EUROPEAN CHEMICALS AGENCY

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background Document

to the Opinion on the Annex XV dossier proposing restrictions on

Undecafluorohexanoic acid (PFHxA), its salts and related substances

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ECHA/SEAC/Opinion N°(opinion number will be added after adoption)

EC Number	CAS Number
n/a	n/a

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Abbreviations

AF	assessment factor
AFFF	aqueous film forming foams
ALP	Alkaline phosphatase
ALT	alanine aminotransferase
APFHx	ammonium salt of perfluorohexanoic acid
ASAT	aspartate aminotransferase
BAF	bioaccumulation factor
BCF	bioconcentration factor
BDD	boron doped diamond
BMF	biomagnification factor
CEA	cost effectiveness analysis
CEN	European Committee for Standardization
CMF	ceramic membrane filtration
decaBDE	decabromodiphenyl ether
diPAP	polyfluoroalkyl phosphoric acid diesters
DMEL	derived minimum effect level
DNEL	derived no-effect level
DOC	dissolved organic carbon
DWR	durable water repellent
ECF	edible part concentration factor
EEA	European Economic Area
ERC	environmental release category
EtOH	ethanol
FOD	frequency of detection
FT	fluorotelomer
FT(M)A	fluorotelomer (meth)acrylate
FTAL	fluorotelomer aldehyde
FTCA	fluorotelomer carboxylic acid
FTI	fluorotelomer iodide
FTO	fluorotelomer olefin
FTOH	fluorotelomer alcohol
FTS	fluorotelomersulfonic acid
FTTAoS	fluorotelomer thioether amido sulfonate
FTU	fluorotelomer urethane
FTUCA	fluorotelomer unsaturated carboxylic acid
FTUI	fluorotelomer unsaturated iodide
GAC	granular activated carbon
HVAC	heating, ventilation and air conditioning
LC-PFCA	longchain-perfluoroalkyl carboxylic acid
LOAEL	lowest observed adverse effect level
LOD	limit of detection

LOEC	lowest observed effect concentration
LOQ	limit of quantification
MDL	method detection limit
monoPAP	polyfluoroalkyl phosphoric acid monoesters
NaPFHx	sodium perfluorohexanoate
NOAEC	no observed adverse effect level
NOEC	no observed effect concentration
OCRA	ozofractionative catalysed reagent addition
PAC	powdered activated carbon
PBT	persistent, bioaccumulative and toxic (substance)
PEC	predicted environmental concentration
PFAA	perfluoroalkyl acid
PFAB	polyfluorinated alkyl betaine
PFAL	perfluoroalkyl aldehyde
PFAS	per- and polyfluoroalkyl substance
PFBA	perfluorobutanoic acid, C4-PFCA
PFBS	perfluorobutansulfonic acid
PFCA	perfluoroalkyl carboxylic acid/ perfluoroalkyl carboxylate
PFDA	perfluorodecanoic acid, C10-PFCA
PFHpA	perfluoroheptanoic acid, C7-PFCA
PFHxA	perfluorohexanoic acid, C6-PFCA
PFHxS	perfluorohexasulfonic acid
PFNA	perfluorononanoic acid, C9-PFCA
PFOA	perfluorooctanoic acid, C8-PFCA
PFOS	perfluorooctansulfonic acid
PFPA	perfluoralkyl phosphonic acid
PFPeA	perfluoropentanoic acid, C5-PFCA
PFPiA	perfluoroalkyl phosphinic acids
PFPrA	Perfluoropropanoic acid, C3-PFCA
PFSA	perfluoroalkyl sulfonic acid
PFUnDA	Perfluoroundecanoic acid, C11-PFCA
PND	postnatal days
PNEC	predicted no effect concentration
PoD	point of departure
R&D	research and development
RCR	risk characterisation ratio
Related substance (to PFCAs)	Substances that may degrade to PFCAs (e.g. fluorotelomers and side-chain fluorinated polymers) …
SFP	side-chain fluorinated polymers
sFTOH	secondary fluorotelomer alcohol
SPAC	super-fine powder activated carbon
sRV	standard respiratory volume
TFA	Trifluoroacetic acid, C2-PFCA

TOF	total organic fluorine
TOP assay	total oxidisable precursor assay
vPvB	very persistent and very bioaccumulative (substance)
WWTP	wastewater treatment plant
ZVO	German national metal plating association

RAC and SEAC box

RAC and SEAC noted several inconsistencies between different sections and between the Background Document and its annexes. These inconsistencies concern the information and values presented (e.g. release estimates differ between sections), as well as the terminology used. For example, categories of use are named differently across the Background Document (e.g. paper and board vs. food contact materials and other paper, clothing in general vs. apparel). Moreover, reference to fluoropolymers and side-chain fluorinated polymers is sometimes inaccurate.

