Fire Fighting Foam Coalition (US association)
FC-3284	2,2,3,3,5,5,6,6-Octafluoro-4-(trifluoromethyl)morpholine
FC-807	Ammonium bis(N-ethyl-2-perfluorooctylsulfonaminoethyl)phosphate
FCM	Food Contact Material
FCS	Food Contact Substance
F-DIOX	Ammonium difluoro{[2,2,4,5-tetrafluoro-5-(trifluoromethoxy)-1,3-dioxolan-4-yl]oxy}acetate
FEC	Federation of European manufactures of cookware and cutlery
FEP	Fluorinated ethylene propylene
FEPM	Tetrafluoroethylene propylene
fEPSP	Field Excitatory Postsynaptic Potential
FEVE	Fluoroethylene Vinyl Ether Resin
FFFC	Fire Fighting Foam Coalition
FFFP	Fluoroprotein Foam Concentrates and Film Forming Fluoro-protein
FFKM	Perfluorelastomers
F-gas	Fluorinated Gas
FHEA	Perfluorohexyl ethanoic acid
FI	Fasting Insulin
FIS	International Ski Federation
FK	Fluoroketones
FK-5-1-12	1,1,1,2,2,4,5,5,5-nonafluoro-4-(trifluoromethyl)-3-pentanone
FKM	Family of Fluorocarbon-based Fluoroelastomer Materials
FMV	Swedish Defence Materiel Administration
FOB	Functional Observational Battery
FOSA	Perfluorooctane sulfonamide
FP	Fluoro Protein
FPA Australia	Fire Protection Association Australia
FPAR	Fluoro-Protein Alcohol-Resistant
FR	France
FRCF	Foilage to Root Concentration Factor
FRV	Fire Rescue Victoria, Australia
FSDT	Fish Sexual Development Test (OECD TG 234)
FSH	Follicle Stimulating Hormone
FTA	Fluorotelomer acrylate
FTAL	Fluorotelomer aldehyde
FTCA	Fluorotelomer carboxylic acid
FTEO	Fluorotelomer ethoxylate
FTIR	Fourier transform infrared (Spetroscopy)
FTI	Fluorotelomer iodide
FTMAf	Fluorotelomer methacrylate
FTOH	Fluorotelomer alcohol
FTO	Fluorotelomer olefin

FTS	Fluorotelomer sulfonate
FTSA	Fluorotelomer sulfonic acid
FTTAoS	Fluorotelomer thioether amido sulfonate
FTUCA	Fluorotelomer unsaturated carboxylic acid
FVQM	Fluorosilicones
GAC	Granular Acticated Carbon
GAC filter	Granular Activated Carbon Filter
GC	Gas Chromatography
GDL	Gas Diffusion Layer
GDP	Gross Domestic Product
GFK	Glass Fiber Reinforced Composite Material
GGMs	Gaussian Graphical Models
GHG	Greenhouse Gas
GHz	Gigahertz
GI	Gastrointestinal
GLP	Good Laboratory Practice
GRP	Glass-fiber Reinforced Plastic
GSAF	Grass-soil Accumulation Factor
GSI	Gonadosomatic Index
GST	Glutathione S-transferase
GWP	Global Warming Potential
H4-PFOS	6:2 fluorotelomer sulfonate
HAC	Hazardous Air Contaminant
HAP	Hazardous Air Pollutant
HC	Hydrocarbon
HCFC	Hydrochlorofluorocarbon
HCWH	Health Care Without Harm
HDL	High-density Lipoprotein
HDL-C	High-density Lipoprotein Cholesterol
HDPE	High-density Polyethylene
HEK293	Human Embryonic Kidney 293
HEPA	High Efficiency Particulate Air (filter)
HF	Hydrogen Fluoride
HFC	Hydrofluorocarbon
HFC-4310-mee	Reaction mass of (R, R)-1,1,1,2,2,3,4,5,5,5-decafluoropentane and (S, S)-1,1,1,2,2,3,4,5,5,5-decafluoropentane
HFE	Hydrofluoroether
HFIP	Hexafluoroisopropanol
HFO	Hydrofluoroolefin
HFP	Hexafluoropropylene
HFPO	Trifluoro(trifluoromethyl)oxirane; Hexafluoro-1,2-epoxypropane; 2,2,3-Trifluoro-3-(trifluoromethyl)oxirane
HFPO-DA	Hexafluoropropylene oxide dimer acid, 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid
HFPO-TA	Hexafluoropropylene oxide trimer acid, 2,3,3,3-tetrafluoro-2-[1,1,2,3,3,3-hexafluoro-2-(heptafluoropropoxy)propoxy]propanoic acid
HFPO-TeA	Hexafluoropropylene oxide tetramer acid

HI	Hazard Index
hpf	Hours Post Fertilization
HPL	High Pressure Laminate
HPG	Hypothalamus-Pituitary-Gonad
HPT	Hypothalamus-Pituitary-Thyroid
HR-MS	High Resolution Mass Spetrometry
HSI	Hepatosomatic Index
HVACR	Heating, Ventilation, Air Conditioning and Refrigeration
HWI	Hazardous Waste Incinerators
IARC	The International Agency for Research on Cancer
IATF	International Automotive Task Force
IBCs	Intermediate Bulk Containers
IC	Ion Chromatography
IC50	Inhibitory Concentration
ICAO	International Civil Aviation Organization
IEC	International Electrotechnical Commission
IED	Industrial Emissions Directive
IEM	Ion Exchange Membrane
IGBT	Insulated Gate Bipolar Transistor
IMO	International Maritime Organization
INCI	International Nomenclature Cosmetic Ingredient
Intertanko	International Association of Independent Tanker Owners
IP	Intellectual Property
IPCC	Intergovernmental Panel on Climate Change
IPCS	International Programme on Chemical Safety
IPEN	International Pollutants Elimination Network
IPRCO	Interstate Technology and Regulation Council
IS	Iceland
ISO	International Organization for Standardization
IT	*Information Technology*
IT	*Italy*
ITRC	Interstate Technology and Regulatory Council
IVDR	In Vitro Diagnostic Regulation
IX	Ion Exchange
K_d	Sediment/water distribution coefficient
KEMI	Swedish Chemicals Agency; Swedish: Kemikalieinspektionen
kg	Kilogram
K_{OC}	Organic carbon-water partition coefficient
K_{OW}	Octanol-water partition coefficient
K_{PW}	Protein water distribution coefficient
KPFBS	Potassium perfluorobutane sulfonate
L	Lactation Effects
Lact.	Lactation
LAN	Local Area Network
LAST	Large Atmospheric Storage Tank
LBD	Ligand Binding Domain
LC	*Long-chain*
LC	*Liquid chromatography*

LC	*Lethal Concentration*
LC50	Lethal Concentration
LCD	Liquid Crystal Display
LDL	Low-Density Lipoprotein
LDL-c	Low-Density Lipoprotein Cholesterol
LfU	Bavarian State Ministry for the Environment and Consumer Protection
LH	Luteinizing Hormone
Li-Ion	Lithium-Ion (battery)
lin-PFOS	Linear PFOS
LLDPE	Linear Low-Density Polyethylene
LOAEL	Lowest Observed Adverse Effect Level
LOD	Limit of Detection
LOEC	Lowest Observed Effect Concentration
log D_{BSAw}	Base-10 logarithm of albumin–water distribution coefficients
log D_{mpw}	Base-10 logarithm of protein–water distribution coefficients
log D_{mw}	Base-10 logarithm of of membrane–water distribution coefficients
log D_{ow}	Base-10 logarithm of octanol–water distribution coefficients
LOQ	Limit of Quantification
LOX	Liquid Oxygen
LRT	Long-Range Transport
LRTP	Long-Range Transport Potential
LTP	Long-Term Potentiation
m	Males
M&A	Mergers and Acquisitions
MAC	Mobile Air-Conditioning
MDI	Metered Dose Inhaler
MDL	Method Detection Limit
MDR	Medical Decives Regulation
MEA	Membrane Electrode Assemblies
MeFASA	N-methyl perfluoroalkane sulphonamide
Me-FBSA	N-metylperfluorobutane sulfonamide
MeFOSA	N-methyl perfluorooctane sulfonamide
MeFOSAA	N-methyl perfluorooctane sulfonamidoacetic acid
MeFOSE	N-methyl perfluorooctane sulfonamidoethanol
MEK	Mitogen-Activated Protein Kinase (MAPK)/ Extracellular Signal-Rregulated Kinases (ERK) Kinase
MetS	Metabolic Syndrome
MFB	Victorian Metropolitan Fire and Emergency Services Board
µg	Microgram
mg	Milligram
MLB	Mobile extinguishing water treatment plant (DE)
MoA	Mode of Action
MoD	Ministry of Defence
monoPAPs/diPAPs	Polyfluoroalkyl phosphoric acid mono-/diesters
MP	Medicinal Products
MRI	Magnetic Resonance Imaging
mRNA	Messenger-RNA

MS	Mass Spectrometry
MSFD	Marine Strategy Framework Directive
Muta.	Mutagenicity
MW	Molecular Weight
MWV	Mineralölwirtschaftsverband (German Association for Mineral Oil Industry)
n:2 FTI	n:2 Fluorotelomer iodide
n:2 FTOH	n:2 fluorotelomer alcohol
n:2 FTSA	n:2 fluorotelomer sulfonic acid
n:2 PAP	n:2 polyfluoroalkyl phosphoric acid ester, PAP
n.a.	Not available
NBR	Nitril Butadiene Rubber
NDAA	National Defence Authorization Act
N-EtFOSAA	N-Ethyl perfluorooctane sulfonamidoacetic acid
ng	Nanogram
NGO	Non-governmental Organisation
NHANES	National Health and Nutrition Examination Survey
NILU	Norwegian Institute for Air Research
NIVA	Norwegian Institute for Water Research
NK	Natural Killer
NL	The Netherlands
N-MeFOSAA	N-Methyl perfluorooctane sulfonamidoacetic acid
NMR	Nuclear Magnetic Resonance
NO	Norway
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
Norflurane	1,1,1,2-Tetrafluoroethane, also HFC-134a
Noviflumuron	1-[3,5-dichloro-2-fluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)phenyl]-3-(2,6-difluorobenzoyl)urea
NOx	Nitrogen Oxide
NPS	Nano-sized Particle Fractionator
NPV	Net Present Value
NTCP	Na^+/Taurocholate Cotransporting Polypeptide
NTS	*Non-destructive Testing System*
NTS	*Non Target Screening*
OAT	Organic Anion Transporter
OATP	Organic Anion Transporting Polypeptide
OBS	p-perfluorous nonenoxybenzenesulfonate
Oct-1	Octamer Motif-Binding Factor 1
OECD	Organisation for Economic Co-operation and Development
OEM	Original Equipment Manufacturer
OLED	Organic Light-Emitting Diode
ORC	Organic Rankine Cycle
OSPAR	The Oslo and Paris Convention for the Protection of the Marine Environment of the North-East Atlantic
PA	*Polyamide*
PA	*Processing Aid*
PAC	Powdered Activated Carbon

PACF	Perfluoroalkanoyl fluoride
PAH	Polycyclic Aromatic Hydrocarbon
PAO	Poly-alpha-olefin
PAP	Polyfluoroalkyl phosphate ester
PASF	Perfluroalkane sulfonyl fluoride
PAVE	Copolymer of tetrafluoroethylene and a perfluoroalkylvinylether
PBSF	Perfluorobutane sulfonyl fluoride
PBT	*Persistent, Bioaccumulative and Toxic*
PBT	*Polybutylene terephthalate*
PBTK	Physiologically Based Toxicokinetic
PC	Polycarbonate
PCB	Polychlorinated biphenyl
PCTFE	Polychlorotrifluoroethylene
PE	Polyethylene
PEC	Predicted Environmental Concentration
PEEK	Polyetheretherketone
PEG	Polyethylene glycol
PEM	*Proton-Exchange Membrane*
PEM	*Polymer Electrolyte Membrane*
PEMFC	Proton-Exchange Membrane Fuel Cell
PET	*Polyethylene terephthalate*
PET	*Positron Emission Tomography*
PEVE	1,1,2-Trifluoro-2-(pentafluoroethoxy)ethene
PEX	Irradiation crosslinked polyethylene
PF-310	1-[3-[4-((Heptadecafluorononyl)oxy)-benzamido]propyl]-N,N,N-trimethylammonium iodide
PFA	*Perfluoroalkoxyl polymer*
PFA	*Perfluoroalkoxy alkane*
PFAA	Perfluoroalkyl acid
PFAE	Perfluoroalkylether
PFAI	Perfluoroalkyl iodide
PFAS	Per- and Polyfluoroalkyl Substance
PFBA	Perfluorobutanoic acid
PFBPA	Perfluorobutyl-phosphonic acid; (Nonafluorobutyl)phosphonic acid
PFBS	Perfluorobutane sulfonic acid
PFC	*Perfluorinated compound*
PFC	*Polyfluorocarbon*
PFC-318	Perfluorocyclobutane
PFCA	Perfluoroalkyl carboxylic acid
PFDA	Perfluorodecanoic acid
PFdiCA	Perfluoroalkyl dicarboxylic acid
PFdiSA	Perfluoroalkane disulfonic acid
PFDoDA	Perfluorododecanoic acid
PFDPA	Perfluorodecylphosphonic acid
PFDS	Perfluorodecane sulfonic acid
PFE alkane	Perfluoroether alkane
PFEA	Perfluoroether acid
PFECA	Perfluoroalkylether carboxylic acid

PFECHS	Perfluoro-4-(ethyl)cyclohexanesulfonate
PFEE	Perfluorodiethyl ether; Perfluoroethyl ether; 1,1,1,2,2-Pentafluoro-2-(pentafluoroethoxy)ethane
PFEPA	Pentafluoroethyl-phosphonic acid; Perfluoroethyl phosponic acid; (Pentafluoroethyl)-phosphonic acid
PFESA	Perfluoroalkylether sulfonic acid
PFEtS	Pefluoroethane sulfonic acid
PFHpA	Perfluoroheptanoic acid
PFHpDA	Perfluroheptadecanoic acid
PFHpS	Perfluoroheptane sulfonic acid
PFHxA	Perfluorohexanoic acid
PFHxDA	Perfluorohexadecanoic acid
PFHxPA	Perfluorohexyl phosphonic acid
PFHxS	Perfluorohexane sulfonic acid
PFME	Perfluorodimethyl ether; Perfluoromethyl ether; Trifluoro(trifluoromethoxy)methane
PFMOBA	Perfluoro-(4-methoxybutanoic) acid
PFMOPrA	Perfluoro-2-methoxypropanoic acid
PFMPA	Trifluoromethyl-phosphic acid; Perfluoromethyl phosponic acid; (Trifluoromethyl)-phosphonic acid
PFMVE	Perfluoromethylvinyl ether
PFNA	Perfluorononanoic acid
PFO4DA	Perfluoro-3,5,7,9-butaoxadecanoic acid
PFO5DoDA	Perfluoro-3,5,7,9,11-pentaoxadodecanoic acid
PFOA	Perfluorooctanoic acid
PFOcDA	Perfluorooctadecanoic acid
PFODA	Perfluorooctadecanoic acid
PFOPA	Perfluorooctyl phosphonic acid
PFOS	Perfluorooctane sulfonic acid
PFOSA	Perfluorooctane sulfonamide
PFOSI	Perfluorooctane sulfinic acid
PFPA	Perfluoroalkyl phosphonic acid
PFPE	Perfluoropolyether
PFPeA	Perfluoropentanoic acid
PFPeDA	Perfluoropentadecanoic acid
PFPeS	Perfluoropentane sulfonic acid
PFPiA	Perfluoroalkyl phosphinic acid
PFPMIE	Perfluoropolymethylisopropylether
PFPPA	Perfluoropentyl-phosphonic acid; (Undecafluoropentyl)phosphonic acid
PFPrA	Prefluoropropanoic acid
PFPrS	Perfluropropane sulfonic acid
PFSA	Perfluoroalkane sulfonic acid
PFSIA	Perfluoroalkane sulfinic acid
PFSIA	Perfluoroalkane sulfinic acid
PFTeDA	Perfluorotetradecanoic acid
PFTrDA	Perfluorotridecanoic acid
PFUnDA	Perfluoroundecanoic acid

PIC	Product of Incomplete Combustion
PIGE	Particle-Induced Gamma-ray Emission Spectrometry
PIR board	Polyisocyanurate boardstock
PM	Particulate Matter
pKa	Acid dissociation constant
pMDI	Pressured Metered Dose Inhaler
PMM	Perfluoro-N-methylmorpholine
PMMA	Poly(methyl methacrylate)
PMVE	1,1,2-Trifluoro-2-(trifluoromethoxy)ethene
PND	Post-Natal Day
PNEC	Predicted No Effect Concentration
PolyFAA	Polyfluoroalkyl acid
PolyFEAA	Polyfluoroalkylalkylether acid
POP	Persistent Organic Pollutant
POPRC	POP Review Committee
POSF	Perfluorooctane sulfonyl fluoride
Pov	Overall environmental persistence
PP	Polypropylene
PPA	Polymer Processing Aid
PPAR	Peroxisome Proliferator-Activated Receptor
ppb	Parts per billion
PPE	Personal Protective Equipment
ppm	Parts per million
PPP	Plant protection product
PPPR	Plant Protection Products Regulation
PPVE	1,1,1,2,2,3,3-heptafluoro-3-[(trifluorovinyl)oxy]propane perfluorpropylvinylether
PRTR	Pollutant Release and Transfer Register
PTF	Polytrimethylene furandicarboxylate
PTFE	Polytetrafluoroethylene
PU	Polyurethane
PV	Photovoltaic
PVC	Polyvinylchoride
PVDF	Polyvinylidene fluoride
PVF	Polyvinylfluoride
PXR	Pregnane X-receptor
qMS	Quadrupole Mass Spectrometry
QSAR	Quantitative Structure-Activity Relationship
R&D	Research & Development
RAC	Risk Assessment Committee; Committee for Risk Assessment
RCF	Root Concentration Factor
REACH	Registration, Evaluation and Authorization of Chemicals
Repr.	Reproductive toxicity
RGP	Rigid Gas Permeable
RISE	Research Institute of Sweden
RIVM	National Institute for Public Health and Environment; Dutch: Rijksinstituut voor Volksgezondheid en Milieu; The National Institute for Public Health and the Environment NL

RMM	Risk Management Measure
RMO	Risk Management Option
RMOA	Risk Management Option Analysis
RO	Restriction Option
SAmPAP	Bis(2-{ethyl[(perfluorooctyl)sulfonyl]amino}ethyl) hydrogen phosphate
SC	Short-chain, Shorter chain
SCF	Shoot-soil Concentration Factor
SCFP	Side-chain Fluorinated Polymer
SDS	Safety Data Sheet
SE	Sweden
SEA	Socio-economic Assessment
SEAC	Committee for Socio-economic Analysis
SEv	Substance Evaluation (under REACH)
SFA	Semifluorinated alkane
sFTOH	Secondary fluorotelomer alcohol
SHB	Southern Hudson Bay
SHF	Shredder Heavy Fraction
SLF	Shredder Light Fraction
SL-MAC	Secondary Loop Mobile Air Conditioning
SME	Small and Medium-sized Enterprises
SOD	Superoxide Dismutase
SOM	Soil Organic Matter
SpERC	Specific Environmental Release Categories
SPIN	Substances in Preparations in Nordic Countries
SPM	Suspended Particulate Matter
SS	Steady State
STOT RE	Specific Target Organ Toxicity following Repeated Exposure
STP	Sewage Treatment Plant
SVHC	Substance of Very High Concern
T3	Triiodothyronine
T4	Thyroxine
TA	Trifluoromethanesulfonic acid
TAA	Trifluoromethanesulfonic anhydride
TBG	Thyroxine-Binding Globuline
TC	Total Cholesterol
TCE	Trichloroethylene
TDAR	T-cell-dependent Antibody Responses
TDFA	Trifluoroacetate salt
TERC	Toxicology & Environmental Research and Consulting, The Dow Chemical Company
Tetraconazole	1-[2-(2,4-Dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1H-1,2,4-triazole
TF	*Transfer Factor*
TF	*Total Fluorine*
TFA	Trifluoroacetic acid
TFAC	Trifluoroacetyl chloride
TFAEt	Trifluoroacetic acid ethyl ester

TFAH	Trifluoroacetic acid anhydride
TFAiP	Trifluoroacetic acid isopropyl ester
TFAMe	Trifluoroacetic acid methyl ester
TFE	Tetrafluoroethylene
TFK	Trifluoroacetone
TFMP	4-(trifluoromethyl)phenol
TFMS	*Trifluoromethanesulfonic acid, triflic acid*
TfOH	*Trifluoromethanesulfonic acid, triflic acid*
TFSA	*Trifluoromethanesulfonic acid, triflic acid*
TFSK	Potassium triflinate
TG	Triglycerides
TH	Tyrosine Hydroxylase
THV	Terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride
TMF	Trophic Magnification Factor
TNF-ɑ	Tumor Necrosis Factor- ɑ
TOC	Total Organic Carbon
TOF	Total Organic Fluorine
TOP	Total Oxidizable Precursor
TOPA	Total Oxidizable Precursor Assay
TrFE	Trifluoroethylene
TSCA	Toxic Substances Control Act (US)
TRR	Total Radioactive Residue
TSCF	Transpiration Stream Concentration Factor
TSH	Thyroid Stimulating Hormone
TTR	Transport Protein Transthyretin
TULAC	Textiles, Upholstery, Leather, Apparel and Carpets
TV	Television
TWI	Tolerable Weekly Intake
UBA	German Environment Agency (Umweltbundesamt)
UHMW-PE	Ultra High Molecular Weight Polyethylene
UK	United Kingdom
ULPA	Ultra Low Particulate Air
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNEP Global PFC group	United Nations Environment Programme Global Perfluorinated Chemicals (PFC) Group
UNFCCC	United Nations Framework Convention on Climate Change
UNU	United Nations University
UNR	United Nations Regulation
UOF	Unidentified Organic Fluorine
UPLC	Ultra Performance Liquid Chromatography
URAT	Urate Transporter
USA	United States of America
US EPA	U.S. Environmental Protection Agency
US FDA	United States Food and Drug Administration
US NFPA	US National Fire Protection Agency

UTV	Unabhängige Tanklagerverband e.V. (German Independent Tank Farm Association)
UV	Ultraviolet
UWWTD	Urban Wastewater Treatment Directive
VDF	Vinylidene fluoride
VDI	Verein Deutscher Ingenieure e.V. (Association of german engineers)
VF	Vinyl fluoride
VOC	Volatile Organic Compound
vPvB	Very Persistent and very Bioaccumulative
VRF	Variable Refrigerant Flow
VTG	Vitellogenin
WEEE	Waste of Electrical and Electronic Equipment
WFBC	Women Firefighters Biomonitoring Collaborative
WFD	Water Framework Directive
WFVD	Der Verband Bundesverband Betrieblicher Brandschutz (German Industrial Fire-Fighters Association)
WHB	Western Hudson Bay
WHO	World Health Organisation
WI	Waste Incineration
WSR	Waste Shipment Regulation
WSTS	World Semiconductor Trade Statistics
WtE	Waste-to-Energy
ww	Wet Weight
WWTP	Wastewater Treatment Plant
XPS	Extruded Polystyrene Foam

Summary

Introduction

This Annex XV report addresses the risks to the environment and human health of the use of per- and polyfluoroalkyl substances (PFASs) and provides an assessment of the effectiveness, practicability, monitorability and socio-economic impacts of two restriction options (ROs) under REACH as the most suitable risk management option (RMO) to address the identified risks.

PFASs are a group of thousands of mainly man-made substances that are used in numerous applications in the EU. These applications comprise uses in textiles, (food) packaging, lubricants, refrigerants, electronics, construction and many more. The substances are used as substances on their own (either non-polymeric or polymeric) and as constituents in mixtures and (complex) articles for consumer, professional, and industrial uses.

Concern

The main concern for all PFASs and/or their degradation products that are in the scope of this restriction proposal is the very high persistence, exceeding the criterion for very persistent (vP) according to Annex XIII of the REACH Regulation by far. PFASs and their degradation products may persist in the environment longer than any other man-made chemical. Further supporting concerns are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects. PFASs enter the environment via emissions during manufacture, the use phase, and the waste stage.

When these substances and their degradation products continue to be released to the environment, the concentration in the environment will increase as mineralization under natural conditions does not take place for the PFASs in the scope of this restriction proposal. Once present in the environment, the removal of PFASs from surface water, groundwater, soil, sediment and biota is technically extremely difficult and very costly, if at all possible. Environmental monitoring of PFASs demonstrates ubiquitous distribution in the environment, including organisms and drinking water sources and food crop, as well as remote and pristine areas making exposure unavoidable and irreversible for now and future generations. Human biomonitoring shows the omnipresence of PFASs in humans, with highly exposed communities showing the highest levels. With the constantly increasing concentrations of PFASs in the environment due to their persistence and ongoing emissions, the exposure of humans and the environment to these substances will inevitably lead to negative effects. Also, exposure to PFASs has a high potential for intergenerational effects. Some scientists argue that the planetary boundaries for PFASs have already been exceeded, and human biomonitoring studies show that the cocktail of PFASs to which parts of the general population are exposed to through different sources (e.g. food, drinking water, products containing PFASs, dust, air) already may result in health risks.

Regulatory risk management options

The irreversibility of the process of a growing environmental stock of PFASs, with associated exposure of humans and the environment, make it necessary to reduce emissions of PFASs to a minimum. Different regulatory risk management options have been considered, e.g. CLH and authorisation, but these options follow a substance by substance approach. In contrast, a restriction offers the possibility to define a broad chemical scope, thereby avoiding regrettable substitution of one PFAS by another PFAS (which may not even be engineered yet). At the same time, it allows to tackle the problem of ongoing, uncontrollable emissions at the source, as manufacture and use can be banned, instead of an end-of-pipe solution that is not achievable, as PFASs are ubiquitously present in a wide range of products intended for industrial, professional and consumer uses. A restriction can cover a wide range of uses and can address the risks arising from the manufacture and use of the substances as such as well as in other substances, in mixtures and in articles, including imported articles from outside the EU. Hence, a restriction is the most appropriate and effective option to adequately control such a large and complex group of substances which are used in numerous applications.

Scope

The chemical scope of the restriction proposal is 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). There are however a few exceptions (see para below).

It is aligned with the OECD definition[1] of PFASs that was published in 2021, and that has been scrutinized by the international scientific community and is widely accepted. This definition encompasses more than 10 000 PFASs, including a few fully degradable PFAS subgroups. As these fully degradable subgroups, which can be described by their key structural elements, do not fulfil the underlying concern of high persistence (see above), they are excluded from the scope of this restriction proposal.

As outlined above, the restriction proposal is tailored to address the manufacture, placing on the market, as well as the use of PFASs as such and as constituents in other substances, in mixtures and in articles above a certain concentration. All uses of PFASs are covered by this restriction proposal, regardless of whether they have been specifically assessed by the Dossier Submitters and/or are mentioned in this report or not, unless a specific derogation has been formulated.

Socio-economic analysis

The Dossier Submitters have identified main PFAS uses in which the largest amounts of PFASs are used and emitted. This has been done by literature research, stakeholder consultations, and a call for evidence. Fourteen sectors and/or applications – subdivided in numerous sub-uses - have been addressed in detail in this report. For the EU, this resulted in an estimated amount of 140 000 to 310 000 tonnes of PFASs introduced to the market in 2020, which – due to the expected economic growth in several sectors – is expected to increase even further under the baseline scenario. Over a 30-year period the expected mean PFAS tonnage in the EEA is 49 million tonnes, leading to emissions of about 4.4 million tonnes during the manufacture and use phase when no action is taken. The emissions during the waste phase, which may be significant, are not accounted for in that estimate as they are highly uncertain. Hence, it can be assumed that emission estimates are severely underestimated.

The overall annual health costs following from exposure to PFAS in Europe has been estimated in a Nordic Council report from 2019 to be between €52 and 84 billion.

Two restriction options (ROs) have been assessed. A full ban with no derogations and a transition period of 18 months (RO1), and a full ban with use-specific time-limited derogations (18 month transition period plus either a five or 12 year derogation period). As specific information on costs of a ban of PFASs for the different actors associated with the addressed uses was scarce and mainly qualitative, the derogations and their duration were mainly based on the availability and applicability of alternatives to PFASs. RO2 also includes a few time-

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[1] 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).

unlimited, more general derogations, e.g. for PFASs used as active substances in Plant Protection Products (PPP), Biocidal Products (BP) and human and veterinary Medicinal Products (MP), as these are addressed under their respective regulations.

Besides the proposed derogations, the Dossier Submitters also identified uses for which a derogation could be warranted, but for which the evidence base is weak. These uses are between brackets, which indicates that additional information is needed and should be provided during the third party consultation of the restriction proposal to substantiate a derogation. Only if substantial evidence is provided, the Dossier Submitters can assess this and consider whether a derogation is warranted. For the time being, uses between brackets should be read as 'no derogation'.

Conclusions on proportionality

For the 14 use sectors and/or uses that have been addressed in detail in this dossier, the Dossier Submitters conclude that the extent of PFAS emissions warrants regulatory action. This need is further strengthened by the fact that additional emissions from use sectors and/or uses (as well as from the waste stage) that have not been addressed (in detail), only add to the concern and consequently to the call for regulatory risk management measures. For a large number of uses, functional alternatives are already available.

Both RO1 and RO2 are deemed proportionate to the risk, as eventually the societal cost of inaction will always surpass the costs of a ban on the use of PFASs. This has its basis in the persistence of PFASs and their degradation products in the environment. It has to be realized that once a restriction is in place, emissions will go on for many years to come due to the presence of PFASs in technical stock ((long-lived) products in use and on shelf) and waste, leading to increasing environmental stock of PFASs and consequently increasing exposure to PFASs to humans and the environment.

Although both restriction options (RO) are deemed proportionate to the risk, the Dossier Submitters propose RO2 as the most balanced option. RO2 leaves room to mitigate unwanted effects to society due to the sudden unavailability of products for which alternatives are not yet in place and allows stakeholders and industry to prepare for a smooth transition to alternatives. It should be noted, however, that a delay of banning PFASs as a result of the proposed derogations under RO2 will shift the cost burden arising from health and environmental impacts to future generations.

Proposed restriction - Annex XVII entry PFASs (Restriction Option 2)

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
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). A substance that only contains the following structural elements is excluded from the scope of the restriction: CF_3-X or X-CF_2-X′, where X = -OR or -NRR′ and X′ = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR′′, -SR′′ or –NR′′R′′′; and where R/R′/R′′/R′′′ is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).	1. Shall not be manufactured, used or placed on the market as substances on their own; 2. Shall not be placed on the market in: a. another substance, as a constituent; b. a mixture, c. an article in a concentration of or above: i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification) iii. 50 ppm for PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs. 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction. 4. By way of derogation, paragraphs 1 and 2 shall not apply to a. active substances in biocidal products within the scope of Regulation (EU) 528/2012 b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009 c. active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC Manufacturers and importers of the active substances referred to in points a) – c) shall submit to the Agency every two years the following information: i. the derogation that the intended use belongs to; ii. the identity and quantity of the active substance placed on the market

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	The Agency shall publish on its website a summary of the submitted information referred to in points i) – ii) 5. By way of derogation, paragraphs 1 and 2 shall not apply to: a. polymerisation aids in the production of polymeric PFASs until 6.5 years after EIF. This derogation does not apply to the production of PTFE, PVDF and FKM. b. textiles used in personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c), until 13.5 years after EiF; c. textiles used in personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m), until 13.5 years after EiF; d. impregnation agents for re-impregnation of articles referred to in paragraph 5b and 5c until 13.5 years after EiF; e. textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence until 6.5 years after EiF; f. refrigerants in low temperature refrigeration below -50°C until 6.5 years after EiF; g. refrigerants in laboratory test and measurement equipment until 13.5 years after EiF; h. refrigerants in refrigerated centrifuges until 13.5 years after EiF; i. maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternative exist until 13.5 years after EiF; j. refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives; k. industrial precision cleaning fluids until 13.5 years after EiF; l. cleaning fluids for use in oxygen-enriched environments until 13.5 years after EiF;

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	m. clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health until 13.5 years after EiF; n. diagnostic laboratory testing until 13.5 years after EiF; o. additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry until 13.5 years after EiF; p. refrigerants in mobile air conditioning-systems in combustion engine vehicles with mechanical compressors until 6.5 years after EiF; q. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF; r. insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EIF s. lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment until 13.5 years after EIF; t. calibration of measurement instruments and as analytical reference materials. *The following potential derogations are marked for reconsideration after the Annex XV report consultation:* u. [textiles for the use in engine bays for noise and vibration insulation used in the automotive industry until 13.5 years after EiF]; v. [hard chrome plating until 6.5 years after EiF]; w. [foam blowing agents in expanded foam sprayed on site for building insulation until 6.5 years after EiF]; x. [industrial and professional use of solvent-based debinding systems in 3D printing until 13.5 years after EiF]; y. [industrial and professional use of smoothing agents for polymer 3D printing applications until 13.5 years after EiF]; z. [propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiF]; aa. [preservation of cultural paper-based materials until 13.5 years after EiF]; bb. [cleaning and heat transfer: engineered fluids for medical devices until 13.5 years after EiF];

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	cc. [membranes used for venting of medical devices until 13.5 years after EiF]; dd. [use as refrigerants and for mobile air conditioning in vehicles in military applications until 13.5 years after EiF]; ee. [the semiconductor manufacturing process until 13.5 year after EiF]. 6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in: a. food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF; b. implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF; c. tubes and catheters in medical devices until 13.5 years after EiF; d. coatings of Metered Dose Inhalers (MDIs) until 13.5 years after EiF; e. proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF; f. fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF. *The following potential derogations are marked for reconsideration after the Annex XV report consultation:* g. [non-stick coatings in industrial and professional bakeware until 6.5 years after EiF]; h. [hernia meshes until 13.5 years after EiF]; i. [wound treatment products until 13.5 years after EiF]; j. [coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF]; k. [Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF]; l. [PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 13.5 years after EIF]; m. [PTFE in ophthalmic solutions packaging until 13.5 years after EIF]; n. [packaging of terminally sterilised medical devices until 13.5 years after EIF]; o. [applications affecting the proper functioning related to the safety of transport vehicles, and

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	affecting the safety of operators, passengers or goods until 13.5 years after EiF]. 7. Manufacturers and importers of PFASs or PFAS containing articles as well as formulators of PFAS containing mixtures making use of any of the derogations according to paragraphs 5 b)-d) and f) – t) [and u), w)-ee)],and 6 b)-d) and f) [and h)-o)], shall from (EiF + 18 months) provide by 31 March of each calendar year a report to the Agency containing: i. the derogation that the intended use belongs to; ii. the identity and quantity of the substances placed on the market in the previous year. The Agency shall forward the information to the Commission by 30 June every year; 8. Without prejudice to paragraph 7, importers and downstream users of fluoropolymers and perfluoropolyethers making use of any of the derogations in paragraphs 5 or 6 shall establish a site-specific management plan which shall include: i. information on the identity of the substances and the products they are used in ii. a justification for the use; iii. details on the conditions of use and safe disposal. The management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request. 9. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.

Explanatory notes

General

For clauses in between brackets ([]) the evidence base is currently too weak to propose them as derogation even though the Dossier Submitters recognize that such a derogation could potentially be warranted. For these ‘potential derogations’, additional evidence is needed to justify the derogations. After the Annex XV report consultation, the newly submitted information will be reviewed and the evidence base re-assessed, on the basis of which it will be concluded whether the evidence base is strong enough to propose a derogation with an appropriate derogation duration (5 or 12 years after the transition period). In case the evidence base remains weak, no derogation will be proposed.

Column 1 – Substance identity

PFASs form a broad group of substances that include inter alia non-polymeric PFASs like perfluoroalkyl carboxylic acids, perfluorocarbons, perfluoroalkane sulfonic acids and trifluoromethyl substituted substances as well as polymeric PFASs like fluoropolymers, perfluoropolyethers and side-chain fluorinated polymers. All PFASs subject to this restriction proposal are either persistent themselves or degrade to persistent PFASs, except for a few specific PFAS subgroups with combinations of key structural elements for which it can be expected that they will ultimately mineralize in the environment. As they do not form ultimately persistent PFAS arrowheads, these PFAS subgroups are excluded from the scope definition of this restriction proposal. In section 1.1.1, the substance identity and scope are further explained and justified.

Column 2 - Conditions

(1) Paragraph 2:

This paragraph sets the concentration limits above which the use of PFASs in other substances, in mixtures or in articles shall be restricted. Three different concentration limits are proposed.

The first two values (25 ppb for individual PFASs and 250 ppb for the sum of PFASs) refer to a targeted analysis of PFASs contained in another substance, mixture or article, i.e. the measurement of PFASs with an available analytical method for a specific set of substances and quantified against reference standards. The concentration limit for the sum of PFASs (250 ppb) may be calculated from targeted PFAS analysis either analysed directly as sample or after chemical degradation of the sample material. The latter may include degradation products from e.g. side-chain fluorinated polymers.

However, polymeric PFASs as such are not quantified and are therefore not included in the sum value for comparison with this concentration limit.

The third value (50 ppm) shall apply if targeted analysis is not applicable, e.g. in the case of fluoropolymers. In this case, a total fluorine content analysis is used to demonstrate the presence of organic fluorine. As the measured value will also include potential fluorine from sources other than PFASs, it is necessary to differentiate between PFAS and non-PFAS. Hence, if total fluorine exceeds 50 mg F/kg during enforcement analysis, proof for the fluorine measured being part of either PFASs or non-PFASs should be provided to the authorities. The proof could be either supply chain information or based on analysis. The information put forward should be compared with the 50 ppm limit value.

The relationship between mg F/kg sample material and mg PFASs/kg depends on the percentage of F in the molecular structure of PFASs in the sample. How to calculate this transformation is explained in Annex E.4. In the case of e.g. PFOS, 50 mg F/kg corresponds to 77.4 mg PFOS/kg (PFOS consists of 64.6% F).

(2) Paragraph 5

For the uses listed in this paragraph, derogations from paragraphs 1 and 2 are proposed. It needs to be noted that it is the Dossier Submitters' intention to define the derogations as narrow and specific as possible.

Some derogations in this paragraph refer to typical uses of fluorinated gases, some of which are also regulated in the F-gas Regulation (Regulation (EU) 517/2014). The F-gas Regulation does not per se restrict the use of the substances but rather aims for a reduction of their use.

In addition, there are other fluorinated gases fulfilling the PFAS definition in column 1 which can be used for the same purpose. Therefore, these substances should be in the scope of this restriction proposal. Nevertheless, for some key applications of fluorinated gases alternatives are not yet available. In order to ensure the availability of these commercially relevant applications, specific derogations are proposed by the Dossier Submitters.

In some derogations, reference is made to industrial and/or professional uses. These terms are not defined under REACH. However, the ECHA Guidance on Information Requirements and Chemical Safety Assessment in its chapter R.12 on use description recommends understanding the concept of "professional use" as means to distinguish between use at industrial sites and uses outside industrial sites, but not by consumers or the general public. Uses at industrial sites usually are considered better controlled and less widespread in contrast to uses by professionals.

In the following, some specific derogations of paragraph are further outlined:

5e) PFASs in filtration and separation media have a very broad range of applications across several market sectors. The products affected are capable of operating under severe operating conditions, exhibiting, and maintaining the level of performance for long periods of harsh operating conditions to remove sub-micron dust, water, oil, or salt particles without restricting flow of air or other filtered media. Due to the important functions fulfilled and the low releases into the environment and in line with previous restriction proposals for PFASs, a time-limited derogation is proposed for this use in industrial and professional settings.

5j) The derogation for refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives is included to make sure that such equipment is available where non-PFAS alternatives are restricted at the national level according to standards and building codes due to properties like e.g. flammability. Such standards and codes are reviewed at regular intervals (e.g. every 4th year) and updated according to technical development. The development in HVACR equipment gradually makes refrigerant loadings lower and equipment safer and it is expected that the standards and codes over time are allowing more use of PFAS-free refrigerants.

5m) The derogation applies to fire-suppressing agents in the form of fluorinated gases used for extinguishing fires in high-risk situations where alternatives pose significant risk to health or the assets to be protected. These situations may include aviation, data centres and cultural/historic resources. Such agents are different from fire-fighting foams which are aqueous mixtures.

5n) The derogation for diagnostic laboratory testing includes precision refrigeration (blood bank refrigerator, vaccine storage), ultra-low temperature freezers or cryogenic storage, refrigerated centrifuges for sample separation, process chillers for precise temperature control and freeze-drying equipment. Use in in-vitro diagnostic devices is also covered. Additional information on uses of PFASs in the relevant applications can be found in Table A.103. in Appendix A.3.10.

5s) The derogation relates to the use of lubricants in industrial or professional settings for operations and equipment that require performance under harsh conditions (very high or low temperatures, very high or low pressure, chemical resistance, resistance to radiation etc.) or for safe functioning and safety of equipment (e.g. circuit breakers and switchgear that has to work reliably when required even if not being used for years).

5t) In the quantification of a substance in a sample an analytical reference standard of the same substance is needed. Likewise, some instruments or equipment may rely on calibration standards in relevant PFAS analyses. These applications require only minimal amounts of PFAS material which are handled under controlled conditions. It is not expected that this will change in the foreseeable future, and the derogation is therefore proposed without a time limit.

Potential derogations marked for reconsideration after the Annex XV report consultation:

5w) The potential derogation related to spray foam applies to expanding foam sprayed on site for buildings for insulation purposes. This application and derogation is not related to fire-fighting foam, which is a different use and is covered in a separate restriction proposal.

5bb) The potential derogation covers use of perfluorinated engineered fluids that can be used to deposit a wide variety of coatings, including silicone, PTFE and heparin. These coatings can be deposited on many different types of surfaces, including metals, plastics and elastomers. Specific deposition applications include hypodermic needles, surgical and cutting blades, blood bags, filters and PVC tubing. Engineered fluids applied as solvents during chemical reactions, as inert media, and in microfluidic applications are also covered.

5cc) The potential derogation refers to fluoropolymer-based membranes with fluorinated side-chain polymer coatings used for (sterile) venting of medical devices, for example cell culture devices, analytical devices, blood tube systems for dialyzer systems, and tube systems for eye surgery.

(3) Paragraph 6

6a) For food contact materials used in the industrial production of food and feed, a time-limited derogation is proposed. The following applications are *inter alia* covered by this derogation:

- Piping and tubing for drinking water applications;
- Filters to capture contaminants from, for example, steam filtration in food processing;
- Seals, O-rings, gaskets, tubing and pipes, expansion joints;
- Valves and fitments, conveyor belting, chutes, guiding rails, rollers, funnels and sliding plates, tanks, funnels, rollers, linings, blades of knives and scissors, springs, filter membranes and sensor covers, lubricants;

Packaging of food and feed products, non-stick coatings in the industrial and professional food and feed production (e.g. industrial cookware, covered under paragraph 6g) as well as food contact materials for use in consumer articles shall not be covered by this derogation.

6b) The derogation covers use in implantable medical devices. A non-exhaustive list of implantable medical devices where PFASs are commonly used can be found in Table A.99. in Appendix A.3.10.

Potential derogations marked for reconsideration after the Annex XV report consultation:

6h) The potential derogation covers hernia meshes made from fluoropolymers, as well as hernia meshes where fluoropolymer coatings are applied to other base materials.

6i) The potential derogation covers wound treatment products such as bandages, surgical tapes and surgical staples.

6j) The potential derogation covers the use of PFASs (primarily fluoropolymers) as coating of medical devices other than Metered Dose Inhalers (MDIs). A list of coatings reported during stakeholder consultations is included in Table A.100. in Appendix A.3.10. Coatings of the inside of Metered Dose Inhalers (MDIs) are covered by the proposed derogation in paragraph 6d.

6k) The potential derogation covers fluoropolymer coatings on ophthalmic lenses and fluorinated monomers used in the polymer matrix of rigid gas permeable contact lenses.

6o) This potential derogation refers to all parts of vehicles where fluoropolymers and perfluoropolyethers are needed to ensure the safety of the vehicles and no alternatives are currently available (e.g. actuator or engine compartment, fuel system or safety features like airbags, ABS, or fire protection). This derogation shall not include the use of fluoropolymers and perfluoropolyethers purely for increasing comfort or optical enhancement (e.g. coating of trim materials, or textiles for carpets or seat covers).

(4) Paragraph 7

Reporting requirements are proposed for derogations with a duration of 13.5 years as well as for all applications of fluorinated gases, with a view of creating an understanding of the magnitude of continuing emissions as well as the progress made in relation to substitution. These reporting obligations would help the European Commission to gather data on the use of these substances in these sectors and to monitor any changes. In the event that the data reveals any concerns for the sector, further actions can be initiated. The reporting requirement will help to monitor whether there are any changes to uses and quantities which in turn may indicate changes in the emissions.

Reporting obligations shall apply to manufacturers, importers of PFASs and PFAS containing articles as well as formulators. The Dossier Submitters are aware that the formulator is, in contrast to the downstream user, not defined in the REACH Regulation. However, reporting by all downstream users is not considered practical by the Dossier Submitters. Manufacturers and importers often lack detailed knowledge on the whole supply chain, in particular if these are complex. Limiting the reporting obligation only to these actors might not provide sufficient use information to enable reviewing of the derogations. Formulators are usually the first downstream users of a substance and already have a good knowledge of the remaining supply chain and the (end)uses of substance. Therefore, it is proposed to include formulators, but not further downstream users in the reporting obligation.

1. Problem identification

Per- and polyfluoroalkyl substances (PFASs) are a group of thousands of synthetic chemicals that are used widely in the EU as well as in the rest of the world, in a broad range of applications such as textiles, food packaging, lubricants, refrigerants, and electronics. All PFASs in the scope of this restriction proposal are either very persistent themselves, or degrade into very persistent PFASs in the environment. This is the key hazardous property common to all PFASs in this restriction proposal. 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 become inevitable. In such an event these exposures are practically irreversible as it is technically extremely difficult, if at all possible, to remove PFASs from the environment.

Most PFASs, including persistent PFAS metabolites, are either mobile in water or accumulate in biota, and both lead to unavoidable exposure of humans and the environment. For example, it has been documented that contamination of groundwater, surface water (freshwater, estuarine and marine) and biota with PFASs is already widespread. Drinking water contamination is already widely reported and it is very difficult and costly to remove PFASs. Deterioration of drinking water sources represents a societal concern, especially as drinking water is gradually becoming less available due to the effects of global warming. Plants also accumulate PFASs via soil and water. 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. In both humans and animals, PFASs are transferred to the foetus via the placenta and to the offspring via breast milk. Hence, also offspring exposure is unavoidable.

Some PFASs are distributed to remote areas and pristine environments by long range transport processes. Some PFASs are gases. Once released, these PFASs are distributed around the globe where they contribute substantially to global warming and climate change.