Annex A: Manufacture and uses

PFHxA itself is not manufactured or used in the EU. The ammonium salt APFHx is used as a processing aid in fluoropolymer and side-chain fluorinated polymer (SFP) manufacture and is imported into the EU. Mainly, low molecular PFHxA-related substances, like 6:2 FTOH or 6:2 FT(M)A that may degrade to PFHxA are manufactured and used in the EU in large quantities. These substances in a large part are used as monomers in fluorotelomer polymer manufacture. These polymers again are applied in an enormous number of uses.

Only known substances could be assessed regarding their manufacture and uses and the following possible release into the environment. There are many fluorinated substances that may degrade to PFHxA. These substances may themselves be produced by degradation of other substances. Therefore, there is a high uncertainty about these unknown substances.

Large amounts of articles and products, containing fluorochemicals are imported into the EU. The quality and the quantity of the containing substances often are unknown und bear high level of uncertainties.

A.1 Manufacture, import and export

A.1.1 REACH-Registrations

Table 1: Uses and tonnage bands of registered APFHx and registered related substances (ECHA dissemination site).

CAS number	Name	Tonnage band in t/a	Uses
21615-47-4	Ammonium perfluorohexanoate	10-100	at industrial sites
133331-77-8	1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluorotetradecane	> 10	at industrial sites and in manufacturing
73609-36-6	dichloromethyl(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silane	1-10	at industrial sites and in manufacturing
2043-57-4	1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-8-iodooctane		intermediate
647-42-7	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol		intermediate

27619-89-2	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonyl chloride		intermediate
96383-55-0	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-chloroacrylate	1-10	at industrial sites
17527-29-6	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (6:2 FTA)	100-1000	at industrial sites and in manufacturing
2144-53-8	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (6:2 FTMA)	100-1000	at industrial sites and in manufacturing
27619-97-2	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonic acid (6:2 FTS)	10-100	in formulation or re-packing and at industrial sites
26650-09-9	thiocyanic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester		intermediate
34455-22-6	N-[3-(dimethylamino)propyl]-3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-octane-1-sulfonamide		intermediate
1189052-95-6	sodium hydrogen (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)phosphonate	1-10	perfumes, fragrances, cosmetics and personal care products
-	reaction mass of ammonium bis(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphate and diammonium 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl phosphate and diammonium P,P’-bis(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) pyrophosphate	1-10	
85995-91-1	alkyl iodides, C8-14, γ-ω-perfluoro		intermediate
-	ammonium salts of mono- and bis[3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluroctyl and/or hydropoly(oxyethylene)] phosphate	1-10	coating products, non-metal-surface treatment products, inks and toners, polishes and waxes and washing & cleaning products
108196-44-7	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 3-dibutylaminopropionate	Conf.	notification of new substances (NONS)[1]

A.2 Uses

Detailed description of uses, emissions, exposure, alternatives and impacts of the planned restriction on uses are presented in Annex B and E. The following paragraphs give a brief overview over the different uses.

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[1] Substance previous notified under Directive 67/548/EEC

PFHxA, its salts and related substances are used for the production of (per-)fluorinated polymers, either as monomers or as processing aids to control the polymerisation process. Fluoropolymers are used for several applications as finishing agents or as repellents. Therefore, they are used in a wide range of sectors e.g. aqueous based products based on fluorinated polymer dispersions are used to impart functional oil and water repellency when applied to textile, leather, hard surfaces or paper fabrics (industrial and consumer applications). A large quantity of the fluoropolymers is further processed into a variety of specialized articles such as fibres and tubes.
There are several distinct subsets of fluorinated polymers (stakeholder information, Buck et al., 2011; Henry et al., 2018).

Fluoropolymers, such as polytetrafluoroethylene (PTFE), have a carbon-only polymer backbone where fluorines are directly attached to the backbone carbon atoms.

Fluoroelastomers can be regarded as a distinct subset of fluoropolymers. Fluoroelastomers are rubbery materials based on several of the same monomers as used for producing fluoropolymers. They are produced as highly viscous liquids and then are cross-linked (or 'cured', or 'vulcanized') to harden them and impart their elasticity. The main difference between the two families is that fluoroelastomers have unique elastomeric properties, resulting from the cross-linking process.

Perfluoropolyether polymers are polymers in whose backbone one, two or three carbons containing fluorine (e.g., -CF2-, -CF2CF2-, and possibly -CF(CF3)CF2-) units are separated by oxygen atoms.

Side-chain fluorinated polymers (SFPs) consist of a non-fluorinated polymer backbone with fluorinated side-chains. Non-fluorinated side-chains can be present as well. The fluorinated side-chain is typically composed of a terminal perfluoroalkyl moiety, a spacer and a linker.