The most thoroughly researched PFASs (PFOS and PFOA) are suspected carcinogens, cause harm to the developing child (as a result of intergenerational exposure) and trigger effects at low concentrations in organs such as the liver or in the immune system. There are also data identifying some PFASs as potential endocrine disruptors, and the environmental effects of some PFASs (e.g. 6:2 FTOH) are sufficient to warrant classification of these PFASs as hazardous to the aquatic environment. Although for most PFASs there are insufficient data to adequately assess their effects on human health and the environment, increasing research efforts that progressed beyond PFOS and PFOA reported similar adverse effects for other PFASs. Hence, there is a growing concern for the harmful effects of the complete PFAS family, given that concerns similar to the well-studied PFASs may be also expected for the currently less studied substances. Adverse effects resulting from 'combined exposure' to complex mixtures of PFASs are likely for both humans and wildlife. However, these effects cannot currently be assessed quantitatively with sufficient certainty for regulatory purposes. A group approach to regulation of PFASs is efficient to address this complex interplay of concerns.

This chapter defines PFASs and characterises environmental and human health hazards and risks of the use of PFASs in a broad range of applications.

1.1. Hazard, exposure/emissions and risk

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

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 similar 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 noted exceptions, any chemical with at least a perfluorinated methyl group (–CF_3) or a perfluorinated methylene group (–CF_2–) is a PFAS." (OECD, 2021). For the restriction proposal however one exception is introduced (see rationale given below). The exception concerns certain fully degradable PFASs subgroups that only contain some specific structural elements.

For the purpose of the Annex XVII restriction entry, the Dossier Submitters propose the following definition of PFASs:

> 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).
>
> A substance that only contains the following structural elements is excluded from the scope of the restriction:
>
> CF_3-X or X-CF_2-X′,
>
> where X = -OR or -NRR′ and
>
> X′ = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR″, -SR″ or –NR″R‴;
>
> and where R/R′/R″/R‴ is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).

PFASs, according to the definition used in this restriction proposal, form a broad group of substances, including volatile as well as non-volatile PFASs, anionic, cationic, zwitterionic and non-ionic substances, polymers of different kinds as well as non-polymers, amphoteric liquids (surfactants), etc., with various chain-lengths and degree of fluorination. The group of PFASs therefore cannot be characterized by (a) specific (range of) physicochemical properties. Nevertheless, they (or their PFAS degradation products) share very high persistence as a common characteristic. Information about the physicochemical properties of a selection of PFASs is provided in Annex B.1.2.

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

The substance scope includes PFASs 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 nor 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.

Rationale

Figure 1 shows the main PFAS subgroups as defined in the OECD 2021 report, including the division in subgroups of stable metabolites or 'arrowheads' (perfluoroalkyl acids or PFAAs), and the precursors to these PFAAs. The terminal degradation products are often referred to as **arrowhead substances**, while the parent substances degrading to the arrowheads are referred to as **precursors**. The term **related substance(s)** is used interchangeably with the term precursors. It should be noted that the polyfluoroalkyl acids (PolyFAAs) and most of the other PFASs are not necessarily all direct precursors to PFAAs in the short term, but will ultimately somewhere in their life-cycle be able to form PFAAs over time. The figure is adapted from Figure 9 in the OECD 2021 report, where more details on the grouping and nomenclature of PFASs are available.


🟩 Nomenclature including acronyms well covered by Buck et al. (2011)
▨ Nomenclature including acronyms partially covered by Buck et al. (2011)
🟦 Common nomenclature including acronyms exists
→ Indicating that it is a synthesis pathway, instead of examples
Polymeric PFASs
PFASs
perfluoroalkyl acids (PFAAs; including perfluoroalkylether acids, PFEAAs)
perfluoroalkyl carboxylic acids (PFCAs), C_nF_{2n+1}-COOH
perfluoroalkane sulfonic acids (PFSAs), C_nF_{2n+1}-SO_3H
perfluoroalkyl phosphonic acids (PFPAs), C_nF_{2n+1}-PO_3H_2
perfluoroalkyl phosphinic acids (PFPIAs), $(C_nF_{2n+1})(C_mF_{2m+1})$-$PO_2H$
perfluoroalkylether carboxylic acids (PFECAs), e.g. $C_2F_5OC_2F_4OCF_2COOH$
perfluoroalkylether sulfonic acids (PFESAs), e.g. $C_6F_{13}OCF_2CF_2SO_3H$
perfluoroalkyl dicarboxylic acids (PFdiCAs), HOOC-C_nF_{2n}-COOH
perfluoroalkane disulfonic acids (PFdiSAs), HO_3S-C_nF_{2n}-SO_3H
perfluoroalkane sulfinic acids (PFSIAs), C_nF_{2n+1}-SO_2H
polyfluoroalkyl acids (PolyFAAs; including polyfluoroalkylether acids, PolyFEAAs)*
polyfluoroalkyl carboxylic acids (PFCAs or PolyFCAs), e.g. H-C_nF_{2n}-COOH, n>1
polyfluoroalkylether carboxylic acids (PFECAs), e.g. $CF_3OC_3F_6OCHFCF_2COOH$
polyfluoroalkylether sulfonic acids (PFESAs), e.g. $ClC_6F_{12}OCF_2CF_2SO_3H$
PFAA precursors
n:1 fluorotelomer alcohols, $C_nF_{2n+1}CH_2OH$**
perfluoroalkanoyl fluorides (PACFs), $C_nF_{2n+1}COF$
perfluoroalkyl iodides (PFAIs), $C_nF_{2n+1}I$
perfluoroalkane sulfonyl fluorides (PASFs), $C_nF_{2n+1}SO_2F$
perfluoroalkylether non-polymers, e.g. $C_4F_9OC_2F_4OC_2F_4OCF_2$-$CH_2OH$, CAS No. 317817-24-6
perfluoroalkylether side-chain fluorinated polymers
perfluoroalkenes (C_nF_{2n}, n>2)
semifluorinated alkanes (SFAs), C_nF_{2n+1}-C_mH_{2m+1}
hydrofluorocarbons (HFCs, e.g. C_nF_{2n+1}-C_mH_{2m+1}), hydrofluoroethers (HFEs, e.g. $C_nF_{2n+1}OC_mH_{2m+1}$), hydrofluoroolefins (HFOs, e.g. C_nF_{2n+1}-$CH=CH_2$) that have a perfluoroalkyl chain
perfluoroalkyl (e.g. $C_nF_{2n+1}C(O)C_mF_{2m+1}$) and semi-fluorinated ketones (e.g. $C_nF_{2n+1}C(O)C_mH_{2m+1}$)
perfluoroalkyl alcohols ($C_nF_{2n+1}OH$), e.g. $(CF_3)_3C$-OH, CAS No. 2378-02-1
n:1 fluorotelomer-based substances, $C_nF_{2n+1}CH_2$-R**
PACF-based substances, $C_nF_{2n+1}CO_2$-R
n:2 fluorotelomer-based substances, $C_nF_{2n+1}CH_2CH_2$-R
PASF-based substances, $C_nF_{2n+1}SO_2$-R
side-chain fluorinated polymers
e.g. (meth)acrylate, urethane or oxetane polymers, silicones
non-polymers
R = NH, $NHCH_2CH_2OH$, etc
perfluoroalkene derivatives, e.g.
$[(CF_3)_2CF]_2C=C(CF_3)OC_6H_4SO_3Na)$, CAS No. 70829-87-7
other PFASs
fluoropolymers (FPs)
perfluoropolyethers (PFPEs), e.g. $HOCH_2O$-$(C_mF_{2m}O)_n$-CH_2OH
side-chain fluorinated aromatics***, e.g. C_nF_{2n+1}-aromatic rings
perfluoroalkanes (C_nF_{2n+2})
perfluoroalkyl-*tert*-amines $(C_nF_{2n+1})_3N$
perfluoroalkylethers (e.g. $C_nF_{2n+1}OC_mF_{2m+1}$)
others****
polytetrafluoroethylene (PTFE)
polyvinylidene fluoride (PVDF)
fluorinated ethylene propylene (FEP)
perfluoroalkoxyl polymer (PFA)
Other FPs

Figure 1. Main PFAS subgroups , including the subgroup of stable m▢olites (PFAAs) or ‘arrowheads’ (🟥nd the precursors to the PFAAs ( ). It should be noted that the Polyfluoroalkyl acids (PolyFAAs) and most of the other PFASs are not necessarily all direct precursors to PFAAs in the short term but will ultimately somewhere in their life-cycle be able to contribute to the release of PFAAs. Figure adapted from OECD (2021) – see Figure 9 therein for more details on the grouping and nomenclature.

Per- and polyfluoroalkyl substances (PFASs) are a group of synthetic organic chemicals that have been in use since the 1950s, i.e. as ingredients or intermediates for industrial and consumer applications. They have attracted much public attention since the late 1990s and early 2000s, when the hazards and ubiquitous occurrence in the environment of two PFASs, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), started to be reported and recognized. Early communications used many different terminologies for what nowadays are called PFASs (e.g. per- and polyfluorinated chemicals, perfluorinated organics, perfluorochemical surfactants or highly fluorinated compounds).

Research and risk management measures have expanded from PFOA and PFOS to a wider range of PFASs, and regulators and scientists across the globe show a growing concern for legacy as well as novel PFASs. A study by the OECD/UNEP Global PFC Group identified 4 730 CAS-numbers associated with individual PFASs or PFAS mixtures (OECD, 2018) (OECD/UNEP, 2018). A recent analysis of PFASs registered under REACH and/or notified to the CLP classification and labelling inventory in 2019 and comparison with the OECD/UNEP list revealed that there may be as many as > 9 000 different individual PFASs. The US EPA has a master list of PFASs which combines information from several existing lists into one consolidated list. In 2019 this list contained 6 330 different PFASs, while in July 2022 it contained 12 034 PFAS. Hence, a fair statement is that the current number of PFASs is at least 10 000.

In perfluoroalkyl substances all C-H bonds have been replaced by C-F, while in polyfluoroalkyl substances two or more C-H bonds 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 ($-CF_2-$ or $-CF_3$, not being directly attached to -H, -Cl, -Br or -I) are within the definition.

For clarification, a perfluorinated olefinic carbon atom ($=CF_2$) or an aromatic ring bound directly to an F-atom (–CF=) does not fulfil the PFAS definition alone (text from OECD, 2021). Consequently, olefins and aromatic substances would need additional fluoroalkyl elements to be regarded as PFASs.

PFASs can be divided into (functional) 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, amongst others, perfluoroalkyl carboxylic acids (PFCAs e.g. PFOA), perfluoroalkane sulfonic acids (PFSAs e.g. PFOS)[2], fluorotelomer-based compounds (e.g. 6:2 FTOH), per- and polyfluoroalkanes (e.g. perfluorooctane), 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), side-chain fluorinated polymers (polymers consisting of non-fluorinated polymer backbones with per- or polyfluoroalkyl/alkyl ether side-chains attached;

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[2] 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].

(OECD/UNEP, 2022)) and perfluoropolyethers (PFPEs; ether polymer backbone with F atoms directly attached) are included.

Some substances contain only a single $–CF_3$ group attached to carbon, and because of their structure they are potential precursors to trifluoroacetic acid (TFA). To this subgroup belong, amongst others, some fluorinated gases and active ingredients in biocides, plant protection products and pharmaceuticals containing a $-CF_3$ group bound to an aromatic ring. Fluorinated gases fulfilling the scope definition form the largest contribution by production volume to this subgroup.

The OECD definition of PFASs is based on chemical structure. Hazardous properties or risks are not part of it. The substance scope of the proposed restriction is additionally a concern-based one as it intends to cover PFASs that are very persistent, with the aim to address the concerns associated with the persistent nature of these substances.

Generally, PFASs are either very persistent themselves or will ultimately degrade to very persistent degradation products (so-called PFASs arrowheads). There are however a few specific PFAS subgroups with combinations of key structural elements for which it can be expected that they will ultimately mineralize in the environment. Substances belonging to these PFAS subgroups have been shown to fully degrade under environmental conditions[3] (see relevant available degradation data summarized in Annex B.4.1.4.) and thus do not form ultimately persistent PFAS arrowheads (perfluoroalkyl acids (PFAAs)). These PFAS subgroups are hence excluded from the scope definition of this restriction proposal. A schematic illustration of the excluded substance groups is depicted in Figure 2, and some examples are presented in Figure 3.

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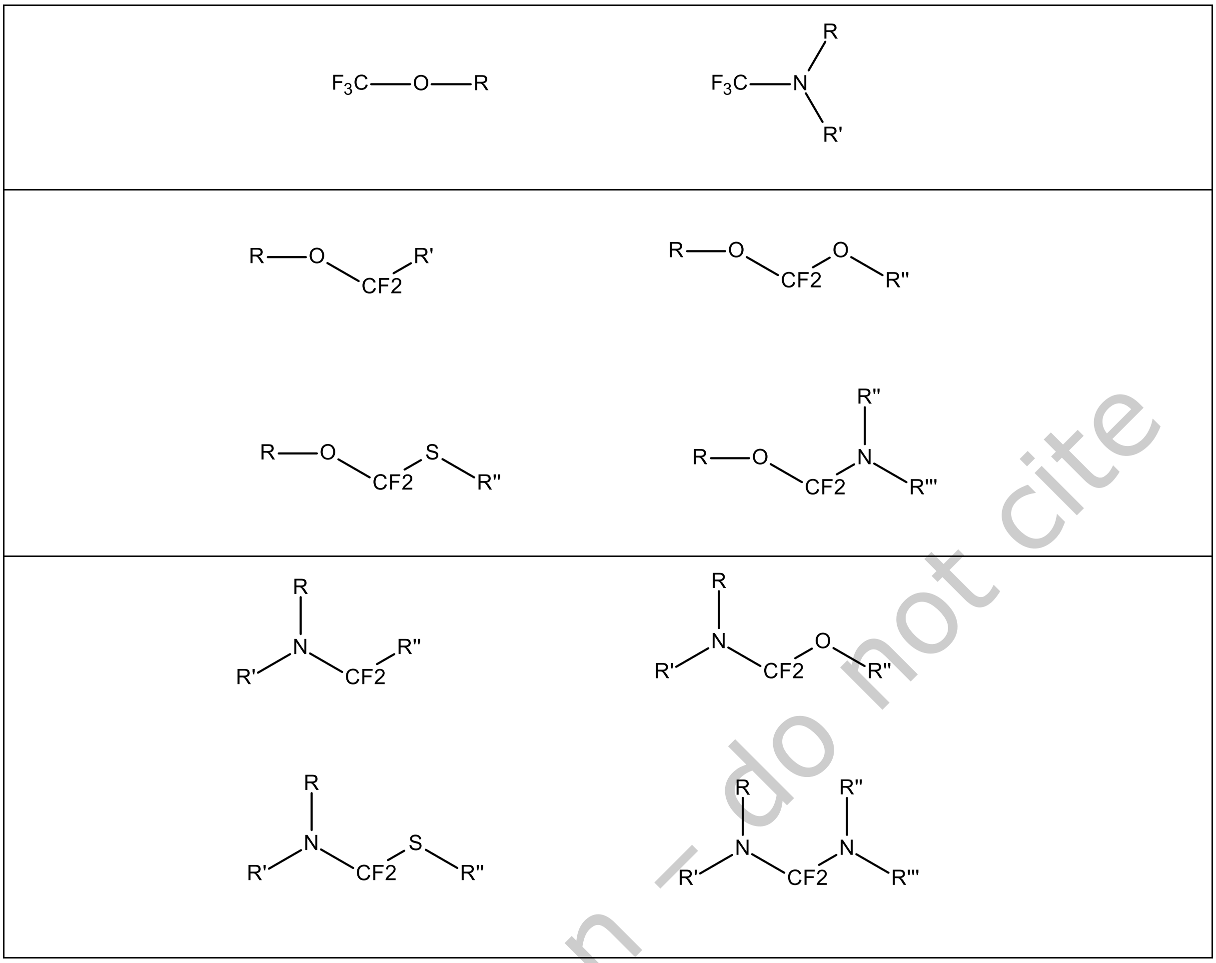
[3] Fully degrade implies mineralize to CO_2, H_2O and HF, leaving no persistent fluorinated organic metabolites that would fulfil the scope definition.



R, R', R'', R''' = hydrogen (-H), methylene (-CH2-), methyl (-CH3), an aromatic group or a carbonyl group (-C(O)-)

Figure 2. Substances excluded from the scope of the restriction proposal (schematic overview).

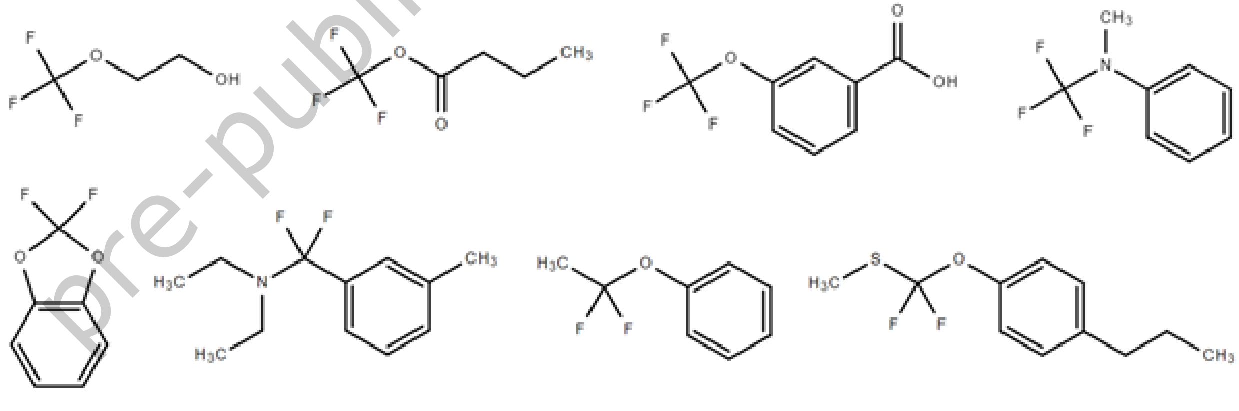


Figure 3. Examples of PFASs that are excluded from the scope of the restriction proposal.

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 Annex B.1.3.). 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 perfluoroheptyl moiety. PFASs have been allocated to subgroups based on their respective terminal degradation product (respective common perfluorinated moiety) (see Figure 1). Over sufficient time horizons all precursor substances will contribute to environmental stocks of their corresponding arrowhead substances (see Annex B.4.1.3. for further details). This grouping approach is acknowledged as a basis for risk assessment also by several scientists, who consider that regulation of PFASs on the basis of persistence alone should already suffice (see e.g. Cousins et al. (2020b); Scheringer et al. (2022)).

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 similar 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 other, restricted PFASs, or due to new uses.

To summarise, the grouping is based on structural similarity (common perfluoroalkyl moieties) that triggers equivalent hazards and risks among the substances covered, primarily related to the very persistent property of the substances (due to the parent compounds and/or degradation/transformation products). 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.

1.1.3. Classification and labelling

Around 6 600 PFASs have a classification (mostly self-classification) for at least one environmental, human health, and/or physicochemical endpoint in ECHA's classification and labelling notifications database.

When looking specifically at human health endpoints considered of most concern following long-term exposure of humans (i.e. carcinogenicity (Carc.), mutagenicity (Muta.), reproductive toxicity (Repr.) including effects on or via lactation (Lact.), and specific target organ toxicity (STOT RE)), 357 PFASs have a classification for at least one of these five endpoints, of which 41 are harmonised classifications (Q4 2020), see Annex B.3. for more information.

With regard to the environmental hazards (hazardous to the aquatic environment and hazardous to ozone layer) 1 129 PFASs have a self-classification.

1.1.4. Hazard assessment

1.1.4.1. Overview

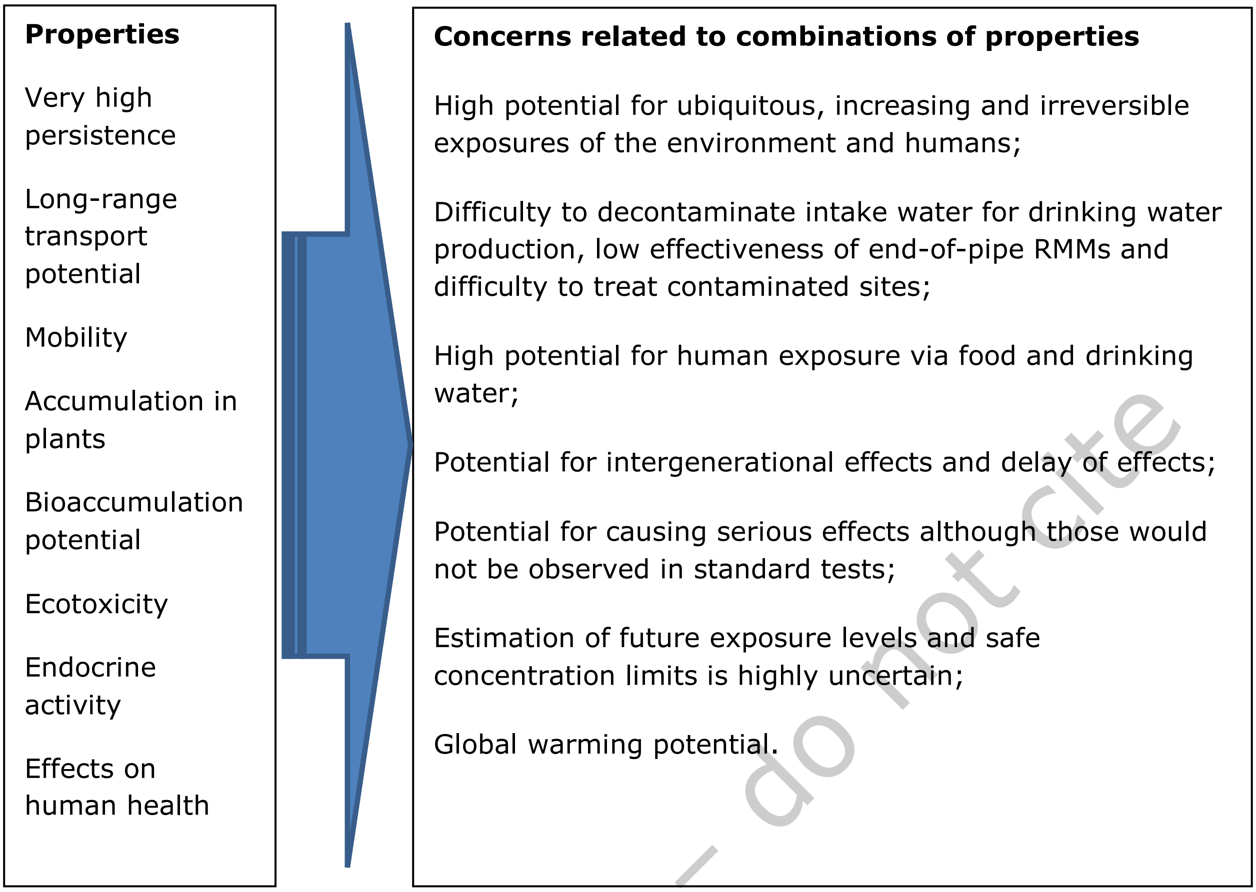
PFASs is a broad term used to cover at least 10 000 specific chemical substances which have a wide range of uses. These uses are principally based around the carbon-fluorine bond which is particularly strong and highly persistent (see below section 1.1.4.2 on persistence, and Appendix 3 of the study on the use of PFASs in fire-fighting foams (Wood, 2020)). All PFASs in the scope of this restriction proposal are either very persistent themselves, or degrade into very persistent PFASs in the environment. This is the key hazardous property common to all PFASs in this restriction proposal. Further supporting concerns vary among these PFASs. These properties include bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects (sections 1.1.4.3-9) and concerns related to a combination of properties (section 1.1.4.10). Taken together this can create concerns where PFASs, emitted to the environment, reach and contaminate important resources such as groundwater, on which abundant literature is available (see also Annex B.4.2.).

Goldenman et al. (2019) indicate 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.

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 there are indications that the long-chain substances PFOS and PFOA can cause reproductive and developmental, liver and kidney, and immunological effects in laboratory animals. Furthermore, both chemicals have caused tumours in animal studies. The use of PFOS and PFOA is already regulated in the Stockholm Convention. Other PFASs like PFHxS, PFBS and HFPO-DA have 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).

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.

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 PFAS. Properties of concern identified in investigated PFASs as well as concerns resulting from specific combinations of properties are listed in Figure 4 and further described below.



Properties

- Very high persistence
- Long-range transport potential
- Mobility
- Accumulation in plants
- Bioaccumulation potential
- Ecotoxicity
- Endocrine activity
- Effects on human health

Concerns related to combinations of properties

- High potential for ubiquitous, increasing and irreversible exposures of the environment and humans;
- Difficulty to decontaminate intake water for drinking water production, 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 4. PFAS properties and property-related concerns resulting from combinations of the properties.

1.1.4.2. Persistence

As detailed in Annex B.4.1. on degradation, 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, 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 e.g. PFCAs, PFECAs and PFSAs. There is a common understanding about grouping PFASs according to their stable degradation end-products (e.g. Cousins et al. (2020a)).

After gradual degradation of the non-fluorinated part, the degradation stops when only perfluorinated carbons, and often 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 intermediates 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.

Degradation half-lives 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 a very long time (see further details in Annex B.4.). 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 et al. (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 (Cousins et al., 2020b; Klöpffer, 1994; Mackay et al., 2014; Persson et al., 2013; Scheringer et al., 2022; Stephenson, 1977), see also Annex B.4.1.5.

1.1.4.3. Long range transport potential (LRTP)

The LRTP is assessed and discussed in more detail in Annex B.4.2.8. 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. Consequently, PFAS discharges from some regions could affect the whole earth, even remote areas like the Antarctic. 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 generally complex, also for other precursor-PFASs due to the change of the fate-determining properties during degradation into their arrowheads. The residence time of a substance in a certain compartment may strongly vary and depending on the respective compartments moving capacity, the transport of PFASs to remote areas occurs time delayed.

As provided by monitoring data (see Annex B.4.2.7.) 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 insoluble (see examples in Annex B.1.2.). 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. Generally, short-chain PFAAs and many long-chain PFAAs can be considered mobile in water (see Annex B.4.2.1. 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. The same occurs, e.g. to side-chain fluorinated polymers.

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 K_{OC} values with increasing chain length (e.g. PFCAs logK_{OC} 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 PFAS with a functional group of the same chain length. 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 partition to the suspended particulate matter phase.

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.1.2.).

Measured data illustrating the distribution of PFASs in the environment is provided in Annex B.4.2.7. These are reflected by the 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 persistence to increase of internal exposures in biota, see further discussion on mobility as a concern in Annex B.4.2.1. and the subsection 1.1.4.10 below.

For those PFASs, which are volatile (see Annex B.4.2.4.), distribution in the environment occurs mainly via air.

1.1.4.5. Accumulation in plants

A detailed assessment of accumulation in plants is provided in Annex B.4.4.

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. According to the review by Li et al. (2022), the reported average log Bioaccumulation factor (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 in the study by 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 PFSA < 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 are highly variable, 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 PFCAs are more effectively taken up by plants compared to the long-chain PFCAs (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.4.2.3. and Annex B.4.4. for an example case).

1.1.4.6. Bioaccumulation

A detailed assessment of bioaccumulation of PFASs is provided in Annex B.4.2.9., while monitoring data also provide information on bioaccumulation in the field as outlined in Annex B.4.2.6. and Annex B.4.2.7. 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 the liver.

Generally, Bioconcentration factor (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 PFASs 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 threshold for fulfilment of the B-criterion in REACH Annex XIII. For example, PFASs such as F-53B and p-perfluorous nonenoxybenzenesulfonate (OBS) were recently shown to significantly accumulate in common carp (Shi et al., 2020; Shi et al., 2015). The existing studies suggest that PFPiAs and PFPAs follow similar patterns as PFCAs where the total number of perfluoroalkyl carbons correlate with the BCF. In a BCF study by 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.4.2.9.).

Furthermore, PFASs, particularly the PFAA 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 in general (see Annex B.4.2.9.5.). 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.4.2.9.1. and Annex B.5.1.

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, bioconcentration factors below 2 000 L/kg could potentially reach similar levels in biota compared to substances that are known to bioaccumulate due to increasing and irreversible exposure to PFASs (see section 1.1.4.10/ Annex B.4.3.). Furthermore, the relationship between chemical structure, affinity to proteins and accumulation pattern is complex 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 Annex B.4.2.9.6.). 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 some PFASs (e.g. PFBA, PFBS, PFHpA, PFHxA, PFHxS, PFOS, FOSA, 6:2 FTOH, F-53B, TFA, and C9-C11 PFCAs) are found in various environmental compartments (Annex B.4.2.6. and Annex B.4.2.7.) while particularly PFOS and long-chained PFCAs are detected in elevated levels 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) 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 on bioaccumulation behaviour are available, substantial and large uncertainties remain. 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. 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 as outlined in Annex B.4.2.6. Hence, the actual combined exposure to PFASs is expected to be even higher than observed in the monitoring programs.

Yet in conclusion, considering the increasing lines of evidence from modelling, laboratory and monitoring studies, there is a justified concern for a subset of PFASs being bioaccumulative while large uncertainties remain for the majority of compounds due to lack of data.

1.1.4.7. Ecotoxicity

There is evidence for a subset of PFASs that they cause adverse effects in ecotoxicological tests with various environmentally relevant species e.g. invertebrates, fish, amphibians, birds, reptiles, mammals, plants or wildlife (see Annex B.7.1. and Annex B.7.2.). Adverse effects occur on the molecular level (e.g. genotoxic effects), the organ-level (e.g. steatosis (fatty liver)) as well as organism level (e.g. mortality or reproduction) the latter of which may also have relevance at the population level. The large number of different substances with heterogenous properties (e.g. due to different functional groups) in the group of PFASs makes the assessment of their ecotoxicity very complex. Additionally, conventional ecotoxicological tests may not be suitable to detect long term effects from exposure to PFASs across several generations. Lastly, it is noted, that 6:2 FTOH was evaluated by RAC to warrant a classification of Aquatic Chronic 1 (ECHA, 2021b).

1.1.4.8. Endocrine Activity / Endocrine Disruption

Collected evidence of endocrine activity (EA)/endocrine disruption (ED) of several PFASs indicates that adverse effects through interaction of certain PFASs with the hormone system as well as cross generational exposure cannot be excluded (see details in Annex B.7.5.). In summary, the data from *in silico*, *in vitro* and *in vivo* studies listed in Annex B.7.5. provide indications of interactions of certain PFASs with the endocrine system of environmental species. Adverse effects observed in those studies comprise e.g. altered receptor activity, changes of hormone levels, reduced fecundity, changes in sex-ratio, or developmental inhibition. Similar limitations apply to the assessment of EA/ED of PFASs as described above for the ecotoxicity of PFASs. Additionally, it should be mentioned that the substance evaluation (SEv) for 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctylacrylate (6:2 FTA) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (6:2 FTMA) was recently concluded, stating that "Available studies indicate that 6:2-FTOH (one main degradation product of 6:2 FTA / 6:2 FTMA) interacts with the HPG (hypothalamic-pituary-gonadal) axis and PFHxA (another important degradation product) interacts with the HPT (hypothalamic-pituary-thyroid) and HPG axis"[4].

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 scientific attention and available hazard information is increasing. Some precursors to PFAAs may be of less direct 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 indirectly add to the concern. Below, the human health effects reported for PFASs are summarized per main PFAS category.

PFAAs (arrowheads and 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.5.1.1.1.). 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 half-lives for PFAAs range from a few days to a month (e.g. PFBA, PFBS, PFHxA) to a couple of years (such as PFOA, PFNA, PFDA, PFHxS or PFOS) to over 10 years (e.g. PFUnDA). Half-lives are much shorter in rodents (and other experimental animal models) than in humans and a difference in half-lives between sexes is often observed. Consequently, the observed toxicity in rodents may underestimate the toxicity to humans. PFAAs are mainly excreted via urine and faeces and are released to the environment. Some PFAAs have a strong potential for bioaccumulation in humans as shown by the long half-lives (details in Annex B.5.1.1.4.) due to the protein-binding properties (details in Annex B.4.2.9.2.).

EFSA extensively reviewed the epidemiological evidence for association between PFAS exposure and adverse effects in humans (EFSA, 2018; EFSA, 2020). Most data were related to 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 an association between increased serum levels of various PFCAs and PFSAs and reduction in vaccine antibody response, increased serum cholesterol, increased serum alanine transferase (ALT) and reduced birth weight. EFSA also identified some evidence of increased propensity of infections (see Annex B.5.2.1.5. and Annex B.5.3.1.1.). The association with immune effects was the most sensitive endpoint in humans and was a sensitive endpoint also in experimental rodents. 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

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[4] Once published, the conclusion document can be found here: https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ebe59, date of access: 2023-01-05.

(Annex B.5.3.1.1.). 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 PFAAs demonstrate that liver, kidney, thyroid, immune system, and reproduction are main targets of PFAAs' toxicity, as outlined in Annex B.5.2. 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.5.2.1.1.). For PFOS, PFHpA, PFOA, PFNA, and PFDA and their salts this has resulted in harmonized classifications for carcinogenicity (Carc. 2, except for PFHpA), reproductive toxicity (Repr. 1B), effects on or via lactation (Lact., except for PFHpA) and specific target organ toxicity - repeated exposure (STOT RE 1, except for PFDA), see Table B.2. in Annex B.3.1. Harmonized classification for 6:2 FTOH (STOT RE 2) has been agreed by RAC but is 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.5.2.). 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 doses compared to PFOS/PFOA. Another example is HFPO-DA, 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 a lower reference dose than for PFOA and PFOS (EPA-US, 2021a).

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 fluorotelomers (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.3.2.). Exemplarily of note, HFPO-DA, POSF, 6:2 FTSA and 8:2 FTSA have self-classifications for STOT RE, and POSF as well for Repr. 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 potential 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 most of these substances are expected to ultimately degrade in the environment to TFA (details in Annex B.4.1.), 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 (see Annex B.5.2.).

Oligomeric/polymeric PFASs

The Dossier Submitters identified oligomers as well as diverse groups of polymeric PFASs, such as side-chain fluorinated polymers, fluoropolymers, incl. fluoroelastomers, and perfluoropolyethers (details e.g. in Annex A.2.1.2. and Annex A.2.1.4.). Under the REACH regulation, oligomers are not defined. They are composed of a small number of linked monomer units but do not fulfil the criteria of the polymer definition in the REACH regulation (Article 3(5)). For polymers defined under REACH, no registration is required to date. No toxicity information was found in the REACH registered substance database for oligomeric or polymeric PFASs. Potential risks of polymers to human health are still under estimation (BIO by Deloitte, 2015; Bougas et al., 2020). Solid polymer particles (non-fluorinated and fluorinated) are partially restricted under REACH in the restriction for intentionally added microplastics (ECHA, 2019b; ECHA, 2020b). The microplastics restriction discusses concerns related to synthetic polymer microparticles in general (ECHA, 2019b; ECHA, 2020b), which may cover the concerns related to solid particles of polymeric PFASs. Some occupational studies showed effects of particles of polymeric PFASs (see Annex B.5.4.), but PFAS-specificity remains unclear.

Properties within the group of oligomeric/polymeric PFASs can vary considerably. Oligomers/polymers can vary in terms of molecular weight distribution, physical state, and possible inclusion of co-monomers and others, but can carry the same name and/or CAS number. Moreover, unique identifiers for oligomeric/polymeric PFASs are often not available which can further complicate clear assignment of the substance to health effects. Additives and non-intentionally added substances (NIAS) can also play a relevant role in the final oligomer/polymer product. For further details see Annex B.5.1.2. and ECETOC (2019). Furthermore, the end-of-life fate of the polymers is uncertain (Annex B.4.2.7.8.).

Only a few studies with toxicological information are available for this diverse group of oligomeric and polymeric PFASs. Most available toxicological studies of oligomeric/polymeric PFASs investigated oligomeric PCTFE oils and pure PCTFE oligomers.

Repeated oral and inhalation animal studies (mainly rodents) with oligomeric PCTFE oils as well as pure trimer and tetramer oligomers, reported adverse health effects such as liver and kidney effects as well as loss of body weight or reduced body weight gains, which would generally fit the typical effects observed for non-polymeric PFASs (details in Annex B.5.2.1.). The available data indicate that oligomeric PCTFE can be bioavailable.

For human inhalation, following occupational exposure to degradation products of polymeric PTFE (e.g. pyrolysis products) or particles (e.g. spray application), severe toxic lung effects are reported (details in Annex B.5.4.).

The structures of side-chain fluorinated polymers as well as perfluoropolyethers are different from that of fluoropolymers. Little to no data is available on the toxicity of these two groups of polymeric PFASs. Side-chain fluorinated polymers are considered potential PFAA precursors, as it is expected that they release PFAAs at any point in their lifecycle (details in Annex B.4.1.3.). For a polymeric PFPE product in one study, male rats showed mild degenerative change in the basophilic tubules of the kidney following oral exposure (Malinverno et al., 1996) (details in Annex B.5.2.1.3.).

Clarity on effects after repeated exposure of the diverse group of oligomeric/polymeric PFASs cannot be given on the basis of available data. However, given that at any point in their lifecycle oligomeric/polymeric PFASs may generate and/or release non-polymeric PFASs, e.g. PFAAs, in particular at end-of life (Lohmann et al., 2020), oligomeric/polymeric PFASs contribute to the overall exposure to and risks of non-polymeric PFASs.

Fluorinated gases

For fluorinated gases, some effects are similar to those observed for PFCAs and other PFAA arrowheads, in particular effects on liver of some HFCs, HFOs and HFEs and effects on lymphoid organs of some HFCs and HFOs (see Annex B.5.2.1.). Available data indicate that most of the fluorinated gases have lower potencies compared to the arrowheads. Moreover, some fluorinated gases (e.g. some HFOs) ultimately degrade to PFAAs, e.g. TFA or PFBA (Annex B.4.1.3.2.). Hence, also these gases will contribute to the overall exposure to and risks of PFAAs.

Combined effects of co-occurring PFASs

Many different PFASs co-occur in the environment, drinking water, food, and in human blood (see Annexes B.4.2.6., B.4.2.7., B.9.7., B.9.21., B.9.22.). Thus, there is combined exposure to multiple PFASs, many of which 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 more realistic exposure conditions than single compound assessments.

The similarity of the effects of most PFAS groups, often targeting the same organs, raises concerns about cumulative effects of PFASs (Annex B.5.5.). 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 may 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 proposal. 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.

Conclusion on human health effects/concerns

In conclusion, for the majority of the PFAA arrowheads identified (and many of their precursors) there is reasoned concern for long-term human health hazards especially with continuously increasing exposure due to ongoing emissions, persistence, mobility and/or bioaccumulation. Despite different potencies of different substances, overall effect patterns are similar for a variety of PFASs, especially arrowhead substances. Additionally, co-occurrence of PFASs leads to combined exposure and raises concerns of potential combined effects.

Considering the increasing lines of evidence for effects of well-studied PFASs occurring at lower levels than previously anticipated (EFSA, 2020), the human exposure to the combination of the four PFASs PFOA, PFNA, PFHxS, and PFOS already exceeds the existing limit value established by EFSA. Also recent human biomonitoring data on PFAS from the

HBM4EU program confirm that PFAS exposure is too high and may result in a human health risk ((Bil et al., 2023); see also Annex B.9.22.2.). Furthermore, remediation/decontamination of PFASs from the environment and drinking water is insufficient with current conventional and advanced treatment methods (see Annex B.4.5.). Hence, any additional exposure to other PFASs can add to the overall toxicity potential in the future. Exposure therefore needs to be minimised.

1.1.4.10. Concerns triggered by combinations of properties

Most of the PFASs manufactured, used and released to the environment can be expected to have several of the above listed properties of concern (i.e. LRTP, mobility, etc.), depending on the specific identity of the PFAS. Confirmation of these properties of concern through scientific studies is only available for a few, well-studied, PFASs. A combination of at least two or more properties is expected in particular for the arrowhead PFASs (see more details in Annexes B.1.2., 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.

<u>High potential for ubiquitous, increasing and irreversible exposure of the environment and humans</u>

Although exceptions may occur, the overall assumption is, 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 and most persistent among the PFASs. This is based on 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 (Annex B.4.2.4.).

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., 2012). 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. (2012) discuss 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 Annexes B.4.2.6. and B.4.2.7.).

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 PFASs exposures.

For the very persistent PFASs, environmental concentrations increase as a result of releases until reaching a steady state at a time in the distant future. In consequence also PFASs having less or no bioaccumulative properties can show elevated levels in biota as illustrated by monitoring data (Annex B.4.2.6.). Recent models demonstrate that mobile and persistent PFASs will ultimately reach over time—unless the exposure is removed—such high levels in organisms that they 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 2 000 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 5 000 L/kg, if time allows for steady state to be reached, see Annex B.4.3. 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 1 736 (Campo et al., 2015). The outcome of the modelling of development of biota concentrations for PFBS over time is shown in Figure 5. The model substances (A, B, C and D) have combinations of half-life and BCF as shown in Figure 5. 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.

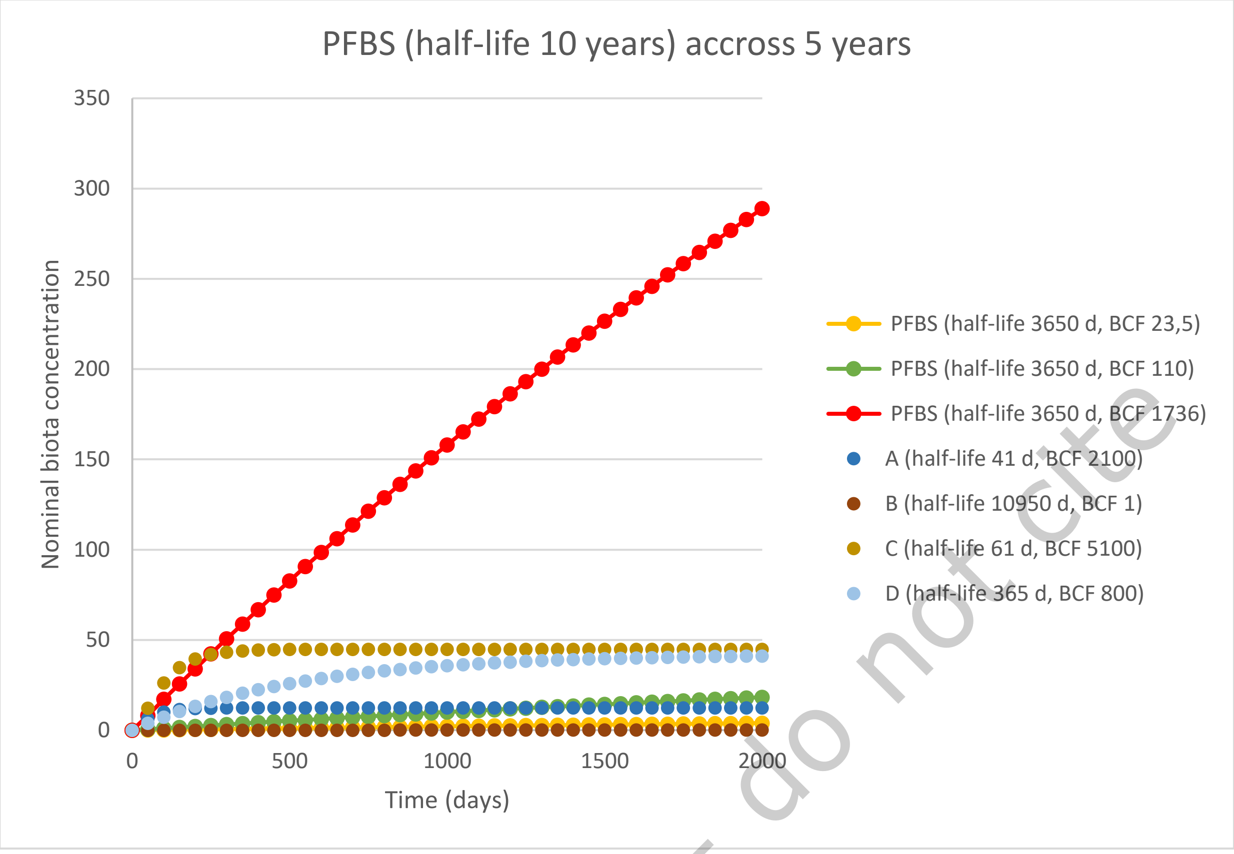

Figure 5. Modelling of development of nominal biota concentrations for PFBS over time.

Figure 5 demonstrates in a simplified way that when considering an appropriate long time scale, e.g. few decades (note Figure 5 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 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 2 100, 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 PFASs, 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. Regarding bioaccumulation this is due to the slowly reversible internal exposure caused by 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 impacts 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 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. intake water used for drinking water production 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 by the available micro-organisms within the retention time. 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 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.4.2.7.).

Conventional and advanced intake water treatment methods applied to produce process water for industry and drinking water are unable to effectively remove PFASs due to their persistence and inertness to chemical and thermal reaction. Thermolysis and sonolysis might achieve complete mineralization but come with high process costs. 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 production of 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 riverbank filtrates used for the preparation of drinking water (see Annex B.4.2.7.). A recent review paper from Li et al. (2020) on drinking water treatment concludes that short-chain PFASs 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 and thus misses a large fraction of total PFASs.

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 some PFASs in fishery products (and other products) and the very high persistence and mobility as discussed above human exposure via food. Furthermore, drinking water is also a source of PFAS exposures due to the difficulty to decontaminate intake water used for production of drinking water. The exposure via drinking water and 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 of 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 the available biomonitoring data (see Annexes B.9.21. and B.9.22.).

Potential for intergenerational effects and delay of effects

Several PFASs are transferred to the offspring (see Annexes B.4.2.9.1. and B.5.1.). 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, and most likely impossible, 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 well-studied PFASs (e.g. (ECHA, 2021a)) 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 (see section 1.1.4.8 and Annex B.7.5.) 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.5.5., 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 predict future exposures reliably. The prediction is further complicated for PFASs by the degradation of the precursors to the arrowhead PFASs. Thus, it can be expected that the total amount of arrowhead PFASs present in the environment at the same time is even higher than the amount of arrowhead PFASs produced and used. The environment is also exposed to intermittent degradation products. For example, side-chain fluorinated polymers, which degrade in the environment at a very slow rate, are a long-lasting constant source for arrowhead PFASs 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)toxicity 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), findings for less studied PFASs (ECHA, 2021a), and the lack of (eco)toxicity data for the vast majority of PFASs. On the other hand, the prediction of safe levels is more challenging, if not impossible, due to the complex mixture of used PFASs 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 Annexes 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 Annex B.5.5. 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 global warming. In fact, some of the strongest greenhouse gases known are PFASs, for details see Annex B.7.3.

One of the most relevant subclasses of PFASs that contribute to global warming are the fluorinated gases, e.g. hydrofluorocarbons (HFCs), hydrofluoroolefins (HFOs) and hydrofluoroethers (HFEs). Emitted gases reside in the atmosphere, and eventually, they 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 substances like HF and CO_2. However, also other PFAS subgroups are volatile and contribute to global warming while they reside in the atmosphere (Oltersdorf et al., 2021).

1.1.5. Exposure assessment

1.1.5.1. Emission to the environment

Emissions of PFASs are, in combination with the environmental fate of persistent substances and/or the persistence of degradation products, the driver of the increasing PFAS pollution burden in the environment. The very persistent nature of PFASs results in a long-term, possibly infinite, potential for environmental exposure and, hence, negative impacts to ecosystems and humans, once emitted. The high mobility of certain (groups of) PFASs allows for long-distance transport via air or surface water and ground water on a global scale ((Brase et al., 2021); see also section 1.1.4.3).