There are several uses of PFAS in the production of electrical devices and their components (e.g. semiconductors or printed circuit boards). The semiconductor industry uses PFASs as processing agents for the photolithography process, etching process and furthermore in cleaning fluids. Besides surface activity, also purity and stability of PFASs are relevant properties for semiconductor industry. Furthermore, usage of PFASs in photo-acid generators (PAGs) allows the creation of strong acids and non-diffusive, highly soluble and non-agglomerating PAG molecules (Stakeholder Consultation, 2018). A C6 fluorinated polymer is used in a coating process to achieve high levels of water repellency to protect electronic devices. Furthermore, fluorosurfactants are used due to their anti-corrosion and electrostatic properties in applications such as zinc battery scale inhibitor, effective plating bath aid, non-corrosive wetting in photoresist strippers and low foam.

Fire extinguishers based on foams are used for class B fires (flammable liquids) as well as in special cases for class A fires (combustible materials). The fluorinated surfactants contained in fire-fighting foams lower the surface tension and allow the formation of an aqueous film between fuel and foam, thereby cooling the surface, acting as a vapor barrier, allowing a fast spreading of the foam on the fuel and preventing re-ignition. Furthermore, fuel shedding is prevented. Diverse areas of application can be found, e.g. aviation, petrochemical industry, defence applications, other industrial uses such as plant fire brigades or other uses such as hand-held fire extinguishers.

Adding fluorinated surface-active substances to inkjets improves the working of modern printers as well as enhancing picture quality with different media. The surface-active fluorinated substance improves surface wetting during the printing process (UNEP, 2012b). During stakeholder consultation it was confirmed that C6 based short-chain fluorinated surfactants are used in some water-based inkjet inks and latex inks. The main function is the reduction of the water surface tension, when applied on nonporous substrates.

6:2 FTS is used in hard chrome plating processes as well as decorative chrome plating processes as surfactant to lower the surface tension of the plating solution. The aim of hard chrome/ functional chrome plating is to provide e.g. hardness, corrosion and wear resistance, lubricity and high resistance against chemicals. Hard metal plated parts are used e.g. in automotive industry, aircraft construction, shipbuilding and engineering like hydraulic cylinders and rods, railroad wheel bearings and couplers, moulds for the plastic and rubber industry (Blepp et al., 2017; UNEP, 2018a). Decorative chrome plating is used for decorative surface finish e.g. for sanitary industry, kitchen appliances, car and truck pumpers or motorcycle parts (Blepp et al., 2017; UNEP, 2018a). A further electroplating process is the electroplating of plastics in combination with decorative chrome plating.

PFASs are used in different building materials. Fluorinated substances are for example added in paints to improve flow, wetting, and levelling. In coatings fluorinated substances are used to achieve water, oil or dirt repellent properties and protect building materials from weather influence. The substances are also used in non-woven fabrics for construction or in textiles for flexible civil construction to bring weathering resistance and dirt repellency. Fluorinated surfactants can yield in higher stability or resilience of foams for the formation of low-density concrete building blocks. Due to the good wetting property, fluorinated surfactants are also used as additives in adhesives and glues. PFHxA or related substances are used in oil and water repellents in special glass for construction as well as in the solar sector and were detected in treated floor waxes and stone/wood sealants and wood insulation materials.

C6-based fluorinated surfactants are used in small tonnages in photographic equipment or in coatings when manufacturing conventional photographic films (Stakeholder Consultation, 2018). These substances are applied for coating printing plates, coating of photographic layers for various applications (e.g. for medical applications) and for production of conductive screen ink and coating formulations. In these applications the substances are used as surfactants, as static control agents, as dirt repellents during coating operations and as friction control agents. Additionally, PFHxA occurs as an impurity during the production of polytetrafluoroethylene (PTFE) micro-powders. In the handling and processing of optical fibres ethylene-tetrafluoroethylene (ETFE), containing PFHxA related substances, is used for cable tubes. These tubes hold and carry the actual fibre optics, protecting them from the adjacent environment. Optical fibres are used e.g. for data transmission.

Products made by PFHxA, its salts and related substances have properties that are essential for handling of fragrance and odour compounds in products and articles, such as they are surface-active and inert to different chemicals. However, the use of PFHxA, its salts and related substances in the field of fragrance and flavour is not clear so far.

PFASs occur in various mixtures intended for end-use by consumers. These include impregnating agents, ski or floor wax, cleaning products, car care and polishes (Jensen et al., 2008; KEMI, 2015; Knepper et al., 2014; Posner et al., 2013). Only limited information is available regarding the use of PFHxA-related substances in these products.

Recent studies indicate that fluorinated substances are used in various cosmetic products such as foundations, concealer and sunscreen. PFASs serve as emulsifiers and surfactants and are added to cosmetic products for binding, bulking and skin/hair conditioning purposes. Only limited information is available regarding the use of PFHxA-related substances in these products.