Emissions occur during PFAS production and processing, in product manufacturing (PFAS application in form of substances, mixtures and articles), in the use phase and in the end-of-life phase. See also Table 4, section 1.3.1 and Annex B.9. for specific information on emissions. Environmental emissions also depend on the rate of environmental release of PFASs. This depends on the physical state of the PFAS: Emissions of fluorinated gases are fast and direct, while emissions from solid PFASs (e.g. polymers) can span over long periods of time (i.e. decades or even centuries). The PFAS application (i.e. open or closed) also determines the speed of environmental release. For ski wax or consumer mixtures the release is quick. For side-chain fluorinated polymers, in e.g. textiles, the release is slower (mainly during washing and wear and tear). For durable applications, e.g. PFAS applications in electronics and automotive, the environmental release is very slow in the use phase and most PFAS load enters the waste stage.

For PFASs in durable articles like painted/coated articles, construction materials, electronics, solar panels, etc. there is a long use phase in between production and waste stage. These articles are a potential long-term source of emissions to the environment e.g. through wear and tear. PFASs in products that are not emitted during the use phase, will eventually enter the waste stage. In the waste phase additional PFAS emissions are to be expected. The amount of PFASs emitted during the waste phase depends on the waste (pre-)treatment method, e.g. recycling/re-use, landfilling and incineration (EPA-US et al., 2020; Stoiber et al., 2020).

Significant amounts of PFASs are stored in "technical stock", meaning there is a significant amount of PFASs that can potentially be released from products that are in use or on shelf, but will ultimately reach the end-of-life phase. Also in the waste stage, especially in landfills, "environmental stock" is present because of build-up of PFASs over time. Especially for highly persistent pollutants, stock pollution is a relevant problem as the environmental stock will grow over time, mainly from emissions from technical stock of long-lived products, both in the use and waste phase. Therefore, even with a full PFAS restriction in place, due to prolonged article use, recycling of old materials, and slow release of PFASs from landfills, emissions of PFASs and their arrowheads will continue for a long period even if a full ban is in place.

Emission calculations are predominantly based on the yearly PFAS tonnage brought to the EEA market, excluding emissions from the waste phase (which are described in Annex B.9.18.). For some uses, specific emission factors (see section 2.4.3) could be derived based on stakeholder input and/or literature, but for the majority of uses ECHA's Environmental Release Categories (ERCs) are used because of the lack of industry specific data. ERCs are also applied for the waste stage (recycling, incineration and landfilling): see Annex B.9.18.

Finally, PFASs may also be formed as by-products in other processes (e.g. aluminium processing (EPA-US, 2019; Marks et al., 2016)). Emissions coming from these kinds of processes where PFASs themselves are not used or placed on the market are not considered in this dossier, just as other possible sources of uncontrolled PFAS emissions, e.g. as result of (factory) fires, uncontrolled landfill fires, as these fall outside the scope of the EU REACH regulation.

Emissions from PFASs production

Information from stakeholders and literature reviews give insights into the presence and locations of the most important manufacturers/suppliers of PFASs in Europe. About twenty PFAS manufacturing sites in the EEA were identified (see Annex A.2.1.).

The Industrial Emissions Directive and European Pollutant Release and Transfer Register (E-PRTR) provide information about industrial point source emissions but information on PFAS emissions is very scarce and limited to a few fluorinated gases. No specific data was obtained for emissions from PFAS processors (e.g. drying, granulating), see Annex B.9.2. for further details. It must be noted that indirect emissions via waste from manufacturing could be a significant source of environmental emissions as was shown at the Chemours site in the Netherlands where indirect PFAS emissions via waste were 11 times higher than emissions via water (ILT, 2018; Tweede Kamer, 2019).

Article and mixture manufacturing emissions

Factories that process PFASs and apply PFAS-containing articles in products (i.e. manufacturing sites, metal finishing and surface treatment plants, textile industries, formulation of mixtures like paints, coatings, impregnation fluids, production of plastics, etc.) contribute to PFAS point source emissions. Many more facilities and sites are involved in PFAS processing than in PFAS production. In the EEA, there are for instance over 61 000 installations that may emit C6 fluorochemicals and polymers containing C6 side-chains (ECHA, 2019a; Goldenman et al., 2019). If all uses mentioned in Table 2 in section 1.3.1 are included, it is to be expected that there could be over 100 000 possible PFAS point sources from product manufacturing/PFAS processing alone in the EEA (estimate from EC (2020a)) with activities not concentrated in a few Member States, but spread throughout the whole EEA (Goldenman et al., 2019).

However, hardly any information on actual emissions from the PFAS processing industry has been found. In Flanders, PFAS processing industry (galvanic industry, textile industry, paint industry and paper industry) was studied (OVAM, 2018). Environmental monitoring data show elevated concentrations in matrices (soil, surface water, ground water) near sites where activities involving PFASs take place (see Annexes B.4.2.6 and B.4.2.7 on environmental monitoring data).

Application of fluoropolymer coatings, an important PFAS application method in many sectors, could lead to emissions from product manufacturing sites (Langberg et al., 2021). Although processes are likely closed, some PFAS (micropowder) emissions might occur that are not accounted for in ERCs. During the call for evidence and the 2nd stakeholder consultation, the amount of information received on emissions related to article manufacturing was very limited. Based on US permit information, in PFAS paste extrusion lines, printing lines, melt extrusion lines and fuse lines there is potential to generate toxic thermal PFAS decomposition products. Emissions are not quantifiable as they are highly variable due to variations in e.g. oven temperature and line speed. But emissions are likely. Therefore, the emissions calculated for product manufacturing using ERCs might be an underestimation.

Product use emissions

PFAS emissions from the use phase occur both as point source emissions and as diffuse emissions. Diffuse emissions mainly result from wide-dispersive and widespread professional uses and from consumer uses of PFAS-containing products e.g. via wear and tear or improper use. Diffuse emissions are harder to control than point source emissions. Examples of these widespread and wide-dispersive uses are use (including washing) of treated textiles, use (including wear and tear) of impregnated building and construction materials, use of ski wax, use of paints and lubricants under uncontrolled conditions, use of cosmetics, use of cookware, etc. These types of uses result in direct emissions to the environment or indirect emissions, e.g. by run-off and discharge to sewage systems and subsequent discharge to surface waters by WWTPs.

The production and use emissions are presented in Table 1. For emissions related to the use of PFAS-containing articles, literature data were available for some applications (e.g. partly on food contact material). For most uses in Table 1, ECHA ERC factors (ECHA, 2015) have been used to calculate PFAS emissions, although in some cases more specific emission factors were available (e.g. for paper and board food contact materials).

Table 1. Estimated annual emissions from the use phase for PFAS manufacture and major PFAS use sectors in 2020 (low, mid and high estimates)[a]. Emissions relate to new products on the market, unless stated otherwise. Mid points are used in impact assessment.

Application	**PFAAs and PFAA precursors (tonnes/year)**			**Fluorinated gases (tonnes/year)**			**Polymeric PFASs (tonnes/year)**			**Total PFASs (tonnes/year)**		
	low	**mid**	**high**	**Low**	**mid**	**high**	**low**	**mid**	**high**	**low**	**mid**	**high**
Manufacture	54	86	118	309	1 973	3 637	15	23	30	**378**	**2 082**	**3 785**
TULAC[b]	2 058	6 177	10 295				8 326	16 643	24 960	**10 384**	**22 820**	**35 255**
Food contact materials and packaging	123	491	858				99	100	100	**222**	**591**	**959**
Metal plating and manufacture of metal products[c]	0.5	6	11.4							**1**	**6**	**11**
Consumer mixtures										**23**	**23**	**23**
Cosmetics										**0.015**	**32**	**64**
Ski wax										**1**	**1**	**1**
Applications of fluorinated gases[d,e]				*38 806* 1 696	*38 806* 1 696	*38 806* 1 696				***38 806*** **1 696**	***38 806*** **1 696**	***38 806*** **1 696**
Medical devices	128	239	350	3 772	5 586	7 400	32	76	120	**3 932**	**5 901**	**7 870**
Transport[d]							*269* 35	*439* 58	*609* 80	***269*** **35**	***439*** **58**	***609*** **80**
Electronics and semiconductors	348	513	677	7	7	7	11	152	292	**366**	**671**	**976**
Energy sector	42	42	42				12	13	13	**53**	**55**	**56**
Construction products	88	152	216				1 364	2 338	3 311	**1 451**	**2 489**	**3 527**
Lubricants	0.11	0.6	1.1	29	46	62	123	174	225	**152**	**220**	**288**
Petroleum and mining[c]	0.3		2.3							**0**	**1**	**2**
TOTAL[f]	**2 842**	**7 707**	**12 571**	**42 923**	**46 418**	**49 912**	**10 251**	**19 958**	**29 660**	**56 038**	**74 137**	**92 232**
Total[g]	2 842	7 707	12 571	5 813	9 308	12 802	10 017	19 577	29 131	18 694	36 646	54 593

a) In some cases a basis for providing a range is lacking. There the available estimate is applied throughout; b) TULAC = Textile, upholstery, leather, apparel and carpets; c) No data available for emission of polymeric PFASs; d) For these sectors the emissions relate to stock (presented in italics). For reference only, the emissions from tonnage brought new to market in 2020 are also given; e) Includes emissions of fluorinated gases in transport sector; f) Total based on emissions from best available data (stock if available, new to market if stock is not available); g) For reference only, also the total emissions from tonnage brought new to market in 2020 are presented.

PFASs in applications of fluorinated gases and PFASs in TULAC applications are applications with the largest PFAS load to the environment (excluding the waste stage), see Table 1. ForTULAC this is partly linked to the high PFAS tonnages used in the products. High emission percentages compared to tonnage used are seen in consumer mixtures, cosmetics, ski wax and fluorinated gas applications (see Table 4 in section 1.3.1).

The numbers presented in Table 1 are based on current emission estimations. Technological and market developments can cause specific markets to shrink or grow, with the pace of shrinking or growth depending on developments and demand. See section 1.3.2 for information on market developments.

Next to existing uses, new uses are likely to emerge. These could add to future emissions. Finally, it should be noted that for non-researched uses (see e.g. Annex A, Table A.1.) no emission data are available. Emissions presented here are therefore likely an underestimation of actual PFAS emissions.

Emissions from waste management

PFASs enter the waste stage for many of the investigated applications. The fraction of PFASs entering the waste stage may differ between uses. For some applications nearly all emissions occur during use phase, e.g. application of fluorinated gases as propellant, for other uses the largest part will enter the waste stage, e.g. fluoropolymers in electronics. The end-of-life stage/waste management can be an important secondary (point) source of PFAS emissions and can be considered a cyclical problem, as current waste management approaches return either the original PFASs or their degradation products to the environment (Stoiber et al., 2020).

Waste collection and transport is one of the first steps before waste treatment. Uncontrolled spreading and diffuse emissions of (surfactant-like) PFASs in waste transport have been documented. In the Netherlands, solid and liquid waste containing HFPO-DA was emitted to the environment as a result of waste management supply chain activities (transport) in 2018/2019 (ILT, 2018; ILT, 2019). After collection, waste is often bulked and pre-sorted at waste transfer stations. There are at least 2 400 waste transfer stations in the EEA (FEAD, 2021). As research has shown, emissions, especially to water, are very likely at waste transfer/recycling stations (RWS, 2020).

Recycling of PFASs, especially fluoropolymers, is difficult – particularly for post-consumer waste – as PFASs, and mainly fluoropolymers, are typically compounded with other materials and fillers (and vice versa). The presence of PFASs in materials that are generally intended to be recycled after use, can be a relevant emission source of PFASs to the environment, e.g. foam blowing agents used for insulating for district heating pipes is released again when pipes are shredded for recycling purposes, including the PFAS-containing insulation material. Also, emissions and worker exposure in/around sites where electronic waste are handled for recycling have been reported (e.g. Garg et al. (2020), Peng et al. (2022)).

Except for fluorinated gases under the F-gas regulation, there is no legal obligation and/or incentive to recycle (or fully destruct) PFAS-containing waste. Landfilling, wastewater treatment and incineration are the most relevant waste treatment methods. In landfills, PFASs are not destroyed and eventually may enter the environment via leachate / air or are sequestered in the landfill (possibly leading to delayed emissions when environmental conditions change). In waste incineration, PFAS are destructed but 100% complete destruction is not to be expected at operational conditions, especially for municipal waste incineration, since PFAS removal and destruction efficiencies depend on the structure of

PFASs, but also on the operational conditions like the presence or absence of oxygen, the presence or absence of other chemical substances, temperature, etc. (Longendyke et al., 2022). In general, PFAS emissions from waste incineration are not well studied, but it is clear efficiency of the destruction method depends on numerous (operational) conditions (e.g. mentioned in Appendix 2 in ECHA (2022b)). Discharge of PFAS-containing wastewater to wastewater treatment plants (WWTPs) asks for advanced removal techniques to eliminate PFASs before discharge to surface water. In general, (municipal) WWTPs are not equipped to remove PFASs from influent, leading to discharge of PFASs to surface waters (STOWA, 2021). In several cases, PFAA concentrations in effluents were even higher than in influents, with biodegradation given as the primary mechanism responsible for the transformation of (measurable) PFAS precursors to PFAAs (Lenka et al., 2021).

Waste management and treatment facilities are relevant point sources for PFAS waste stage emissions. It is estimated by PlasticsEurope that in the EEA approximately 15% of fluoropolymer waste is landfilled and 80% is incinerated going through (municipal waste) incineration with energy recovery (Conversio, 2022). According to European waste statistics for 2018, 38% of the waste is landfilled. Significant differences can be found between different EU Member States, ranging from approximately 5% to 100% landfilling[5].

Emission factors for landfilling, WWTP and incineration, based on PFAS input/output tonnage, could not be derived by the Dossier Submitters (see Annex B.9.18.). In many studies PFAS output from different types of waste treatments has been partly determined with (mostly dedicated) PFAS sampling and analyses. However total PFAS input for these types of waste treatment options are unclear and therefore a reliable emission factor cannot be derived. Literature studies suggest (very low) waste stage emissions of 1 – 6 t/y in the EEA. Additional calculations based on ECHA ERCs (see Annex B.9.18.2.10.) lead to far higher EEA waste stage emissions ranging from approximately 3 700 to 7 300 t/y.

New PFAS destruction technologies are being investigated, but often on a laboratory scale and these new technologies all have their specific advantages and disadvantages (Meegoda et al., 2022; Trang et al., 2022; Verma et al., 2023). These technologies have in common that they cannot be efficiently or in an economically feasible manner applied to PFASs that already entered the environment.

Conclusion

PFASs are used in many sectors, and even within the same sector there are many sub-applications. Around 850 000 tonnes of PFASs/y (excluding production) are used in substances, mixtures and articles in the EEA (midpoint, see Table 3 in section 1.3.1). Emissions to the environment as a result of the use phase (but excluding the waste phase) are estimated to be around 75 000 tonnes of PFASs/y (midpoint) in the EEA (see Table 1). Regarding applications, the application of fluorinated gases, TULAC and medical devices (MDI use mainly) are the most relevant sectors. A major part of PFAS emissions come from applications of fluorinated gases in HVACR and medical uses which are responsible for the emission of approximately 45 000 tonnes of PFASs/y (excluding waste stage emissions).

Regarding PFAS tonnage, TULAC, application of fluorinated gases, medical devices, construction products and food contact material & packaging are the most relevant sectors according to the research. According to stakeholders (Wood, 2022) the transport sector

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[5] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Waste_statistics#Waste_treatment, date of access: 2022-12-21.

(including aviation, trains and boats) is also very large and possibly the largest sector using PFAS polymers. Emissions from uses that have not been considered (e.g. chemical industry), from expected growth markets (e.g. immersion cooling, electrification in transport, oil fracking), and emissions from the waste phase are not considered in the 75 000 tonnes PFAS emissions per year, so actual emissions likely are higher than this estimate.

PFAS emissions resulting from article production are largely unclear, as important information is missing. With an estimated number of EEA point sources over 100 000, this could be a relevant PFAS emission source. For many products there is a long use phase in between production and waste stage. Significant amounts of PFASs are therefore in "technical stock", i.e., in long-lived products like coated articles, construction materials, electronics, solar panels, applied paints and lubricants, etc. Fluoropolymers are the main group of PFASs to enter the waste stage and waste stage emissions are highly uncertain.

The effectiveness of incineration to destroy PFAS and the tendency for formation of fluorinated or mixed halogenated organic by-products is not well understood (Lohmann et al., 2020).

Especially in landfilling, sequestration or 'building up' of PFASs may occur. Leaching is concentration dependent, with more rapid leaching found at higher concentrations of PFAAs (Kah et al., 2021; McLachlan et al., 2019). PFAS emissions to air and water (leachate) will continue for decades to come, even if landfills are closed (Propp et al., 2021). As a result "environmental stocks" will build up resulting from the waste stage of PFAS-containing substances and products, mainly in landfills and WWTP sludge that is not incinerated. Another example is sequestration in landfill: up to 85-99% of PFAS is (temporarily) sequestered (SANBORN, 2019).

Even with a restriction in place, due to prolonged article use, recycling of old materials, and slow release of PFASs from landfills, PFAS emissions are expected to continue far after a restriction is in place.

1.1.5.2. Environmental monitoring data

PFASs are ubiquitously found in European environments and biota. Numerous examples of highly contaminated environmental matrices, such as soil and drinking water, near different types of point-sources have been reported and many more cases are likely to go undetected. This section provides a short summary of environmental monitoring data findings, for more information and detail see Annexes B.4.2.6. and B.4.2.7.

Monitoring studies of targeted PFASs in environmental matrices show that PFOS and PFOA, which are restricted, still are the dominating PFASs in soil, sediment, sludge, and biota, and among the most abundant PFAAs in aquatic environments. Thus, despite the phase-out of PFOS and PFOA, they are still detected at high levels worldwide, illustrating that contamination of PFASs is poorly reversible and underpins the need to restrict also other PFASs to avoid similar problems in the future. Furthermore, the presence of precursors, such as side-chain fluorinated polymers, will remain a long-lasting source of PFAAs in the environment even after a phase-out of production.

The ban of PFOS and PFOA has resulted in a transition to other PFASs, such as shorter chain PFAAs and PFAEs. For example, HFPO-DA is widely detected in the European environment, whereas 6:2 Cl-PFESA is found in high levels in China, but currently not in Europe (Heydebreck et al., 2015; Joerss et al., 2019; Pan et al., 2018). Besides these most studied PFAEs, studies have clearly shown the presence of other, sometimes even more abundant PFAEs in the vicinity of fluorochemical industries (Song et al., 2018; Strynar et al., 2015; Sun et al., 2016).

However, little is known about the general environmental levels of these and other PFAEs. Furthermore, very little is known about the levels of polymeric PFASs in the environment, partly due to analytical limitations. However, both side-chain fluorinated polymers and fluoropolymer microparticles have been detected in the environment.

Shorter chain PFAAs often account for a major part of the total known PFAA content in water samples, including drinking water. In particular, the ultra-short (C1-C3) PFAAs (including TFA), have been found at high levels and constitute a large part of the total PFAS content in aquatic matrices such as drinking water, WWTP effluents, waters close to point-sources, and precipitation (Aro et al., 2021; Björnsdotter et al., 2019; Chen et al., 2019; Freeling et al., 2020; Neuwald et al., 2022; Wang et al., 2020). In the light of the high persistence of these non-restricted compounds, their high mobility, low adsorption to organic carbon and the difficulty to remove them from water, the concentrations of these compounds will increase if emissions of these compounds and/or their precursors to the environment continue.

Studies on EOF/AOF in environmental samples and mass balance analysis show that varying but significant fractions of organofluorine are unknown and therefore not captured by monitoring using only targeted PFAS analysis (Table B.82. and Table B.83. in the appendix of Annex B). There are indications that higher trophic levels display a lower fraction of unknown organofluorine, possibly due to metabolism of precursors into the stable PFAAs which are often included in the targeted analyses. Studies of abiotic and biotic samples utilizing TOPA demonstrate that considerable fractions of PFASs in the samples may be comprised of unknown oxidizable PFASs that are not detected in routine target analyses, including precursors to the rarely analyzed C2-C3 PFCAs (Gockener et al., 2022; Joerss et al., 2020; Simonnet-Laprade et al., 2019). Thus, environmental samples commonly contain PFASs with unknown identity and regulatory status and the total PFAS mass balances may be underestimated without treatment with TOPA. Similarly, non-target and suspect screening methods, applied to identify compounds constituting the unknown organofluorine fraction, have (tentatively) identified hundreds of different PFASs in various environmental samples (Liu et al., 2019). These substances would go undetected if only targeted analyses with available reference standards were performed. However, the suspect and non-target screening can only provide qualitative and semi-quantitative data of substances, and not quantitative, giving limited value to mass balance calculations. Although this information clearly demonstrates that targeted analyses of individual PFASs do not provide the full picture of PFAS contamination, the vast majority of studies have applied such methods. While most of these studies have analysed a limited number of compounds, limited data are available on the occurrence and/or concentration of other PFASs, such as PFAEs and C1-C3 PFAAs.

Whereas time trends of PFOA and PFOS are decreasing in humans, the trends in biota are inconsistent (Land et al., 2018). Regarding time trends in aquatic environments, the levels of PFOS and PFOA seem to be decreasing in European and North American coastal, sea and river waters (Land et al., 2018; Muir and Miaz, 2021). However, it has to be noted that phased-out PFASs that may show declining trends locally are not disappearing on a global scale due to their potential for long-range transport and persistence in various compartments. For most PFASs, including PFAEs and shorter chain PFAAs, there is limited or no temporal trend data. The clearest increasing time trend is observed for the fluorinated gases that have replaced CFC after the implementation of the Montreal Protocol (AGAGE, 2022; NILU, 2021). A simultaneous increase of TFA in air, precipitation and plants is likely a result of the increase of TFA-yielding gases (Freeling et al., 2020; Freeling et al., 2022; Zhai et al., 2015). In addition, analyses of ice/firn cores show increasing atmospheric deposition of TFA, PFPrA and PFBA over time (Kirchgeorg et al., 2013; Pickard et al., 2020).

1.1.5.3. Human exposure assessment

The ubiquitous presence of PFASs in environmental media and widespread use in many types of consumer products lead to an array of potential exposure sources (see Annexes B.9.21. and B.9.22.). For the general population (i.e. individuals who are not occupationally exposed or living in contaminated hot spots), exposure routes include ingestion of food and water, intake of indoor dust, inhalation of air and contact with consumer products (De Silva et al., 2021; Haug et al., 2011; Poothong et al., 2020; Vestergren et al., 2012; Vestergren and Cousins, 2009). The dominating exposure route varies greatly for different PFAAs, reflecting their physico-chemical properties and use patterns. For hydrophobic and bioaccumulative long-chain PFAAs, dietary intake (especially of fish and meat) is typically the most important exposure route, whereas for highly water soluble short-chain PFAAs, drinking water and other food categories, such as vegetables, tend to be the dominating exposure routes (EFSA, 2020; Vestergren et al., 2012). For precursor compounds, exposure to consumer products (e.g. impregnation products) via the indoor environment is probably the major exposure route (Vestergren et al., 2008). For occupationally exposed individuals, who often may have a higher exposure, the primary routes to PFAA exposure are inhalation, ingestion of dust and dermal uptake at the workplace (De Silva et al., 2021; Fu et al., 2015). Regarding other non-polymeric PFASs, such as PFAEs, the relative contribution from different exposure routes in the general population has not been described.

The bioavailability and thus the potential for human exposure to fluoropolymers has been an issue for discussion. In summary, it has been proposed that absorption of fluoropolymers in humans is obstructed due to their large sizes (Henry et al., 2018). On the contrary, it has been argued that the production, processing, use, and end-of-life treatment of fluoropolymers lead to emissions of bioavailable compounds (e.g. monomers, oligomers, decomposition and combustion products, PFAA/PFEA polymerisation aids, additives, unintentional PFAS by-products, impurities, and particles), which may be relevant for human exposure (Lohmann et al., 2020). Toxicokinetics of oligomeric/polymeric PFASs are further described in Annex B.5.1.2. Regarding side-chain fluorinated polymers, potential degradation to more bioavailable PFASs may add to the exposure to these compounds in humans.

Human biomonitoring studies of known PFASs unambiguously demonstrate world-wide exposure to a wide range of PFASs, with especially high exposure levels in populations living in areas close to PFAS point sources as well as in occupationally exposed individuals. In the general European population, PFOS, PFOA, PFHxS and PFNA are the most studied and most abundant PFAAs. Furthermore, exposure of a considerable part of the European population exceeds the tolerable weekly intake derived by EFSA (2020) for these PFASs. The high levels of PFASs that have been phased out demonstrate that the historic exposure takes a long time to reverse. In addition, it is evident that the European population is also exposed to PFAAs that are not covered by current or proposed restrictions.

In the US and China, several PFAEs have been detected in blood from populations living close to fluorochemical manufacturing facilities. In addition, 6:2 Cl-PFESA is generally the third most abundant PFAS in blood of the Chinese population. These studies indicate that a potential increased use of PFAEs as substitutes for legacy PFASs could lead to increased human exposure also in Europe. However, blood levels of the most studied PFAEs (ADONA, HFPO-DA, 6:2 Cl-PFESA) are currently low in the general European population.

In addition to known PFASs analysed by targeted analysis, humans are exposed to a considerable amount of organofluorine compounds for which the identity and consequently the regulatory status and health effects are unknown. Fluorine mass balance analyses of human blood show substantial variation (0-97%) in the proportion of unknown organofluorine to the total concentration of organofluorine reported in different studies, demonstrating that human exposure is likely underestimated when only taking known PFASs into consideration, and emphasise the need for a universal PFASs restriction to protect human health.

1.1.6. Risk characterisation

The PFASs in the scope of this restriction proposal exceed the vP criteria of Annex XIII of REACH, either themselves or when degrading to arrowhead PFASs. The half-lives of the most stable PFASs (e.g. PFAAs) are known to be in the order of decades to centuries, thus exceeding by far the vP criteria, which vary from 40 to 180 days depending on the matrix. Due to the high diversity of the PFASs the bioaccumulation potential and ecotoxicity/toxicity are expected to vary among the substances. Therefore, no overall conclusion on B/vB and T criteria was derived for each PFAS substance/(sub-)group (see also sections 1.1.4.6 and 1.1.4.7). 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 is very similar to those of the PBT/vPvB substances. Therefore, the case-by-case approach is investigated below.

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

The procedures in Sections 1 to 6 in REACH Annex I are impracticable to describe the particular effect of PFASs in the scope of this restriction proposal, as these PFASs are very persistent (vP) in combination with identified and possible other concerns. Therefore, the risk is described on a case-by-case basis.

As summarised in section 1.1.4 on the properties of concern, PFASs have a high potential for ubiquitous and increasing exposure of the environment. This can lead to irreversible damage to the environment and humans. With current use patterns, and considering the expected market growth of several sectors using PFASs, the environmental pollution burden (i.e. the environmental pollution stock, which is the mass or concentration of PFASs at the local, regional, continental and global scale) can be expected to continue to increase over time. PFASs or their degradation products have half-lives of many years. Thus, a constant emission path will result in a growing stock in the environment. The stock path over time depends on (i) PFAS emissions during the production, use, and end-of-life (waste) phase, (ii) persistence, physico-chemical and fate properties (e.g. water solubility, volatility, mobility), and (iii) environmental conditions.

Considering the growing environmental PFAS stock in combination with a difficulty for decontaminating soil or intake water used for drinking water production at large scales, as well as the low effectiveness of end-of-pipe wastewater treatment, this triggers a high potential for very long-term human exposure via food and drinking water. These properties together, in addition with long-term transfer mechanisms, lead to a high potential for intergenerational 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, quantification of future exposure levels and safe concentration levels is highly uncertain for PFASs, due to the exposure to mixtures 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. Combined effects may be expected for PFASs. The significant global warming potential of many volatile PFASs adds yet another concern to the picture.

Because of the very high persistence of PFASs, their mobility and long-range transport potential, concerns have been expressed about whether their releases into the environment might ultimately reach or have arguably already reached 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. In consequence, the release, if discovered too late, can have a disruptive and irreversible effect on ecosystem functioning and on a vital earth system as a whole (Cousins et al., 2022). Any effects of such a pollutant cannot be readily reversed (Diamond et al., 2015; Persson et al., 2013). At the time when notable effects from PFASs 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 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 (in particular provisioning services and regulating services).

Continued emissions of PFASs (including from the end-of-life phase of products) will result in an increasing environmental stock and, hence, increasing exposures. This creates a high likelihood that known thresholds of PFASs to cause adverse effects – as well as yet unknown thresholds - are exceeded. These would be caused by single PFASs and/or in a mixture with other PFASs. It should be noted that for the most sensitive endpoints related to human health, 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).

Overall, PFASs should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances. Their releases can be accordingly used as a proxy for risk. To minimise the likelihood of adverse effects in the future, all releases should be minimised.

Section 1.1.5 summarises the information on the current releases of PFASs 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, PFASs in firefighting foams), however most of the PFASs still need to be addressed by regulatory risk management. Monitoring data for some PFASs show that PFASs are ubiquitously distributed in the environment (see Annex B.4.2.). 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 an incomplete picture of the overall exposures to PFASs (see Annexes B.4.2.6. and B.4.2.7.).

In conclusion, the ongoing releases of PFASs are causing the environmental pollution stock and subsequent exposures to increase over time. Combined with the non-threshold nature of the hazard, this warrants an urgent need for minimisation of the releases. The proposed restriction aims to effectively stop or considerably reduce environmental PFAS pollution, which could otherwise lead to very long-lasting and potentially irreversible damage.

It is noted that RAC supported the proposal to restrict intentionally added microplastics and PFHxA based on a closely similar case-by-case hazard and risk assessment approach (ECHA, 2020b; ECHA, 2021a). 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 PFAS is not very persistent itself and does not degrade into a very persistent PFAS. This is also addressed in section 1.1.1.

Emissions as a proxy for risk

Without restriction of the manufacture, placing on the market and use of PFASs, emissions of these substances will continue. As a result, due to the persistence of PFASs, the environmental stock will continue to grow both in the EU and globally. This leads to a growing risk of negative environmental and health impacts and, thus, damages over time. A restriction will reduce emissions. This will lead to a reduction of the pollution stock in the environment, though it comes with a delay depending on the persistence of PFASs. For PFASs which do not degrade at all, or where degradation is very limited, a restriction can at least prevent the stock from increasing further.

In case of very persistent substances, the relevant unit for a concern-based evaluation of restriction measures' risk reduction potential is the environmental stock (Conrad and Olson, 1992; Gabbert et al., 2022; Hart and Brady, 2002; Mackay et al., 2014). Stock assessments have been used earlier for evaluating the effectiveness of restriction measures for persistent chemicals in general, and for PFASs in particular, for example in the REACH Annex XV dossier on PFHxS (ECHA, 2020a). Assessing the stock requires information about physico-chemical and fate properties of PFASs, and about their persistence under environmental conditions. For a large number of chemicals covered by the restriction proposal this information is still incomplete. Furthermore, existing information is often uncertain. Therefore, emissions will be used as a proxy for risk. To evaluate the effectiveness of restriction options, and the corresponding expected emission reduction, emissions will be used as a proxy for the risk reduction capacity of the specific restriction options. While emission estimates inform about the pollution flow into the environment, they do not reflect the accumulation of pollution over time due to persistence. It is therefore important to note that a use of emission estimates as a proxy for risk will likely underestimate impacts to be expected, and in particular long-term impacts and damage costs.

1.2. Justification for an EU-wide restriction measure

Section 1.1 illustrates the hazards and combined concerns associated with PFASs. In section 1.1.5 an overview of the current releases and exposures due to the ubiquitous use of PFASs is 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. Based on this unacceptable risk for human health and/or the environment identified for the group of PFASs, measures are needed to minimize the releases to the environment and reduce human exposure to a minimum.

PFASs are manufactured globally. The global PFAS tonnage manufactured is not entirely clear. It is estimated that in between ca. 120 000 and 400 000 t/a of PFASs are manufactured in the EEA (see Annex A.2.). Due to their properties, perfluorinated substances are used for manufacturing of articles and mixtures in large quantities and for a large variety of applications in the EU/EEA. While in some sectors and uses PFASs have been increasingly replaced by fluorine-free alternatives, in some cases substitution is not happening even though PFAS-free alternatives are available (see Annex E.2.). Additionally, numerous sources indicate that globally fluoropolymer production will increase significantly in the next years. A large variety of emission sources contribute to the exposure of humans and the environment to PFASs (see Annex B.9.) 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).

Based on the information presented in section 1.1.4.2, 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 as well as technical stock (stock of PFASs in existing articles) and PFAS-containing waste would continue to be a source of exposure for generations. For technical stock, the size and longevity are determined by the length of the lifespan of the various articles, some of which (e.g. in construction products) can be used for decades. In combination this leads to irreversible adverse effects on the environment and on human health over time (see Annexes B.4., B.5. and B.7.). Removal of contamination is technically challenging, energy intensive, and thus costly. Additionally, costs of health care, loss of biodiversity, loss of ecosystem services and loss of property value (Cousins et al., 2020b) need to be taken into account. Therefore, a preventive approach of not using highly persistent synthetic organic substances is more protective and also overall less costly for society.

Monitoring studies demonstrate the ubiquitous presence of perfluorinated substances of both, known (e.g. PFOA, PFOS, PFHxS and other long chain perfluorinated substances (C9-C14 PFCAs and PFSAs)) and varying fractions of unknown organofluorine substances in all environmental media including ground water and drinking water (see Annexes B.4.2.6. and B.4.2.7.). Widespread occurrence of the very persistent substances in the environment, e.g. via aqueous compartments or via the atmosphere, potentially lead to global distribution (see Annex B.4.2.8.). Additionally, soil can serve as long-term reservoir for PFASs and potentially be a long-term source of contamination for groundwater (see Annex B.4.2.3.). Thus, effects will not only occur at the point of release but also at some distance from that point. Therefore, it may affect a very large number of people. Human biomonitoring demonstrates that the EU/EEA population is exposed to various PFASs (see Annex B.9.22.).

Furthermore, exposure via food and drinking water leads to elevated concentrations of various PFASs in human blood (see Annexes B.9.21.1. and B.9.21.2.). Consumer articles are a source of PFASs for human exposure both directly at use and indirectly via the indoor environment (e.g. house dust and air, see Annexes B.9.6. and B.9.21.4.). Relevant articles such as food contact materials or textiles are placed on the market and used in all EU/EEA Member States. A considerable share of articles containing PFASs is imported from outside the EU/EEA (see Annex A.2.2.). Exposure of perfluorinated substances to humans, wildlife and the environment occurs in all EU/EEA Member States. A Union-wide restriction is needed as the mobility and persistence of PFASs lead to cross-border pollution that cannot be adequately managed by several national regulatory actions.

An EU/EEA wide restriction will prevent and reduce the manufacture, placing on the market (including imports), use and release of PFASs within the EU/EEA in a harmonised manner. PFASs and articles containing PFASs produced in one Member State may be transported to and used in other Member States. Even if 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, and transition periods). This has implications not only for the degree to which the environment and human health is protected, but also in terms of ensuring the functioning of the internal market. Union-wide action avoids trade and competition distortions within the EU/EEA, thereby ensuring a level playing field in the internal EU/EEA market as compared to action undertaken by individual Member States. Additionally, the emitted substances are transported across global borders via air and water. Hence, EU-wide measures for risk reduction are the only way to implement controls efficiently and uniformly within the EU/EEA. An EU/EEA restriction also allows an adequate regulation of imported articles containing these substances. Moreover, a restriction within the EU/EEA may be the first step for global action, which is needed as PFASs and PFAS-containing products are manufactured and distributed in a global market.

1.3. Baseline

1.3.1. Manufacture and use – Introduction and current situation

Due to their typical properties like chemical inertness, radiation resistance, temperature resistance, weathering resistance, oil-, water- and stain repellence, electrical inertness, corrosion protection, low coefficient of friction and non-flammability, PFASs are used in many industry sectors, in a very broad range of applications. From literature, two stakeholder consultations (call for evidence and 2nd stakeholder consultation) and additional stakeholder input, e.g. from targeted stakeholder interviews, the various uses and sub-uses of PFASs were identified and data on the types of PFASs applied, the tonnages associated with the use of PFASs and their emissions were assessed in detail for all major uses/use sectors. Table 2 presents an overview of these major uses/use sectors (and sub-uses within). Table 3 presents the estimated tonnages for these sectors for 2020, supplemented with the 2020 estimated tonnages for PFAS manufacture (see Annex A for detailed information on manufacture and use). These tonnages were used as basis for estimation of the PFAS manufacture, PFAS use and service life emissions in 2020 (see section 1.1.5.1 for details and Table 1 therein). The estimated tonnages and emissions form the basis for the impact assessment. For impact assessment purposes, tonnages are not only presented for total PFASs per sector but, where possible, also for three main PFAS groups therein, i.e.:

1. PFAAs and PFAA precursors
2. Fluorinated gases
3. Polymeric PFASs

While side-chain fluorinated polymers chemically belong to polymeric PFASs, i.e. Group 3, their tonnages are allocated to PFAAs and PFAA precursors, i.e. Group 1, for impact assessment purposes.

It is also important to note that information density varied substantially across sectors and uses and therefore not every single application has been assessed in detail regarding the aspects described above. However, *all* applications are covered by the scope of the restriction proposal because PFASs used eventually end up in the environment due to releases resulting from PFAS manufacture, use, service life or due to waste handling operations.

Table 2. PFAS main applications and sub-uses.

Main applications	**Sub-uses (non-exhaustive) of thoroughly investigated PFAS main applications**								
Firefighting foam	Covered by separate restriction proposal								
TULAC (Textile, upholstery, leather, apparel and carpets)	Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather				
Food contact materials and packaging	Consumer cookware	Industrial food and feed production, e.g. in valves and conveyor belts, and for non-stick coatings	Food and feed packaging, including paper & board packaging and plastic packaging						
Metal plating and manufacture of metal products	Hard chrome plating	Decorative plating with chrome, plating on plastics and plating with metals other than chrome	Manufacture of metal products						
Consumer mixtures	Cleaning agents	Waxes and polishes	Dishwashing products	Windscreen treatments and windscreen wiper fluids	Mixtures used for musical instruments				
Cosmetics	Skin care	Toiletries	Hair care	Perfumes and fragrances	Decorative cosmetics				
Ski wax	Kick wax	Glide wax	Ski skin treatment						
Applications of fluorinated gases	Refrigeration	Air conditioning and heat pumps	Foam blowing agents	Solvents	Propellants	Magnesium casting	Fire suppressants	Preservation of cultural paper-based materials	

Main applications	**Sub-uses (non-exhaustive) of thoroughly investigated PFAS main applications**								
Medical devices	Implantable medical devices	Wound treatment products	Tubes and catheters	Metered Dose Inhalers (MDIs), e.g. as coating and propellant	Cleaning and heat transfer: engineered fluids	Sterilization gases	Diagnostic laboratory testing	Rigid gas permeable (RGP) contact lenses and ophthalmic lenses	Packaging of medical devices
Transport	Body-, hull- and fuselage construction	Sealing applications	Combustion engine systems	Electrical engineering and information technology	Safety equipment (incl. fire prevention and protection)	Hydraulic fluids	HVACR*-systems	Coating and finishings	
Electronics and semiconductors	Wires and cables	Coating, solvents and cleaning	Electronic components	Heat transfer fluids	Advanced semiconductor packaging	Photolithography			
Energy sector	Photovoltaic cells	Wind energy	Coal based power plant	Nuclear power plant	Proton exchange membrane (PEM) fuel cells	Electrolysis technologies (not PEM)	(Lithium-ion) batteries		
Construction products	Roofing	Bridge bearings	Sealings and adhesives	Processing aids and polymer processing aids	Coatings, paints, varnishes and impregnation	Coatings for wind turbine blades and solar cells			
Lubricants	Low viscosity lubricants	Solid/dry-film lubrication	Release-agents	Greases					
Petroleum and mining	Drilling fluids	Well stimulation chemicals	Anti-foaming agents	Water and gas tracers	Metal salts recovery	Lining of piping, seals, sensors, cables, etc.			

Table 3. Estimated annual tonnages for PFAS manufacture and major PFAS use sectors for 2020 (low, mid and high estimates)[a]. Tonnages are for PFAS used or placed on the market (as substance on their own, in mixtures or articles), unless stated otherwise. Mid points are used in impact assessment.

Application	**PFAAs and PFAA precursors (tonnes/year)**			**Fluorinated gases (tonnes/year)**			**Polymeric PFASs (tonnes/year)**			**Total PFASs (tonnes/year)**		
	low	**mid**	**high**	**Low**	**mid**	**high**	**low**	**mid**	**high**	**low**	**mid**	**high**
Manufacture	53 902	85 977	118 051	15 000	95 774	176 548	49 000	75 381	101 763	**117 902**	**257 132**	**396 362**
TULAC[b]	8 092	20 620	33 148				33 091	71 318	109 544	**41 183**	**91 938**	**142 692**
Food contact materials and packaging	3 267	6 305	9 342				15 330	17 880	20 430	**18 597**	**24 185**	**29 772**
Metal plating and manufacture of metal products	2	30	57				960	960	960	**962**	**990**	**1 017**
Consumer mixtures										**21**	**26**	**30**
Cosmetics										**0.028**	**32.1**	**64.2**
Ski wax										**1.6**	**1.6**	**1.6**
Applications of fluorinated gases[c,d]				*493 173* 30 671	*493 173* 30 671	*493 173* 30 671				***493 173*** **30 671**	***493 173*** **30 671**	***493 173*** **30 671**
Medical devices	1 279	2 387	3 495	20 160	33 080	46 000	3 233	7 633	12 032	**24 672**	**43 100**	**61 527**
Transport[c]							*97 216* 6 410	*159 712* 10 532	*222 208* 14 653	***97 216*** **6 410**	***159 712*** **0 532**	***222 208*** **14 653**
Electronics and semiconductors	841	1 195	1 549	140	140	140	1 560	3 088	4 615	**2 541**	**4 423**	**6 304**
Energy sector	293	294	294				2 592	2 756	2 920	**2 885**	**3 050**	**3 214**
Construction products	987	1 696	2 405				4 254	7 287	10 320	**5 241**	**8 983**	**12 725**
Lubricants	1	6	10	70	110	150	1 100	1 550	2 000	**1 171**	**1 666**	**2 160**
Petroleum and mining	4.4	7	9.5				3 500	5 500	7 500	**3 504**	**5 507**	**7 510**
TOTAL (excl. manufacture)[e]	**14 766**	**32 540**	**50 310**	**513 543**	**526 503**	**539 463**	**162 836**	**277 684**	**392 529**	**691 168**	**836 787**	**982 398**
Total[f]	14 766	32 540	50 310	51 041	64 001	76 961	72 030	128 504	184 974	137 860	225 105	312 341

a) In some cases a basis for providing a range is lacking. There the available estimate is applied throughout; b) TULAC = Textile, upholstery, leather, apparel and carpets; c) For these sectors the tonnages relate to "technical stock volume" (presented in italics), representing an estimated 2020 PFAS volume in use in the sector as a whole. For reference only, the tonnages brought new to market in 2020 are also given; d) Includes tonnages for fluorinated gases in transport sector; e) Total based on best available data (stock if available, new to market if stock is not available); f) For reference only, also the total new manufactured tonnage put on market in 2020 is presented.

For a quick overview of the various sector contributions to the tonnages and emissions of total PFASs, see Table 4.

Table 4. Tonnages and emissions of major use sectors and manufacture for 2020 (sorted on tonnage range)

Application	**Tonnage range**	**Emission range % emitted in manufacturing and use phase**	**Emission contribution Contribution to total emission**
Applications of fluorinated gases	5	2	5
TULAC	5	2	4
Medical devices	5	2	3
Manufacture	5	1	2
Food contact materials and packaging	5	1	1
Transport	5	1	1
Construction products	4	3	2
Electronics and semiconductors	4	2	1
Lubricants	4	2	1
Petroleum and mining	4	1	1
Energy sector	4	1	1
Metal plating and manufacture of metal products	3	1	1
Cosmetics	2	5	1
Consumer mixtures	2	4	1
Ski wax	1	3	1

Table legend

Tonnage range (tonnes/year)		Emission range (%)		Emission contribution (%)	
1	0 – 10	1	0 – 5	1	0 – 1
2	10 – 100	2	5 – 25	2	1 – 5
3	100 – 1 000	3	25 – 75	3	5 – 10
4	1 000 – 10 000	4	75 – 95	4	10 – 50
5	> 10 000	5	> 95	5	> 0 – 50

1.3.2. Manufacture and use – Market developments

The baseline scenario is the situation in absence of the proposed restriction. This is not equal to the current situation as new legislation may affect the uses being proposed for restriction during the timeframe considered for analysis or annual use volumes might change (in comparison to the volumes for 2020 shown in Table 3) due to growth trends in manufacturing, PFAS use and import of PFASs. In this baseline chapter, the market growth rates as assumed for the baseline are summarised. The start year of the assessment is 2020, for which volume data is available to the Dossier Submitters. In Annex E, the baseline tonnage and emission estimates are projected for a time path of 30 years (2025-2055) and 45 years (2025-2070) for each assessed sector. These estimates are used in the Environmental Impact Assessment.

PFAS use volumes may not only grow due to market growth in existing markets but also due to development of new markets for which PFASs can be used. Identified potential markets, with a potentially strong growth potential, are the immersion cooling of datacentres, the cooling of electric cars, including the battery, during charging as well as oil fracking.

<u>PFAS manufacturing</u>

The baseline of manufacturing does not necessarily follow the combined baseline of uses as PFAS applications (e.g. cars and textiles) are of global relevance, with production also taking place in other parts of the world. As such, PFAS manufacture in the EU and EEA is not only dependent on downstream market developments in the EU and EEA but also other parts of the world.

As mentioned in Annex E.2.1.1., there is an expectation of market growth in the absence of regulatory action for all PFASs. While no specific data is available for PFAAs and PFAA precursors, there is an expectation of a global growth in demand from downstream uses related to the textile industry, which constitutes one of the most extensive users of non-polymeric PFASs. In the absence of other information, a steady growth of 2% per year is used by the Dossier Submitters. In relation to fluorinated gases, an annual decline of production of HFCs by 10% has been considered by the Dossier Submitters based on evidence pointing to a decline in the EU-28 production of HFCs due to the regulatory phase-down of HFCs and no known production of HFOs - the alternative to HFCs. For polymeric PFASs, the Dossier Submitters use a yearly growth rate of 5%.

TULAC

The use of PFASs in TULAC is expected to increase. This is primarily driven by growth in the use of polymeric PFASs. Under the baseline scenario, it is assumed that usage of several PFAS groups (i.e. non-polymeric C2-C3 substances, C6 substances and other non-polymeric substances) in all TULAC uses grows at a standard steady 2% rate per year over the assessment period. The use of non-polymeric C4 substances in technical textiles is also assumed to increase by 2% per year, while the use of these substances in home textiles and consumer apparel is expected to be broadly static based on information from the call for evidence (CfE). Stakeholder interviews pointed to more demand in home textiles than consumer apparel, as a result of which the market growth in the baseline assumes an annual increase of 1% for home textiles and an annual decline of 1% for consumer apparel. The same trend is assumed for non-polymeric C5 substances. Non-polymeric C9-C14 substances will be restricted (under Regulation (EU) 2021/1297), so their use is expected to cease. The fluoropolymer market is expected to grow very strongly in the short to medium term (with assumed growth rates for different applications and periods ranging from 5% to 8%), but such strong growth is deemed unsustainable in the long term (with lower growth rates ranging between 1% and 2% being assumed after 2030). The use of side-chain fluorinated polymers is assumed to be static in the relation to consumer apparel due to growing awareness about its relevance as a source of emission of non-polymeric PFASs, while a steady growth rate of 2% is assumed for other textile applications.

Food contact materials and packaging

For assessing the time path of PFAS use (tonnage) and emissions in food contact materials and packaging a mean real growth rate of 4% per year was assumed. This growth rate was derived from information about market growth rates in the following three specific sub-sectors (FoodDrinkEurope, 2019):

Packaging: Paper and board use in packaging has been relatively steady in the EU since 2015 (CEPI, 2020). In 2015, 38.95 million tonnes of paper were consumed in the EU by packaging, whilst in 2019, this figure had risen to 41.35 million tonnes, representing an annual growth rate of 1.5% per year. However, the single-use plastics directive could lead to much more moulded fibre being used, a PFAS impregnated technology.

Plastic packaging use is expected to grow strongly. Although PFASs have no function in the final product, for thermoplastic packaging extrusion PFASs are used as processing aid.

Consumer cookware: The global non-stick cookware market is estimated to be growing strongly at annual rates of around 6% (Grand View Research, 2021; IndustryARC, 2020).

Industrial food and feed production equipment: In the industrial bakeware (food and pharmaceutical operations) segment the assumption is that a growth of 1.5% is expected.

Metal plating and manufacture of metal products

Information about growth rates is not available. Therefore, in metal plating a 0% growth rate per year is assumed.

Consumer mixtures

For consumer mixtures, information about market growth rates could not be retrieved. No further information on historic tonnages and future (expected) tonnages is available.

Cosmetics

At European scale, a stable market is foreseen. This prediction is based on historic trends where there was no growth in market value in real terms in a three-year period ending in 2019. As such, a growth rate of 0% is assumed.

Ski wax

For PFAS use in ski wax a market decline of 8% per year until 2030 and of 1% per year until 2040 is foreseen as there are already voluntary initiatives to reduce the use of PFAS-containing waxes. After 2040, the market of ski waxes is assumed not to decline any further.

Applications of fluorinated gases

Information for different applications, generally suggests market growth. For commercial refrigeration, a yearly growth rate of 3% is, for example, assumed. The EU market for air conditioning has also seen strong growth over the last 25 years, originally in the commercial sectors, but such growth is now also taking place in the domestic sector. Over the next 30 years, demand in both sectors is expected to roughly double (IEA, 2018). Market data for fire suppressing agents suggests a strong growth over the period 2018 to 2025 at a compound annual growth rate of 5.9% (Research and Markets, 2019). Projecting market growth at sector level is not possible with sufficient reliability. However, taking available information about market growth in different sub-sectors into account, a yearly real growth rate of 2% is assumed.

Medical devices

For the use of fluorinated gases as anaesthetics and contrast media an annual growth of 3 - 9% is foreseen based on commercial reports. The use of prescribed PFAS-pharmaceuticals in the EU in 2019 is estimated by the Dossier Submitters to increase with 3.4% per year. Even though these examples are not medical devices, the Dossier Submitter assumes that they are reasonable proxies for the growth of PFAS use in medical devices. Furthermore, positive growth rates are expected for fluoropolymer invasive use as well as medical packaging (mainly fluoropolymers). For other PFAS applications in this sector there is no reliable information about market trends. Taking available information about market growth in different sub-sectors into account, and the ageing population in Europe, a yearly real mean growth rate of 5 % is assumed for the sector[6].

Transport

For assessing the time path of PFAS use (tonnage) and emissions in the transport sector a mean real growth rate of 1% per year is assumed. Though information about market trends is neither available at sector level, nor for specific PFAS uses within this sector, it seems likely that the market will further expand in the future.

Electronics and semiconductors

For PFAS use in electronics a growth rate of 10% per year is assumed as the general electronics industry (including semiconductors) experiences growth. As new technology emerges, and the world becomes more digitalized a higher demand for electronics and semiconductors is likely. The growth may mainly be driven by semiconductors, where microchip production will be a significant factor.

Energy sector

For PFAS uses in the energy sector, an annual growth rate of 10% is assumed. Overall, no robust information is available, but growth in use of PFASs is expected because of their increasing application in electronics, fuel cells and hydrogen technology, rechargeable batteries, and electroactive (ferro-, pyro-, and piezoelectric) devices. In general it can be concluded that for at least some of the uses (e.g. fuel cells, lithium-ion batteries and photovoltaic cells) a significant growth of PFAS use in this sector is expected because of the European Green Deal ambitions. JRC estimate that the EU production of lithium-ion batteries will increase strongly until 2030. Additionally, an increase in the use of PFASs to be used in PEM electrolysis technology (proton exchange membrane – a fuel cell) is foreseen to accomplish the 2030 EU hydrogen Strategy goal of 40 GW electrolysis capacity within the EU.

Construction products

For the baseline scenario of PFAS use and emissions in the construction sector a declining growth rate is assumed. For fluoropolymers a yearly real growth rate of 5% is applied from 2020 to 2030, which declines to 2.5% from 2030-2040, and to 1% for the remaining years of the assessment period assuming that the growth rate of 1% will also apply in the period from 2050 to 2070. For non-polymeric PFASs the market growth is 1% during the entire assessment period.

Lubricants

For PFAS-based lubricants an annual growth rate of 5% is assumed between 2020 and 2030, after which it is assumed to slow due to market saturation, increasing thereafter at 2.5% annually to 2040 and 1% annually after 2040. The same trends have been applied to PFAS-based solvents and additives in lieu of better data, and to PFAS–based solvents used as cleaning agents before lubrication. The future projections do not include any consideration of changes in usage (increase, decrease or replacement) as a result of changes in technology. Likewise, the projections do not consider changes in abatement technology which may affect emissions.

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[6] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Ageing_Europe_-_statistics_on_population_developments, date of access: 2023-01-05.

Petroleum and mining

Precise growth rates for PFAS use in petroleum and mining are not known. According to a recent report NEA (2021), PFAS use in petroleum and mining can be expected to decline significantly in the coming decades. Furthermore, the oil and gas infrastructure is expected to become increasingly decommissioned, with over 200 platforms to be partially or fully removed, and over 2,500 wells to be decommissioned in the North Sea before 2030. However, input from manufacturers and suppliers has indicated that the demand for PFAS-based tracer and anti-foaming agents is expected to increase in future years, as the industry is likely to explore more ‘challenging’ environments for oil and gas production. In the absence of more detailed information or estimates from industry, an annual growth rate of 1% has been assumed for the three product categories (PFAS-based tracers, antifoaming agents, solid fluoropolymers).

2. Impact assessment

2.1. Introduction

The impact assessment in this restriction proposal is prepared to demonstrate whether the restriction is the most appropriate Risk Management option (RMO) to control the risks; and to identify which of the restriction options (ROs) is the best option.

Impacts comprise both positive (benefits) and negative impacts (costs) of different ROs in comparison to the baseline scenario. Benefits of restriction options comprise benefits for the environment, and for human health. Environmental benefits are expressed as the expected total amount of emissions avoided for a defined time period (30 and 45 years). Benefits to human health are evaluated qualitatively as data is limited, or missing, to assess (i) the hazard of many of the individual PFASs; (ii) the associated thresholds below which exposure is not expected to lead to adverse health effects, if such limits exist, and (iii) the prediction of future human exposure levels.

Costs of ROs comprise different components, for example costs to industry in the form of producer surplus losses resulting from business closures or substitution, whereby producer surplus losses resulting from business closures can in some sectors be offset by producer surplus gains of companies that are already supplying alternative-based products and can take over the market shares of companies ceasing operation. In sectors with a high share of business closures and limited offsetting potential, producer surplus losses might also be incurred by companies in the upstream supply chain. Further possible costs include consumer surplus losses as a result of changes to the product price, welfare losses and/or costs resulting from changes in the characteristics of goods, e.g. their quality and lifetime, welfare losses resulting from the absence of the product (where substitution is not feasible) as well as job losses. In most cases, these costs are assessed qualitatively due to insufficient data. In addition to the benefit and cost components mentioned above, restriction options can impact future remediation or decontamination costs associated with contaminated watersheds used as supply for drinking water production and contaminated soils.

2.2. Regulatory risk management options

In response to the identification of the risk related to the use of PFASs, the Dossier Submitters have conducted an analysis of various regulatory risk management options (RMOs) to identify the most appropriate option for addressing the identified risks, including various permutations of a REACH restriction[7]. As explained in section 1.1.2, the common concern (persistence) regarding PFASs should be addressed via a group approach to prevent regrettable substitution.

For information purposes, in section 2.2.1 a (non-exhaustive) overview of current relevant regulatory measures is given.

Additional different European regulatory measures are shortly discussed in section 2.2.2. It is concluded that measures in different EU legislation could be taken to manage risks and some of them could be considered as complementary to a REACH restriction. Many RMOs directly related to REACH processes are not considered manageable for the whole group of PFASs. This is the case for CLH, SVHC identification and authorisation. For particular (groups

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[7] https://echa.europa.eu/documents/10162/a59647fb-fcc5-869b-10d4-c14258bbea1d, date of access: 2023-01-05.

of) PFASs harmonised classification and labelling and authorisation could be taken into consideration as is current practice. A REACH restriction is considered the most effective tool to manage the risk from substances, such as PFASs, with a widespread use in industrial processes but also in products placed on the market for use by professionals and consumers.

Finally, in section 2.2.3 the use of PFASs as active substances in Plant Protection Products (PPP), Biocidal Products (BP) and Medicinal Products (MP) is discussed.

2.2.1. Overview of current regulatory measures

2.2.1.1. Stockholm Convention and POP Regulation

The Stockholm Convention is an international treaty aiming to eliminate or restrict the production and use of Persistent Organic Pollutants (POPs) in order to protect human health and the environment from those chemicals. POPs are considered chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in humans and wildlife, and have harmful impacts on human health or on the environment.

The Stockholm Convention (UNEP, 2018) is implemented in the EU via the POP Regulation (Regulation (EC) 2019/1021). PFOS and PFOA are restricted in the Stockholm Convention. PFOS has been identified as a POP and was included into Annex B (restrictions) of the Stockholm Convention. PFHxS and long chain PFCAs are in progress.

Even before the EU REACH Regulation came into force, an EU-wide ban on PFOS (perfluorooctane sulphonic acid, C8 PFSAs) was agreed (see EC Directive 2006/122), which was shortly afterwards incorporated into the EU POP Regulation in order to take over the corresponding regulation from the international Stockholm Convention (Regulation (EU) 757/2010). Therefore, the REACH restriction entry for PFOS was deleted (see EU Regulation 207/2011). The Stockholm convention for PFOS covers: "PFOS, salts and perfluorooctane sulfonyl fluoride". In the EU POP Regulation the definition of the scope is "Perfluorooctane sulfonic acid and its derivatives (PFOS) $C_8F_{17}SO_2X$ (X = OH, metal salt (O-M+), halide, amide, and other derivatives including polymers)". Therefore, also derivatives (related substances that can degrade to PFOS) are covered in both the POP convention and EU POP Regulation. In 2019, the PFOS ban under the Stockholm Convention was re-examined and all exemptions granted in the EU until then were deleted, except for the use of PFOS as a spray suppressant for non-decorative hard chrome plating (chromium VI) in closed loop systems.

2.2.1.2. REACH Regulation

Under REACH, PFOA, its salts and related substances (i.e. substances that can degrade to PFOA) are restricted with certain derogations within the EU as of 4 July 2020. In May 2019, PFOA, its salts and PFOA-related compounds were included into Annex A of the Stockholm Convention. Therefore, the inclusion of PFOA in the EU POP Regulation was also being prepared and also took place by inclusion into Annex I of the POP Regulation in April 2020[8]. This overrides the REACH restriction - and thus also the applications and deadlines regulated therein. The Annex XV entry for PFOA in REACH (entry 68) has recently been deleted (amended by Regulation (EU) 2020/2096 of 15 December 2020). It should be noted that the

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[8] Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council.

exemptions granted under the Stockholm Convention are not exactly the same as before under REACH.

Perfluorohexane sulfonic acid (PFHxS), its salts and related substances will be included in the Stockholm Convention in autumn 2022. A proposal for a restriction under REACH for this substance was prepared by Norway and has been through the scientific opinion making process at ECHA. This proposal is now awaiting decision making by the European Commission for uptake in the EU POP Regulation.

The following PFAS restrictions and SVHC dossiers have been handled under REACH so far.

Restriction:

2006 – PFOS ban (restriction moved to EU POP Regulation)

2019 –TDFAs in solvent-based spray applications (Annex XVII entry 73)

2020 – PFOA, salts and related substances ban (restriction moved to EU POP Regulation)

2021 – C9-C14 PFCAs (Annex XVII entry 68)

2021– PFHxS and related substances (proposal expected to be included in EU POP Regulation)

2022 – Aqueous firefighting foams (proposal in preparation)

2023 – PFHxA salts and related substances (proposal waiting for decision making)

SVHC identification:

2012 - C11-C14 PFCAs listed as very persistent and very bioaccumulative (vPvB)

2013 – C8 PFCA (PFOA + Salts) listed as persistent, bioaccumulative and toxic (PBT)

2015 – C9 PFCA (PFNA + Ammonium & Na salts) listed as PBT

2016 - C10 PFCA (PFDA + Ammonium & Na salts) listed as PBT

2017 - C6 PFSA (PFHxS + Salts) listed as vPvB

2019 - 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides listed as Persistent Mobile and Toxic (Equivalent Level of Concern(ELoC))

2020 – C4 PFSA (PFBS + Salts) listed as ELoC

2022 - Perfluoroheptanoic acid (PFHpA) + its salts listed as PBT, vPvB, ELoC

2.2.1.3. Montreal protocol

The Montreal Protocol on Substances that Deplete the Ozone Layer is a landmark multilateral environmental agreement implemented in the EU via Regulation (EC) No 1005/2009 on substances that deplete the ozone layer that regulates nearly 100 man-made chemicals referred to as ozone depleting substances (ODS). The protocol regulates production, import, export, placing on the market, use, recovery, recycling, reclamation and destruction of ODS. When released to the atmosphere, those chemicals damage the stratospheric ozone layer, earth’s protective shield that protects humans and the environment from harmful levels of ultraviolet (UV) radiation from the sun. Adopted on 15 September 1987, the protocol is to date the only UN treaty that has been ratified by every country on earth - all UN Member States.

The Montreal protocol predominantly covers CFCs and HCFCs ranging from C1-C3 as core, and being partly or fully halogenated. Hydrochlorofluorocarbons (HCFCs) are gases used worldwide in refrigeration, air-conditioning and foam applications, but they are being phased out under the Montreal Protocol. HCFCs are both ozone depleting substances and powerful greenhouse gases: The most commonly used HCFC is nearly 2 000 times more potent than carbon dioxide in terms of its global warming potential (GWP).

The quantitative limits and allocating of quotas for substances controlled under Regulation (EC) No 1005/2009 on substances that deplete the ozone layer are yearly updated by means of a decision which lists the amounts, the addressees and the quota per group of companies. The latest ones are Decision (EU) No 2019/2079 and (EU) No 2018/2029. A number of substances that are used as process agents are derogated from the restrictions. Substances such as chlorofluorocarbon 113 (CFC 113) and hydrochlorofluorocarbon 22 (HCFC 22), which are used as intermediates in the production of fluoropolymers, are not phased out. These substances are not covered by this restriction proposal either, since they are not fulfilling the PFAS definition.

A complete list of ozone depleting substances and the goods in which these may be present is provided in EC (2016). The CFCs, Halons or HCFCs, among other substances, all contain chlorine or bromine.

The Kigali amendment to the Montreal Protocol that regulates the consumption and production of HFCs due to climate effects is an international agreement to gradually reduce the consumption and production of HFCs. It is a legally binding agreement designed to create rights and obligations in international law.

HFCs were used to replace the substances banned in the Montreal protocol because they have zero impact on the ozone. However, HFCs are powerful greenhouse gases that contribute to climate change, so this Kigali amendment adds HFCs to the list of chemicals that countries promise to phase down.

As of October 15, 2021, 136 states and the European Union have ratified the Kigali Amendment.

2.2.1.4. Regulations of fluorinated gases

In addition to the regulation with respect to ODS, there is a specific regulation on fluorinated greenhouse gases ((EU) No 517/2014). Since the mid-1990s the ODS have been substituted by certain fluorinated greenhouse gases (F-gases), in particular hydrofluorocarbons (HFCs). Regulation (EU) No 517/2014 aims to reduce emissions (measured as CO_2 equivalents) from industry by 70 % in 2030 compared to those in 1990. This reduction is to be realised by three means:

1. Gradual phase-down of the quantities of HFCs used by means of quota (measured as CO_2 equivalents). The phase-down only applies to HFCs and not to perfluorocarbons (PFCs) or sulphur hexafluoride (SF_6).
2. Prohibitions on use and placement on the market, insofar as technically feasible and more climate friendly alternatives are available.
3. Continuation and expansion of the scope of regulations concerning leak tests, certification, disposal and labelling.

Annex I section I to the abovementioned regulation lists a number of HFCs, whereas section 2 lists a number of PFCs that may overlap with the current restriction proposal under development.

MAC Directive

The Mobile Air-Conditioning (MAC) Directive (EC, 2006) prohibits the use of F-gases with a GWP of more than 150 in new types of cars and vans introduced from 2011, and in all new cars and vans produced from 2017.

The traditionally used refrigerant in MAC systems, HFC-134a (CH2FCF3), has a GWP of 1 430 and has been phased out for use in air condition equipment in new cars in the EU. The Directive does not specify any particular refrigerant or system, leaving the technical choice on the car manufacturers.

The MAC Directive is limited to the use of fluorinated gases in air-conditioning systems in cars and vans, but not in buses, trains, ships etc. Air condition equipment is only one of several applications of fluorinated gases.

2.2.1.5. Examples of legislation outside the EU

USA

The PFAS Action Act of 2019 requires the U.S. EPA to establish destruction and disposal guidances for a range of materials, including landfill leachate, biosolids, and “solid, liquid, or gas waste streams” from facilities that manufacture or use PFASs. The legislation requires that over a five-year period EPA reviews all other PFASs and decides whether to list them under the Superfund program. The Superfund program is designed to investigate and clean-up sites contaminated with hazardous substances. During these five years, the bill will require comprehensive health testing of all PFASs. The bill includes a voluntary PFAS-free label for cookware, which may be expanded through amendments to include additional categories of consumer products. This label will empower consumers to take steps to protect themselves from exposure to PFASs. And the bill requires guidance for first responders to help them minimising their exposure to PFASs, important because PFASs are commonly found in firefighting foams.

On October 18, 2021 the PFAS Strategic Roadmap was announced: EPA's Commitments to Action 2021-2024 (EPA-US, 2021b). The roadmap sets timelines by which EPA plans to take specific actions and commits to bolder new policies to safeguard public health, protect the environment, and hold polluters accountable. The actions described in the PFAS Roadmap each represent important and meaningful steps to safeguard communities from PFAS contamination. Cumulatively, these actions will build upon one another and lead to more enduring and protective solutions.

With the National Defense Authorization Act, 2019, the Pentagon will be restricted from purchasing fluorinated fire-fighting foams (FFF) after 2022, and prohibited from using FFF after 2023. The list of proposed stand-alone PFAS legislation divides into four key elements. These elements include: (1) enhanced detection and research; (2) new regulatory mandates; (3) cleanup assistance; and (4) exposure to PFAS contamination at or near military installations.

Figure 6 documents publicly known PFAS pollution in public water systems and military bases, airports, industrial plants and dumps, and firefighter training sites in the US.

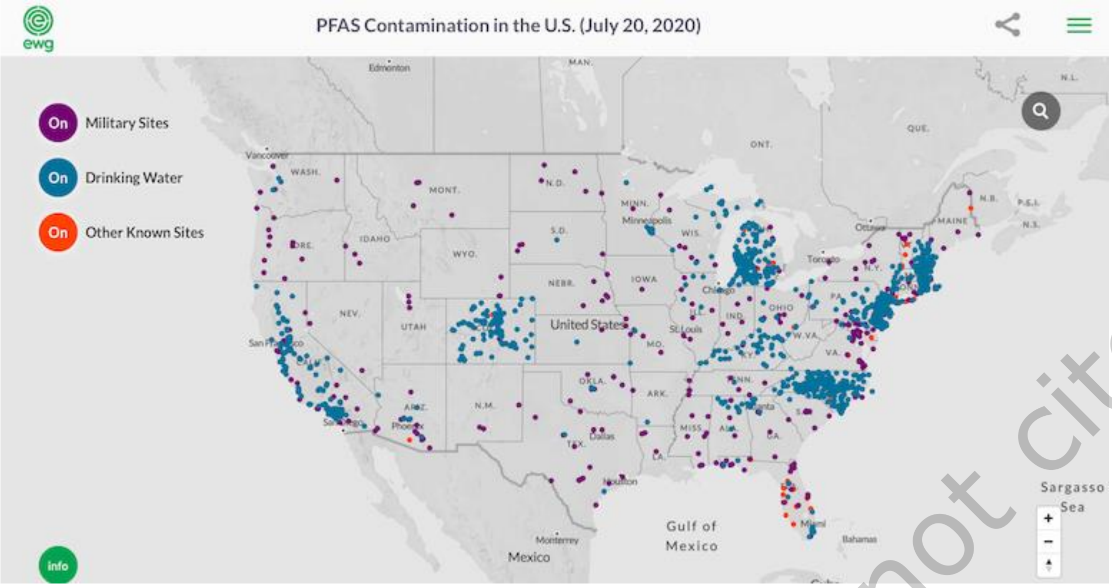

Figure 6. The latest update of an interactive map by EWG and the Social Science Environmental Health Research Institute, at Northeastern University.

It should be noted that many States of the U.S. have their own legislation and acts upon PFASs.

Canada

In Canada most uses for PFOS were prohibited in 2016 aside from exemptions for specific uses. In 2012, the Federal Government concluded that PFOA was of ecological concern. Nevertheless, Health Canada maintains the point of view that PFOS and PFOA are not of concern for human health at current levels of exposure. In June 2019, Transport Canada allowed airports to use PFAS-free firefighting foam, which shows a more precautionary approach as it targets the whole class of PFASs.

In 2018, the Canadian Federal-Provincial-Territorial Committee on Drinking Water and the Federal-Provincial-Territorial Committee on Health and the Environment released a technical guideline document, which reviewed and assessed all identified health risks associated with PFOS and PFOA in drinking water. It incorporated available studies and approaches and took into consideration the availability of appropriate treatment technology. Based on the review, the drinking water guideline for PFOS and PFOA was set at a maximum acceptable concentration (MAC) of 0.6 µg/L (600 ppt) and 0.2 µg/L (200 ppt) based on the general population.

New Zealand and Australia

The PFAS National Environmental Management Plan (NEMP), January 2020, from the National Chemicals Working Group of the heads of EPAs Australia and NZ, provides nationally agreed guidance on the management of PFAS contamination in the environment, including prevention of spreading of contamination. It supports collaborative action on PFASs by the Commonwealth, state and territory and local governments around Australia. The NEMP is an appendix to the Intergovernmental Agreement on a National Framework Responding to PFAS Contamination. The NEMP reflects the current state of knowledge and is updated regularly to reflect new scientific evidence and guidance. The NEMP recognises the need for sound regulation of PFASs by each jurisdiction in a way that can adapt to local circumstances and emerging priorities.

Australia will continue to participate in the Stockholm Convention's processes and to address any domestic implementation requirements that may result if PFHxS or other PFASs are listed. In the meantime, the globally accepted standards outlined in the convention for the use and management of persistent organic pollutants are a fundamental point of reference for the guidance provided in the NEMP.

Ratification of the PFOS and PFOA listings or future listings of PFHxS or other PFASs in the Stockholm Convention would mean Australia accepting and implementing international standards for the management of these chemicals. For example, this would include requirements regarding waste that contains listed chemicals, including related substances as defined by the listing, at a level above the content limit of 50 mg/kg.

2.2.2. Discussion of possible regulatory measures

2.2.2.1. REACH restriction

A restriction on manufacturing, marketing and use of PFASs, and articles containing PFASs is assessed to be the most appropriate way to limit the risks for human health and the environment. In particular, the import of articles containing PFASs can be controlled this way. The information on occurrence of PFASs in articles is limited.

In line with risk management of other substances of the PFASs group the Dossier Submitters suggest a restriction as the most appropriate measure to minimise concentrations in the environment. The advantages of a restriction are:

- The possibility to address a group of substances, including all potential precursors.
- The possibility to cover imported articles, which in this case is a considerable source of PFAS emissions into the environment.

The regrettable substitution seen in the case of long-chain PFASs and the very high number of PFASs on the market show that the approach taken until now of regulating them individually (or in small groups of closely related substances) is not efficient and does not fully address the concerns they pose. Widespread use of multiple substances from the PFASs group increases the risk of combined effects from PFASs. This leads to the conclusion that it would be beneficial if a future regulatory initiative concerning PFASs addresses them as a group (see section 1.1.2 on Justification for grouping).

Recent publications have investigated various approaches that could be taken to regulate PFASs as a chemical class or as sub-groups, based on their intrinsic properties (e.g. persistence, bioaccumulation, potential, toxicity, mobility and molecular size). The authors conclude that an approach to grouping based on persistence alone could be justified considering that the continuous release of persistent chemicals will lead to widespread, long-lasting, irreversible and increasing contamination. It will also result in increasing probabilities of adverse effects on human health and the environment.

Because of the many sources of PFASs in the environment and considering their high persistence, in addition to limiting the emissions at the source, there is a need to identify and reduce existing pollution in the different environmental compartments as much as possible. Restricting PFAS uses under the chemicals and product specific legislations could therefore be complemented with actions under other legislative frameworks (water, food, industrial emissions and waste) and non-legislative initiatives (soil).

A restriction under the chemicals legislation (REACH) is considered the most effective tool to manage the risk from substances, such as PFASs that are used in industrial processes but also in products. A restriction can include the ban of the manufacture, placing on the market or use of a chemical substance, or a group of substances. Additionally, it can use other requirements to address risks (such as use of RMM). It applies also to imported products and it is flexible, because it can include derogations, unlimited in time or time limited. Therefore, the most appropriate EU-wide instrument to address PFAS concerns at the source is a REACH restriction.

2.2.2.2. SVHC identification

Eleven different PFASs have been listed on the Candidate List (see section 2.2.1.2). In some cases it is specified that the listing includes salts and isomers. The substances are identified as SVHC (published in accordance with Article 59(10) of the REACH Regulation), based on PBT/vPvB, as ELoC or toxic for reproduction properties. An inclusion of PFASs in general in the Candidate List would, however, clearly establish that the substances have properties that warrant consideration as substances of very high concern based on REACH Article 57 criteria. Intrinsic properties of PFASs as a group of substances can also be discussed in detail in an Annex XV restriction dossier which is not limited to define criteria for the concern of SVHC. In addition, the outcome and benefit of a restriction dossier regarding emission reduction would be clear and direct and would be a less time-consuming process compared to a sequence with SVHC identifications followed by restriction.

2.2.2.3. Authorisation

According to Article 58(3) of the REACH regulation, priority for inclusion of SVHC in Annex XIV shall normally be given to substances with (a) PBT or vPvB properties, or (b) wide dispersive use, or (c) high volumes. Only substances that were previously added to the Candidate List can subsequently be included into Annex XIV following prioritisation and become subject to authorisation. No PFASs are listed on the Authorisation List (Annex XIV) so far.

As explained above, the SVHC identification of all PFASs fitting the chemical definition would be very difficult. Authorisation addresses the use of a substance as such, including the incorporation into articles, and in mixtures above 0.1%. Since the aim is to minimise the exposure of the environment and humans to PFASs, these substances need to be substituted where technically and economically feasible including in imported articles and uses in concentration below 0.1%. An inclusion in Annex XIV and authorisation would, however, not address PFASs in imported articles or uses in concentration below 0.1%. However, both aspects could be addressed in a restriction.

An advantage of authorisation is that the burden of proof is on the user of the substance. For each application, the user should demonstrate that the socio-economic benefits outweigh the risk and that there are no adequate alternatives. A disadvantage is that with an authorisation it cannot be prevented that a substance similar to a substance on the Authorisation List with comparable negative properties for human health and the environment is used if it has not yet been included in the authorisation procedure itself. Therefore, one PFAS could be replaced by another PFAS, i.e. regrettable substitution.

Furthermore, relying on the authorisation procedure for PFASs with numerous applications, it can be expected that there will be an extensive number of authorisation requests which all need to be evaluated by RAC and SEAC. This would mean an unrealistic overall workload. This would not only happen once (as for restriction), but repeatedly as authorisation is granted for a limited period.

2.2.2.4. Harmonised classification and labelling (CLH) and/or self-classification

The main concern for all PFASs in scope of this restriction proposal is their persistence, which is not among the classification criteria under CLP. CLH is therefore concluded only to be an appropriate risk management option for (groups of) selected PFASs with additional dangerous properties that justify the classification. However, data on harmful properties is lacking or insufficient for many of the members of the PFASs family, and for these CLH is not an applicable option.

2.2.2.5. Other regulations outside REACH and CLP

An overview of regulations next to REACH that could provide risk mitigation, is given in Table 5. However, these regulations could not prevent the manufacture, placing on the market and use of PFASs. In the view of the Dossier Submitters, it is necessary to restrict the manufacture and use of PFASs as much as possible to prevent continued environmental pollution by these very persistent substances.

Table 5. EU Legislations other than REACH

Relevant EU-legislation other than REACH	**Community-wide option for risk management**
Water Framework Directive, Directive 2000/60/EC	Releases of PFASs occur to the surface water and ground water. The aquatic compartment is an important media for PFASs in the environment and WWTPs are a main source of emissions into that compartment. Therefore, it is proposed to include PFASs as priority hazardous substances including setting an EQS (Directive on Environmental Quality Standards (EQS) (Directive 2008/105/EC amended by 2013/39/EC)) and considering the Groundwater Directive (2006/118/EEC). However, WWTP is not the only source and the aqueous media is not the only environmental media of concern and therefore the use of the directive alone is insufficient.
EU Soil health law	The European Commission has announced it will propose a Soil Health Law in 2023. The aim of the Soil Health Law proposal announced in the EU soil strategy for 2030 is to specify the conditions for a healthy soil, determine options for monitoring soil and, lay out rules conducive to sustainable soil use and restoration.
Directive on the quality of water intended for human consumption Directive 2020/2184 (EC, 2020b) Drinking Water Directive, Directive 98/83/EC	Some PFASs have a low solubility in water, while others have a high solubility. High levels for some PFASs have been detected. For example, short chain polar PFASs are already widely detected in water. Limit values for some PFASs are already included and for and for other PFAS limit values are proposed, including as a sum for several substances. The limit for total organofluorine (when method is available) is also set in the DWD[9]
Sewage Sludge Directive,	Limit values for PFASs in sludge should be established.

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[9] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_6060_2020_REV_1&from=EN, date of access: 2023-01-05, Annex I part B and Annex III, part B, point 3.

Relevant EU-legislation other than REACH	**Community-wide option for risk management**
Directive 86/278/EEC	However, only levels in sludge would be regulated, not manufacture, use and emissions that ultimately result in contamination of sludge.
Waste legislation (e.g. recollection, or classification as hazardous waste	Waste management requirements can be considered as complementary to a restriction to manage risks related to derogations. In addition, waste management requirements can be applied to control emissions from articles already in use (i.e. in the 'technical stock').
Directive on industrial emissions (integrated pollution prevention and control), Directive 2010/75/EU	This Directive addresses pollution from large industrial installations, which can be considered as complementary to a restriction to manage risks related to derogations and risks related to articles already in use. On 5 April 2022, the Commission adopted proposals for revised EU measures to address pollution from large industrial installations, in line with EU Green Deal.
Volatile Organic Compounds (VOC) Directive, Directive 1999/13/EC	It has to be assessed if PFASs could fulfil the VOC criteria.
EU legislation Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food	According to Article 5 of this regulation, specific measures for certain groups of materials or articles can be established. In the course of that, the use of PFASs in or their migration from food contact materials (e.g. paper, rubber, coatings) could be regulated (i.e. only be allowed below a certain limit value). A restriction covers food contact materials.
EU legislation Commission regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	Only substances listed in Annex I of this regulation are allowed to be used as monomers or additives for plastic food contact materials. In Annex I of this regulation, there are already migration limits or use restrictions set (e.g. for PFOA), which result in minimal or no release into food. However, regulation (EU) No 10/2011 could be changed to prohibit use of PFASs in plastic food contact materials (above a certain limit).

2.2.3. Active substances in Plant Protection Products (PPP), Biocidal Products (BP) and Medicinal Products (MP)

In the EU, active substances in PPP, BP and human and veterinary MP are regulated by an approval system under their respective regulations (see Table 6). In contrast to (industrial) chemicals, active substances will not be marketed in the EU or any of the Member States unless a product authorization has been granted by the national competent authorities in collaboration with European agencies EFSA, ECHA or EMA.

Active substances that fulfil the PFAS definition are commonly characterized by the presence of one or more CF$_3$-group(s) in their molecular structure. Introducing this group in the molecular structure of biologically active substances could enhance specific properties, such as stability, lipophilicity, etc. In the following paragraphs these legislations are briefly described.

Table 6. Active ingredients in PPP, BP and MP and their respective legislation

Uses	Legislation
Active substances in plant protection products	Regulation (EC) No 1107/2009 (PPPR)
Active substances in biocidal products	Regulation (EU) No 528/2012 (BPR)
Active pharmaceutical ingredients (API) in human medicinal products	Directive 2001/83/EC (human) Regulation (EC) 726/2004 (human and veterinary)
Active pharmaceutical ingredients (API) in veterinary medicinal products	Regulation (EC) 726/2004 (human and veterinary)

For non-exhaustive lists of PFAS active substances in PPP, BP and MP see Appendix A.3.17. in Annex A.

- PPP protect plants and crops against weeds, diseases and pests and are usually applied directly on outdoor crops and therefore direct emission to the environment takes place. Although the use of PFASs as active substances in PPP leads to intentional environmental emissions, a rough estimate indicates that PPP accounts for 2% of total EU sales of substances that fulfil the PFAS definition, see Annex A.3.17. Extensive environmental risk assessments are already conducted under the PPP-regulation. A general restriction of PFASs in PPP would entail that at least 48 active substances in over 200 products cannot be used anymore. This would have consequences in terms of availability of e.g. fungicides, insecticides and herbicides used in a variety of crops. Limiting the number of different PPPs generally aggravates resistance management.

- BP control fungi, pests or organisms (e.g. bacteria, viruses, parasites), which are harmful to the health of humans, animals or the environment, or damage materials. BP have various applications which do not necessarily have direct emission to the environment. Substances which could be identified as PFASs are addressed under the comparative assessment in the BPR procedure, since these substances are candidates for substitution.

- Human MP are important for the protection of humans from diseases. Residues of medicines are released via sewage in the environment. A general PFAS restriction for these applications would impact the security of supply of both human medicines and their alternatives.

- Veterinary MP are important for the protection of animals and humans from diseases. Also, for the welfare of animals and the supply of food. Residues of medicines are released via manure in the environment. A general PFAS restriction for these applications could impact the security of supply of veterinary medicines.

While many PFAS subgroups are heavily fluorinated, active substances in PPP, BP and MP often only contain one or more CF_3-group(s) in an otherwise complex non-fluorinated molecular structure. In many cases the CF_3-groups are attached to aromatic rings[10]. Introducing the CF_3-group in the molecular structure of biologically active substances could enhance specific properties, such as stability and lipophilicity (Johnson et al., 2020).

EFSA is involved in the risk assessment of active substances, ECHA in the classification evaluations. For PPP and BP mainly a risk assessment is made. A risk/benefit analysis for PPP and BP is considered for candidates for substitution, in the form of a comparative assessment at product level. The risk/benefit analysis of the active substances in MP is performed as part of the assessment under the corresponding directive/regulation.

In the PPP-regulation, persistence (P) is not in itself an exclusion criterion. However, since PPPs are designed to be toxic, the majority of substances are classified as T. The result is that substances that are also classified as P become candidate substances for substitution (criterion: 2/3 PBT). If an active substance becomes a candidate for substitution, a comparative assessment must be made at national level for each product application that includes this active substance. In the comparative assessment, national authorities for agriculture first will check the agricultural consequences of an authorisation of the PPP compared with available alternatives. Factors to be considered are consequences for minor uses, risk of developing resistance, the effectiveness of the alternatives and practical and economic consequences. This assessment of whether available alternatives are sufficient for agriculture then governs the outcome, i.e. whether the product can be authorised or not. Such an investigation would need to identify EU's different agricultural areas and their different needs and conditions, what crops these substances are used for, if there are possible effective alternatives, how they are used in strategies against resistance development, etc.

For biocides, extensive assessments are carried out regarding the environment. This also includes consideration of the persistence of possible degradation products. If risks are identified from the active substance or the degradation products, no approval is granted for the active substance. Since many active substances fulfil the T-criterion due to their function, numerous PFASs are substitution candidates in the biocide process (if 2 of the 3 PBT criteria are fulfilled). Of the 9 PFAS active substances approved so far, this is the case for 5 active substances, i.e. in the context of product authorisation the national authorities check whether there are products with suitable alternative active substances for the intended use.

The use of a BP containing PBT and/or vPvB substances that are approved in accordance with the derogation shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised as much as possible.

MP are considered important for the protection of the health of humans. During the assessment of medicines possible negative effects on the environment are indicated, however they have no decisive effect on the authorization process. A general restriction would have a possible impact on the availability and security of supply of PFAS-containing medicines and their alternatives. By the end of 2022, it will be discussed how the environmental impact will be assessed in the authorisation of medicinal products, and the authorization process may be revised (EC, 2019).

Due to the specific regulatory status of these active substances, REACH is applicable to a limited extent. According to REACH Article 2(5)a, substances in medicinal products for human

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[10] Co-formulants present in PPP, BP, and MP may also be defined as PFASs. These substances are not covered here.

or veterinary use are exempted from different REACH requirements like registration, evaluation and authorisation. REACH Article 15 indicates that active substances in PPP and BP are considered to be (automatically) registered under REACH, and REACH Article 56(4) that the authorisation requirement for substances included in REACH Annex XIV does not hold for the use of these substances in PPP and BP. From the above it can be seen that a REACH restriction, however, could still apply for active substances in PPP, BP and MP.

The use of certain fluorinated fragments in PPP, BP and MP contributes to the release of PFASs to the environment. In the sense that persistent PFASs are formed as degradation products, the ambition should be a minimization. This could be achieved by including the active substances that fulfil the PFAS definition in the current restriction proposal. However, it is recognized that the use of these substances is specifically regulated in the EU with extensive evaluations and approval processes by designated bodies with specific expertise and experience. Hence, it is proposed to derogate the use of PFASs as active substances (but not the use of PFASs as co-formulants) in PPP, BP and MP in the restriction proposal for PFASs. At the same time, however, it is acknowledged that the predominant concern for the restriction, i.e. persistence, is not sufficiently taken into account during the current authorization processes following PPP, BP and MP regulations. Given the risks associated with PFASs in the scope of the restriction proposal, the derogation therefore comes with a recommendation to the European Commission to address these concerns in the respective regulations, in order to reduce the use and emissions of PFASs as much as possible. To assist these further actions the proposed derogation includes reporting requirements for the placing on the market, applicable to manufacturers and importers of PFAS active substances in PPP, BP and human and veterinary MP. To create a common understanding of the magnitude of continuing emissions as well as the progress made in relation to substitution and/or minimization of releases, the main purpose of the reporting obligations is to help the European Commission to gather data on the use of PFASs in these sectors and to monitor any developments/changes. The data would also assist the Commission and EU Member States in discussing the necessity and proportionality of further (EU) action or measures (e.g. REACH, other regulations, non-EU-wide measures).

2.2.4. Conclusion on the most appropriate regulatory risk management options

A restriction is considered the most effective and efficient way to manage such a large and complex group of substances that are used in numerous applications. In addition, a restriction can cover imported articles. A broad restriction is therefore preferable to authorisation.

A broad restriction under REACH covering all PFASs as a group would:

- limit as many uses as practically possible and thereby minimise emissions and human and environmental exposures to PFASs;
- include currently unknown PFASs and PFAS uses;
- prevent regrettable substitution of restricted PFASs with other PFASs with similar concerns.

With basis in these arguments, a restriction is considered the preferred risk management option. However, it is proposed that PFASs used as active substance (but not as co-formulants) in PPP, BP and human and veterinary MP should be generally derogated from this REACH restriction (see section 2.2.3) as they are addressed under their respective regulations. This derogation comes with a reporting requirement recommendation.

2.3. Restriction scenario(s)

2.3.1. Main restriction options assessed

Based on the conclusions of the risk assessment, the releases of PFASs are considered to pose a risk to the environment that is not adequately controlled. In response to the identification of this risk, diverse risk management options (RMOs) were analysed to identify the most appropriate risk management measure to address the risk. In Section 2.2.4, it is concluded that a REACH restriction is the preferred risk management option. The proposed restriction should avoid releases of PFASs to the environment as much as possible. Since PFASs are chemically very stable, it is important to consider releases during all stages of the life cycle, including the waste stage. The best option to avoid PFAS emissions to the environment during manufacture, the production and use of PFAS-containing articles and at the waste stage is to prohibit the manufacture and use of PFASs to the largest extent possible.

As a starting point, the proportionality of a full ban (i.e. Restriction Option 1, henceforth referred to as RO1) of all PFASs is therefore analysed. RO1 is suggested to enter into force after a transition period of 18 months. This most stringent restriction option is then compared to a Restriction Option 2 (RO2), being a ban of all PFASs except, in most cases, time-limited defined use-specific derogations, of either a duration of five or 12 years after the end of the transition period, proposed on the basis of the criteria described below. The duration of the transition period and derogations are summarised in Table 7.

Table 7. Restriction options (ROs) assessed.

Restriction option (RO)	**Transition period before RO takes effect**	**Duration of derogation**
RO1: Full ban	18 months	Not applicable
RO2: Ban with use-specific derogations		5 years after transition period ends
		12 years after transition period ends
		Time-unlimited (only for specific uses)

Under RO2, two types of time-limited derogations are considered. The first one is for a five-year derogation, which is proposed when sufficiently strong evidence is available that

(i) points to the non-existence of technically and economically feasible alternatives on the market at the entry-into-force (EiF) date but where possible alternatives to the PFAS use have already been identified that are however still in the development phase, or

(ii) known alternatives are not available in sufficient quantities on the market at the EiF date or known alternatives cannot be implemented before the transition period ends.

The second one, a 12-year derogation, is proposed when sufficiently strong evidence is available that:

(i) points to the non-existence of technically and economically feasible alternatives on the market at the EiF date, e.g. Research and Development (R&D) efforts did not identify possible PFAS-free alternatives so that it is likely that they will not become available in the near future, or

(ii) certification or regulatory approval of PFAS-free alternatives cannot be achieved within a five-year derogation period.

The Dossier Submitters consider these time periods normally sufficient for industry to take benefit from technical progress and to carry out scientific R&D activities to find and deploy technically and economically feasible alternatives.

For some specific uses there may be reasons of practical nature on the basis of which time-unlimited derogations could be necessary. At submission of the restriction proposal, the Dossier Submitters consider such time-unlimited derogations justified for (i) use of PFASs in refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives (see section 2.4.1.1), (ii) use of PFASs in calibration of measurement instruments and as analytical reference materials (because this is necessary for the targeted analysis of PFASs in the monitoring of these substances in various matrices, see section 2.5), and (iii) use of PFASs as active ingredients (but not as co-formulants) in PPP, BP and human and veterinary MP (see section 2.2.3).

As indicated in the criteria above, a derogation requires a sufficiently strong evidence base to justify its necessity. Consequently, in cases where the available evidence base is considered weak, a derogation is not supported at the moment, even though the Dossier Submitters recognize that such a derogation could potentially be warranted. Only if additional information strengthening the evidence base becomes available during the Annex XV report consultation of the restriction dossier, such a derogation will be reconsidered for inclusion in the restriction proposal.

The environmental and socio-economic impacts of the proposed restriction options are assessed per sector, i.e., separately for manufacturing of PFASs, TULAC, food contact materials and packaging, metal plating and manufacture of metal products, consumer mixtures, cosmetics, ski wax, applications of fluorinated gases, medical devices, transport, electronics and semiconductors, the energy sector, construction products, lubricants, and petroleum and mining.

For RO1, environmental impacts are assessed quantitatively for all sectors, based on available emission data at sector level, and information on the expected market growth for the different sectors. The applied growth rates are described in section 1.3.2. For RO2, environmental impacts are assessed either quantitatively (where evidence in terms of emission data is available) or qualitatively (where such data is lacking). Further details about the approach are provided in section 2.4.3.

2.3.2. Proposed restriction option

A detailed description of the proposed Annex XVII entry text is available in the summary at the beginning of this dossier. This proposed entry text is equivalent to RO2, i.e., a ban with use-specific derogations of a duration of five or 12 years after the transition period of 18 months ends and including some time-unlimited derogations for exceptional cases based on practical considerations.

2.4. Assessment of the restriction options

2.4.1. Economic and other impacts

2.4.1.1. Economic impacts on producers and customers and other impacts (e.g. employment losses)

As mentioned in section 2.1, costs of ROs include various components including producer surplus losses of directly affected companies, i.e. users of PFASs, as well as companies in the upstream supply chain, consumer surplus losses as a result of changes to the product price, welfare losses and/or additional costs resulting from changes in the characteristics of goods or their absence (where substitution is not feasible) as well as job losses.

The types of costs resulting from different ROs depend on the reaction chosen by affected companies. A company that substitutes, for example, faces Research & Development costs in relation to the identification and testing of relevant alternatives and the reformulation/re-design of the product. The company might, furthermore, face one-off costs for purchasing and installing new equipment, so-called capital costs, if the switch to alternatives makes changes to the production process necessary. In addition, companies might also face changes in operating costs such as changes in raw material costs resulting, for example, from differences in the unit cost of the alternative in comparison to the cost of PFASs and/or a higher volume of the substance being required. Changes to the production process might also result in more energy use with associated cost increases for companies. If such cost increases can be passed on to customers via higher product prices, limited economic impacts on affected companies are expected, while customers will face consumer surplus losses. If the ability to pass on costs to customers is limited, e.g. due to high competition, companies will face producer surplus/profit losses. A company that stops production in response to the restriction also faces producer surplus/profit losses – although at a higher magnitude. In addition, it might face costs in relation to dismantling plants. In a sector, where many companies decide to cease operation, welfare losses and/or additional costs to customers due to the absence of certain products on the EU/EEA market might occur in addition to impacts on the economy as a whole as a result of employment losses.

The reaction chosen by the affected company is determined by the technical feasibility of alternatives, their economic feasibility and whether alternatives are available in sufficient quantities. Where technically feasible alternatives do not exist, company closures will occur. Where technically feasible alternatives exist, substitution is a possible option for affected companies, but it does not guarantee the absence of business closures in the relevant sector. Whether substitution is chosen as the preferred reaction by individual companies depends – amongst other factors – on whether individual companies consider it economically viable to them to substitute and whether they consider it possible to find suppliers that can provide the identified alternative in sufficient quantities. Due to differences in, for example, the financial resources of companies, the chosen reaction might differ.

Given the importance of the most likely behavioural reaction of companies for understanding the costs associated with different ROs, this section describes the extent to which technically and economically feasible alternatives are available in different sectors together with the anticipated impacts. Table 8 provides summary information on alternatives as well as the anticipated costs resulting from a full ban of PFASs, i.e. RO1, for all use sectors, while the impacts of RO2 are described in Table 9. For some of the use sectors, various specific uses are listed but it is important to stress that the use sector is not limited to the uses listed.

Further details on the anticipated costs and underlying assessment can be found in Annex E. The relevant section of Annex E for each sector is indicated in the tables.

As explained in section 2.3.1, the strength of evidence is an important criterion considered by the Dossier Submitters in proposing derogations. As such, Table 8 and Table 9 also provide information on the strength of the underlying evidence, whereby evidence can consist of (a combination of) (i) literature, (ii) stakeholder information from the CfE (carried out in 2020), the 2nd stakeholder consultation (carried out in 2021) and/or targeted stakeholder interviews, (iii) precedence[11], principles[12], consistency arguments (e.g. with other regulations or guidance documents), as well as defaults, and (iv) expert judgement. Considered aspects include the quality of evidence, e.g. the representativeness of samples underlying quantitative information, the extent of evidence available from one or different lines of evidence and the extent to which available evidence corroborates or contradicts itself.

The Dossier Submitters distinguish between the following levels of evidence:

- **Sufficiently strong evidence:** Good evidence from one or more lines of evidence, where conflicting information can be explained and reconciled;
- **Weak evidence:** Insufficient information has been identified, or received from consultation, to establish a firm conclusion;
- **Inconclusive evidence:** Conflicting evidence from one[13] or different lines of evidence, where conflicts cannot be explained and reconciled; and
- **No evidence.**

Conclusions based on precedence, principles, consistency arguments, defaults, and assumptions based on expert judgement are considered to be sufficiently strong where they are well-grounded, e.g. in academic theory.

An example of weak evidence is the evidence underlying the assessment of alternatives for textiles for use in engine bays in automotives (for noise and vibration insulation) – a sub-use of TULAC. This use was identified during the 2nd stakeholder consultation only and did not become known as a result of desktop research and the CfE. While three stakeholders reported this use during the 2nd stakeholder consultation, only one stakeholder provided information on alternatives. Based on information from upstream actors in its supply chain, the stakeholder reports that alternative substances or technologies are not available. The

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[11] An example of precedence is a case in which the Dossier Submitters conclude that the volume of waste expected to be treated in a certain way, e.g. landfilling instead of incineration or recycling, will decline based on related EU policy targets.

[12] An example of principles is a case in which the Dossier Submitters conclude that demand for products in a certain sector is price inelastic and that companies are therefore expected to pass on possible substitution costs fully to customers, which will limit producer surplus losses at the expense of additional consumer surplus losses. Demand in sectors with mass markets producing goods for the general public (such as the consumer apparel sector) is, for example, deemed to be comparatively price elastic, i.e. deemed to change more in response to a price change, due to price being a key factor considered by customers in their purchasing decision. Demand in sectors producing highly specialised products for industrial and/or professional users is deemed less price elastic. This is the case as such users likely also value other factors such as a longstanding supplier relationship highly. As a result, their purchasing decision is likely less dominated by price considerations.

[13] Conflicting evidence from one line of evidence refers, for example, to different literature sources that come to conflicting conclusions or conflicting information provided by stakeholders.

evidence is considered to be weak due to only being based on one source type, i.e. the 2nd stakeholder consultation, and due to being based on information from one stakeholder only.

Further details on the strength of evidence associated with different components can be found in Annex E.

The level of evidence regarding the non-existence of alternatives at EiF determines how the Dossier Submitters deal with derogations:

- Only when there is **sufficiently strong evidence**, a derogation is **proposed**.
- When there is **weak evidence**, a derogation could potentially be warranted but is not supported at the moment due to the weak evidence base. These 'potential derogations' need additional evidence from the Annex XV report consultation of the restriction dossier for justification, and thus need reconsideration at a later stage. In Table 9 the 'potential derogations' are marked **for reconsideration** and they are put in between brackets.
- When there is **inconclusive evidence** or **no evidence**, a derogation is not supported at all and is therefore not proposed.

Table 8. RO1 - Summary table of alternatives and cost impacts for PFAS manufacture and major PFAS use sectors resulting from a full ban of PFASs

Use sector (with sub-uses)	Alternatives	Cost impact
Manufacture (Annex E.2.1.)		
Sector as a whole	The analysis of alternatives for PFASs use is performed at the level of use in the various sectors. • Use of PFASs as polymerisation aids in manufacture of fluoropolymers: Sufficiently strong evidence that technically and economically feasible alternatives exist for non-polymeric PFASs as polymerisation aids in the production of PTFE, PVDF and FKM. • Sufficiently strong evidence that technically and economically feasible alternatives for non-polymeric PFASs as polymerisation aids in the production of polymeric PFASs other than PTFE, PVDF and FKM will become available within 10 years from 2022. Conclusion: High substitution potential at EiF in the production of PTFE, PVDF and FKM and low substitution potential at EiF for other types of polymeric PFASs [sufficiently strong evidence]	• High producer surplus losses (order of magnitude: ~€42 billion NPV over 30 years) as a result of business closures [sufficiently strong evidence] due to (i) a high share of business closures [sufficiently strong evidence], (ii) high producer surplus losses at company level due to high margins [sufficiently strong evidence], (iii) an unknown offsetting potential, i.e. producer surplus losses are balanced out to some extent by producer surplus gains by producers of alternative-based products [no evidence] and (iv) high producer surplus losses in the wider supply chain [sufficiently strong evidence]. • High employment losses (order of magnitude: ~€2.5 billion NPV) as a result of high share of business closures [sufficiently strong evidence]
TULAC (Annex E.2.2.)		
Home textiles • Estimated number of companies active in the sub-sector: 20 200 • Not all companies are deemed to use PFASs based on voluntary industry commitments, but the share using PFASs is likely higher than for consumer apparel	• Sufficiently strong evidence that technically feasible alternatives exist, i.e. dendrimers, hybrid blends (silicone/hydrocarbon), hydrocarbons, polyurethanes, silicones, as well as sufficiently strong evidence (in the form of practical examples of completed substitution) pointing to the economic feasibility of alternatives • No evidence pointing to a shortage in supply	• Low producer surplus losses as a result of business closures [sufficiently strong evidence], also due to (i) low producer surplus losses at company level due to low margins [sufficiently strong evidence] and (ii) a medium offsetting potential [sufficiently strong evidence] • High producer surplus losses as a result of substitution [sufficiently strong evidence], despite comparatively low costs at company level [sufficiently strong evidence], due to (i) the medium number of companies being affected [sufficiently

Use sector (with sub-uses)	Alternatives	Cost impact
• Number of companies affected by the restriction (in comparison to other TULAC sub-sectors): Medium [sufficiently strong evidence] • Sales volume of goods (with and without PFASs) sold to EU customers (in comparison to other TULAC sub-sectors): High (> 3 million tonnes) [sufficiently strong evidence]	Conclusion: High substitution potential at EiF [sufficiently strong evidence]	strong evidence], (ii) the high share of substitution [sufficiently strong evidence] and (iii) partial internalization of costs [sufficiently strong evidence] • High consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence] despite comparatively low price changes [sufficiently strong evidence] due to the high annual sales volume [sufficiently strong evidence] • Some welfare losses or additional costs as a result of lower functionality, e.g. in relation to oil and dirt repellence [sufficiently strong evidence] • Low level of employment losses due to low share of business closures [sufficiently strong evidence]
Consumer apparel • Estimated number of companies active in the sub-sector: 59 300, including professional sportswear and footwear • Not all companies are deemed to use PFASs based on voluntary industry commitments and the market penetration of alternatives is deemed to be comparatively high • Number of companies affected by the restriction (in comparison to other TULAC sub-sectors): High [sufficiently strong evidence] • Sales volume of goods (with and without PFASs) sold to EU customers (in comparison to other TULAC sub-sectors): High (> 4 million tonnes, and likely much higher due to the estimate only being based on information on indoor and outdoor wear, while footwear, accessories and	• Sufficiently strong evidence that technically feasible alternatives exist, i.e. dendrimers, hybrid blends (silicone/hydrocarbon), hydrocarbons, polyurethanes, silicones, alternative technologies, as well as sufficiently strong evidence (in the form of numerous examples of completed substitution) pointing to the economic feasibility of alternatives • No evidence pointing to a shortage in supply Conclusion: High substitution potential at EiF [sufficiently strong evidence], but not all companies are deemed to substitute as substitution is a less promising endeavour for affected companies in the consumer apparel industry due to more established competition and more price pressure.	• Low producer surplus losses as a result of business closures [sufficiently strong evidence] despite a medium share of business closures [sufficiently strong evidence], due to (i) low producer surplus losses at company level due to low margins [sufficiently strong evidence], (ii) a high offsetting potential, due to the high market penetration of alternative-based products [sufficiently strong evidence] and (iv) low producer surplus losses in the wider supply chain [sufficiently strong evidence] • High producer surplus losses as a result of substitution [sufficiently strong evidence] despite comparatively low substitution costs at company level [sufficiently strong evidence], due to (i) the high number of companies being affected [sufficiently strong evidence], (ii) the medium share of substitution [sufficiently strong evidence] and (iii) partial internalization of costs [sufficiently strong evidence] • High consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence] despite comparatively low price changes [sufficiently strong evidence] due to the high annual sales volume [sufficiently strong evidence]

Use sector (with sub-uses)	Alternatives	Cost impact
sportswear are not covered) [sufficiently strong evidence]		• Some welfare losses or additional costs as a result of lower functionality, e.g. in relation to oil repellence, which is deemed to be an important functionality in relation to sportswear and footwear, and additional costs resulting from high replacement frequencies or more frequent re-impregnation due to the lower ability of alternatives to withstand household laundering [sufficiently strong evidence] • Some[14] employment losses due to medium share of business closures [sufficiently strong evidence]
Professional apparel (including PPE) • Estimated number of companies active in the sub-sector: 2 900, excluding professional sportswear and footwear • Share of companies affected by the restriction is unknown, but the market penetration of alternatives is deemed to be low • Number of companies affected by the restriction (in comparison to other TULAC sub-sectors): Low [sufficiently strong evidence] • Sales volume of goods (with and without PFASs) sold to EU customers (in comparison to other TULAC sub-sectors): Low (around 100 000 tonnes, and likely slightly higher due	• Professional sportswear and footwear: Sufficiently strong evidence that technically feasible alternatives exist, i.e. dendrimers, hydrocarbons, polyurethane, silicones, alternative technologies. • PPE: Sufficiently strong evidence that technically feasible alternatives exist for seven of 13 assessed categories of PPE, e.g. hydrocarbons, polyurethanes, silicones and alternative technologies • Sufficiently strong evidence that alternatives are economically feasible, e.g. based on information pointing to the proven use of alternatives for professional sportswear and footwear and sufficiently strong evidence for consumer apparel applications (which are deemed to be comparable to some extent) • No evidence pointing to a shortage in supply	• High producer surplus losses as a result of business closures [sufficiently strong evidence] despite low number of affected companies [sufficiently strong evidence] due to (i) high share of business closures [sufficiently strong evidence], (ii) high producer surplus losses at company level due to high margins [sufficiently strong evidence], (iii) a low offsetting potential [sufficiently strong evidence] and (iv) high producer surplus losses in the wider supply chain [sufficiently strong evidence] • Low producer surplus losses as a result of substitution [sufficiently strong evidence] especially due to (i) the low share of substitution [sufficiently strong evidence] and (ii) low internalization of costs [sufficiently strong evidence] • Low consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence], mainly in relation to professional sportswear and some types of PPE, despite comparatively high price changes resulting from medium to high substitution costs [sufficiently strong evidence], which are passed on to customers to a high extent

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[14] The magnitude in comparison to other TULAC sub-sectors could not be estimated due to the significant uncertainty about the number of companies that would cease operation and a lack of representative data on the average number of employees in relevant companies (which might differ between TULAC sub-sectors depending on how labour-intensive the associated production process is).

Use sector (with sub-uses)	Alternatives	Cost impact
to only being based on PPE, while professional sportswear and footwear is not covered) [sufficiently strong evidence]	Conclusion: High substitution potential at EiF for professional sportswear and footwear and seven of 13 types of PPE and low substitution potential at EiF for the other six PPE applications [sufficiently strong evidence]	[sufficiently strong evidence], due to (i) the low annual sales volume[15] [sufficiently strong evidence] • High welfare losses or additional costs mainly as a result of (i) the absence of certain types of PPE due to no technically feasible alternatives and (ii) earlier disposal of PPE as a result of the unavailability of impregnation agents [sufficiently strong evidence] • Some employment losses as a result of high share of business closures [sufficiently strong evidence]
Technical textiles[16] • Estimated number of companies active in the sub-sector: 24 500 • Share of companies affected by the restriction is unknown, but the market penetration of alternatives is deemed to be low • Number of companies affected by the restriction (in comparison to other TULAC sub-sectors): High [sufficiently strong evidence] • Sales volume of goods (with and without PFASs) sold to EU customers (in comparison to other TULAC sub-sectors): Medium (> 1 million tonnes of outdoor technical textiles alone;	• Outdoor technical textiles: Sufficiently strong evidence that technically feasible alternatives exist, e.g. polyurethanes, as well as sufficiently strong evidence pointing to the economic feasibility of alternatives, e.g. stakeholder information on the proven use of alternative membranes and evidence for consumer apparel applications (which are deemed to be comparable to some extent) • Medical textile applications: Inconclusive evidence on whether technically feasible alternatives exist for all medical textile applications, with polyurethane being a possible alternative for membranes employed in some medical textile applications	• High producer surplus losses as a result of business closures [sufficiently strong evidence] due to (i) a high number of affected companies [sufficiently strong evidence], (ii) a high share of business closures (especially in relation to high performance membranes) [sufficiently strong evidence], (iii) high producer surplus losses at company level due to high margins (for high performance membranes) [sufficiently strong evidence], (iv) a low offsetting potential [sufficiently strong evidence] and (iv) high producer surplus losses in the wider supply chain [sufficiently strong evidence] • Medium producer surplus losses as a result of substitution [sufficiently strong evidence], despite comparatively low substitution costs (for outdoor technical textiles) in comparison other TULAC sub-sectors, due to (i) the high share of substitution in relation to outdoor technical textiles [sufficiently strong evidence], (ii) the likely considerable number of substituting companies [sufficiently strong evidence], (iii)

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[15] Given that substitution is only an option for some types of PPE, consumer surplus losses form price changes will likely only be incurred in relation of a share of the estimated volume of around 100 000 tonnes. As substitution and associated consumer surplus losses will also be incurred in relation professional sportswear and footwear, the estimated annual sales volume is deemed to be good basis for estimating the magnitude of consumer surplus losses.

[16] Technical textiles include textiles for medical applications. Medical devices covered further below however also include textile-related applications. To maintain clarity, medical textiles covered under technical textiles refer to any use of textiles in a medical setting, excluding use within or on the patient. Examples are mattress protectors for hospital beds, curtains/drapes around beds and gowns used by medical professionals. Implantable textiles like gauzes or applications used upon the body like bandages are included under medical devices.

Use sector (with sub-uses)	Alternatives	Cost impact
and around 125 000 tonnes of imported medical textiles), and likely much higher due to data not covering medical textiles produced in the EU and high performance membranes [sufficiently strong evidence]	• High-performance membranes: Sufficiently strong evidence that technically feasible alternatives do not exist for all types of high performance membranes, with polyurethanes potentially being a relevant alternative for some applications • No evidence pointing to a shortage in supply Conclusion: High substitution potential at EiF for outdoor technical textiles [sufficiently strong evidence]; unclear substitution potential at EiF for medical textile applications [inconclusive evidence]; and low substitution potential at EiF for high performance membranes [sufficiently strong evidence]	partial internalization of costs [sufficiently strong evidence], and (iv) information on sold production volumes (of outdoor technical textiles) of EU producers of > 1 million tonnes [sufficiently strong evidence] • Medium consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence], mainly in relation to outdoor technical textiles, despite comparatively low price changes [sufficiently strong evidence] due to the medium sales volume [sufficiently strong evidence] • High welfare losses or additional costs as a result of (i) the non-existence of technically feasible alternatives for some filtration applications, with impacts the lifetime of industrial equipment, (ii) changes in filtration efficiencies for other filtration applications, (iii) higher energy use in relation to these applications, (iv) more frequent replacement (and associated higher process downtimes) due to shorter lifetimes of filters, (v) some welfare losses as a result of lower functionality leading to inferior aesthetic appearance for outdoor technical textiles (or additional costs for counteracting changes in functionality), and (vi) additional costs in relation to outdoor technical textiles due to changes in lifetime [sufficiently strong evidence] • Some employment losses as a result of high share of business closures [sufficiently strong evidence]
Leather • Number of companies active in the sub-sector: Unknown • Share of companies affected by the restriction due to using PFASs: Unknown, but the market penetration of alternative is deemed to be comparatively low as substitution does	• Sufficiently strong evidence that technically feasible alternatives exist, i.e. hybrid blends (silicone/hydrocarbon), hydrocarbons, polyurethanes, silicones, as well as sufficiently strong evidence (in the form of practical examples of completed substitution for consumer apparel) pointing to the economic feasibility of listed alternatives • No evidence pointing to a shortage in supply	• Low producer surplus losses as a result of business closures [sufficiently strong evidence], mainly due to (i) a low share of business closures [sufficiently strong evidence] in combination with (ii) low producer surplus losses at company level due to low margins [sufficiently strong evidence] • Medium producer surplus losses as a result of substitution [sufficiently strong evidence], despite comparatively low costs at company level [sufficiently strong evidence], due to (i) a high share of substitution [sufficiently strong evidence], (ii) partial internalization of costs [sufficiently strong evidence] and

Use sector (with sub-uses)	Alternatives	Cost impact
not seem to be as widespread as for home textiles • Number of companies affected by the restriction (in comparison to other TULAC sub-sectors): Unknown • Sales volume of goods (with and without PFASs) sold to EU customers (in comparison to other TULAC sub-sectors): Medium (around 900 000 tonnes, estimated without consideration of imports and exports due to a lack of information) [sufficiently strong evidence]	Conclusion: High substitution potential at EiF [sufficiently strong evidence]	(iii) information on sold production volumes of EU producers of around 900 000 tonnes [sufficiently strong evidence] • Medium consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence] despite comparatively low price changes [sufficiently strong evidence] due to the medium sales volume [sufficiently strong evidence] • Some welfare losses or additional costs as a result of lower functionality, e.g. in relation to oil and dirt repellence [sufficiently strong evidence] • Low level of employment losses due to low share of business closures [sufficiently strong evidence]
Other: Home fabric treatments (sprays) • Number of companies active in the sub-sector: Unknown • Share of companies affected by the restriction due to using PFASs: Unknown • Number of companies affected by the restriction (in comparison to other TULAC sub-sectors): Unknown • Sales volume of goods (with and without PFASs) sold to EU customers (in comparison to other TULAC sub-sectors): Unknown	• Sufficiently strong evidence that technically feasible alternatives exist, i.e. silicones, as well as sufficiently strong evidence (in the form of practical examples of completed substitution for home textiles and consumer apparel) pointing to the economic feasibility of the listed alternative • No evidence pointing to a shortage in supply Conclusion: High substitution potential at EiF [sufficiently strong evidence]	• Low producer surplus losses as a result of business closures [sufficiently strong evidence] mainly due to (i) a low share of business closures [sufficiently strong evidence] in combination with (ii) low producer surplus losses at company level due to low margins [sufficiently strong evidence] • No evidence on the magnitude of producer surplus losses as a result of substitution, due to no evidence on the number of affected companies and the magnitude of substitution costs • No evidence on the magnitude of consumer surplus losses resulting from price changes associated with substitution, due to no evidence on magnitude of price changes and no evidence on annual sales volumes • Some welfare losses or additional costs as a result of lower functionality, e.g. in relation to oil and dirt repellence [sufficiently strong evidence] • Low level of employment losses due to low share of business closures [sufficiently strong evidence]
Other: Textiles for use in engine bays in automotives (for noise and vibration insulation)	• Weak evidence that technically feasible alternatives do not exist (Evidence is considered weak due to only being based on one source type, i.e. the 2nd stakeholder consultation, and due to being	• High producer surplus losses as a result of business closures [weak evidence] due to (i) the high share of business closures [weak evidence], (ii) high producer surplus losses at company level due to high margins [sufficiently strong evidence], (iii) a

Use sector (with sub-uses)	Alternatives	Cost impact
• Number of companies active in the sub-sector: Unknown • Share of companies affected by the restriction due to using PFASs: Unknown • Number of companies affected by the restriction (in comparison to other TULAC sub-sectors): Unknown • Sales volume of goods (with and without PFASs) sold to EU customers (in comparison to other TULAC sub-sectors): Unknown	based on information from one stakeholder only) Conclusion: Low substitution potential at EiF [weak evidence]	low offsetting potential [weak evidence] and (iv) high producer surplus losses in the wider supply chain [weak evidence] • No producer surplus losses as a result of substitution, due to no substitution taking place as result of the lack of technically feasible alternatives [weak evidence] • High socio-economic costs to customers due to the unavailability of textiles for use in engine bays [weak evidence] • Some employment losses as a result of high share of business closures [weak evidence]
Food contact materials and packaging (Annex E.2.3.)		
Consumer cookware	There is sufficiently strong evidence that technically and economically feasible alternatives are widely available on the market. These include 'ceramic' coatings, anodised aluminium and stainless steel (recognising that the preferred option may vary across applications). Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Producer surplus losses are dependent on the extent to which companies are dependent on PFASs. Some companies already do not produce PFAS-treated goods, some market a mix of PFAS-treated and non-PFAS goods and some appear to sell only PFAS-based cookware. The extent to which the latter group have researched alternatives is not known. For the first two groups the potential for business closure is either not present or very low. Business closure may be a possibility for companies in the third group in the event of RO1, with associated job losses. [weak evidence] From a survey of goods on the market, it is anticipated that there would be negligible consumer surplus losses. [sufficiently strong evidence] Welfare losses are not anticipated given the performance of current alternatives. [sufficiently strong evidence] A scoping analysis of cost-effectiveness indicates that the measure would be proportionate.
Industrial food and feed production	There is sufficiently strong evidence that technically and economically feasible alternatives are not immediately available for	Dependence of the industry on fluoropolymers in various applications (valves, conveyor belts, electronics, etc) strongly suggests the need for significant R&D by equipment

Use sector (with sub-uses)	Alternatives	Cost impact
	the various uses of PFASs in industrial food and feed production. Companies need to invest in further R&D before identified alternatives may be implemented. Conclusion: Low substitution potential at EiF [sufficiently strong evidence]	manufacturers. Under RO1, it is anticipated that there would be insufficient time for manufacturers to make the change to alternatives particularly for complex products which contain PFAS components. In the event that RO1 was applied to this sub-sector, it is anticipated that there would be significant producer surplus losses through an inability to market equipment until all PFAS elements had been removed. Done on a short timescale, this would likely increase costs to the companies that purchase machinery. Reduced reliability of machinery would also have consequences for purchasers of food and drinks. [sufficiently strong evidence]
Non-stick coatings in industrial and professional bakeware	Affected activities here include both the production of non-stick bakeware and the recoating of the bakeware and other applications where non-stick coatings provide benefit to industrial and professional food and feed production. There is sufficiently strong evidence that technically and economically feasible alternatives are available for some applications but not all. Conclusion: High substitution potential at EiF for the sector as a whole [sufficiently strong evidence] and low substitution potential at EiF for some products [weak evidence].	Potential for producer surplus losses for both manufacturers of goods with non-stick coatings and recoating operations. Recoating activities tend to be performed by small and medium-sized enterprises (SMEs) that may be particularly vulnerable to a change in process, given potentially high investment requirements. These could feed through to consumer surplus losses as higher prices are passed on to consumers. There would be some risk of business closures for those that have difficulty financing changes to their processes. [sufficiently strong evidence]
Paper & board packaging	There is sufficiently strong evidence that technically and economically feasible alternatives are widely available on the market for an extensive range of paper and board packaging. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Companies already producing PFAS-free options would likely benefit from RO1, whilst others that are currently using PFASs would need to undertake R&D and adapt existing equipment leading to some producer surplus loss. Delay may feed through to loss of market share for those companies. The extent to which the paper and board packaging market that currently uses PFASs is dependent on imports from outside the EU is unknown. Low risk of job losses overall, given the need to maintain supplies of packaging materials, though impacts at the company level may be variable with some possibility of business closures.

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
		Low risk of consumer surplus losses given availability of alternatives covering a range of packaging applications.
Plastic packaging	Sufficiently strong evidence that alternatives exist to replace polymeric PFASs used as processing aids in the production of plastic film to improve flow behaviour, speed up production rates, also enabling the production of thinner films. Several alternatives (e.g. boron nitride, polyethylene waxes) are available on the market. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	The potential for cost impacts hinges on the extent to which alternatives are able to replicate the performance of fluoropolymers with respect to the speed and quality of production. Stakeholders have commented that fluoropolymers are expensive compared to alternatives and hence would not be used if they did not convey significant advantages for production or product performance. The occurrence of some functional losses is thus likely. Producer losses, e.g. as a result of costs associated with the need to adapt existing equipment, might occur but there is weak evidence on the extent to which existing systems using polymeric PFASs would need to be adapted.
Other packaging applications	There is sufficiently strong evidence of the availability of technically and economically feasible alternatives for: • packaging uses of f-HDPE (fluorinated high density polyethylene) • use of PTFE wax on the outer surface of drinks cans • temporary wrapping of new vehicles for delivery Conclusion: High substitution potential at EiF [sufficiently strong evidence]	No further information available.
Metal plating and manufacture of metal products (Annex E.2.4.)		
Hard chrome plating	Evidence on the availability of alternatives for the hard chrome plating sector is mixed, with some reporting satisfactory performance of alternatives and others not. Responses to the CfE and 2nd stakeholder consultation from industry are concluded to reflect the precise specifications of product lines provided by different companies, and these specifications	High producer surplus losses [weak evidence] as a result of business closures due to a significant share of business closures [weak evidence]. Some producer surplus [sufficiently strong evidence] losses as a result of substitution, due to additional expenditure on R&D and additional capital costs [sufficiently strong evidence].

Use sector (with sub-uses)	Alternatives	Cost impact
	causing some to be more advanced in transition than others. Conclusion: High substitution potential at EiF for the sector as a whole [sufficiently strong evidence] and low substitution potential at EiF in relation to some goods [weak evidence].	High socio-economic costs to customers [weak evidence] due to the unavailability of, or reduced quality of, hard chrome plating, though this may be negated by import of plated goods from outside of the EU where the restriction would not apply [weak evidence]. High employment losses [weak evidence] as a result of significant share of business closures [weak evidence].
Decorative plating with chrome, plating on plastics and plating with metals other than chrome	Based on existing experience it is concluded that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives that are already on the market for decorative chrome plating and plating on plastics. Based on the experience of the decorative chrome and plastic plating industries, there is evidence that alternatives exist for plating with other metals [weak evidence]. Conclusion: High substitution potential at EiF [sufficiently strong evidence for decorative chrome and plastic plating, weak evidence for plating with other metals]	Cost impacts for industry and consumers for the decorative chrome plating and plastics plating sectors are concluded to be negligible given the availability and take-up of alternatives that has already occurred. On this basis, it is not expected that there would be job losses in the sector linked to RO1. It is also concluded that there are no functional losses associated with this substitution [sufficiently strong evidence]. The situation for plating with other metals (primarily nickel, copper and tin) is less clear given a lack of information beyond the observation that the role of PFASs appears to be similar to decorative chrome plating for these metals. On this basis, it is expected that there will be negligible cost impacts for industry and consumers and negligible job losses [weak evidence].
Manufacture of metal products not addressed elsewhere	No evidence was identified through literature search or through the CfE and 2nd stakeholder consultation regarding use of PFASs in the manufacture of metal products other than those addressed under other sectors (e.g. construction products and transport).	No evidence was obtained to demonstrate that RO1 would be problematic for the manufacture of metal products other than those addressed specifically under other sectors (e.g. transport and construction products].
Consumer mixtures (Annex E.2.5.)		
Cleaners (for glass, metal, ceramic, carpet and upholstery)	Sufficiently strong evidence that technically feasible alternatives exist, i.e. silicones, as well as sufficiently strong evidence (in the form of practical examples of completed	No further information available.

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
	substitution for glass cleaners) pointing to the economic feasibility of alternative Conclusion: High substitution potential at EiF [sufficiently strong evidence]	
Waxes and polishes (for e.g. furniture, floors and cars)	Sufficiently strong evidence that technically feasible alternatives exist (e.g. carnauba wax for car polishing), i.e. in the form of patent information, as well as sufficiently strong evidence (in the form of practical examples of completed substitution) pointing to the economic feasibility of alternative Conclusion: High substitution potential at EiF [sufficiently strong evidence]	No further information available.
Dishwashing products (as rinse aid)	Sufficiently strong evidence that technically feasible alternatives exist, i.e. silicones, as well as sufficiently strong evidence (in the form of practical examples of completed substitution for rinse aids) pointing to the economic feasibility of alternative Conclusion: High substitution potential at EiF [sufficiently strong evidence]	No further information available.
Windscreen treatments for automobiles and also windscreen wiper fluids	Sufficiently strong evidence that technically feasible alternatives exist, i.e. patents, as well as sufficiently strong evidence (in the form of practical examples of completed substitution for windscreen treatments) pointing to the economic feasibility of alternative Conclusion: High substitution potential at EiF [sufficiently strong evidence]	No further information available.
Guitar strings	Sufficiently strong evidence that technically feasible alternatives exist, i.e. strings from nylon, gut, metal, lubricants based on mineral oil, as well as sufficiently strong evidence (in	Moderate producer surplus losses as a result of substitution, due to cost for research on additional alternatives (weak evidence, information on guitar strings based on confidential information from one stakeholder).

Use sector (with sub-uses)	Alternatives	Cost impact
	the form of practical examples of completed substitution) pointing to the economic feasibility of alternatives Conclusion: High substitution potential at EiF [sufficiently strong evidence]	No further information available.
Use in pianos	No information available, including no evidence to the contrary on technically and economic feasibility of alternatives Conclusion: No evidence available [no evidence]	No further information available.
Cosmetics (Annex E.2.6.)		
Sector as a whole	Sufficiently strong evidence that technically and economically feasible alternatives exist. No evidence pointing to a shortage in supply of alternatives. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Net product reformulation costs estimated to be €13.1 million over the time period 2025-2055. Over the extended assessment period 2025-2070, the net reformulation costs are estimated to be €14.5 million. No information indicating that substance substitution costs would be a barrier to implementation of the proposed restriction. The Dossier Submitters assume that these costs are negligible. No information available indicating any significant losses in product performance. The Dossier Submitters assume that the associated consumer losses are non-existent or negligible.
Ski wax (Annex E.2.7.)		
Sector as a whole	Sufficiently strong evidence that technically and economically feasible alternatives exist. No evidence pointing to a shortage in supply of alternatives. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Lower consumer expenditure on ski wax is likely. This reduction in expenditure could lead to a reduction in producer surplus, the extent of the latter is however unclear. Loss in consumer surplus expected to be negligible. No evidence of costs relating to testing, equipment, occupational safety measures and product development available to the Dossier Submitters.
Applications of fluorinated gases (Annex E.2.8.)		

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
Note that mobile air conditioning (MAC) and transport refrigeration, including military applications, are covered under Transport below.		
Refrigeration	Domestic refrigeration: Technically and economically feasible alternatives exist for all types of domestic refrigeration. Commercial and industrial refrigeration: There is growing acceptance of the use of natural refrigerants in the commercial and industrial markets. Specialist applications: Three specialist applications have been identified where alternatives are not currently available. • Refrigerants in low temperature refrigeration below -50°C • Refrigerants in lboratory test and measurement equipment • Refrigerants in refrigerated centrifuges used for example in medical laboratories where natural refrigerants pose hazards due to flammability or the use of high pressures as rotor failure could compromise the refrigerant system. Conclusion: • High substitution potential at EIF for domestic, commercial and industrial refrigeration [sufficiently strong evidence] • Low substitution potential at EiF for the three specialist applications identified [sufficiently strong evidence]	Domestic refrigeration: No cost impacts given that equipment using fluorinated gases is no longer placed on the market given the price and performance of alternatives. [sufficiently strong evidence] Commercial and industrial refrigeration: Growing acceptance of alternatives indicates that they are cost-competitive with fluorinated gas systems. Cost impacts under RO1 may focus on manufacturers that are slow to transition to the use of alternative refrigerants with significant loss of producer surplus and risk of business closure. [sufficiently strong evidence] Specialist applications: The lack of availability of alternatives would be problematic for both producers and consumers. RO1 would cause loss of producer surplus from the likely withdrawal of some product lines with some risk of business closure and loss of consumer surplus through the lack of availability of alternatives that are either safe to use or provide the necessary level of performance. [sufficiently strong evidence] A further issue concerns maintenance of existing equipment given a lack of drop-in alternatives. There are a limited number of trained and certified personnel for commercial and industrial refrigeration equipment for maintaining existing systems, including topping up equipment where leaks have occurred. Application of RO1 leading to an inability for maintenance of systems would generate significant added costs through the early retirement of existing equipment. [sufficiently strong evidence]

Use sector (with sub-uses)	Alternatives	Cost impact
Air conditioning and heat pumps	Domestic air conditioning: Technically and economically feasible alternatives exist for smaller (single-household) facilities, via use of hydrocarbons. Safety concerns have limited the application of hydrocarbons as an option in some domestic settings, for example shared residential space where refrigerant charge sizes may be large and high-rise buildings where there is heightened concern over fire risks. In both cases local or national building codes may limit the use of hydrocarbon refrigerants. Domestic tumble driers: Heat pumps using hydrocarbons for heat transfer have gained a significant market share in the tumble drier market. Commercial air conditioning: There is growing acceptance of the use of alternatives in this sector, particularly CO_2 and hydrocarbons, or CO_2 in cascade systems with other gases such as ammonia. Industrial air conditioning: Efficient systems based on ammonia have been in place for many years in industrial refrigeration and air conditioning. This is one possible solution for large data centres, though others exist. Small systems could be cooled using natural refrigeration or small air conditioning systems where refrigerant charge size is not problematic.	Domestic and commercial air conditioning: Risks to producer surplus and of business closure under RO1 for the domestic and commercial markets would be present for manufacturers that are slow to transition to the use of alternative refrigerants. There would also be loss of trade in cases where application is prohibited by local or national building codes. This would lead to reduced consumer surplus given a lack of alternatives that are compliant with the codes. [sufficiently strong evidence] Domestic tumble driers: Cost impacts linked to the domestic tumble drier market are likely negligible given widespread use of alternatives to fluorinated gases already, combined with the experience of the same companies in the domestic refrigeration market. [sufficiently strong evidence] A further issue concerns maintenance of existing equipment given a lack of drop-in alternatives. There are a limited number of trained and certified personnel and maintenance staff for air conditioning and heat pump systems. Application of RO1 to maintenance activities, including the topping up of systems during servicing would generate significant added costs through the early retirement of existing equipment. To the extent that this affects the heat pump market it would also compromise decarbonisation activities for mitigation of climate change. [sufficiently strong evidence]

Use sector (with sub-uses)	Alternatives	Cost impact
	Conclusion: High substitution potential at EiF for most stationary applications [sufficiently strong evidence]. Low substitution potential at EiF for uses where (particularly fire) regulations prohibit use of hydrocarbons [sufficiently strong evidence].	
Foam blowing agents	The major use that has commonly used fluorinated gases as blowing agents relates to foams used for insulation in buildings and vehicles. There has been some shift away from the use of fluorinated gases in some parts of the market. Alternatives are available but have performance constraints linked to fire performance, energy efficiency and durability. Hydrofluoroolefins (HFOs) provide the best level of insulation (the gases contained within the foam themselves providing an effective barrier to heat transfer). In some applications (e.g. spraying on-site) the use of hydrocarbons would not be permitted given the risk of flammability. Some stakeholders claim that low-pressure spray polyurethane foams in self-contained cylinders is a niche reliant on fluorinated gases as blowing agents. Conclusion: High substitution potential at EiF for most applications [sufficiently strong evidence]. Low substitution potential at EiF for foam blowing agents in PU spray foam [weak evidence].	Loss of producer surplus through loss of market for high value fluorinated gases that are significantly more expensive than alternatives (by as much as a factor of ten). Loss of consumer surplus through lower performance of alternatives in some insulation applications. This may lead to increased heat loss (conflicting with climate mitigation actions) or the need for thicker insulation which may be problematic where space is limited or valued (e.g. cargo space in vehicles) Welfare losses linked to increased risks of flammability in some applications, notably on-site spraying. [sufficiently strong evidence].
Solvents	This is a very diverse sector with solvents used for a wide variety of applications. In many cases, there are alternatives. However,	Producer surplus loss through reduction in market opportunity, given applications where alternatives are not considered suitable. Potential for growth in not-in-kind alternatives

Use sector (with sub-uses)	Alternatives	Cost impact
	in addition to the literature search, stakeholders have reported that there are no alternatives to fluorinated gases for: • Industrial precision cleaning fluids • Cleaning fluids for use in oxygen-enriched environments For 3D printing, limited information has been submitted by industry to indicate alternatives do not exist for some specific applications: • Solvent-based debinding systems in 3D printing for industrial and professional applications • Smoothing agents for polymer 3D printing applications for industrial and professional applications. A case has been made for 3D printing of metals and medical devices though not for other parts of the market. Comparative evidence of the performance of alternatives is lacking. <u>Conclusion:</u> High substitution potential at EiF across a diverse range of applications [sufficiently strong evidence] and low substitution potential at EiF for specialist cleaning fluid applications [sufficiently strong evidence] and for 3D printing [weak evidence].	Loss of consumer surplus where alternatives are more expensive For industrial precision cleaning fluids there are further potential impacts on consumers through flammability of alternatives, increased drying times, inability of solvent to penetrate confined spaces leading to reduced performance, incompatibility with electronic systems, etc. These may feed through to impacts on the durability of systems. [Sufficiently strong evidence] It is not clear how broadly the 3D printing sector would be affected by a restriction – whether difficulties are restricted to 3D printing of metals and medical devices, or affect other products as well. This clearly affects the scale of producer and consumer surplus losses linked to a restriction. [Weak evidence]
Propellants	A variety of options are available on the market in the form of alternative propellants and delivery systems (e.g. bag-on-valve) though in some applications toxicity and	The increasing price of fluorinated gas propellants via the move from HFCs to HFOs already provides encouragement to switch to alternatives. Acceptance of this added cost has been cited by several in industry as strongly indicative of the added value of

Use sector (with sub-uses)	Alternatives	Cost impact
	flammability of alternatives are a concern. Limitations apply, for example, where the propellant is the payload (air dusters) or the propellant is a solvent for the payload (cans that need to be shaken before use). A small number of companies in niche industries (e.g. supplying air dusting equipment, or propellant/solvents for applying specific finishes, lubricants, etc. in industrial settings), indicated that they would not be able to continue operations in the markets for which they currently provide aerosols given the extent to which they have specialised their product lines. Conclusion: High substitution potential at EiF across a diverse range of applications [sufficiently strong evidence] and low substitution potential at EiF in niche industries [weak evidence].	using fluorinated gases, though there appears to remain some use in personal and household care products where any added benefit cannot be significant. However, safety and performance constraints for some technical aerosols should be recognised as these could lead to significant consumer surplus losses [sufficiently strong evidence for some applications].
Magnesium casting	Several alternatives are used already to act as cover gases in magnesium casting to prevent oxidation at the metal/air interface. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	SO_2 has been identified as a cost-effective alternative to HFC134a for die casting operations, with a substitution cost in the order of €6 to €60 per kg of HFC134a emitted. Very limited data has been identified for sand casting operations, but there is no indication that a restriction without derogation would not be proportionate [sufficiently strong evidence].
Fire suppressants	Alternatives available, but for some applications they have a range of drawbacks, for example risk of asphyxiation (e.g. CO_2), potential to damage protected assets (e.g. water), slower speed of action than fluorinated gases. Critical applications include aviation and military vehicles.	Price already provides a mechanism favouring alternatives to fluorinated gases and has led to a significant shift in the market where they are not considered necessary. Remaining users which include safety critical applications such as fire prevention on aircraft and in military vehicles, and protection of cultural assets, consider the benefits of fluorinated gases sufficient to accept higher prices indicating potential for significant consumer surplus losses. [sufficiently strong evidence]

Use sector (with sub-uses)	Alternatives	Cost impact
	Conclusion: High substitution potential at EiF for some uses [sufficiently strong evidence] and low substitution potential at EiF for other applications [sufficiently strong evidence].	
Preservation of cultural paper-based materials	This process involves suspending magnesium oxide (MgO) in a fluorinated gas solvent for treatment of paper materials to stop acid corrosion hence preserving artefacts. Fluorinated gas solvents have the ability to deliver the alkaline buffer without degrading ink, binding materials, glue or discolour the paper. Alternative approaches have not been described. New approaches would need extensive testing to ensure that they are safe to use on irreplaceable materials. Conclusion: Low substitution potential at EiF [weak evidence].	There would be some loss of producer surplus through the loss of market opportunity, though associated use volumes may be small. Consumer surplus losses are likely more important, with potential long-term consequences for the preservation of cultural materials [sufficiently strong evidence].
Insulating gas in electrical equipment	Clean air technology has been introduced to replace both SF6 and fluorinated gases as insulating gas in electrical equipment, together with dry air (mix of nitrogen and oxygen) and vacuum. However, for high-voltage switchgear the technology is still in development. A full fluorinated gas free portfolio up to 145kV is already available and in operation. For high-voltage switchgear >145kV, alternatives are not yet on the market. Conclusion: High substitution potential at EiF for most uses [sufficiently strong evidence]. Low substitution potential at EiF for high-voltage switchgear (above 145kV) [sufficiently strong evidence]	Socio-economic costs due to delayed power grid expansions, inadequate electricity transmission and increased risk of outages
Medical devices (Annex E.2.9.)		

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
Implantable medical devices (not including meshes, wound treatment products, and tubes and catheters)	Sufficiently strong evidence that technically and economically feasible alternatives are not generally available. Conclusion: Low substitution potential at EiF [sufficiently strong evidence]	High socio-economic costs can be expected from the public health effects resulting from increased risk of implant failures and higher frequency of replacements.
Hernia meshes	Weak evidence that technically and economically feasible alternatives are not generally available. Conclusion: Low substitution potential at EiF [weak evidence]	If technically feasible alternatives are indeed not available, a ban of PFASs would lead to increased risk of adverse health impacts (intestinal damage and fistula formation) in patients. These impacts are likely to be associated with high socio-economic costs.
Wound treatment products	Weak evidence that technically and economically feasible alternatives are not generally available. Conclusion: Low substitution potential at EiF [weak evidence]	No information was provided on the cost impacts of a ban, therefore the costs are unknown.
Tubes and catheters	Sufficiently strong evidence that technically and economically feasible alternatives are not generally available. Conclusion: Low substitution potential at EiF [sufficiently strong evidence]	The information obtained indicates that a ban on PFASs in these applications would lead to more procedures that are more invasive and/or more painful for the patient. The socio-economic costs related to these implications can be expected to be high.
Coatings of Metered Dose Inhalers (MDIs)	Sufficiently strong evidence that technically and economically feasible alternatives are not generally available. Conclusion: Low substitution potential at EiF [sufficiently strong evidence]	Regarding coating of metered dose inhalers, the lack of technically feasible alternatives and the high societal value of the medicinal product indicates that a full ban would be associated with high socio-economic costs.
Other coating applications	Weak evidence that technically and economically feasible alternatives are not generally available.	For other coating applications, there was no information provided on the cost impacts of a ban, and therefore the costs are unknown.

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
	Conclusion: Low substitution potential at EiF [weak evidence]	
Cleaning and heat transfer: engineered fluids	Weak evidence that technically and economically feasible alternatives are not generally available. Conclusion: Low substitution potential at EiF [weak evidence]	No information provided on the cost impacts of a ban, therefore the costs are unknown.
Sterilization gases	A wide range of economically feasible sterilization methods are available, but some uncertainty prevails regarding their technical feasibility in the applications where PFASs are currently used. Conclusion: High substitution potential at EiF [weak evidence]	If any of the identified sterilization methods is technically feasible for the applications where PFASs are currently used, the cost impacts of a full ban are expected to be low.
Diagnostic laboratory testing	Sufficiently strong evidence that technically and economically feasible alternatives are not generally available. Conclusion: Low substitution potential at EiF [sufficiently strong evidence]	A ban of PFASs could have substantial impacts on the feasibility of diagnostic laboratory testing, which in turn would have severe implications on public health.
Rigid gas permeable (RGP) contact lenses and ophthalmic lenses	Alternatives are widely available, but there is weak evidence that these alternatives are not technically and economically feasible. Conclusion: Low substitution potential at EiF [weak evidence]	A transition away from PFASs could lead to some negative socio-economic impacts in terms of: • Quality-of-life reductions for users of eyeglasses and RGP contact lenses, and • Increased costs due to more frequent replacements of eyeglasses. The information provided does not allow for quantification of these impacts.
Propellants in Metered Dose Inhalers (MDIs)	Sufficiently strong evidence that technically and economically feasible alternatives are generally available.	Apart from potential transition costs, the costs of substitution are likely to be very small.

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
	Conclusion: High substitution potential at EiF [sufficiently strong evidence]	No additional administrative costs for industry or authorities are expected.
Membranes used for venting of medical devices	Weak evidence that technically and economically feasible alternatives are not generally available. Conclusion: Low substitution potential at EiF [weak evidence]	No information on the socio-economic implications of a ban of PFASs in these applications, if feasible alternatives indeed do not exist, is available to the Dossier Submitters. The socio-economic costs of a ban of PFASs in these applications are unknown.
Packaging of medical devices	Weak evidence that technically and economically feasible alternatives are not generally available for the following packaging of medical devices: • PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics, • PTFE in ophthalmic solutions packaging, and • Packaging of terminally sterilised medical devices. For other packaging of medical devices, there is no information on alternatives. Conclusion: Low substitution potential at EiF for some packaging applications [weak evidence]	In applications where packaging is vital for functionality and safety, and where no available alternatives exist that meet the technical requirements, there is sufficiently strong evidence that a ban on PFASs is likely to have high socio-economic costs. The Dossier Submitters do not have the information available to identify these applications. In applications where packaging is not vital for the functionality and safety of the medical devices or where available alternatives can meet the technical requirements for functionality and safety, the Dossier Submitters assume that a ban of PFASs would have low socio-economic costs.
Transport (Annex E.2.10.)		
Use of PFASs in applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods, to the extent not addressed under other parts of this restriction (e.g. under	Alternatives covering the full range of applications of PFASs in these applications for the transport sector are not yet on the market. Use of alternatives would require testing, certification and in some, perhaps many, cases re-design of equipment.	The transport sector has an extremely high dependence on PFASs, including use in complex products (e.g. seals, O-rings and gaskets in engines). The properties of PFASs can provide input to the design of such products, with the result that drop-in substitutes will not always be available. Even where they are, testing and certification procedures would need to be followed. It

Use sector (with sub-uses)	Alternatives	Cost impact
lubricants, electronic equipment and TULAC)	Conclusion: Low substitution potential at EiF [sufficiently strong evidence]	is therefore concluded that a full ban is not feasible for the transport sector [sufficiently strong evidence]. In the event of a full ban, there would be significant disruption to the industry leading to very high producer surplus losses including business closures, which would also lead to substantial employment losses. In the event that it is possible to produce vehicles, there is also a strong likelihood of consumer surplus losses through the sale of vehicles with limited capabilities and reduced reliability. Disruption to the market would also affect the transition to electric vehicles, with consequences for climate and air quality policies.
Hydraulic fluids	No acceptable non-PFAS alternatives have been approved for use in the aviation sector and for aerospace industry, where PFASs are used for example for anti-erosion/anti-corrosion purposes in hydraulic systems, including landing gear [sufficiently strong evidence]. Alternatives are not available on a short timescale given the need for approval under various specification schemes [sufficiently strong evidence]. Conclusion: Low substitution potential at EiF [sufficiently strong evidence]	Not feasible for the aviation and aerospace industry under a full ban given the need to develop, test and certify alternatives [sufficiently strong evidence]. No data for other transport sectors is available. A full ban would cause major disruption to the industry leading to significant producer and consumer surplus losses, and impacts on employment.
Mobile Air Conditioning (MAC)	Alternatives are available for electrical and hybrid cars, while not necessarily for combustion engine vehicles with mechanical compressors. Such systems may need to be redesigned by each manufacturer to enable use of alternative refrigerants, for example to address higher pressures of CO2 systems and secondary loop systems for R152a.	Alternatives have been identified for combustion engine vehicles, with an estimated cost-effectiveness in the order of €100 to 500/kg PFAS for passenger cars, depending on lifetime leakage rates over the service life of vehicles, the fate of the fluorinated gas at end of life and the chosen alternative. However, they are not drop-in replacements and systems would need to be redesigned to enable their use [sufficiently strong evidence]. Impacts of RO1 related to mobile air conditioning are dependent on the time taken for most manufacturers to design alternative

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
	Conclusion: High substitution potential for electric and hybrid vehicles at EiF, low substitution potential at EiF for combustion engine vehicles with mechanical compressors [sufficiently strong evidence]Low substitution potential at EiF [sufficiently strong evidence]	mobile air conditioning systems that can be integrated with existing vehicle designs. This leads to some loss of producer surplus through costs of R&D, capital costs etc. to provide new MAC-systems [sufficiently strong evidence]. There is no reason to expect exports of vehicles from the EU to be affected as systems could be filled with fluorinated gases after export. Lower costs of alternative refrigerants would mitigate costs to consumers in the longer term when gas levels need to be topped up.
Transport refrigeration	Sufficiently strong evidence that alternatives exist for both marine and land-based applications (active and passive CO_2 systems and NH_3 systems). However, except for marine applications these may require re-design of equipment as alternatives are not drop-in replacements for PFASs. It is considered by industry that the adoption of alternatives can reduce capacity of, for example, refrigerated trucks, given that alternatives can require more space than systems based on PFAS refrigerants. Conclusion: High substitution potential at EiF for marine applications [sufficiently strong evidence] and low substitution potential at EiF for other applications [sufficiently strong evidence].	Alternative systems have some market penetration indicating that they can be cost-competitive but there remain significant barriers to widespread adoption. There is sufficiently strong evidence that for some parts of the transport sector significant re-design of equipment would be needed, raising questions about the feasibility of substitution in the timescale available until a full ban takes effect. This would then cause loss of both producer and consumer surplus, though costs have not been estimated.
MAC- and refrigeration in military applications	Refrigeration (both mobile and stationary) and MAC in military applications faces additional barriers to substitution due to strong operation and safety conditions in higher risk situations (e.g. battle or training exercises) as alternative natural refrigerants could pose significant risk of fire	Costs of existing alternatives for military applications would be similar to those for options applying to civilian applications for many routine goods. It is likely that goods that are not to be used in higher risk situations that procurement would follow the civilian market simply on price grounds. However, additional design considerations and further R&D may be required to ensure the protection of service personnel in higher risk activities and

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
	(hydrocarbons), toxicity (NH3) or asphyxiation (CO2). Alternative approaches to refrigeration in military transport vehicles may be required, but these are not currently available for the sector Conclusion: Low substitution potential at EiF [sufficiently strong evidence].	these will likely be at an increased cost relative to civilian situations [weak evidence].
Electronics and semiconductors (Annex E.2.11.)		
Electronics	Inconclusive evidence on whether technically feasible alternatives (i.e. EPDM and silicone) exist for fluoroelastomers in all sealing applications, however sufficiently strong evidence (in the form of stakeholder information) that generally alternatives are cheaper than fluoroelastomers. Inconclusive evidence whether technically feasible alternatives (e.g. PEEK, PC, EPDM) exist for wire insulation. Sufficiently strong evidence that technically feasible alternatives exist for heat transfer fluids for immersion cooling. No evidence on the economic feasibility of alternatives. Weak evidence that technically feasible alternatives exist, i.e. cyano group instead of CF_3, for liquid crystal displays. No evidence on the economic feasibility of alternatives. Inconclusive evidence for uses other than mentioned above: Several stakeholders point out that alternatives are not available. However other stakeholders confirm that it is likely that alternatives are already available or might be found for a lot of components	High producer surplus losses as a result of business closures [weak evidence] due to not being able to manufacture electronic devices [weak evidence] High socio-economic costs to customers due to the unavailability of electronic devices [weak evidence] Employment losses as a result of high share of business closures [weak evidence]

Use sector (with sub-uses)	Alternatives	Cost impact
	depending on concrete circumstances for each use. Conclusion: High substitution potential at EiF for heat transfer fluids for immersion cooling [sufficiently strong evidence] and liquid crystal displays [weak evidence]. Unclear substitution potential at EiF for fluoroelastomers in all sealing applications, in wire insulation and all other uses [inconclusive evidence].	
Semiconductors	Weak evidence that technically feasible alternatives exist for: • Photolithography (photoacid generators), • Fluoroelastomers used for chip manufacturing, • Immersion cooling of semiconductor devices, and • Flame retardancy in plastics Stakeholder information suggests the non-existence of alternatives for several uses because of the chemical properties necessary for semiconductor manufacturing process [weak evidence]. In addition, alternatives that could be available for one specific use cannot be used for other similar uses [weak evidence]. Conclusion: High substitution potential at EiF for photolithography (photoacid generators), fluoroelastomers used for chip manufacturing, immersion cooling of semiconductor devices and flame retardancy in plastics [weak evidence]. Low substitution potential at EiF for the semiconductor manufacturing process [weak evidence].	• High producer surplus losses as a result of business closures due to not being able to manufacture semiconductors [weak evidence] • High producer surplus losses as a result of substitution processes due to costs associated with R&D [weak evidence] • High socio-economic costs to customers due to the unavailability of articles using semiconductors [weak evidence] • Employment losses as a result of high share of business closures [weak evidence]
Energy sector (Annex E.2.12.)		

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
Sector as a whole	Sufficiently strong evidence that technically and economically feasible alternatives exist for: • Backsheets for photovoltaic cells (PET, EVA), but also claimed to be less durable, a There is sufficiently strong evidence for the existence of technically feasible alternatives for membrane applications in PEM fuel cells, with hydrocarbon membranes, PEEK membranes being mentioned as relevant alternatives identified through ongoing R&D. These alternatives are reported to provide a reasonable performance but are inferior in terms of durability. Evidence points however to potential shortages in supply, with stakeholders reporting that it will take ten or more years from 2022 until validated alternative materials are available in sufficient volumes. There is sufficiently strong evidence for the existence of alternatives for reinforcement materials for use in PEM fuel cells, with promising undertakings in relation to replacing PTFE by fluorine-free compounds like electrospun polybenzimidazole-type materials. Evidence points however to significant time requirements for alternatives to become commercially available, with commercial use not being expected to start before five to 10 years from 2022. There is sufficiently strong evidence that technically and economically feasible alternatives exist for sealing materials used in PEM fuel cells (e.g. hydrocarbon elastomers,	Not enough information to conclude on costs associated with specific uses. For uses for which substitution is deemed possible, examples of costs that will be incurred include: • Costs associated with more frequent replacement, resulting from quicker deterioration and/or more frequent defects, e.g. as a result of the lower weather resistance and inferior vapour barrier properties of alternatives with respect to photovoltaic cells, or lower chemical resistance in the case of nuclear power plants

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
	PEEK). These alternatives are however also claimed to be less durable, e.g. due to lower chemical resistance. Given the good gas-permeability and lower cost, replacement of substituted elastomers is reported to be desirable when possible. In addition, there is weak evidence pointing to lower flame-retardant properties. As such, alternatives might not be technically feasible for applications with particularly high stability, and durability and flame-retardance requirements. Weak evidence, based on information from one stakeholder, that alternatives for gasket material for nuclear power plants exist but are less durable. Weak evidence that technically feasible alternatives exist for gaskets, tubes, and inliners of pipes/tanks used in relation to non-PEM electrolysis technologies. Weak evidence that alternative batteries, e.g. PFAS-free solid-state batteries could be used as a substitute for lithium-ion and flow batteries: While stakeholders report that there might be alternatives to PFASs for use in solid-state batteries, the feasibility of using such batteries as a replacement for flow batteries is still investigated Inconclusive evidence for uses not mentioned above: Several stakeholders point out that alternatives are not available. However other stakeholders confirm that it is likely that alternatives are already available or might be found for a lot of components depending on concrete circumstances for each use.	

Use sector (with sub-uses)	Alternatives	Cost impact
	Conclusion: • High substitution potential at EiF for photovoltaic cells [sufficiently strong evidence] • High substitution potential at EiF for at least some applications of sealing materials in PEM fuel cells [sufficiently strong evidence] and for gasket material for nuclear power plants and gaskets, tubes and inliners used in relation to non-PEM electrolysis technologies [weak evidence] • High substitution potential at EiF for at least some battery applications [weak evidence] • Low substitution potential at EiF for membrane applications and reinforcement materials in PEM fuel cells [sufficiently strong evidence] • Unclear substitution potential at EiF for all other uses [inconclusive evidence]	
Construction products (Annex E.2.13.)		
Architectural coatings and paints	Sufficiently strong evidence that technically and economically feasible alternatives exist, and no evidence points in the direction of shortages in the supply of alternatives. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Sufficiently strong evidence that substitution costs are expected to be limited. No evidence on reformulation costs, one-off capital costs or administrative costs related to the transition have been identified, and the economic implications for downstream users are expected to be limited. There is sufficiently strong evidence that a ban on PFASs in architectural coatings and paints is likely to have low socio-economic costs.
Wind turbine blade coating	Sufficiently strong evidence that technically and economically feasible alternatives exist, and no evidence points in the direction of shortages in the supply of alternatives.	Sufficiently strong evidence that substitution costs are expected to be limited. No evidence on reformulation costs, one-off capital costs or administrative costs related to the transition have been

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
	Conclusion: High substitution potential at EiF [sufficiently strong evidence]	identified, and the economic implications for downstream users are expected to be limited. There is sufficiently strong evidence that a ban on PFASs in wind turbine blade coating is likely to have low socio-economic costs.
Coil coating	Sufficiently strong evidence that technically and economically feasible alternatives to replace fluoropolymer binders in coil coating exist. Weak evidence that available alternative formulations might contain micro-powder PTFE as additive. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	The existence of alternatives to fluoropolymer binders in coil coating is not doubted, as they dominate the market (even with some potential changes to the lifetime). Cost impacts are uncertain as a result of the uncertainty associated with the content of micro-powder PTFE in (some) alternative formulations. The substitution costs depend on the number/volume of alternative formulations without micro-powder PTFE as additive. If this number is high, costs will be low as drop-in alternatives are then available (with some potential changes to the lifetime). If the number is low, reformulation is needed and new weathering studies may also be needed and costs will be higher. As a result, the socio-economic costs of a full ban are uncertain.
Architectural membranes (composite membranes with top coating)	Sufficiently strong evidence that technically and economically feasible alternatives to replace fluoropolymers in composite membrane top coating exist - but with some loss of functionality (less soil repellence for some types) and reductions in lifetime. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Some alternatives are available on the market and likely at a lower unit cost than fluoropolymer top coating. Substitution costs are likely to be limited, if alternatives are available in sufficient quantities. The available alternatives might have negative impacts on the lifetime of polyester/PVC membranes and fiberglass fabric under harsh environmental conditions. Siloxane has less soil/dirt repellence. As a result, higher maintenance costs are expected. As such, there is sufficiently strong evidence that a ban of PFASs will likely be associated with moderate socio-economic costs.
Architectural membranes (pure fluoropolymers)	Sufficiently strong evidence that technically and economically feasible alternatives to replace pure fluoropolymer architectural membranes with non-PFAS composite	Some alternatives are available on the market and likely at a lower unit cost than pure fluoropolymer membranes. Substitution costs are likely to be limited, if alternatives are available in sufficient quantities.

Use sector (with sub-uses)	Alternatives	Cost impact
	membranes exist – but with some loss of functionality (less soil repellence for some types) and reductions in lifetime. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	The available alternative composite architectural membranes (polyester/PVC membrane with TiO_2 and fiberglass fabric coated with siloxane) will have negative impacts on the lifetime under harsh environmental conditions, and fiberglass fabric coated with siloxane have less soil/dirt repellence. As a result, higher maintenance costs are expected. As such, there is sufficiently strong evidence that a ban of PFASs will likely be associated with moderate socio-economic costs.
ETFE film/foil for greenhouses	Sufficiently strong evidence that technically and economically feasible alternatives to replace ETFE film/foil in greenhouses exist. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Sufficiently strong evidence that substitution costs are likely to be limited, following the availability of alternatives (traditional products: glass and polyethylene foil) that likely dominate the market. The economic implications for downstream users are expected to be moderate, as functional losses and reductions in lifetime will lead to higher maintenance costs (polyethylene foil has a shorter lifetime and glass is less flexible, requires more construction material (e.g. wood or metal) and is not self-cleaning). There is sufficiently strong evidence that a ban on ETFE film/foil for greenhouses is likely to have moderate socio-economic costs.
Windows frames (laminated with fluoropolymers)	Sufficiently strong evidence that technically and economically feasible alternatives to replace PVC and HPL window frames laminated with fluoropolymers (PVDF) exist. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Sufficiently strong evidence that substitution costs are likely to be limited, following the availability of alternatives. Alternatives to PVC and HPL frames include traditional materials for window frames such as wood and metal. These alternatives have a high market share. The economic implications for downstream users are expected to be limited. Window frames made of wood will likely require more maintenance, but they also have a long lifetime if maintained properly.

Use sector (with sub-uses)	Alternatives	Cost impact
		There is sufficiently strong evidence that a ban of PFASs will likely be associated with low socio-economic costs.
Bridge and building bearings	Weak evidence that technically and economically feasible alternatives to replace fluoropolymers (PTFE) in bridge and building bearings exist. Steel rollers are considered technically feasible, but more expensive and will likely require redesign. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [weak evidence].	The magnitude of capital costs associated with substitution is unknown, as it is unknown if steel rollers are available as drop-in alternatives. Steel rollers are stated to be significantly more expensive by stakeholders. The economic implications for downstream users could be high, as alternatives require more space in constructions. Bridges and buildings will therefore likely have to be designed differently, which might also be associated with additional costs. If the higher costs of alternatives are passed on to downstream users, downstream users will also face consumer surplus losses. There is weak evidence that a ban of PFASs could be associated with high socio-economic costs.
PTFE thread sealing tape	Weak evidence that technically and economically feasible alternatives to replace PTFE thread sealing tape exist. Liquid/paste pipe thread is considered a technically feasible alternative for permanent seals but the technical feasibility is uncertain for non-permanent seals. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF in relation to permanent seals [weak evidence] and unclear substitution potential at EiF for non-permanent seals [inconclusive evidence]	The magnitude of capital costs associated with substitution is unknown and liquid/paste pipe thread may only partly be an alternative. If this is the case, some R&D costs may also be expected. There is weak evidence that substitution costs are low, following the availability of alternatives and no indication pointing to significant capital costs or significant changes to operating costs.

Use sector (with sub-uses)	Alternatives	Cost impact
Polymeric PFASs used as processing aids for production of non-PFAS polymers/plastics	Sufficiently strong evidence that technically and economically feasible alternatives to replace polymeric PFASs as processing aids for the production of thermo- and thermoset plastics in use in the building/construction sector exist. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence].	Substitution costs are likely to be minimal as alternatives (e.g. boron nitride and siloxanes) are available. There is however uncertainty on whether alternatives can be considered drop-in alternatives or if reformulation or adaptations to existing systems would be needed. The economic implications for downstream users depend on whether alternatives can be considered to be drop-in alternatives. There is weak evidence that substitution costs are low, following the availability of alternatives, evidence pointing to lower costs of alternatives and no indication pointing to significant capital costs.
Side-chain fluorinated polymers used for surface protection/sealants	Sufficiently strong evidence that technically and economically feasible alternatives to replace side-chain fluorinated polymers for surface protection/sealants exist. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Sufficiently strong evidence that substitution costs are limited, following the availability of (though not always drop-in) alternatives. The alternatives are likely of lower costs. The economic implications for downstream users are expected to be moderate, as functional loss will lead to higher maintenance costs due to lower soil/dirt repellence which can be relevant for some applications. There is sufficiently strong evidence that a ban on side-chain fluorinated polymers used for surface protection/sealants is likely to have moderate socio-economic costs.
Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives	Sufficiently strong evidence that technically and economically feasible alternatives to replace non-polymeric PFASs (fluorosurfactants) exist. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters.	Sufficiently strong evidence that substitution costs are likely to be limited, following the availability of alternatives. The alternatives are likely of lower costs, but might require higher amounts. There are no drop-in alternatives, except products (e.g. solvent-based architectural paints and coatings) without fluorosurfactants that are available on the market and that can be seen as alternatives for certain applications. Sufficiently strong evidence that substitution costs are limited; reformulation might be required for some uses, however the

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
	Conclusion: High substitution potential at EiF [sufficiently strong evidence]	costs are to some extent likely to be absorbed by the PFHxA restriction proposal. Potentially some welfare losses following lower functionality, as some specific types of fluorosurfactants provide dirt/soil repellence, which is not the case for alternatives. There is sufficiently strong evidence that a ban on PFASs is likely to have low socio-economic costs in relation to fluorosurfactants as wetting/levelling agents in products such as coatings, paints, and adhesives.
Non-polymeric PFASs as processing aids	Sufficiently strong evidence that technically and economically feasible alternatives to replace the final products (architectural membrane-like product) manufactured with a non-polymeric PFAS processing aid exist. No evidence pointing to a shortage in the supply of alternative final products is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Sufficiently strong evidence that substitution costs are limited, following the availability of alternative final products (not produced with non-polymeric PFAS processing aids) as drop-in. Alternative final products dominate the market. According to a stakeholder, alternative final products also meet building regulations (not further specified). There is sufficiently strong evidence that a ban on PFASs is likely to have low socio-economic costs in relation to processing aids for production of an architectural membrane-like product.
	Inconclusive evidence on whether technically and economically feasible alternatives exist for replacing non-polymeric PFAS processing aids for production of acrylic foam tape. Conflicting information - one stakeholder stated that no alternatives is available. However, later the stakeholder announced to end manufacturing and use of PFASs. Conclusion: Unclear substitution potential [inconclusive evidence]	Not assessed due to unclear substitution potential

Use sector (with sub-uses)	Alternatives	Cost impact
Window film manufacturing	Inconclusive evidence on whether technically and economically feasible alternatives exist for replacing non-polymeric PFASs (fluorosurfactants) for manufacturing of window film. Conflicting information - one stakeholder stated that no alternatives is available. However, later the stakeholder announced to end manufacturing and use of PFASs. Conclusion: Unclear substitution potential [inconclusive evidence]	Not assessed due to unclear substitution potential
Lubricants (Annex E.2.14.)		
Sector as a whole	Sufficiently strong evidence that technically and economically feasible alternatives do not exist for the uses where lubricants containing PFASs are applied under harsh conditions or for safe functioning or safety of equipment. There is inconclusive evidence on the existence of alternatives for PFAS-based lubricants not applied under conditions considered harsh or safety-related: for some they are available, but probably not for all. Conclusion: Low substitution potential at EiF for lubricants applied under harsh conditions or for safe functioning or safety of equipment [sufficiently strong evidence]. Unclear substitution potential at EiF for lubricants not applied under harsh conditions or for safe functioning or safety of equipment [inconclusive evidence].	High socio-economic costs are to be expected due to the non-existence of alternatives. Functionality loss, e.g. related to performance level and lifetime, is likely to affect an unknown number of industries and end-users. Product reformulation costs are estimated to range between tens of thousands and several million euros, but reformulation is unlikely to be possible within the given timeframe.
Petroleum and mining (Annex E.2.15.)		

Use sector (with sub-uses)	**Alternatives**	**Cost impact**
Non-polymeric PFAS applications (tracers and anti-foaming agents)	Sufficiently strong evidence that technically and economically feasible alternatives exist. No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Substitution costs and transitional costs are expected to be relatively small. No reformulation costs, one-off capital costs or administrative costs related to the transition have been identified. The economic implications for downstream users are expected to be minimal. As a result, there is sufficiently strong evidence that a ban on PFAS in oil and gas tracers and anti-foaming agents is likely to have low socio-economic costs.
Fluoropolymer applications	Sufficiently strong evidence that technically and economically feasible alternatives are not generally available. Conclusion: Low substitution potential at EiF [sufficiently strong evidence]	Product reformulation costs can range from tens of thousands of euros to millions of euros for any single formulation. Product reformulation will also imply costs relating to quality assurance. Loss of functionality of products in this sector could have substantial economic implications, including shorter operational lifetime of components, increased frequency and costs of maintenance, and increased operational downtimes. The costs of substitution are likely to be borne in full (in the form of reduced producer surplus/profits) by the firms active in the sector.

Table 9. RO2 - Summary table of derogations ('proposed' or 'for reconsideration') for PFAS manufacture and major PFAS use sectors, with substantiation for the derogation period (5 or 12 years) and with cost impacts for the 5 and 12 year derogation periods.

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
Manufacture (Annex E.2.1.)			
Sector as a whole	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for: - Polymerisation aids in the production of polymeric PFASs other than PTFE, PVDF and FKM	Ban with a transition period of 18 months and a **5-year** derogation, because fluorine-free polymerisation aids in the production of polymeric PFASs other than PFFE, PVDF and FKM are expected to become available within 10 years from 2022.	Ban with a transition period of 18 months and a 5-year derogation: Lower producer surplus losses compared to RO1 because of business closures [weak evidence] Ban with a transition period of 18 months and a 12-year derogation: Lower costs compared to 5-year derogation.
TULAC (Annex E.2.2.)			
Home textiles	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Consumer apparel	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Professional apparel (including PPE)	In light of the sufficiently strong evidence pointing to the unavailability of alternatives at EiF for six of 13 PPE applications, derogations are **proposed** for: - Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c) - Personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks	Ban with a transition period of 18 months and a **12-year** derogation. Based on current knowledge, PFASs are deemed to be required to achieve performance standards for six of 13 PPE applications. As no potential alternatives are identified as of now, it is likely that they will not become available in the near future. Stakeholder information presented in Annex E.2.2.4.1 suggests furthermore that between 12 and 36 months might be needed to complete substitution once a suitable alternative has been identified	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1 Ban with a transition period of 18 months and a 12-year derogation: Assuming that an alternative will be identified Low producer surplus losses as a result of business closures [weak evidence] due to low share of business closures [weak evidence]

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
	as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m) - Impregnation agents for re-impregnating of articles referred to above	due to time requirements for product development, testing and approval in the supply chain and certification [sufficiently strong evidence base].	Low producer surplus losses as a result of substitution [sufficiently strong evidence], despite (i) high share of substitution [weak evidence] and (ii) medium to high costs at company level [sufficiently strong evidence], due to (i) the low number of companies being affected [sufficiently strong evidence] and (ii) low internalization of costs [sufficiently strong evidence] Low consumer surplus losses from price changes [sufficiently strong evidence] due to (i) the low annual sales volume [sufficiently strong evidence] Some additional costs**,** as a result of earlier disposal of PPE as a result of the unavailability of impregnation agents for some types of PPE [sufficiently strong evidence] Low level of employment losses due to low share of business closures [weak evidence]
Technical textiles[17]	In light of the sufficiently strong evidence pointing to the low substitution potential at EiF for many types of high-performance membranes, a derogation is **proposed** for: - Textiles for the use in filtration and separation media used in high	Ban with a transition period of 18 months and a **5-year** derogation. Stakeholder information and the Annex XV dossier for PFHxA points to a high substitution potential for high performance membranes given that alternatives are already in the R&D stage [sufficiently	Ban with a transition period of 18 months and a 5-year derogation: If trials and approval processes for alternatives in the R&D stage are successful, substitution will be encouraged by the high margins and low price elasticity of demand allowing affected

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[17] Technical textiles include textiles for medical applications. Medical devices covered further below however also include textiles in some cases. To maintain clarity, medical textiles covered under technical textiles refer to any use of textiles in a medical setting, excluding use within or on the patient. Examples are mattress protectors for hospital beds, curtains/drapes around beds and gowns used by medical professionals. Implantable textiles like gauzes or applications used upon the body like bandages are included under medical devices.

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
	performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence	strong evidence base] and that the time required for approval and commercialization is in line with the available timeframe. The Annex XV dossier for PFHxA suggests the same derogation as this dossier, despite acknowledging that some alternatives might already be available or will become so in the near future. Stakeholder information (described in Annex E.2.2.2.) suggests that alternatives to PTFE membranes and PFAS-coated products are produced but that PFASs are used for the production process. While filter media can also be produced without PFASs, such alternatives still need to be trialled, tested and validated. Stakeholder information presented in Annex E.2.2.4.1 suggests furthermore that between three and 36 months might be needed for testing and approval, while a supplier of filters for mist and dust removal suggests that at least three years are required for commercializing an alternative technology and receiving customer validation and approval.	companies in the filtration industry to pass on substitution costs to their customers: Low producer surplus losses as a result of business closures [sufficiently strong evidence] due to a low share of business closures [sufficiently strong evidence] Medium producer surplus losses as a result of substitution [sufficiently strong evidence], despite low internalization of high substitution costs in relation to high performance membranes [sufficiently strong evidence], due to (i) the high number of affected companies [sufficiently strong evidence] (ii) the high share of substitution for both applications [sufficiently strong evidence], and (iii) medium substitution costs in relation to outdoor technical textiles, which are partially internalized [sufficiently strong evidence] Medium (possibly high[18]) consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence], due to (i) the medium sales volume for outdoor technical textiles alone [sufficiently strong evidence], and (ii) additional consumer surplus losses in relation to high performance membranes resulting

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[18] Sales volumes are deemed to be the main determinant of the magnitude of consumer surplus losses as mentioned in Annex E.2.2.4. Due to a lack of data on sales volumes of high performance membranes, no definite conclusion on whether consumer surplus losses will be medium or high in comparison to other TULAC sub-sectors can be drawn as it is not clear whether the sales volume of high performance membranes results in a total sales volume of technical textiles that is comparable in magnitude to consumer apparel and home textiles, for which consumer surplus losses are found to be high.

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
			from high price changes caused by high substitution costs, which are fully passed on to customers [sufficiently strong evidence] <u>Some welfare losses or additional costs</u> as a result of (i) changes in filtration efficiencies for some filtration applications, (ii) higher energy use in relation to these applications, (iii) more frequent replacement (and associated higher process downtimes) due to shorter lifetimes of such filters, (iv) some welfare losses as a result of lower functionality leading to inferior aesthetic appearance for outdoor technical textiles (or additional costs for counteracting changes in functionality), and (vi) additional costs in relation to outdoor technical textiles due to changes in lifetime [sufficiently strong evidence] <u>Low level of employment losses</u> due to low share of business closures [sufficiently strong evidence] <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Lower costs compared to 5 year derogation.
Leather	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
Other: Home fabric treatments (sprays)	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Other: Textiles for use in engine bays in automotives (for noise and vibration insulation)	Given the weak evidence pointing to the unavailability of technically feasible alternatives at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: - [Textiles for the use in engine bays for noise and vibration insulation used in the automotive industry]	Ban with a transition period of 18 months and a **12-year** derogation, because information from one stakeholder (submitted during the 2nd stakeholder consultation) suggests that a minimum of 10 to 15 years would be required for developing and evaluating components once an alternative is identified [weak evidence base].	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1 Ban with a transition period of 18 months and a 12-year derogation: Low producer surplus losses as a result of business closures due to low share of business closures [weak evidence] Low producer surplus losses as a result of substitution [weak evidence], despite high share of substitution [weak evidence] and comparatively high costs at company level [sufficiently strong evidence] due to low internalization of costs [sufficiently strong evidence] Consumer surplus losses[19] resulting from price changes associated with substitution [weak evidence] resulting from comparatively high substitution costs at company level [sufficiently strong evidence], which are fully passed on to customers [sufficiently strong evidence] Low level of employment losses due to low share of business closures [weak evidence]
Food contact materials and packaging (Annex E.2.3.)			

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[19] Due to a lack of information on annual sales volumes, the magnitude of consumer surplus losses (in comparison to other TULAC sub-sectors) could not be estimated.

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
Consumer cookware	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Industrial food and feed production	Given the sufficiently strong evidence indicating at EiF most users would need further R&D to be able to implement alternatives, a derogation is **proposed** for: • Food contact materials for the purpose of industrial and professional food and feed production	Ban with a transition period of 18 months and a **5-year** derogation, because of a significant number of comments in the 2nd stakeholder consultation indicating the sector needs time for performance of R&D targeted at implementing alternatives	Ban with a transition period of 18 months and a 5-year derogation: A 5 year derogation would permit a longer period for implementation and would reduce costs for producers whilst maintaining production rates and quality. This would also limit potential impacts on consumers and the risk of job losses. Ban with a transition period of 18 months and a 12-year derogation: Lower costs compared to 5 year derogation.
Non-stick coatings in industrial and professional bakeware	Given the weak evidence indicating some companies (particularly SMEs) at EiF may have difficulty transitioning to alternatives and need time for adaptation and testing for some product lines, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [Non-stick coatings in industrial and professional bakeware]	Ban with a transition period of 18 months and a **5-year** derogation, because some companies within the sector need time for performance of R&D targeted at implementing the identified alternatives that are technically and economically feasible for many operations. Added time would be useful for understanding the optimal applications of available alternatives.	Ban with a transition period of 18 months and a 5-year derogation: Added time for adaptation of operations to handle non-PFAS alternatives would reduce producer surplus losses compared to RO1. There may still be potential for business closure, but again this would be at least partly mitigated by the derogation period. [sufficiently strong evidence] Ban with a transition period of 18 months and a 12-year derogation: Lower costs compared to 5 year derogation.

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
Paper & board packaging	Given sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Plastic packaging	Given sufficiently strong evidence pointing to the availability of alternative processing aids at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Other packaging applications	Given sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Metal plating and manufacture of metal products (Annex E.2.4.)			
Hard chrome plating	Given the weak evidence that technically and economically feasible alternatives are not available in relation to some goods at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [Hard chrome plating]	Ban with a transition period of 18 months and a **5-year** derogation, because some companies involved in hard chrome plating are finding the transition away from PFASs difficult as a result of the precise specifications of their products lines, whilst maintaining standards, although some companies have successfully transitioned from PFASs in the hard chrome plating sector already [weak evidence base].	Ban with a transition period of 18 months and a 5-year derogation: A 5 year derogation would permit a longer period for R&D and would reduce costs for producers whilst maintaining production rates and quality. This would also limit potential impacts on consumers and the risk of job losses. Ban with a transition period of 18 months and a 12-year derogation: Lower costs compared to 5-years derogation.
Decorative plating with chrome, plating on plastics and plating with metals other than chrome	Given sufficiently strong evidence indicating the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Manufacture of metal products not	No evidence was identified through literature search or through the CfE and 2nd stakeholder consultation regarding use	Not applicable	Same as under RO1

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
addressed elsewhere	of PFAS in the manufacture of metal products other than those addressed under other sectors (e.g. construction products and transport).		
Consumer mixtures (Annex E.2.5.)			
Sector as a whole	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Cosmetics (Annex E.2.6.)			
Sector as a whole	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1.
Ski wax (Annex E.2.7.)			
Sector as a whole	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1.
Applications of fluorinated gases (Annex E.2.8.) *Note that mobile air conditioning (MAC) and transport refrigeration, including military applications, are covered under Transport below.*			
Refrigeration	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, derogations are **proposed** for: • Refrigerants in low temperature refrigeration below -50°C • Refrigerants in laboratory test and measurement equipment • Refrigerants in refrigerated centrifuges	Ban with a transition period of 18 months and a **5-year** derogation for refrigerants in low temperature refrigeration below -50°C, because stakeholders indicated that low temperature refrigeration below -50 °C in large capacities is expected to still depend on fluorinated gases for 10 years from 2022 [sufficiently strong evidence base]. Ban with a transition period of 18 months and a **12-year** derogation for refrigerants in laboratory test and measurement	Ban with a transition period of 18 months and a 5-year derogation: For low temperature refrigeration below -50°C, a 5 year derogation would permit a longer period for R&D and would reduce costs for producers whilst maintaining production rates and quality. This would also limit potential impacts on consumers and the risk of job losses. Ban with a transition period of 18 months and a 12-year derogation:

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
		equipment and refrigerants in refrigerated centrifuges, because no potential alternatives are identified as of now and because it is unlikely that they become available in the near future [sufficiently strong evidence base].	For laboratory test and measurement equipment and refrigerated centrifuges, additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses.
Air conditioning and heat pumps	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, derogations are **proposed** for: • Maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternatives exist • Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives	Ban with a transition period of 18 months and a **12-year** derogation for maintenance and refilling of existing HVACR equipment without drop-in alternative(s), because the alternative to permitting maintenance including topping up of systems would be to require system replacement. There is insufficient capacity in the market to carry out this work on a short or medium timescale. Drop-in alternatives are not available [sufficiently strong evidence base]. A **time-unlimited** derogation for refrigerants in HVACR-equipment in buildings, where national safety standards and building codes prohibit the use of alternatives [sufficiently strong evidence base].	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1 <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses. The gradual replacement of aging refrigeration and air conditioning systems will reduce the need for maintenance of commercial and industrial systems using PFASs over time, though it is to be expected that many such systems will still be operational after a 12- year derogation. Scrappage of those systems through a lack of suitable refrigerant rather than technical or economic obsolescence would generate consumer surplus loss. The need for public confidence in fire safety systems indicates potential for significant welfare loss in the event that the safety of alternatives in high rise

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
			(etc.) buildings is not demonstrated and restrictive building codes remain in force.
Foam blowing agents	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [Foam blowing agents in expanded foam sprayed on site for building insulation]	Ban with a transition period of 18 months and a **5-year** derogation, because information from stakeholders indicates the reliance on fluorinated gases for this application in a 10-years perspective from 2022 [weak evidence base]	Ban with a transition period of 18 months and a 5-year derogation: Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from use of less effective or more hazardous foam blowing agents. Ban with a transition period of 18 months and a 12-year derogation: Lower costs compared to 5-years derogation.
Solvents	Given sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, derogations are **proposed** for: • Industrial precision cleaning fluids • Cleaning fluids for use in oxygen-enriched environments Given the weak evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, the following potential derogations are marked **for reconsideration** after the Annex XV report consultation: • [Industrial and professional use of solvent-based debinding systems in 3D printing]	Ban with a transition period of 18 months and a **12-year** derogation for cleaning fluids, because no alternatives have been identified and from information on the constraints affecting adoption of alternatives it is considered likely that they will not become available in the near future [sufficiently strong evidence base]. Ban with a transition period of 18 months and a 12-year derogation for solvent-based debinding systems and smoothing agents in 3D printing for industrial and professional use, because available information indicates that alternatives will not be available in the short/medium term [weak evidence base].	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1 Ban with a transition period of 18 months and a 12-year derogation: Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from use of less effective solvents.

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
	• [Industrial and professional use of smoothing agents for polymer 3D printing applications.]		
Propellants	Given the weak evidence that technically and economically feasible alternatives are not available at EiF for some companies in niche applications, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required]	Ban with a transition period of 18 months and a **12-year** derogation, because the information provided in the CfE suggests the unavailability of alternatives [weak evidence base]	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1 <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from use of less effective or more hazardous propellants.
Magnesium casting	Given sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Fire suppressants	Given the sufficiently strong evidence indicating the unavailability of alternatives at EiF for some applications, a derogation is **proposed** for: • Clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health	Ban with a transition period of 18 months and a **12-year** derogation, because the information provided in the consultation suggests the unavailability of alternatives. Current R&D development appears to focus on alternative fluorinated gases, rather than on non-PFAS alternatives [weak evidence base].	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1 <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from use of less effective fire suppressants.
Preservation of cultural paper-based materials	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential	Ban with a transition period of 18 months and a **12-year** derogation, because the information provided in the 2nd	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
	derogation is marked **for reconsideration** after the Annex XV report consultation: • [Preservation of cultural paper-based materials]	stakeholder consultation suggests the unavailability of alternatives and indicate new approaches would need extensive testing [weak evidence base].	Ban with a transition period of 18 months and a 12-year derogation: Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from an increased risk of damage to cultural assets.
Insulating gas in electrical equipment	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for: • Insulating gases in high-voltage switchgear (above 145kV)	Ban with a transition period of 18 months and a **5-year** derogation, because the information provided in the 2nd stakeholder consultation suggests that by 2026 high-voltage electricity products up to 420 kV may start to be replaced with non-PFAS alternatives. However, it is expected that time beyond 2026 will be needed before a full transition to clean air technology for high voltage applications is applicable [sufficiently strong evidence].	Ban with a transition period of 18 months and a 5-year derogation: The additional time provides manufactures and downstream uses the opportunity to substitute instead of ceasing operation thereby limiting producer surplus losses, employment impacts and impacts on customers Ban with a transition period of 18 months and a 12-year derogation: Lower costs compared to 5-year derogation
Medical devices (Annex E.2.9.)			
Implantable medical devices (not including meshes, wound treatments products, and tubes and catheters)	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for: • Implantable medical devices (not including meshes, wound treatment products, and tubes and catheters)	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [sufficiently strong evidence]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1. Ban with a transition period of 18 months and a 12-year derogation: If feasible alternatives are identified, developed and approved, the public health concerns (and their related socio-economic costs) due to reduced

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
			functionality of the devices would be avoided.
Hernia meshes	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: - [Hernia meshes]	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [weak evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> If feasible alternatives are currently not available, but become available during the derogation period, then the public health concerns (and their related socio-economic costs) due to reduced functionality of the devices would be avoided.
Wound treatment products	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: - [Wound treatment products]	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [weak evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1, i.e. uncertain costs. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality of the devices would be avoided.
Tubes and catheters	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for: - Tubes and catheters	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [sufficiently strong evidence base].	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> If feasible alternatives are identified, developed and approved, the public health

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
		Continued R&D increases the chance that alternatives for the relevant applications will be identified.	concerns (and their related socio-economic costs) due to reduced functionality of the devices would be avoided.
Coatings of Metered Dose Inhalers (MDIs)	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for: • Coatings of Metered Dose Inhalers (MDIs)	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [sufficiently strong evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> If feasible alternatives are identified, developed and approved, the public health concerns (and their related socio-economic costs) due to reduced functionality of the devices would be avoided.
Other coating applications	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [Coating applications for medical devices other than Metered Dose Inhalers (MDIs)]	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [weak evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1, i.e. uncertain costs. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality of the devices would be avoided.
Cleaning and heat transfer: engineered fluids	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation:	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [weak evidence base].	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1, i.e. uncertain costs. <u>Ban with a transition period of 18 months and a 12-year derogation:</u>

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
	• [Cleaning and heat transfer: engineered fluids for medical devices]	Continued R&D increases the chance that alternatives for the relevant applications will be identified.	If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality of the devices would be avoided.
Sterilization gases	Given the weak evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1.
Diagnostic laboratory testing	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for: • Diagnostic laboratory testing	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [sufficiently strong evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> If feasible alternatives are identified, developed and approved, the public health concerns (and their related socio-economic costs) due to reduced functionality of the devices would be avoided.
Rigid gas permeable (RGP) contact lenses and ophthalmic lenses	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [Rigid gas permeable (RGP) contact lenses and ophthalmic lenses]	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [weak evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1, i.e. uncertain costs. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality of the devices would be avoided.

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
Propellants in Metered Dose Inhalers (MDIs)	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1.
Membranes used for venting of medical devices	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [Membranes used for venting of medical devices]	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [weak evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1, i.e. uncertain costs. Ban with a transition period of 18 months and a 12-year derogation: If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality of the devices would be avoided.
Packaging of medical devices	Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogations are marked **for reconsideration** after the Annex XV report consultation: • [PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics] • [PTFE in ophthalmic solutions packaging] • [Packaging of terminally sterilised medical devices]	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [weak evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1. Ban with a transition period of 18 months and a 12-year derogation: If feasible alternatives are identified, developed and approved, the eventual socio-economic costs due to reduced functionality of the packaged devices would be avoided.
Transport (Annex E.2.10.)			
Use of PFASs in applications affecting the proper functioning related to the safety of	Given the sufficiently strong evidence that alternatives for the full range of applications are not available at EiF, but at the same time recognizing the broad use scope and the weak evidence base to	Ban with a transition period of 18 months and a **12-year** derogation, because of the diversity of applications of PFASs in the transport sector and design cycles operating over longer periods than offered	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
vehicles, and affecting the safety of operators, passengers or goods, to the extent not addressed under other parts of this restriction (e.g. under lubricants, electronic equipment and TULAC)	narrow down the scope for a derogation, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: - [Applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods]	by a 5 year derogation. Substitution requires further research on existing non-PFAS polymers and possible development of new ones, combined with testing of equipment to ensure compatibility or design modifications [sufficiently strong evidence base].	<u>Ban with a transition period of 18 months and a 12-year derogation:</u> Extent of impacts on producers is not estimated and will be dependent on the extent to which drop-in alternatives can be identified without the need for redesign of equipment. A long derogation period provides opportunity to mitigate costs by enabling redesign to be factored into product development cycles [weak evidence]. Given vehicle safety standards and an additional 12 years for development, it is anticipated that safety will not be compromised. Vehicle reliability may however be impacted leading to some consumer surplus loss [weak evidence]. There is no information on the extent to which different parts of the sector are able to pass on added cost to consumers.
Hydraulic fluids	Given sufficiently strong evidence that alternatives are not available at EiF, a derogation is **proposed** for: - Additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry	Ban with a transition period of 18 months and a **12-year** derogation, because of a stakeholder estimated transitioning time of at least 10 years once an alternative has been identified [sufficiently strong evidence base].	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Reduced producer surplus loss compared to RO1 particularly given the need for recertification of components using alternative substances in their hydraulic fluid.
Mobile Air Conditioning (MAC)	Given the sufficiently strong evidence pointing to a low substitution potential at EiF, a derogation is **proposed** for:	Ban with a transition period of 18 months and a **5-year** derogation because of the time needed to (re)design MAC-systems.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u>

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
	• Refrigerants in mobile air conditioning (MAC)-systems in combustion engine vehicles with mechanical compressors	The derogation is designed to be long enough for manufacturers to undertake the necessary R&D, etc. to bring the alternatives to the mass market. The 5 year derogation is considered long enough to avoid significant producer and consumer losses [sufficiently strong evidence].	Low producer surplus losses through the development of alternative systems as drop-in alternatives are not available. Low consumer losses, depending on the extent to which manufacturers are able to pass costs onto consumers. Cost effectiveness for passenger cars estimated at €100 to 500/kg PFAS, depending on leakage rates, fate of the fluorinated gas at end of life and the alternative selected. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Lower costs compared to 5-years derogation.
Transport refrigeration	Given the sufficiently strong evidence pointing to a low substitution potential at EiF, a derogation is proposed for: • Refrigeratants in transport refrigeration other than in marine applications	Ban with a transition period of 18 months and a **5-year** derogation, because significant modification of vehicle/trailer design as well as new refrigeration systems are needed for refrigeration in these transport vehicles.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> In some areas, principally parts of the shipping sector, alternatives are already well-established and the restriction may have only limited cost impact. In others, particularly road transport, there is further work to do to develop new refrigeration systems taking account of the specific characteristics of the vehicle fleet. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Lower costs compared to 5-years derogation.
MAC- and refrigeration in	Given the sufficiently strong evidence pointing to a low substitution potential at	Ban with a transition period of 18 months and a **12-year** derogation, because	<u>Ban with a transition period of 18 months and a 5-year derogation:</u>

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
military applications	EiF, and the weak evidence for the need of an extended transition period for military applications, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [Use as refrigerants and for mobile air conditioning (MAC) in vehicles in military applications]	current alternative MAC- and refrigeration systems could pose additional hazards under military service conditions and therefore need more time to identify further alternatives.	Same as under RO1. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Added time for the derogation provides manufacturers with more opportunity to screen alternative systems to ensure that they can be optimised to the demanding military environment. This is likely to be more cost-efficient for the manufacturers and reduce risks of job losses. It is also likely to facilitate a safer on-vehicle environment for service personnel with associated welfare benefits. It is envisaged that price pressures would mean that this derogation is only used where safety considerations for service personnel are a significant issue: for non-critical applications it is likely that goods supplied as standard to the civilian market would be cheaper.
Electronics and semiconductor (Annex E.2.11.)			
Electronics	Given the evidence pointing to the existence of technically and economically feasible alternatives at EiF for heat transfer fluid for immersion cooling and liquid crystal displays, in combination with the inconclusive evidence pointing to the non-existence of technically and economically feasible alternatives at EiF in all other uses, no derogation is proposed.	Not applicable	Same as under RO1
Semiconductors	Given the weak evidence pointing to the non-existence of technically and economically feasible alternatives at EiF,	Ban with a transition period of 18 months and a **12-year** derogation, because the information provided suggests	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1.

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
	the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: - [The semiconductor manufacturing process]	considerable transition times (3-10+ years) when alternatives become available.	<u>Ban with a transition period of 18 months and a 12-year derogation:</u> Added time for the derogation provides manufacturers with more opportunity to identify and develop cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses.
Energy sector (Annex E.2.12.)			
Sector as a whole	Given the sufficiently strong evidence pointing to a low substitution potential at EiF, a derogation is **proposed** for: - Proton-exchange membrane (PEM) fuel cells	Ban with a transition period of 18 months and a **5-year** transition period, because of available evidence pointing to problems in relation to the availability of validated alternatives (for membranes) in sufficient quantities and significant time requirements for the commercialization of reinforcement materials, for which at least 5-10 years are deemed to be required from 2022.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> The additional time provides manufacturers of PEM fuel cells the opportunity to substitute instead of closing business, thereby limiting producer surplus losses, employment impacts and impacts on customers resulting from the unavailability of PEM fuel cells. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Lower costs compared to 5-year derogation.
Construction products (Annex E.2.13.)			
Architectural coatings and paints	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Wind turbine blade coating	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
Coil coating	Given sufficiently strong evidence pointing to the existence of alternatives at EiF for fluoropolymer binders in coil coating and weak evidence indicating that available alternative formulations might contain micro-powder PTFE as additive, no derogation is proposed.	Not applicable	Same as under RO1
Architectural membranes (composite membranes with top coating)	Given sufficiently strong evidence pointing to the existence of alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Architectural membranes (pure fluoropolymers)	Given sufficiently strong evidence pointing to the existence of alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
ETFE film/foil for greenhouses	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Windows frames (laminated with fluoropolymers)	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EIF, no derogation is proposed.	Not applicable	Same as under RO1
Bridge and building bearings	Given weak evidence pointing to the existence of alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
PTFE thread sealing tape	Given weak evidence pointing to the existence of alternatives for PTFE thread sealing tape at EiF, especially in relation to permanent seals, no derogation is proposed.	Not applicable	Same as under RO1

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
Polymeric PFASs used as processing aids for production of non-PFAS polymers/plastics	Given sufficiently strong evidence pointing to the availability of alternative processing aids at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Side-chain fluorinated polymers used for surface protection/ sealants	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Fluorosurfactants as wetting/ levelling agents in e.g. coating, paints and adhesives	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Non-polymeric PFASs as processing aids	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF to replace the final products (architectural membrane-like product) manufactured with a non-polymeric PFAS processing aid, and the inconclusive evidence on the non-existence of alternatives for replacing non-polymeric PFAS processing aids for production of acrylic foam tape, no derogation is proposed	Not applicable	Same as under RO1
Window film manufacturing	Given inconclusive evidence (conflicting stakeholder information) on whether technically and economically feasible alternatives exist at EiF, no derogation is proposed.	Not applicable	Same as under RO1
Lubricants (Annex E.2.14.)			

Use sector (with sub-uses)	**Proposed derogation or derogation for reconsideration**	**Duration of derogation period, including substantiation**	**Cost impact of 5 and 12 year derogation periods**
Sector as a whole	Given the sufficiently strong evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, a derogation is **proposed** for: • Lubricants where the use takes place under harsh conditions or use is for safe functioning and safety of equipment	Ban with a transition period of 18 months and a **12-year** derogation, because extended time will enable further research and development to identify alternatives.	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1 Ban with a transition period of 18 months and a 12-year derogation: The losses of functionality identified under RO1 are likely to be avoided, while costs related to reformulation and development will be spread out over a longer period of time.
Petroleum and mining (Annex E.2.15.)			
Non-polymeric PFAS applications (tracers and anti-foaming agents)	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1.
Fluoropolymer applications	In light of the sufficiently strong evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, a derogation is **proposed** for: • Fluoropolymer applications	Ban with a transition period of 18 months and a **12-year** derogation, because manufacturers and suppliers have indicated that it could take a relatively long time (several years to several decades) to transition towards using alternatives that can achieve the same level of performance. Furthermore, given the relatively large (up to hundreds or thousands) number of individual products supplied in this sector, all with different specific formulations, this would be a complex undertaking needing sufficient time [sufficiently strong evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1. Ban with a transition period of 18 months and a 12-year derogation: If technically and economically feasible alternatives are identified: • The costs related to loss of functionality would be avoided. • The costs related to product reformulation and quality assurance would (at least partly) remain but would be postponed or spread out over a longer period of time.

2.4.1.2. Economic impacts on public actors: Enforcement and certification costs

Enforcement costs

In addition to economic impacts on manufacturers of PFAS-containing articles and on customers, a restriction on PFASs will also lead to costs for public authorities. Enforcement authorities will incur costs for enforcing the restriction, which includes administrative and analytical or testing costs. Administrative costs thereby consist of incremental costs for staff salaries, materials, equipment and overhead costs, while analytical costs consist of the cost for developing testing methods and conducting tests for various products to determine whether they meet the requirements of the restriction.

As noted in other Annex XV dossiers, e.g. the Annex XV dossier on intentionally added microplastics (ECHA, 2019b), the incremental **administrative costs for restrictions** are estimated by ECHA to equal approximately €55 000 per year based on a fixed budget approach assuming that enforcement authorities have a limited budget for enforcement, which they allocate to enforcing restrictions on the basis of the expected risk of non-compliance. The Dossier Submitters recognize the limitations of this approach. In the absence of other estimates, it is however assumed – in line with the approach employed in the Annex XV dossier on intentionally added microplastics (ECHA, 2019b) which also covers multiple sectors – that enforcement authorities would incur administrative enforcement costs of €55 000 per year for each of the sectors for which a restriction is proposed.

As for the Annex XV dossier on intentionally added microplastics, the approach of assuming a cost of €55 000 for each sector (instead of the restriction as a whole) has been taken to reflect the broad scope of the restriction which impacts diverse uses in several different sectors which may require diverse enforcement expertise. As highlighted in ECHA (2019b), this approach might result in an overestimation of costs to public actors as the administrative cost estimate of €55 000 refers to one restriction entry and has not been differentiated on the basis of a narrow or broad scope and the level of complexity of a restriction. A further potential source of overestimation is – as noted in ECHA (2019b) – that enforcement costs are assumed to be incurred annually from the EiF date until the end of the assessment period. This is seen as a source of overestimation as non-compliance, and therefore, enforcement efforts (and related costs) to ensure compliance decline with time as supply chains become familiar with the restriction requirements. As a result, enforcement costs are deemed to be highest immediately after EiF and to approach zero towards the end of the assessment period.

For several uses considered in this dossier, enforcement activities for already existing legislations, e.g. the restriction on PFOA, its salts and PFOA-related substances, are furthermore deemed to overlap with enforcement of a restriction of PFASs. Due to these possible synergies, enforcement costs for several uses might be overestimated. Overall, enforcement costs are however deemed negligible in comparison to other costs resulting from the restriction.

In addition to administrative costs, analytical costs will be incurred for developing testing methods and conducting tests for various products. These costs could however not be estimated.

Certification

In addition to enforcement costs, a restriction of PFASs is expected to lead to administrative costs for public authorities in relation to the **certification** of products based on alternatives.

For several uses, companies will incur costs in relation to re-certification and re-approval of their products. Such costs are deemed to be relevant for the companies and considered in the corresponding sections of the dossier. Some of those re-certification/re-approval processes are related to regulatory requirements and will thus also result in additional administration costs for national authorities.

Regulatory requirements range from internal documentation to complete re-approval. As such, additional costs for public authorities are anticipated. Due to several uncertainties, e.g. about the requirements, existence of fees and charges to cover additional public costs and number of companies that will apply for certification of re-developed products, the total costs to public authorities incurred in relation to a restriction of PFASs could not be estimated.

In addition, and in line with the fixed budget approach for enforcement costs, annual costs to public authorities are deemed to be bound to fixed budgets with limited room for extending processing capacities (at least in the short term) due to budgetary constraints and challenges with extending available staff capacity by hiring workers with the relevant expertise. As such, administrative costs to public authorities are deemed to be negligible in comparison to other costs resulting from the restriction.

2.4.2. Human health impacts

The impact of continued use of, and increased human exposure to, PFASs on human health that can be prevented through the proposed restriction options cannot be quantified because of limited, or missing, data to assess (i) the hazard of many of the individual PFAS substances; (ii) the associated thresholds below which exposure is not expected to lead to adverse health effects, if such limits exist, (iii) the combined effects of co-occurring PFASs, and (iv) the prediction of future human exposure levels. However, for a large part of PFAAs sufficient information is available to suggest that negative health impacts (see Table 10) in the general population already occur in highly exposed communities or will occur at some point in the future due to increasing pollution stocks in the environment.

Table 10. Current health impacts in the general population due to exposure to the most analysed PFASs (see Annex B.5.3.).

Health impact category	**Type of health effects**
Immune outcomes	■ Reduced vaccine responses in children
	▨ Increased propensity of lower respiratory tract infections
	▨ Increased risk of atopic dermatitis
	□ Asthma- and allergy-related outcomes (hypersensitivity)
Liver toxicity and metabolic disruption	■ Increased serum alanine transferase (ALT) which is a marker of liver toxicity and fatty liver diseases
	▨ Increased total and LDL-cholesterol
	□ Increased risk of cardiovascular diseases
Reproduction and development	▨ Reduced birth weight
	□ Effects on male and female fertility
	□ Effects on sex hormones and related outcomes
	□ Preterm delivery
	□ Miscarriage and preeclampsia
Carcinogenicity	▨ Increased risk of renal cell carcinoma and kidney cancer
Thyroid functioning	□ Thyroid disease or changes in thyroid hormones

Table legend

■	Evidence of an association between exposure and health effect, strengthened by new studies.
▨	Limited evidence of an association between exposure and health effect, supported by new studies.
□	Suggestive evidence of an association between exposure and health effect, inconclusive new studies.

PFASs released during production or during the product life stage remain in the environment and will remain a source of exposure for generations to come. For some PFASs, specifically those already phased out or restricted under REACH in the EU, combined exposure already exceeds existing limit values for highly exposed communities in the population (section 1.1.4.9; (Bil et al., 2023; Olsen et al., 2007; Richterová et al., 2023; Schillemans et al., 2023)). Any additional exposure to other PFASs, that are to date less well investigated but for which comparable effects have already been demonstrated or can be expected because of structural similarities, will contribute to the magnitude of negative human health impacts in the future. Therefore, exposure to PFASs needs to be minimised.

As emission prevention techniques are missing or too expensive, emissions of PFASs from industrial and consumer uses to the environment cannot be avoided completely. Once in the environment it is very costly and impractical or even impossible to remove PFASs through remediation. The combination of these factors creates a risk of long-term, and potentially irreversible health damage at the global scale, which can to some extent be limited by the proposed restriction. In addition to the aforementioned physical health effects, the proximity to environmental contamination hotspots may affect residents' psychosocial health as affected communities may face a spectrum of negative mental and physical effects related to uncertainty around long-term health outcomes {Prior, 2019 #154}.

In summary, the expected impact of the proposed restriction options are the avoided negative human health effects associated with the continued use of PFASs. The magnitude of the impact of continued use of PFASs on human health cannot be quantified but current combined exposure to some regulated PFASs already exceeds existing limit values. Therefore, due to structural similarities and a similar hazard profile, (co-)exposure to other, non-regulated, PFASs should be minimized. This implies that restriction option RO1, that reduces the increase of the environmental pollution burden of PFASs the most, compared to the baseline scenario, will result in the highest benefit to society in terms of avoided long-term human health impacts resulting from exposure to PFASs.

2.4.3. Environmental impacts

2.4.3.1. Approach to environmental impact assessment

Emissions to the environment are estimated at use sector level. For some use sectors, industry specific information on emissions and appropriate emission factors was available and could be used. For the other use sectors, industry specific information was lacking. Therefore, the Dossier Submitters applied default parameters for environmental release rates according to the Guidance on information requirements and Chemical Safety Assessment, Chapter R.16. The environmental release category (ERC) factors describe the broad conditions of use from the environmental perspective, considering also default assumptions about the service-life of uses or applications.

Emissions were assessed for the environment as a whole (one-compartment model), based on the aggregation of emissions across individual compartments (air, water, soil). This approach was chosen for different reasons.

- First, considering the complexity of the dossier (in particular the large number of use sectors), the one-compartment model ensures a sufficiently harmonized and consistent approach to environmental impact assessment, while still exploiting all available information on emissions and releases.

- Second, the high persistence of PFASs is considered the core concern underlying this restriction proposal. As a result of persistence, a continued use of PFASs will inevitably cause environmental exposure to increase further over time, irrespective to which environmental compartment emissions will be released.

- Third, since the one-compartment model is based on assessments of releases to individual compartments, a disaggregation of emission estimates remains possible for the different use sectors should this seem useful.

Note that, where adding up the separate ERC factors to water, soil, and air would exceed 100%, an overall emission factor to the environment of 100% was assumed to ensure that over-estimation errors of emissions are minimized.

Environmental impacts under a particular RO are the expected total emissions avoided in comparison to the baseline scenario, assuming a time path of 30 and 45 years. Sections 2.4.3.2 and 2.4.3.3 show results for the baseline and the defined restriction options, and for a time path of 30 years. Information about total emissions based on a 30- or 45 year time path is provided in Annex E. The time path of emissions considers available information about growth rates in different sectors. The start year for the assessment is 2020 (first year of data documentation of emissions at sector-level). Assuming the restriction to enter into force in 2025 at the earliest, environmental impacts were calculated from 2025 onwards, and considering a transition period of 18 months for all sectors. Furthermore, in line with earlier restriction proposals addressing PBT and vPvB chemicals, the Dossier Submitters assumed a discount rate of 0% for emissions.

In addition to the baseline, environmental impacts are determined for two restriction options. First, under RO1 the impact of a full ban, entering into force after a transition period of 18 months, is analysed. Under RO1 no derogations are considered. Second, under RO2 environmental impacts of a ban in combination with defined, use-specific derogations are analysed. The variants considered under RO2 are (i) a derogation of a duration of five years and (ii) a 12-year derogation, both taking effect after the end of the transition period. While environmental impacts of RO1 can be assessed quantitatively, impacts under RO2 are mainly discussed qualitatively. The reason is that in most cases quantitative emission data for use-specific derogations were not available. Still, for most sectors and the corresponding use-specific derogations there is information which PFASs (PFAAs and PFAA precursors, fluorinated gases, fluoropolymers and PFPEs) are used in a certain application and which, assuming a derogation of this application, would cause additional emissions. Therefore, the level of expected additional emissions compared to a worst-case scenario, i.e. a derogation of an entire PFAS group which may result from a derogation, was evaluated by the Dossier Submitters. This worst-case scenario does not represent a restriction scenario but is used as a reference case to better anchor the evaluation of environmental impacts for RO2.

For several sectors, yearly tonnage and emission estimates vary within a considerably broad range, indicating that there is high uncertainty (see also Annex F). For the assessment of environmental impacts under the baseline and under the sector-specific ROs mean emission estimates where used. For sectors for which information about high and low tonnage estimates was lacking, available values were used as mean estimates.

2.4.3.2. Baseline environmental impacts

Table 11 below summarizes the expected total emissions (in tonnes) resulting from a continued use of PFASs, and for an assumed time path of 30 years. Emission estimates capture assumptions about sector-specific growth rates as discussed in Annex E. Estimates are shown for different use sectors, and for the EU as a whole (being the aggregate of all sectors).

Table 11. Total PFAS use and environmental emissions (mean values) under the baseline scenario for different PFAS use sectors (30 years, in tonnes), and fraction of emissions in relation to PFAS use.

PFAS use sector	**PFAS use [tonnes]**	**Emissions [tonnes]**	**Fraction of emissions compared to PFAS use [%]**
TULAC	5 472 040	1 431 511	26
Food contact materials and packaging	1 495 936	43 708	3
Metal plating and manufacture of metal products	30 675	183	0.5
Consumer mixtures	55	55	100
Cosmetics	995	995**	100**
Ski wax	22	13	59
Applications of fluorinated gases	25 369 435	1 942 313	8
Medical devices	4 116 172	401 132	20
Transport*	9 150 035 (17 056 752)*	16 671 (255 310)	0.2 (2.7)*
Electronics and semiconductors	1 419 743	293 248	20
Energy sector	893 520	16 272	1.8
Construction products	550 564	152 555	13
Lubricants	102 072	13 481	13
Petroleum and mining	209 124	77 018	37
Total use sectors	**48 810 388**	**4 389 155**	**9**

* To avoid double-counting the values in this row do not include tonnage and emission estimates from applications of fluorinated gases. These are counted in the row 'Applications of fluorinated gases'. For the sake of transparency though, the tonnage estimates, expected emissions, and the fraction of emissions related to applications of fluorinated gases in the transport sector are given in between brackets.

** As worst case scenario with emissions going 100% to waste water

In addition to emissions which occur during the use phase, PFASs are emitted during the production phase and at the end of the life-cycle, i.e. during the waste phase. Yearly emission estimates for PFASs during PFAS production were derived from tonnage estimates provided by industry, multiplied with ERC factors (see Annex B for further details). The projections underline that the total environmental impacts arising from PFAS use, expressed in terms of total emissions in the assumed 30-year period (2025-2055), account for about 4.4 million tonnes. It is important to note that this estimate is, for several reasons, likely a large underestimation of true emissions. First, for many sectors emission estimates were derived from tonnage values and environmental release factors (ERCs). The latter are determined for organic substances and likely underestimate the emissions of PBT/vPvB substances like PFASs. Second, the existing pollution burden in the environment, i.e. the environmental stock resulting from past emissions (stretching over several decades of use of PFASs) could not be taken into account due to missing data. Third, there are processes which do not use PFASs but emit PFASs, such as, for example, PVC production and aluminium and magnesium production. Emissions from these processes are not included in the assessment. In addition, the timeline adopted for the assessment (30 years, starting in 2025) is likely much too short to cover long-term emissions arising from products at the end-of-life, and from landfilling/waste.

Figure 7 shows the time paths of expected emissions from PFAS use for a 30 year period (2025-2055). Time paths capture assumptions about sector-specific growth rates as discussed in Annex E.

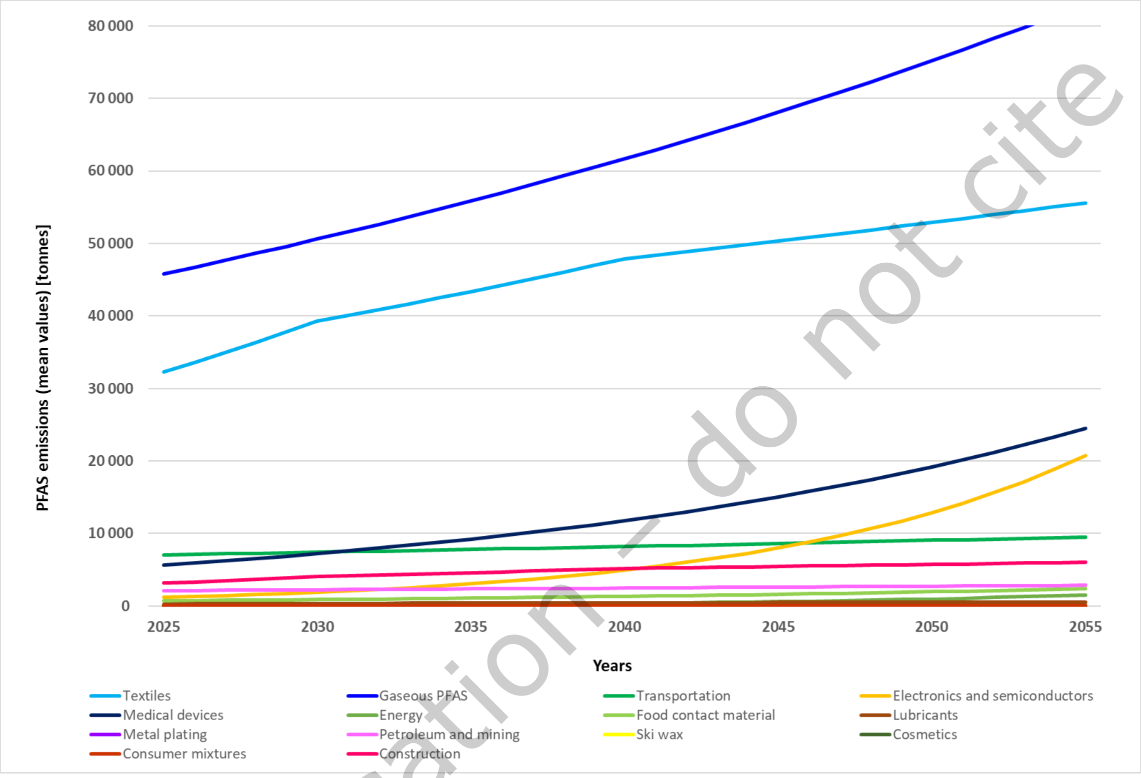

Figure 7. Time path of emissions (mean values) of PFAS use in the EEA for different sectors (30 years, in tonnes).

2.4.3.3. Environmental impacts of restriction options

Mean environmental **emissions under a full ban (RO1)**, and the fraction of the expected emission reduction compared to the baseline scenario, are summarized in Table 12.

Table 12. Environmental emissions under RO1 for a 30-year period (2025-2055; mean values, in tonnes), and fraction of emission reduction compared to the baseline.

PFAS use sector	Emissions [tonnes]	Reduction of emissions compared to the baseline [%]
TULAC	65 871	95
Food contact materials and packaging	1 563	96
Metal plating and manufacture of metal products	12	94
Consumer mixtures	2	96
Cosmetics	64	94
Ski wax	2	90

PFAS use sector	**Emissions [tonnes]**	**Reduction of emissions compared to the baseline [%]**
Applications of fluorinated gases	92 580	95
Medical devices	11 621	97
Transport*	14 202	94
Electronics and semiconductors	2 496	99
Energy sector	188	99
Construction products	6 513	96
Lubricants	884	93
Petroleum and mining	4 284	94
Total use sectors	**200 282**	**95**

* To avoid double-counting, and to be consistent with Table 11, the values in this row do not include tonnage and emission estimates from applications of fluorinated gases. These are counted in the row 'Applications of fluorinated gases'.

A full ban of PFAS use (RO1) leads to a reduction of total emissions of about 95% in all use sectors. Due to the transition period of 18 months, during which emissions continue, RO1 does not lead to a full elimination of PFAS emissions. For some sectors, the reduction of total emissions is close to 100%. Complementary to the emission reduction at use sector level, Figure 8 shows the fraction of the emission reduction of individual sectors in relation to the total emission reduction under RO1 in the EEA.

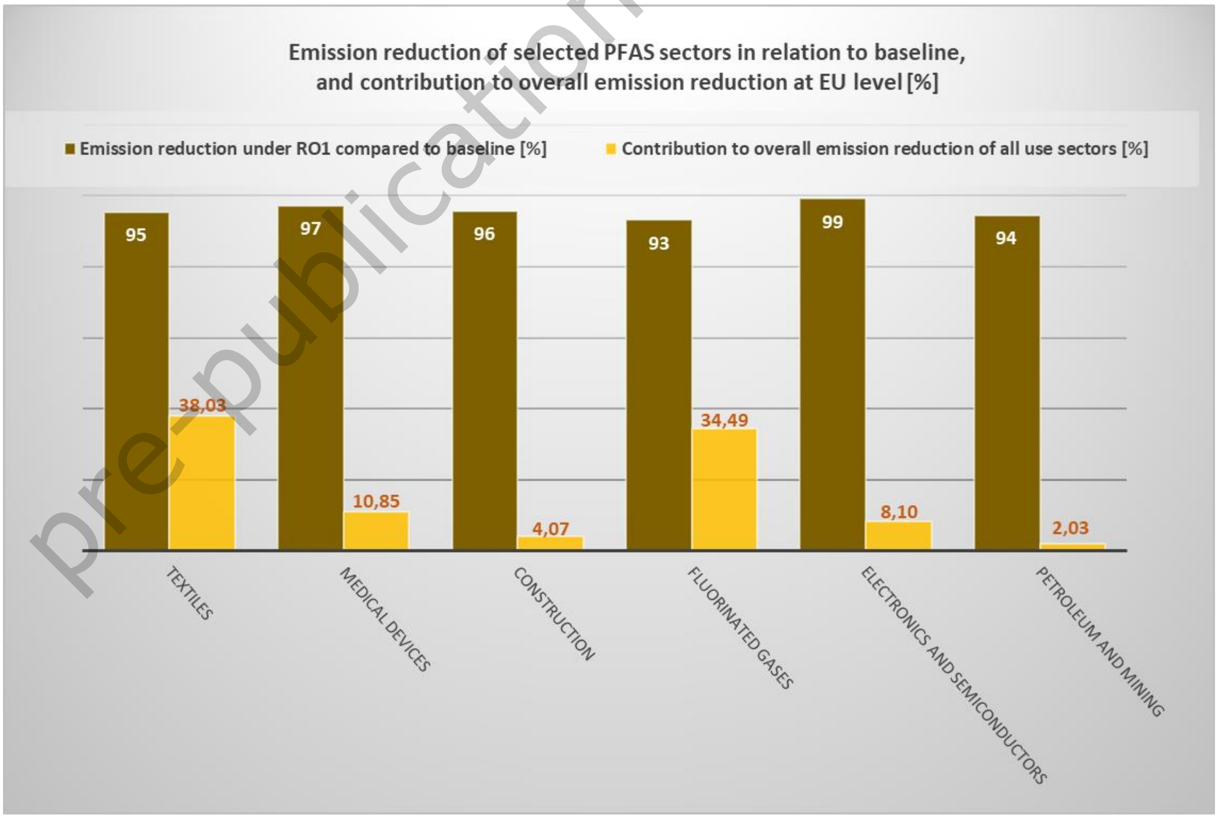

Figure 8. Emission reduction of PFAS sectors in relation to baseline, and contribution to overall emission reduction at EU level [%]. Note: Sectors where the contribution of emission reduction is smaller than 2% were not included in the Figure.

In addition to a ban of all PFASs, a restriction option which considers use-specific derogations is considered (RO2). Under RO2, use-specific derogations are proposed for either 5 years (after the end of the transition period) or for 12 years (after the end of the transition period). Use-specific derogations cause PFAS emissions to continue over time. For the use-specific derogations, emission data are largely lacking but in some cases there is information about the PFASs (PFAAs and PFAA precursors, polymeric PFASs or fluorinated gases) covered. In those cases, where possible, environmental impacts are evaluated as follows:

1. For the PFASs concerned in the derogation (either PFAAs and PFAA precursors, polymeric PFASs or fluorinated gases), additional emissions assuming a full derogation of this PFAS in the entire use sector are determined;

2. Expected maximum additional emissions of RO2 are then estimated as a worst-case reference case by comparing the resulting emissions with the baseline;

3. Based on qualitative arguments the Dossier Submitters evaluated the expected emissions of RO2 (including the proposed use-specific derogations) in comparison with the (worst-case) reference case explained under 2.

In this way the expected additional emissions of RO2 can be compared to RO1 for the respective sector such that the evaluation is sufficiently transparent and consistent across use sectors.

In few exceptional cases tonnage and emission data of proposed use-specific derogations are available. Expected environmental impacts of RO2 are, then, conducted quantitatively.

In the following, the **evaluation of RO2** is presented for each use sector.

a) Evaluation of environmental impacts of RO2 relating to textiles (TULAC)

(i) *Proposed derogation: Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c)*

During stakeholder consultations, three companies in the PPE sector indicated that about 20% of the PFASs used in PPE in the EEA were used in PPEs protecting against Category III risks. The remaining 80% were used in PPE protecting against Category I or II risks. Since these companies account for a small fraction of the market volume (their total annual quantity of PFAS use in PPE articles for the EEA market is approximately three tons), these estimates cannot be extrapolated to the entire EEA market for PPE. As a consequence, a precise quantification of the amount of non-polymeric and polymeric PFASs used in relevant PPE was not possible. Based on existing evidence, an estimation of expected additional emissions assuming a full derogation of the PFAS covered by the proposed derogation (i.e. PFAAs, including PFAA precursors (side-chain fluorinated polymers) and fluoropolymers (in particular PTFEs)) can be provided. A 5-year derogation of PFAAs and PFAA precursors would cause additional emissions of about 1 260 tonnes, and of about 2 700 tonnes assuming a 12-year derogation. Total maximum additional emissions of a 5-year derogation of fluoropolymers including PFPEs would account of about 3 860 tonnes, and of about 5 370 tonnes assuming a 12-year derogation, respectively. While the fraction of PPE use for risk category III in the EEA is small (about 20%, see above), PFAS releases from textile treatment can be assumed to be high (ERC 5, 50% total release). There is **sufficiently strong evidence** that a derogation of PFAS use in PPE (either for 5 or 12 years) will cause substantial additional emissions which are below additional emissions under worst-case scenarios.

(ii) *Proposed derogation: Personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m)*

The proposed derogation comprises PFAAs including PFAA precursors (side-chain fluorinated polymers) and fluoropolymers (in particular PTFEs). Regarding expected environmental impacts from the derogation, the evaluation is equivalent to (i).

(iii) *Proposed derogation: Impregnation agents for re-impregnating of articles referred to above*

The proposed derogation comprises PFAAs including PFAA precursors (side-chain fluorinated polymers). The derogation is proposed corresponding to the potentially exempted uses of PPE (see also under (i)). Regarding expected environmental impacts from the derogation the evaluation is equivalent to (i).

(iv) *Proposed derogation: Textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence*

The proposed derogation comprises PFAAs including PFAA precursors (side-chain fluorinated polymers) and fluoropolymers (in particular PTFEs). Filters / membranes are likely to cause emissions under the baseline to a lesser extent compared to (i), for example due to an assumed lower release factor (ERC 12a, low release), and provided that wear of these filters / membranes occurs under low mechanical impact. If, however, wear occurs under high mechanical impact (ERC12b), emissions from filter / membrane use can be expected to be higher (ERC 20% instead of 2.5%), and may then not be considered negligible. Still, regarding expected environmental impacts from the derogation the evaluation of expected environmental impacts is equivalent to (i).

(v) *Potential derogation marked for reconsideration: Textiles for the use in engine bays for noise and vibration insulation used in the automotive industry*

As mentioned in the baseline assessment for TULAC in Annex E, the assessment does not account for use volumes and emissions relating to textiles used for noise and vibration insulation in automotives as this use only became known during the 2nd stakeholder consultation and no volume data is available to the Dossier Submitters. The environmental impacts of this derogation could therefore also not be assessed.

b) Evaluation of environmental impacts of RO2 relating to food contact materials and packaging

(i) *Proposed derogation: Food contact materials for the purpose of industrial and professional food and feed production*

(ii) This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.*Potential derogation marked for reconsideration: Non-stick coatings in industrial and professional bakeware*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

c) Evaluation of environmental impacts of RO2 relating to metal plating and the manufacture of metal products

(i) *Potential derogation marked for reconsideration: Hard chrome plating*

The derogation is proposed for a duration of 5 years. Considering the available **weak evidence on emissions from hard chrome plating**, expected additional emissions resulting from the derogation can be expected to be very close or even equivalent to emissions of the (worst-case) maximum emission scenario, being 41 tonnes for a period of 30 years (2025-2055, see Annex E.2.4.). The derogation is, therefore, expected to reduce the effectiveness of the restriction considerably, i.e. from 94% under a full ban (RO1) to 77% under RO2.

d) Evaluation of environmental impacts of RO2 relating to consumer mixtures

Same as for RO1 as no derogations are proposed.

e) Evaluation of environmental impacts of RO2 relating to cosmetics

Same as for RO1 as no derogations are proposed.

f) Evaluation of environmental impacts of RO2 relating to ski wax

Same as for RO1 as no derogations are proposed.

g) Evaluation of environmental impacts of RO2 relating to applications of fluorinated gases

(i) *Proposed derogation: Refrigerants in low temperature refrigeration below -50°C*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(ii) *Proposed derogation: Refrigerants in laboratory test and measurement equipment*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(iii) *Proposed derogation: Refrigerants in refrigerated centrifuges*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(iv) *Proposed derogation: Maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternatives exist*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(v) *Proposed derogation: Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives*
A time-unlimited derogation is proposed. The time period required to achieve a significant substitution is not known. Though **no quantitative evidence is available** for evaluating emissions of this derogation, additional emissions compared to the baseline scenario are expected to be medium and declining over time. The latter depends on the speed of substitution. If the gradual replacement occurs slowly, additional emissions can be expected for several years or even decades to come.

(vi) *Potential derogation marked for reconsideration: Foam blowing agents in expanded foam sprayed on site for building insulation*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(vii) *Proposed derogation: Industrial precision cleaning fluids*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(viii) *Proposed derogation: Cleaning fluids for use in oxygen-enriched environments*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(ix) *Potential derogation marked for reconsideration: Industrial and professional use of solvent-based debinding systems in 3D printing*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(x) *Potential derogation marked for reconsideration: Industrial and professional use of smoothing agents for polymer 3D printing applications*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(xi) *Potential derogation marked for reconsideration: Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(xii) *Proposed derogation: Clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(xiii) *Potential derogation marked for reconsideration: Preservation of cultural paper-based materials*
This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(xiv) *Proposed derogation: Insulating gases in high-voltage switchgear (above 145kV)*

h) This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.**Evaluation of environmental impacts of RO2 relating to medical devices**

(i) *Proposed derogation: Implantable medical devices (not including meshes, wound treatment products, and tubes and catheters)*
(ii) *Potential derogation marked for reconsideration: Hernia meshes*
(iii) *Potential derogation marked for reconsideration: Wound treatment products*
(iv) *Proposed derogation: Tubes and catheters*
(v) *Proposed derogation: Coatings of Metered Dose Inhalers (MDIs)*
(vi) *Potential derogation marked for reconsideration: Coating applications for medical devices other than Metered Dose Inhalers (MDIs)*
(vii) *Potential derogation marked for reconsideration: Cleaning and heat transfer: engineered fluids for medical devices*
(viii) *Proposed derogation: Diagnostic laboratory testing*
(ix) *Potential derogation marked for reconsideration: Rigid gas permeable (RGP) contact lenses and ophthalmic lenses*

(x) *Potential derogation marked for reconsideration: Membranes used for venting of medical devices*

(xi) *Potential derogation marked for reconsideration: PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics*

(xii) *Potential derogation marked for reconsideration: PTFE in ophthalmic solutions packaging*

(xiii) *Potential derogation marked for reconsideration: Packaging of terminally sterilised medical devices*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

i) Evaluation of environmental impacts of RO2 relating to the transport sector

(i) *Potential derogation marked for reconsideration: Applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(ii) *Proposed derogation: Additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(iii) *Proposed derogation: Refrigerants in mobile air conditioning (MAC)-systems in combustion engine vehicles with mechanical compressors*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(iv) *Proposed derogation: Refrigerants in transport refrigeration other than in marine applications*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

(v) *Potential derogation marked for reconsideration: Use as refrigerants and for mobile air conditioning (MAC) in vehicles in military applications*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

j) Evaluation of environmental impacts of RO2 relating to electronics and semiconductors

(i) *Potential derogation marked for reconsideration: The semiconductor manufacturing process*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

k) Evaluation of environmental impacts of RO2 relating to the energy sector

(i) *Proposed derogation: Proton-exchange membrane (PEM) fuel cells*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

l) Evaluation of environmental impacts of RO2 relating to construction products

Same as for RO1 as no derogations are proposed.

m) Evaluation of environmental impacts of RO2 relating to lubricants

(i) *Proposed derogation: Lubricants where the use takes place under harsh conditions or use is for safe functioning and safety of equipment*

This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.

n) Evaluation of environmental impacts of RO2 relating to the petroleum and mining sector

(i) *Proposed derogation: Fluoropolymer applications*

A 12-year derogation is proposed. There is **sufficiently strong evidence** (i.e. based on referenced quantitative data) that a derogation of all fluoropolymers leads to substantially higher emissions compared to a full ban (RO1). Expected emissions under a 12-year derogation are more than 4 times higher compared to RO1 (30 246 tonnes compared to 4 284 tonnes under RO1). The increase of emissions compared to RO1 is 40%.

o) Evaluation of environmental impacts of RO2 relating to other applications

(i) *Proposed derogation: Calibration of measurement instruments and as analytical reference materials*

The derogation is proposed without time limit. Analytical reference materials are assumed to remain necessary when measuring substances (e.g. in environmental samples or for enforcement). In particular, the application is required to quantify substances when no analytical reference standards available, e.g. for enforcement and environmental monitoring. The Dossier Submitters expect that the derogation will cause only very small (insignificant) additional emissions. There is, however, **no supporting evidence available**.

2.4.4. Proportionality to the risk

Evaluating the proportionality of restriction options requires to assess whether:

- The restriction options are targeted to the identified risk and do not inadvertently affect users or actors in the supply chain which are not associated with the identified risk (effectiveness);
- The efforts needed from the actors to implement and from the authorities to enforce the restriction options correspond in amount or degree to the adverse effects that are being avoided; and
- Restriction options ensure a good balance between costs and benefits and are cost-effective (ECHA, 2007).

The standard approach adopted to assess proportionality of PBT/vPvB chemicals is a cost-effectiveness analysis (CEA), assuming that cost-benefit analysis cannot be used due to a lack of safe concentration levels of PBT/vPvB chemicals (ECHA, 2016). Moreover, for assessing the effectiveness of restriction options the expected emission reduction is used as a proxy. As discussed in section 1.1.6, emissions represent the pollution inflow into the environment. They do, however, not reflect the accumulation of pollution over time as a result of the persistence of PFASs, indicating the long-term environmental impact potential of PFASs (Gabbert et al., 2022).

Socio-economic costs of PFAS emissions to the environment are considerable and are growing with prolonged PFAS use. Continued PFAS use has a broad range of societal effects, with an unclear or indicative price tag.

There are potentially significant benefits in terms of reduced health costs associated with restricting PFAS use and subsequent emissions to the environment. A lower reduction of emissions will likely lead to increased health impacts, as well as to higher costs for society, e.g. due to increased healthcare costs (Obsekov et al., 2022).

Because of historical, and out of scope of this restriction proposal, environmental contamination of PFASs in soils and water sheds, remediation and purification costs are currently incurred across Europe. Affected areas include PFAS production locations and large airports that used PFAS-containing firefighting foams. The costs associated with the remediation of contaminated soils due to PFAS-containing firefighting foams alone has been estimated to range from hundreds of millions to billions of euros if such use would be allowed to continue in the future (ECHA, 2022a). Around PFAS production sites soils can be contaminated with PFASs leading to significant remediation cost. In Belgium, 3M recently signed a remediation agreement of €571 million with the Flemish government for PFAS-related remedial actions around their PFAS production facility in Zwijndrecht[20]. In addition, PFAS-contaminated soils have led to delays in infrastructure and building projects in the Netherlands and Belgium, leading to increased costs for society. It is therefore plausible that high costs would be incurred in the future under the baseline scenario with continued production and use of the PFASs in scope in Europe due to new needs for soil remediation or clean-up. If remediation or clean–up is even possible at all.

PFASs are detected in drinking water around Europe (see 1.1.5.2). In the Netherlands, PFASs in drinking water produced from surface water (river) are already above acceptable concentrations considering health-based guidance values and exposure to PFASs from other sources (food and environment)[21]. 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. In Italy, the local water supply company Acque del Chiampo S.p.A. invested over €20 million on purification and remediation due to large scale PFAS contamination in the Veneto Region affecting groundwater, surface water, drinking water and land. One of the sources of the contamination has been a fluorochemicals production plant (EurEau, 2020). Continued use and subsequent emissions of PFASs into the environment will increase the share of drinking water inlets that need additional purification efforts to filter out PFASs at significant costs. The European representation of drinking water and waste water operators (EurEau) are particularly concerned about the affordability of water services with increased costs for water purification due to PFAS contamination (EurEau, 2020).

PFAS contaminated surface waters leads to a decrease in fishing grounds as consumption of fish, shellfish and crustaceans from these waters can lead to exceedance of the health-based guidance value for PFASs. To date, recreational and professional fishing in parts of the Dutch Western Scheldt is advised against by the Dutch Fishermen’s Association due to the high PFAS concentrations leading to additional costs for the fishing industry.

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[20] https://news.3m.com/2022-07-06-Agreement-Reached-Between-the-Flemish-Government-and-3M-Belgium-to-Support-the-People-of-Flanders, date of access: 2023-01-06.

[21] https://www.rivm.nl/en/news/pfas-levels-in-drinking-water-from-river-water-need-to-be-brought-down, date of access: 2023-01-06.

2.4.4.1. Comparison of different restriction options

Applying CEA requires quantitative data on the expected costs and the expected emission reduction of each restriction option considered. As illustrated by Table 8 and Table 9, this information is only available in very few cases, e.g. in relation to PFAS manufacturing. As such, a ranking of restriction options based on cost-effectiveness is not possible for most sectors. Cost-effectiveness and proportionality will thus be assessed in a qualitative manner. To propose the most appropriate RO, the Dossier Submitters provide information on the differences between RO1 and RO2 with respect to the extent of emission reduction (used as proxy for the benefits of different restriction options) and costs with a view of highlighting the trade-offs between RO1 and RO2 for different use sectors. In Table 13, derogations are 'proposed' in case the evidence base on the non-existence of technically and economically feasible alternatives is concluded to be sufficiently strong. Derogations are marked 'for reconsideration' in case the evidence base is concluded to be too weak to propose them as derogation even though the Dossier Submitters recognize that such a derogation could potentially be warranted. For those marked 'for reconsideration', additional evidence is needed to justify the derogations.

Table 13. Comparison of RO1 and RO2.

Use sector (with uses)	Derogations under RO2	Cost and other impacts (in comparison to RO1)	Environmental impact (in comparison to RO1)	Other aspects	Overall evaluation
PFAS Manufacturing (Annex E.2.1.)					
Sector as a whole	**5-year** derogation after the transition period **proposed** for: • Polymerisation aids in the production of polymeric PFASs other than PTFE, PDVF and FKM	No information is available to quantify a difference in the producer surplus losses between RO1 and RO2. However, the expected reduction in producer surplus losses could be limited as this depends on the ability to manufacture the PFAS volumes for the derogated uses at competitive prices within the EU.	Evidence for an evaluation of expected additional emissions is lacking.		The additional emissions and reduced producer surplus losses are conditional to the ability of EU manufactures to continue to produce PFASs at competitive prices for use for the proposed derogations.
TULAC (Annex E.2.2.)					
Includes: • Home textiles • Consumer apparel • Professional apparel (including PPE) • Technical textiles • Leather • Home fabric treatments (sprays) • Textiles for use in engine bays (for noise and	**5-year** derogation after the transition period **proposed** for: • Textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence	• Low (instead of high) producer surplus losses as a result of business closures in relation to professional apparel, technical textiles and textiles for use in engine bays, including more limited impacts in the wider supply chain • Producer surplus losses from substitution in the professional apparel sector are higher (in comparison to RO1), but are still found to be low due to low internalization of costs • Producer surplus losses from substitution in relation to technical textiles, which were classified as medium under RO1 as a result of substitution in relation to outdoor technical	The expected emission reduction for all TULAC sub-sectors together under RO1 equals around 95% of baseline emissions (and covers PFAAs and PFAA precursors, fluoropolymers and PFPEs). • While the fraction of PPE use for risk category III in the EEA could be small (about 20%, PFAS releases from textile treatment can be assumed to be high (ERC 5, 50% total release). There is **sufficiently strong**	A derogation for filtration and separation media used in high performance air and liquid applications that require a combination of water-and oil repellence properties is proposed for the REACH restriction on PFHxA, its salts and related substances	Significantly higher emissions, and potential long-term impacts in exchange for: • Lower impacts on industry and industry actors that are not associated with identified risk, i.e. companies in the upstream supply chain; • Less pronounced socio-economic impacts on customers due to preventing absence of certain types of PPE, textiles for the use in engine bays and high-performance membranes (as well avoiding the associated costs in relation

Use sector (with uses)	**Derogations under RO2**	**Cost and other impacts (in comparison to RO1)**	**Environmental impact (in comparison to RO1)**	**Other aspects**	**Overall evaluation**
vibration insulation)	**12-year** derogation after the transition period **proposed** for: • Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c) • Personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m) • Impregnation agents for re-impregnating of	textiles, are higher (in comparison to RO1) due to substitution in relation to high performance membranes, but change is limited by low internalization of costs in relation to this application • Producer surplus losses from substitution for textiles for use in engine bays are higher, but considered to be low given low internalization of cost • Consumer surplus losses from price changes in relation to professional apparel are higher, but are still found to be comparatively low due to low annual sales volume • Consumer surplus losses from price changes in relation to technical textiles are significantly higher[22] (in comparison to RO1) due to additional consumer surplus losses associated with high performance membranes (in relation to which price changes will likely be high given the	**evidence** that a derogation of PFAS use in PPE will cause substantial additional emissions, but below emission levels which would occur under a full derogation of PFAS use in PPE (see Annex E for details). • Filters/membranes are likely to cause emissions to a lesser extent compared to professional apparel applications for which a derogation is proposed, for example due to an assumed lower release factor (ERC12a, low release). If wear occurs under a high mechanical impact (ERC12b) emissions would be higher (ERC20% instead of 2.5%) and may then not be considered negligible. There is		to a shortened lifetime of equipment), which are however balanced out to some extent by increased consumer surplus losses from price changes; and • Lower employment losses

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[22] Due to a lack of data on sales volumes of high performance membranes, no definite conclusion on whether consumer surplus losses will be medium or high in comparison to other TULAC sub-sectors can be drawn as it is not clear whether the sales volume of high performance membranes results in a total sales volume of technical textiles that is comparable in magnitude to consumer apparel and home textiles, for which consumer surplus losses are found to be high.

Use sector (with uses)	Derogations under RO2	Cost and other impacts (in comparison to RO1)	Environmental impact (in comparison to RO1)	Other aspects	Overall evaluation
	articles referred to above **12-year** derogation after the transition period is marked **for reconsideration** after the Annex XV report consultation for: • [Textiles for the use in engine bays for noise and vibration insulation used in the automotive industry]	comparatively high substitution costs, which are full passed on to customers) • Consumer surplus losses from price changes in relation to textiles for use in engine bays, instead of their unavailability • The absence of some types of PPE and their early disposal due unavailability of impregnation agents is avoided, but other types of PPE need to be disposed before the end of the lifecycle due to the inability to re-impregnate them • Impacts on the lifetime of industrial equipment due to the non-existence of suitable high-performance membranes are avoided • Lower employment losses, due lower level of business closure in relation to professional apparel, technical textiles and textiles for use in engine bays	sufficiently strong evidence that additional emissions of a time-limited derogation can be expected to be significantly below additional emissions under the maximum additional emission scenarios (see Annex E for details). • For textiles for the use in engine bays, there is no evidence on the expected environmental impacts of the potential derogation marked for reconsideration.		
Food contact materials and packaging (Annex E.2.3.)					
Includes: • Consumer cookware	**5-year** derogation after the transition period **proposed** for: • Food contact materials for the	A 5-year derogation targeted at use of PFASs in other equipment for food and feed production, recognising that PFAS seals, pipes, gaskets, tubes etc are deeply integrated into	This information will be provided in the version that will be made available for the Annex XV report consultation,		Potentially substantial additional emissions in exchange for: • Reduced producer surplus losses for companies involved in the

Use sector (with uses)	Derogations under RO2	Cost and other impacts (in comparison to RO1)	Environmental impact (in comparison to RO1)	Other aspects	Overall evaluation
• Industrial food and feed production • Non-stick coatings in industrial and professional bakeware Paper & board packaging • Plastic packaging	purpose of industrial and professional food and feed production **5-year** derogation after the transition period is marked **for reconsideration** after the Annex XV report consultation for: • [Non-stick coatings in industrial and professional bakeware]	manufacturing and processing equipment. A derogation would remove the need for rapid transition generating significant pressures on industry leading to high producer surplus losses and potential for business closures, which could have knock-on consequences for consumers. The derogation is considered sufficient to mitigate much of these problems. Whilst non-stick coatings made from alternatives are widely accepted in the domestic market the situation is less clear for professional food and feed production. A 5-year derogation for use of PFASs in non-stick coatings in the industrial and professional food and feed production would provide opportunity for businesses to gradually switch away from PFAS coatings, including the companies (largely SMEs) involved in recoating bakeware. The Dossier Submitters consider that this provides sufficient time to limit inevitable producer surplus losses linked to a switch to the use of alternatives.	which is planned to start on 22 March 2023.		manufacture of non-stick coating materials and other equipment for the industrial and professional food and feed production and associated reduced consumer surplus losses

Use sector (with uses)	**Derogations under RO2**	**Cost and other impacts (in comparison to RO1)**	**Environmental impact (in comparison to RO1)**	**Other aspects**	**Overall evaluation**
Metal plating and manufacture of metal products (Annex E.2.4.)					
Includes: • Hard chrome plating • Decorative plating with chrome, plating on plastics and plating with metals other than chrome • Manufacture of metal products not addressed elsewhere	**5-year** derogation after the transition period is marked **for reconsideration** after the Annex XV report consultation for: • [Hard chrome plating]	For the hard chrome plating sector there is weak evidence of difficulty in transitioning from PFASs. Added time offered by the derogation provides opportunity to develop and implement alternatives, reducing both potential producer and consumer losses	It is estimated that RO1 would reduce emissions by 94% (171t over the 30-year period 2025 to 2055). Expected additional emissions resulting from the derogation can be expected to be very close or even equivalent to emissions of the maximum emission scenario, being 41 tonnes for a period of 30 years (2025-2055). The derogation is, therefore, expected to reduce the effectiveness of the restriction considerably, i.e. from 94% under a full ban (RO1) to 77% compared to the baseline.	This proposal is broadly in line with the PFHxA dossier.	Substantially higher emissions (i.e. close to worst-case reference scenario) in exchange for: Potential reduction of producer and consumer losses and the risk of job losses.
Consumer mixtures (Annex E.2.5.)					
Sector as a whole	No derogations proposed	Not applicable.	Not applicable.	Not applicable.	Impacts of RO2 are equal to RO1
Cosmetics (Annex E.2.6.)					
Sector as a whole	No derogations proposed	Not applicable.	Not applicable.	Not applicable.	Impacts of RO2 are equal to RO1
Ski wax (Annex E.2.7.)					

Use sector (with uses)	**Derogations under RO2**	**Cost and other impacts (in comparison to RO1)**	**Environmental impact (in comparison to RO1)**	**Other aspects**	**Overall evaluation**
Sector as a whole	No derogations proposed	Not applicable.	Not applicable.	Not applicable.	Impacts of RO2 are equal to RO1
Applications of fluorinated gases (Annex E.2.8.) *Note that mobile air conditioning (MAC) and transport refrigeration, including military applications, are covered under Transport below*					
Includes: • Refrigeration • Air conditioning and heat pumps • Foam blowing agents • Solvents • Propellants • Magnesium casting • Fire suppressants • Preservation of cultural paper-based materials • Insulating gas in electrical equipment	**5-year** derogation after the transition period **proposed** for: • Refrigerants in low temperature refrigeration below -50°C • Insulating gases in high-voltage switchgear (above 145kV) **5-year** derogation after the transition period is marked **for reconsideration** after the Annex XV report consultation for: • [Foam blowing agents in expanded foam sprayed on site for building insulation]	Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses: The gradual replacement of aging refrigeration and AC systems will reduce the need for maintenance of commercial and industrial systems using PFASs over time, though it is to be expected that many such systems will still be operational after a 12-year derogation. Scrappage of those systems through a lack of suitable refrigerant rather than technical or economic obsolescence would generate potentially substantial consumer surplus loss, though this is likely to be mitigated to an extent by improved efficiency of newer technology. The need for public confidence in fire safety systems indicates potential for significant welfare	This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.		Higher emissions overall, and substantial emissions for some uses, in exchange for: • The potential benefits for producers of low temperature refrigeration (5-year) and refrigerated centrifuges (12-year) • Avoidance of the impracticality of replacing industrial and commercial refrigeration systems at large scale in a limited time period. • Excluding the potential for significant welfare loss in the event that the safety of alternatives in high rise (etc) buildings is not demonstrated • Limiting the loss of producer and consumer surplus and welfare losses from use of less effective or more hazardous foam blowing agents; less effective solvents,

Use sector (with uses)	Derogations under RO2	Cost and other impacts (in comparison to RO1)	Environmental impact (in comparison to RO1)	Other aspects	Overall evaluation
	12-year derogation after the transition period **proposed** for: • Refrigerants in laboratory test and measurement equipment • Refrigerants in refrigerated centrifuges • Maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternatives exist • Industrial precision cleaning fluids • Cleaning fluids for use in oxygen-enriched environments • Clean fire suppressing agents where current alternatives	loss in the event that the safety of alternatives in high rise (etc) buildings is not demonstrated and restrictive building codes remain in force. Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from use of less effective or more hazardous foam blowing agents; less effective solvents, propellants and fire suppressants; and from an increased risk of damage to cultural assets. With respect to insulating gases in electrical equipment, the additional time provides manufactures and downstream uses the opportunity to substitute instead of ceasing operation thereby limiting producer surplus losses, employment impacts and impacts on customers			propellants and fire suppressants • Limiting a significant risk to human life (e.g. in aircraft or military vehicles; asphyxiation through flooding areas with inert gases) or potential destruction of valued assets that would be damaged by fire and by other fire suppressants such as water (e.g. electronics, historic artefacts) • Preservation of cultural paper-based materials • Limiting socio-economic costs due to delayed power grid expansions, inadequate electricity transmission and increased risk of outages

Use sector (with uses)	Derogations under RO2	Cost and other impacts (in comparison to RO1)	Environmental impact (in comparison to RO1)	Other aspects	Overall evaluation
	damage the assets to be protected or pose a risk to human health **12-year** derogation after the transition period is marked **for reconsideration** after the Annex XV report consultation for: • [Industrial and professional use of solvent-based debinding systems in 3D printing] • [Industrial and professional use of smoothing agents for polymer 3D printing applications] • [Propellants for technical aerosols for applications where non-flammability and high technical				

Use sector (with uses)	**Derogations under RO2**	**Cost and other impacts (in comparison to RO1)**	**Environmental impact (in comparison to RO1)**	**Other aspects**	**Overall evaluation**
	performance of spray quality are required] • [Preservation of cultural paper-based materials] A **time-unlimited** derogation after the transition period proposed for: • Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives				
Medical devices (Annex E.2.9.)					
Includes: • Implantable medical devices (not including meshes, wound treatments products, and tubes and catheters)	**12-year** derogation after the transition period **proposed** for: • Implantable medical devices (not including meshes, wound treatment products, and tubes and catheters)	Public health concerns (and their related socio-economic costs) due to reduced functionality of implantable medical devices are avoided when feasible alternatives are identified, developed and approved during the derogation period. Reduced socio-economic costs can be expected related to tubes and catheters, since no	This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.		Higher and potentially substantial additional emissions in exchange for: • Substantial lower socio-economic costs related to public health effects, in the form of reduced risk of implantable medical device failures and lower frequency of implant replacements.

Use sector (with uses)	Derogations under RO2	Cost and other impacts (in comparison to RO1)	Environmental impact (in comparison to RO1)	Other aspects	Overall evaluation
• Hernia meshes • Wound treatment products • Tubes and catheters • Coatings of Metered Dose Inhalers (MDIs) • Other coating applications • Cleaning and heat transfer: engineered fluids • Sterilization gases • Diagnostic laboratory testing • Membranes used for venting of medical devices • Rigid gas permeable (RGP) contact lenses and ophthalmic lenses	• Tubes and catheters • Coatings of Metered Dose Inhalers (MDIs) • Diagnostic laboratory testing **12-year** derogation after the transition period is marked **for reconsideration** after the Annex XV report consultation for: • [Hernia meshes] • [Wound treatment products] • [Coating applications for medical devices other than Metered Dose Inhalers (MDIs)] • [Cleaning and heat transfer: engineered fluids for medical devices] • [Rigid gas permeable (RGP)	derogation would likely result in more invasive procedures and/or procedures that are more painful for the patient. A reduction of high socio-economic costs can be expected resulting from reduced functionality of metered dose inhalers. A reduction of the impacts on the feasibility of diagnostic laboratory testing can be expected, which in turn would have severe implications on public health. Public health concerns related to the functionality of hernia meshes (increased risk of intestinal damage and fistula formation in patients) and their related socio-economic costs would be avoided. No information is available on the cost impact of a derogation for wound treatment products; other coating applications or membranes used for venting of medical devices. Reduced socio-economic impacts from other coating applications and engineered fluids for cleaning and			• Substantially lower socio-economic costs related to public health effects, in the form of reduced frequency of invasive procedures and/or reduction in pain suffered by the affected patients. • Substantially lower socio-economic costs related to public health effects, in the form of maintained functionality of metered dose inhalers. • Substantially lower socio-economic costs related to public health effects, in the form of availability of feasible diagnostic laboratory testing. • Potential lower socio-economic costs related to public health effects, in the form of reduced risk of intestinal damage and fistula formation in patients • Potential lower socio-economic costs related to public health effects of RGP contact lenses and ophthalmic lenses

Use sector (with uses)	**Derogations under RO2**	**Cost and other impacts (in comparison to RO1)**	**Environmental impact (in comparison to RO1)**	**Other aspects**	**Overall evaluation**
• Propellants in Metered Dose Inhalers (MDIs) • Packaging of medical devices	contact lenses and ophthalmic lenses] • [Membranes used for venting of medical devices] • [PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics] • [PTFE in ophthalmic solutions packaging] • [Packaging of terminally sterilised medical devices]	heat transfer need further clarification. Reduction in socio-economic costs in terms of: • quality-of-life reductions for users of eyeglasses and RGP contact lenses, and • increased costs due to more frequent replacements of eyeglasses. The information provided does not allow for quantification of these impacts. Avoidance of high socio-economic costs in applications where packaging is vital for functionality and safety, and where there are no available alternatives that meets the technical requirements. However, no information is available to identify these applications. Further information is requested in the Annex XV report consultation.			• Potential avoidance of high socio-economic costs in applications where packaging is vital for functionality and safety, and where there are no available alternatives that meets the technical requirements.
Transport (Annex E.2.10.)					
Includes: • Use of PFASs in applications affecting the	**5-year** derogation after the transition period **proposed** for:	Alternatives for MAC and refrigeration are available but would require redesign of MAC and refrigeration systems. The	This information will be provided in the version that will be made available for the Annex		Higher emission amount in exchange for: • Avoidance of significant producer and consumer

Use sector (with uses)	Derogations under RO2	Cost and other impacts (in comparison to RO1)	Environmental impact (in comparison to RO1)	Other aspects	Overall evaluation
proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods, to the extent not addressed under other parts of this restriction (e.g., under lubricants, electronic equipment and TULAC) • Hydraulic fluids • Mobile Air Conditioning (MAC) • Transport refrigeration • MAC- and refrigeration in military applications	• Refrigerants in mobile air conditioning (MAC)-systems in combustion engine vehicles with mechanical compressors • Refrigerants in transport refrigeration other than in marine applications **12-year** derogation after the transition period **proposed** for: • Additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry **12-year** derogation after the transition period is marked	derogation is designed to be long enough for manufacturers to undertake the necessary R&D, etc. to bring the alternatives to the mass market. The 5-year derogation is considered long enough to avoid significant producer and consumer losses. Reduced producer surplus loss compared to RO1 given the need for recertification of components using alternative substances in hydraulic fluid. PFAS components are to be found throughout vehicles (road, rail, sea and air). Whilst drop-in replacements will be available for some components this will not be the case throughout. The derogation provides time for (e.g.) development of new polymers and redesign of affected parts where necessary, and time for approval and certification of new parts. Without a derogation it would not be possible to continue producing vehicles in Europe leading to substantial producer and consumer losses.	XV report consultation, which is planned to start on 22 March 2023.		losses for MAC and refrigeration systems • Reduced producer surplus loss in aircraft and aerospace industry • Potential avoidance of major disruption to the EU's largest manufacturing sector. The derogations proposed are designed to provide the industry with sufficient time to phase PFAS from the sector whilst maintaining product quality. • Potential substantial welfare losses to military service employees and reduced market share for manufacturers of military transport vehicles.

Use sector (with uses)	**Derogations under RO2**	**Cost and other impacts (in comparison to RO1)**	**Environmental impact (in comparison to RO1)**	**Other aspects**	**Overall evaluation**
	for reconsideration after the Annex XV report consultation for: • [applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods] • [Use as refrigerants and for mobile air conditioning (MAC) in vehicles in military applications]	The alternatives available for refrigeration systems in other vehicles could be used in military applications. However, in extreme situations that are not uncommon for the military they could bring added risk linked to flammability, high pressure loading, and toxicity, that would be incompatible with the duty of care to service employees, risking substantial welfare losses and reduced market share for manufacturers.			
Electronics and semiconductor (Annex E.2.11.)					
Includes: • Electronics • Semi-conductors	**12-year** derogation after the transition period is marked **for reconsideration** after the Annex XV report consultation for:	A derogation would limit: • high producer surplus losses as a result of business closures due to not being able to manufacture semiconductors • high socio-economic costs to customers due to the unavailability of articles using semiconductors	This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.		Higher and potentially substantial additional emissions in exchange for: • Limiting producer surplus losses as a result of business closures • Limiting socio-economic costs to customers due to the unavailability of

Use sector (with uses)	**Derogations under RO2**	**Cost and other impacts (in comparison to RO1)**	**Environmental impact (in comparison to RO1)**	**Other aspects**	**Overall evaluation**
	• [The semiconductor manufacturing process]	• Employment losses as a result of high share of business closures			articles using semiconductors • Limiting employment losses
Energy (Annex E.2.12.)					
Sector as a whole	**5-year derogation** after the transition period **proposed** for: • Proton-exchange membrane (PEM) fuel cells	The additional time provides manufacturers of PEM fuel cells the opportunity to substitute instead of closing business, thereby limiting producer surplus losses, employment impacts and impacts on customers resulting from the unavailability of PEM fuel cells.	This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.		Higher and potentially substantial additional emissions in exchange for: • Lower socio-economic impacts i.e. lower producer surplus losses, employment impacts and impacts on customers resulting from the unavailability of PEM fuel cells
Construction products (Annex E.2.13.)					
Sector as a whole	No derogations proposed	Not applicable.	Not applicable.	Not applicable.	Impacts of RO2 are equal to RO1
Lubricants (Annex E.2.14.)					
Sector as a whole	12-year derogation after the transition period **proposed** for: • Lubricants where the use takes place under harsh conditions or use is for safe functioning and	The losses of functionality identified under RO1 are likely to be avoided, while costs related to reformulation and development will be spread out over a longer period of time.	This information will be provided in the version that will be made available for the Annex XV report consultation, which is planned to start on 22 March 2023.		Higher and potentially substantial additional emissions in exchange for: • Lower socio-economic impacts, i.e. lower producer surplus losses for manufacturers and lubricants and lower losses of functionality for downstream users

Use sector (with uses)	**Derogations under RO2**	**Cost and other impacts (in comparison to RO1)**	**Environmental impact (in comparison to RO1)**	**Other aspects**	**Overall evaluation**
	safety of equipment				
Petroleum and mining (Annex E.2.15.)					
Includes: - Non-polymeric PFAS applications (tracers and anti-foaming agents) - Fluoropolymer applications	**12-year** derogation after the transition period **proposed** for: - Fluoropolymer applications	A derogation would allow longer time to bear the costs related to product reformulation that can range from tens of thousands of euros to millions of euros for any single formulation. Product reformulation will also imply costs relating to quality assurance. In addition, loss of functionality of products in this sector could have substantial economic implications, including shorter operational lifetime of components, increased frequency and costs of maintenance, and increased operational downtimes. No quantification of economic impacts available. The costs of substitution are likely to be borne in full (in the form of reduced producer surplus/profits) by the firms in the sector.	It is estimated that RO1 would reduce emissions by 94% compared to the baseline (from 77kt to 4kt over the period 2025 to 2055). There is **sufficiently strong quantitative evidence** that a 12-year derogation of fluoropolymer use (incl. PFPEs) causes additional emissions being more than 4 times higher compared to RO1 (30 246 tonnes compared to 4 284 tonnes under RO1). The increase of emissions compared to RO1 is 40%.		High additional emissions in exchange for: - Avoided costs related to loss of functionality of fluoropolymer articles/components used in this sector. Loss of functionality is likely to have substantial economic implications, including shorter operational lifetime of components, increased frequency and costs of maintenance, and increased operational downtimes.

Based on the available evidence about impacts, it is for most sectors not feasible to conclude about proportionality. However, the current SEAC PBT/vPvB approach acknowledges that in addition to a quantification of impacts, other arguments can be relevant to underline a conclusion on the proportionality of restriction options. In particular, the following arguments can be considered relevant for supporting the proportionality assessment:

- All PFASs in the scope of this restriction proposal are either very persistent themselves or degrade into very persistent PFASs in the environment;
- If releases are not minimised, the environmental stock will continue to increase in the future. As a consequence, humans and other organisms will be exposed to progressively increasing amounts of PFASs;
- Monitoring data show that measured PFASs are already ubiquitously present in the environment;
- There are significant barriers to remove the PFASs from fresh water and wastewater or sludge. Exposure of humans via drinking water cannot be prevented effectively as removal or remediation might only be feasible for contamination hotspots in few specific cases;
- The exposure via drinking water and food is expected to increase in the future unless releases of PFASs cease;
- Exposure to legacy PFASs already exceeds the existing limit value, hence any additional exposure to other PFASs add to the overall toxicity potential and therefore needs to be minimised;
- There is a potential for long-term, intergenerational effects and a late detection of adverse effects after PFAS exposure; and
- Significant societal costs can be expected from a continued PFAS use and emissions of PFASs in the form of loss of natural resources and environmental quality and functioning, as well as health costs and/or massive remediation/purification costs.

Based on the factors described above, the Dossier Submitters consider that RO1 could be proportionate in the medium and long-term due to the expected progressively increasing amounts of PFASs that would be emitted without a ban (under the baseline scenario). Societal costs associated with a continued use of PFASs will likely progressively increase as well and eventually outweigh the societal costs of the restriction option RO1. The Dossier Submitters consider RO2 the most appropriate RO balancing the trade-offs between short term (costs of the PFASs restriction) and long term (societal costs of continued PFASs use) impacts. While RO2 is expected to have a lower total emission reduction, it will cause less severe economic impacts to society in the short-term compared to RO1. Furthermore, specific use sectors will be provided the necessary time to adjust their production processes and products towards a replacement of PFASs. It should be noted, however, that this delay of a full ban of PFASs will shift the cost burden arising from health and environmental impacts to future generations.

2.5. Practicability and monitorability

The current restriction proposal covers the whole class of PFASs, amounting to more than 10 000 different compounds. Different types of PFASs are used in different products and applications according to their properties. Addressing the whole class of PFASs in all relevant applications is complex and requires a broad approach for compliance monitoring and analysis. The two restriction options RO1 and RO2 form the general basis for the restriction and apply to products and applications unless otherwise specified.

Practicability of restriction options

Both RO1 and RO2 are implementable as for different uses in a number of sectors alternatives to PFASs are already being used or product- and process-oriented research is already in a late stage, leading to the possibility for implementation in the short term. Stakeholders in several sectors are currently moving away from the use of PFASs for various reasons, e.g., customer and investor requests, legislative and regulatory actions. This indicates in a number of cases that alternatives for PFASs are sufficiently available, and/or PFAS-containing products are no longer in request. As alternatives seem currently not yet available for all uses and sectors, RO2 may be more readily implementable from an industry perspective as use-specific, time-limited derogations in this option give these stakeholders the opportunity to develop functional alternatives. Only for uses for which stakeholders supplied sufficiently strong information demonstrating that alternatives are not (readily) available, derogations are proposed. This approach was taken since derogations inevitably lead to a longer period that PFASs are being manufactured and brought to market, increasing the technical stock. Consequently, this leads to prolonged emissions of PFASs from the manufacture, use and waste phase to the environment, increasing the environmental stock which affects human health and the environment on an intergenerational level (due to the extreme persistence of the substances). Because of the concerns in this restriction, no derogations were proposed for uses and sectors for which no, inconclusive or weak evidence for the current absence of alternatives was submitted. Implementability of RO1 for these uses and sectors was considered to be sufficient.

Enforceability of both RO1 and RO2 is considered to be sufficient. Competent authorities of EU Member States responsible for REACH enforcement activities have experience with REACH restrictions, including restrictions dealing with specific (groups of) PFASs (see section 2.2.1). Activities relating to RO1 and RO2 of this proposal can be integrated in current enforcement activities. The enforceability is partly dependent on the availability of sufficiently efficient and effective analytical methods for monitoring, which are in rapid development. The enforceability can also benefit from the reporting requirements for manufacturers, importers and formulators of PFAS-containing products that are covered by a derogation. Information on PFASs and type and amount of products containing PFASs can help in targeting uses and sectors for specific enforcement activities and actions. The broad chemical scope proposed in this dossier is beneficial to enforcement, since all PFASs are covered by the scope of the restriction, excluding only a few substances which fully degrade under environmental conditions. This is beneficial in avoiding discussions on applicability of the restriction and legal uncertainties when PFASs are being found during enforcement activities.

The restriction may be broad, the manageability however is sufficiently practical. As this restriction targets manufacture and placing on the market besides use, downstream users of PFASs that are less knowledgeable with regard to regulations and restrictions in particular, have knowledgeable partners (manufacturers). This is similar for import. When the restriction comes into force, manufacturers and importers can no longer provide the less knowledgeable downstream users with PFASs as such or with PFAS-containing products. Therefore these downstream users will be made aware of the restriction conditions.

The reporting requirement is mainly applicable for larger, generally more knowledgeable stakeholders (manufacturers and formulators) and require only annual reporting for 13.5 year time-limited derogations and for one of the time-unlimited derogations, making the administrative burden for both stakeholders and authorities manageable.

Restriction options RO1 and RO2 can both be considered practical with regard to implementability, enforceability and manageability.

Concentration limits

The restriction proposal is based on the following concentration limits as the general rule:

1) 25 ppb for any PFAS (except polymeric PFASs),

2) 250 ppb for the sum of PFASs, optionally with prior degradation of precursors, and

3) 50 ppm for PFASs, including polymeric PFASs*.

*) The term polymeric PFASs is defined in Figure 1 in Section 1.1.1.

The limit value **1) 25 ppb for any PFAS** (except polymeric PFASs) shall be compared with PFAS concentrations measured by targeted PFAS analysis, which currently covers about 40 different PFASs (limited by the availability of reference standards).

The limit value **2) 250 ppb for the sum of PFASs, optionally with prior degradation of precursors**, would apply for the sum of PFASs measured with targeted PFAS analysis or the sum of PFASs measured after degradation, such as in the TOP assay (Total Oxidizable Precursor Assay) or other similar transformative methods. This limit is intended to address the risk for combined effects that may need to be taken into consideration when several PFASs are present at certain levels (and without any single PFAS exceeding the limit value of 25 ppb).

The limit value **3) 50 ppm for PFASs, including polymeric PFASs** shall relate to information disclosed when the information requirement limit value is exceeded, see below. The concentration limit is pragmatically selected to match the sensitivity of the total fluorine methods which are to be used in the measurement and monitoring of PFASs including polymeric PFASs under this restriction.

Information requirement: If, as a part of an authority enforcement campaign, total fluorine exceeds **50 mg F/kg**, the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content originating of either PFASs or non-PFASs. This proof should be submitted as total fluorine and not by calculating an approximate value for total PFASs. Optionally with a preceding extraction or adsorption step. This restriction shall apply, unless the manufacturer, importer or downstream user can demonstrate to the inspectors that the product contains fluorine originated from other substances than the substances covered by this restriction. This could be done, for example, based on measurement data or on information obtained in the supply chain.

If compliance with the 50 ppm limit cannot be adequately demonstrated, the mixture or article should be withdrawn from the market, either permanently or until the total fluorine content has been reduced within the limit.

The relationship between mg F/kg sample material and mg PFASs/kg depends on the percentage of F in the molecular structure of PFASs in the sample. How to calculate this transformation is explained in Annex E.4. Like in the case of e.g. PFOS, 50 mg F/kg corresponds to 77.4 mg PFOS/kg (PFOS consists of 64.6% F).

Summary of analytical methods

An assessment of the availability of analytical methods for PFASs may be found in the appendix of Annex E. This appendix contains an Excel sheet with a collection of information on the available analytical methods for PFASs for the different products/matrices covered by the present restriction proposal. The overview includes a range of technically relevant information, including LODs and LOQs for various methods.

Targeted PFAS analysis is used to quantify individual specific PFAS, for example for the comparison with a concentration limit value for PFAS in a product. To quantify a specific PFAS reliably (e.g. for enforcement), an analytical reference standard for the specific PFAS must be available. Laboratories can currently quantify around 40 different PFASs, and this number is increasing as more reference standards become available. In addition to targeted analysis methods, the total oxidizable precursor (TOP) assay has been used by several laboratories in recent years to analyse a broader spectrum of PFASs. This method simulates accelerated environmental degradation by treating the sample with strong oxidizing agents which leads to quick oxidative degradation. The resulting degradation products are measured with the usual targeted PFAS analysis (i.e. ca. 40 PFASs), and demonstrates the presence of precursors to the PFCAs and other relevant substances. However, other methods for the quantification of precursors besides the TOP assay exist and may also be used for this purpose.

'Total fluorine' methods measure the overall amount of (organic) fluorine in a sample: total fluorine (TF), extractable organic fluorine (EOF) and adsorbable organic fluorine (AOF). The most direct approach is to measure the fluorine content in an untreated sample (i.e. direct combustion of a product sample), TF. In such an analysis all fluorine in the sample will be measured, both inorganic and organic fluorine. However, in common products inorganic fluorine is usually not present and the total fluorine can often be assumed to be organic fluorine. On the other hand, different kinds of sample preparation may separate the different types of fluorine prior to measurement. For example, by introducing an extraction or adsorption step, EOF or AOF is measured, respectively. The total fluorine methods do not identify/differentiate between the origin of fluorine-containing organic substances, like being PFAS sor non-PFASs. Therefore, the total fluorine methods will detect and quantify both PFASs and non-PFASs organic fluorine substances if present in the same sample (i.e. both type of substances that are in- and outside of scope of the restriction). An advantage of total fluorine methods though, compared to targeted PFAS analysis or TOP, is that they detect and quantify PFASs for which no reference standards exist, including polymeric PFASs. An additional advantage of total fluorine methods is that they are significantly faster and cheaper than targeted analyses. Hence, the use of total fluorine methods to quantify PFASs, e.g. for compliance and enforcement purposes, is practical as they are more compatible with the scope of the restriction proposal (which encompasses all PFASs).

Polymeric PFASs (defined in Figure 1, section 1.1.1) cannot be quantified as the specific polymers (e.g. as x mg PTFE/kg sample) in the way non-polymeric PFASs can, as reference standards are missing and the available methods are unsuitable. However, the fluorine content of polymeric PFASs will be included in some of the total fluorine (TF) methods.

One approach to the enforcement of a restriction of PFASs as a class is a tiered approach where targeted PFAS analyses are combined with total fluorine and non-target approaches. The sum of targeted PFAS accounts for varying fractions of the total fluorine in the sample, from very small to large, depending on the characteristics of the sample. Therefore, in many scientific publications a combination of total fluorine measurements with targeted measurements is described for the evaluation of the overall PFAS content.

To address the disadvantage of the total fluorine methods that also non-PFAS fluorine (i.e. not restricted) is included in the measurement if present in the sample, an obligation to disclose information about the fluorine content of a product is introduced. Under this regime, when the measured total fluorine in a product exceeds 50 mg F/kg during enforcement, the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs. This will facilitate the check for compliance with the concentration limit for PFASs, including polymeric PFASs (50 ppm). The information requirement would also facilitate the practicality and enforceability of the proposed restriction using total fluorine analytical methods. This condition would allow the total fluorine limit value to be used in the restriction for overall content of PFASs in addition to the limit for specific PFASs as measured with targeted analysis.

Standard analytical methods for PFASs would be very helpful and facilitate the enforcement of the proposed restriction. Development of such methods is therefore highly encouraged by the Dossier Submitters. However, in the absence of European (or international) standard analytical methods for PFASs in all matrices covered by the restriction, there are different opportunities for checking compliance with the restriction. Methods can be organised as accredited, standard, validated and research methods, where the former has the most stringent classification. It is advised to use an accredited method in an accredited laboratory when this is available. These methods have been (1) extensively developed and tested, (2) have an inherent quality control guarantee, (3) are cross checked regularly between accredited laboratories and regulatory organs and (4) follow a fixed protocol that cannot be deviated from. This leads to results that can be compared between different laboratories, regions, time points, etc. When an accredited method is not available, it is advised to use a standard or at least a validated method. This validation should be as extensive as possible covering accuracy, precision, linearity and application range, limit of detection (LOD), limit of quantification (LOQ), selectivity/specificity, recovery and robustness/ruggedness. Extensive validation leads mostly to results with a sufficient confidence to be used for reporting or as with accredited methods to compare between different laboratories, regions and time points. Considering the availability of analytical methods on the market to measure the content of various PFASs, the ROs are concluded to be practicable and enforceable with regards to analytical methods and concentration limits.

Analytical methods are further described in Annex E.4.

Sampling strategy and approach to enforcement

A sampling strategy and an approach to enforcement is needed for a restriction. One such approach could be the method explained by Koch et al. (2020) in the paper "Towards a comprehensive analytical workflow for the chemical characterisation of organofluorine in consumer products and environmental samples". The authors suggest a top-down approach for the comprehensive assessment of organic fluorine, starting with the measurement of total fluorine or extractable organic fluorine (EOF), see Figure 9 below. Based on the results from the initial analyses, samples of interest are selected for further determination of the specific organic fluorine content. These samples are subjected to targeted PFAS analysis. By comparing the sum of targeted PFAS with the total fluorine measurements, the unquantifiable organic fluorine may be obtained by mass balance calculations. For further identification of unquantifiable organic fluorine, approaches such as total oxidizable precursor assay, suspect and non-target screening may be applied. In cases with limited time or resources, or when the identity of the unknown organic fluorine substances is not needed, elements from this plan could be used without doing the full analysis.

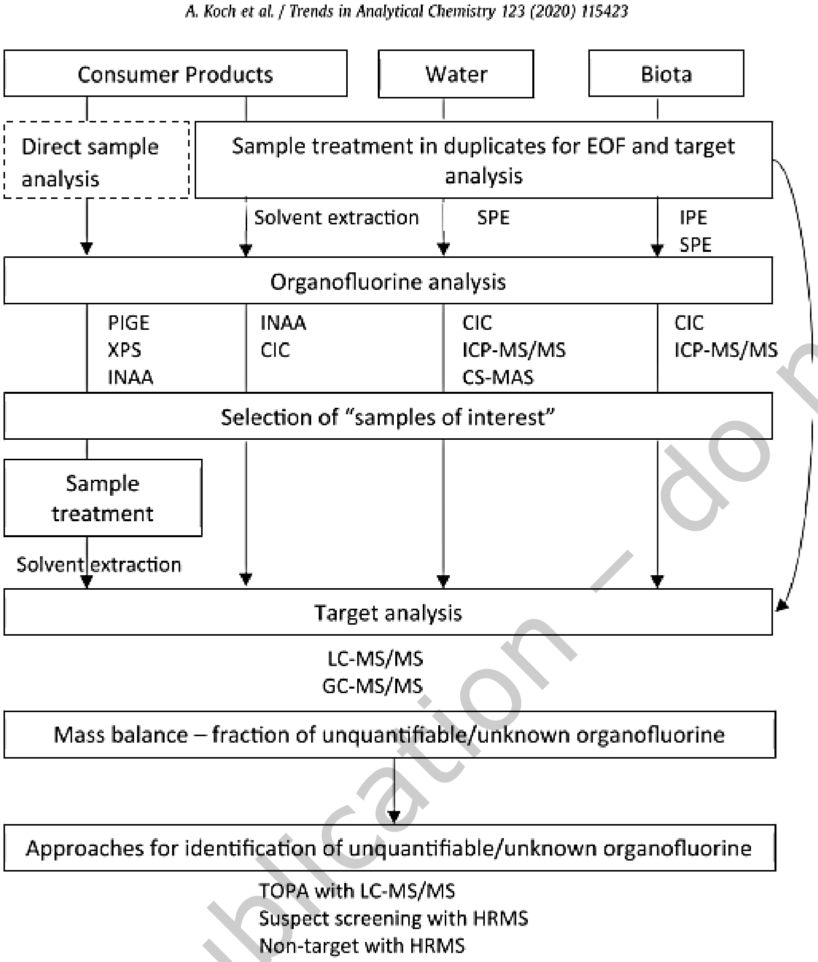

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Figure 9. Proposed workflow for a comprehensive organic fluorine assessment. Source: Koch et al. (2020). SPE = solid phase extraction; IPE = ion pair extraction; PIGE, XPS, INAA, CIC, ICP-MS/MS, CS-MAS = different methods for fluorine measurements, see Annex E.4. or paper.

The mass balance calculations follow the scheme outlined in Figure 10.

This restriction proposal covers a broad range of mixtures and products and selecting a sample for analysis may need careful consideration. The once-a-product-always-a-product principle should be kept in mind, and samples representative for PFAS content should be selected.

A joint approach for enforcement activities with other regulated PFASs, such as PFHxS, PFOS, PFHxA (if adopted), PFOA and C9-C14 PFCAs at the same time would increase cost effectiveness in the enforcement as compared to inspecting the substances individually. In addition, border authorities can control compliance of imported articles using the RAPEX system (Rapid Exchange of Information System) to report any violation of the restriction.

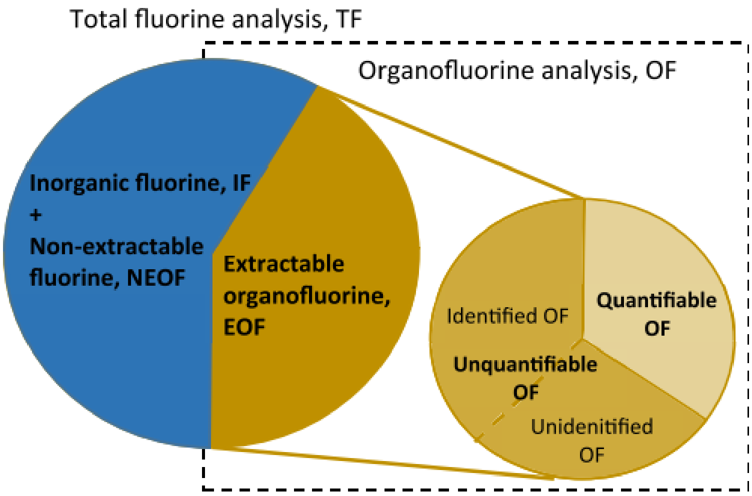

Figure 10. Mass balance analysis of fluorine. Source: Koch et al. (2020).

Sampling strategy and approach to monitoring

To monitor the effectiveness of the proposed restriction, time trend monitoring could be performed with relevant samples from the environment or humans. A reduction 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. Relevant environmental and human samples may be analysed according to the strategy developed by Koch et al. (2020) and described above. However, it may take a long time until such decreasing trends are observed in the environment, partly due to the high persistence of PFASs. In addition, degradation of precursors to arrowhead substances represents a long-term source of the PFASs that are usually measured in environmental samples (i.e. arrowheads).

Analytical methods for individual PFASs in various human samples are available and have already been applied in a harmonized way at EU level to evaluate the body burden and how much EU citizens are exposed to PFASs, for example within the HBM4EU network[23]. In addition, a combination of EOF (determined by CIC) and targeted analysis has proven useful and gives an indication of the amount of unidentified PFASs in human samples.

An overview of current knowledge of monitoring data and trends for the environmental compartment may be found in Annex B.4.2., while measurement of PFASs in human samples is included in Annex B.9.21. and B.9.22.

An alternative approach to monitoring the effectiveness of the restriction is the monitoring of PFASs in emissions like wastewater and waste streams. If PFASs are phased out of products and uses, a reduction of PFASs in these media could be expected within shorter timelines than reduction in environmental and human samples.

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[23] https://www.hbm4eu.eu/hbm4eu-substances/per-polyfluorinated-compounds/, date of access: 2023-01-06.

3. Uncertainties

The breadth of the proposed restriction, covering a large number of substances, sectors and sub-sectors, leads to the presence of a large number of uncertainties in this dossier. These are identified and discussed throughout the dossier and the associated annexes.

Annex F provides an overview of these uncertainties, framed around key questions regarding the presence of risk, the extent of the problem and whether the proposed restriction would be of overall benefit to society. Annex F takes the following approach:

- The structure of the analysis is defined across a series of 28 stages ranging from the identification of sectors using PFASs, the assessment of the quantities of PFASs used and emitted, the environmental and health impact assessment, the analysis of alternatives up to the evaluation of the costs of a restriction.
- The importance of uncertainty at each stage of the analysis is assessed for the final conclusions reached in the dossier.

Returning to the key questions facing the analysis, the following conclusions are drawn on the likely impact of uncertainty:

1. **Is there a risk?**
    a. Persistence of PFASs and degradation products covered by the restriction

The persistence of PFASs is well recognised (Annex B.4.1.). Degradation half-lives of the arrowhead PFASs in the environment exceed the criteria for very persistent substances in Annex XIII of REACH by far.

b. Potential for health and environmental harm

Ecotoxicity and endocrine activity and effects on human health are documented in Annex B.5. and Annex B.7. for a range of PFASs. Studies show the increasing evidence for effects of low exposures and combined exposures and potential for intergenerational effects (Annex B.4.2.9., B.5.1. and B.7.1.). It is acknowledged that experimental data is limited for many PFASs, in part a consequence of the size of the group of chemicals. However, there is a substantial body of evidence available that demonstrates the risks of PFAS exposure.

Conclusion on Question 1:

Despite uncertainties, there is a substantial body of evidence supporting the existence of risks to health and the environment as a result of PFAS use in the EU.

2. **What is the extent of the problem?**
    a. Range of applications of PFASs

Evidence has been gathered (Annex A) to identify a wide range of applications of PFASs both by sector and by specific activities within those sectors. Given the extent of stakeholder engagement, it is envisaged that all of the major applications of PFASs have been identified. It is possible, however, that some applications for which small amounts of PFASs are used are not accounted for. There is a good understanding of the desired functions and properties provided by PFASs for each application.

b. Quantities of PFASs produced/used

Information on amounts of non-polymeric and polymeric PFASs produced and used in the EU/EEA and additionally imported as chemical mixtures and in articles is limited, with the exception of fluorinated gases for which reporting mechanisms exist linked to the UN Framework Convention on Climate Change and the EU's F-Gas Regulation. Some specific problems are noted, for example PFASs are often not listed as ingredients and tonnages imported and exported in articles are unclear. There is also concern that there may be significant illegal import of fluorinated gases. However, sufficient information is available to provide a broad indication on which activities are linked to the most substantial use of PFASs and which are minor uses (see Table 3 and Table 4). Uncertainty in the quantities of PFASs used increases over time, though there is a sound basis for concluding that without regulation the amounts used would increase across a growing list of applications.

c. Quantities of PFASs emitted

A range of ±25% around the central estimate of 75 000 tonnes/y has been calculated for use phase emissions of total PFASs in 2020. When looking at the different PFAS subgroups these ranges are ±50% for polymeric PFASs, ±60% for PFAAs and PFAA precursors, and ±10% for fluorinated gases (see Table 1). Emissions for the waste phase are more uncertain, and a mass balance across the uses of PFASs concludes that there is a deficit, leading to an underestimation of emissions as there are emissions that are not accounted for. Emissions are expected to continue increasing year on year in line with expanding use of PFASs, though the extent of this growth is uncertain.

d. Fate of emissions

Tracking of emissions across the life cycle for each use has not been attempted. However, knowledge of long-range transport potential, mobility, accumulation in plants and bioaccumulation supported by monitoring data is considered sufficient by the Dossier Submitters to support the proposed restriction. It is acknowledged that currently there are no tools available for reliable prediction of future exposures. However, there is high potential for ubiquitous, increasing and irreversible exposure of the environment and humans based on the general knowledge on degradation pathways and, more specifically, the observations from monitoring data, model data, degradation testing and information on mobility and volatility. There is high potential for human exposure via food and drinking water and other routes including dusts and gases in indoor and outdoor air (Annex B).

Conclusion on Question 2:

There are uncertainties in the quantities of PFASs used and emitted in the EU. However, there is good evidence on the overall scale of emissions of PFASs for 2020, these emissions will continue to grow over time due to the expected economic growth. There are uncertainties in use and emissions from individual activities, but information is sufficiently reliable to provide a good understanding of the ranking of activities (see Table 4) and the overall scale of use and emissions. If anything, the uncertainties (missed uses, deficit in mass balance) point towards an underestimation of total tonnages and emissions of PFASs in the EU, only adding to the concern. It is also concluded that there is a high risk of environmental and human exposure linked to PFAS use in the EU.

3. Is the proposed restriction of overall benefit to society?

a. Proportionality of the restriction in general

The dossier reviews evidence on alternatives and their availability and applicability, and on costs to industry, consumers and society from the restriction. There are, inevitably, uncertainties in all of these parameters to a greater or lesser extent. Direct assessment of proportionality has not been possible given that there is insufficient data to enable detailed modelling of costs to industry, etc. and/or of benefits via reduced impacts to ecosystems and human health. However, the persistent nature of PFASs, against a background of high and growing levels of use and emissions will, in the absence of a restriction, lead to a growing environmental stock of PFASs. This strongly indicates that the longer use and emissions continue, the greater the burden on society.

b. Proportionality of specific derogations to the restriction

It is recognised that some applications will have greater difficulty in transitioning away from PFASs than others. Reasons for this include a lack of (assessment of) alternatives at the present time, and the presence of technical or regulatory barriers. Derogation periods have been defined for a number of applications based on the information obtained from the literature and feedback from stakeholders. This is designed to mitigate potentially significant problems that may be encountered. There remains uncertainty however, regarding whether enough time, or too much time is provided under the proposed derogations.

Conclusion on Question 3:

The Dossier Submitters conclude that the proposed restriction would be of overall benefit to society, recognising the consequences of continual use and emissions of PFASs into the future and the availability of viable alternatives for many uses. It is acknowledged that there remain uncertainties in the dossier that may affect the quality of the conclusions reached on specific sectors and applications. Consultation on the dossier provides an opportunity for stakeholders to provide further substantiated information to reduce these uncertainties. A number of questions have been identified for further stakeholder consultation that are designed to address these concerns.

4. Conclusion

All PFASs in the scope of this restriction proposal are either very persistent themselves or degrade into very persistent PFASs in the environment. 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. As a consequence, the resulting damage to the environment and human health will last for very long periods (decades to centuries). Even if further releases of PFASs were immediately prevented, existing technical and environmental stocks would continue to be a source of exposure for generations to come. The social costs arising from such damage cannot be predicted, but existing evidence suggests that they can be very high. There are several additional concerns arising from the use of PFASs, e.g. that a ubiquitous and unavoidable contamination of drinking water resources is unavoidable unless releases are minimised. Human exposures occur via all exposure routes and cannot be avoided or mitigated. Some PFASs can accumulate in plants, especially in edible parts, while others have bioaccumulation potential in biota and humans. Exposures are also transmitted effectively to unborn and breastfeeding children. The various uses of PFASs, as described in section 1.3.1, are substantially contributing to long-term general human and environmental exposures of PFASs.

Information to derive a robust predicted no effect concentration (PNEC) as well as a predicted environmental concentration (PEC) is currently insufficient. Therefore, it is not possible to conclude whether risks are adequately controlled, either now or in the future. Even though not all PFASs are PBT substances, the concerns raised for them compare with the concerns for PBT/vPvB substances. Additional concerns regarding mobility and long-range transport potential of PFASs justify a non-threshold approach. The Dossier Submitters therefore conclude that PFASs should be treated as non-threshold substances for the purpose of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk. The proposed restriction enables a regulatory path to prevent the increase of general PFAS exposures.

In accordance with previous restriction proposals on non-threshold substances, the Dossier Submitters argue that every emission to the environment increases the likelihood of adverse effects. Therefore, current and future emissions have to be minimized. Previous restriction proposals, except for the proposal on PFASs in firefighting foams, only targeted individual PFASs (and their precursors). Furthermore, regulatory initiatives have been taken in non-EU countries such as in Australia, New-Zealand, Canada and several US states. This global trend of moving away from PFASs also helps the implementation of the proposed EU-wide restriction. Based on the consideration of possible regulatory measures (see section 2.2.2), a restriction covering the manufacture, use and placing on the market with specific (mostly time-limited) derogations for some uses is proposed.

The concern should be addressed at EU-level to ensure the functioning of the internal market for PFASs as such, PFASs mixtures and PFAS-containing articles. The substances, mixtures and articles are traded across borders, and it would not be meaningful or possible to restrict them nationally due to internal market considerations. Furthermore, due to their high mobility (at least of some PFASs) and persistence, PFAS emissions will lead to cross-border pollution.

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

- Risks of PFASs are of a 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. Besides, PFASs have already been emitted to the environment for decades and represent a pollution problem both locally (near specific sources) and in the general environment. Future emissions will add to the already existing pollution stock.

- Many PFASs are mobile in water, and their potential for long-range transport is high. In combination with high persistence, this means that PFAS exposures in the general environment and the general population cannot be avoided.

- Various PFASs have been found in several environmental compartments such as in sediments, air, surface waters and in marine waters. Also, some drinking water resources and drinking water itself are already contaminated with various PFASs – further highlighting that PFAS exposures cannot be avoided by humans and environmental organisms.

- 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.

- Once emitted, PFASs can only hardly, if at all, be removed. The high mobility of many PFASs, in combination with the persistence lead to difficulties in removing PFASs from the environment. Filtration of PFASs and degradation during standard treatment processes is difficult and very costly, if possible at all.

- The continued use of PFASs in the various applications described above is estimated to result in about 4.4 million tonnes of emissions to the environment in the EU over the next 30 years unless action is taken. This estimate covers only the use phase, and is therefore likely a severe underestimation of the true emissions to be expected. Moreover, in several sectors high economic growth rates can be expected, which will likely increase emissions even further in the baseline scenario.

The proposed restriction on the manufacture, placing on the market, and use of PFASs is justified because:

- The extent of PFAS emissions (almost 4.4 million tonnes from the use phase alone over the next 30 years, when no action is taken) warrants regulatory action.

- Suitable alternatives are available for many of the applications of PFASs.

- It is proportionate to the risk, as societal costs associated with a continued use of PFASs will likely progressively increase and eventually exceed the societal costs of a ban on the use of PFASs.

- The proposed transition period of 18 months after EIF will allow for selection, testing and implementation of the most appropriate alternatives. For certain uses, time-limited derogations have been proposed to allow for a longer time to identify and/or adapt to non-PFAS alternatives and to ensure that the costs and benefits of the restriction (e.g. in terms of avoided emissions) are well-balanced. The proposed derogations are based on 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 derogation period.

Based on the information provided, it is concluded that the following thresholds are feasible for PFASs on their own, in another substance, as a constituent, in mixtures or in articles placed on the market:

- 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)
- 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification)
- 50 ppm for PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.

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