The occurrence of fluorotelomer alcohols and PFCAs in apparel is (primarily) related to the durable water repellent (DWR) finishing that imparts water, oil and stain resistance to the textile. DWR finishing finds important application in functional clothing such as performance outdoor textiles, which provide weather protection and body moisture management to the wearer (Schellenberger et al., 2018).

In personal protective equipment PFHxA-related substances are used when water, oil and stain resistance are necessary to protect the wearer from risks of chemicals, body fluids, heat and cold for example.

PFHxA-related substances are mainly used in technical textiles in automotive and aerospace applications, as filtration media, in construction materials and medical applications. In vehicles like cars, trains, busses, aircrafts and marine vehicles, textiles are mostly used for interior trim (e.g. seating, carpets, trunk, side panels). Safety items (e.g. seat belts and air bags), engine bay items and filters are also manufactured with technical textiles.

Outdoor technical textiles are e.g. canvas, awnings, tarps, tents, sails, rope, tarpaulins and sacks. PFAS are mainly used for the water, oil and dirt repellent properties.

Home textiles include e.g. carpets and rugs, curtains and blinds and textile-based coverings. PFAS are mainly used for the water and oil repellent properties.

One of the most important application fields is the production of paper and board for the packaging and preparation of food. The PFHxA-related substances are used in the paper pulp as well as for surface refining. They are applied to create water- and grease- /oil-repellent paper products, which can be used at higher temperatures without burning and adherence to food or other materials. Typical articles are baking paper, packaging for pet food, packing of take away food, tablecloths, microwave popcorn bags, cupcake forms and sandwich papers.

PFHxA-related substances are used by the watchmaking industry as epilames where they are applied as coating on mechanical watch-parts that need lubrication due to their movement (e.g. wheels, pivots, escapements, stones).

In the medical sector there are different areas of application for PFHxA related substances such as implantable and non-implantable medical devices, hearing aids, or medical textiles.

Annex B: Information on hazard and risk

B.1 Identity of the substances and physical and chemical properties

This proposal for restriction covers the substances undecafluorohexanoic acid (PFHxA), its salts and related substances. Related substances mean any related substance (including its salts and polymers) having a linear or branched perfluoropentyl group with the formula C_5F_{11}- directly attached to another carbon atom, as one of the structural elements. In addition, related substances also cover any related substance (including its salts and polymers) having a linear or branched perfluorohexyl group with the formula C_6F_{13}- as one of the structural elements. However, the following substances are excluded from this proposal for restriction:

- C_6F_{14};
- C_6F_{13}-C(=O)OH, C_6F_{13}-C(=O)O-X′ or C_6F_{13}-CF2-X′ (where X′ = any group, including salts).
- Any substance having a perfluoroalkyl group C_6F_{13}- directly attached to a sulphur atom

The perfluorinated substance with a fluorine atom attached to the C_6F_{13}-group is not degraded to the corresponding PFCA as the carbon fluorine bond is known to be very stable.

B.1.1 Name and other identifiers of the substances

Table 2 summarizes chemical and regulatory identifiers of the substance PFHxA.

PFHxA-related substances follow a similar structural pattern: a perfluorinated carbon chain with 5-6 carbon atoms connected directly or indirectly (via a non-perfluorinated molecular moiety) to another group (e.g. hydroxyl group, alkyl chain…). A non-exhaustive list of PFHxA salts and related substances, which are covered by this restriction proposal, is provided in Table 5.

Table 2: Substance identity of PFHxA.

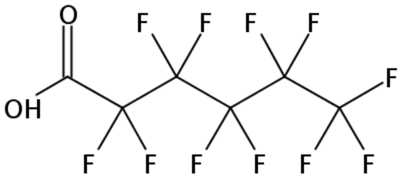
EC number:	206-196-6
EC name:	undecafluorohexanoic acid
CAS number (in the EC inventory):	307-24-4
CAS name:	hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-
IUPAC name:	undecafluorohexanoic acid
Molecular formula:	$C_6HF_{11}O_2$
Molecular weight range:	314.05 g/mol
SMILES notation:	C(=O)(C(C(C(C(C(F)(F)F)(F)F)(F)F)(F)F)(F)F)O
Synonyms:	PFHxA perfluorohexanoic acid
Structural formula:	

Table 3: Substance identity of APFHx.

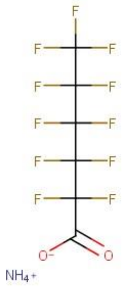
EC number:	244-479-6
EC name:	ammonium undecafluorohexanoate
CAS number (in the EC inventory):	21615-47-4
CAS name:	hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-, ammonium salt (1:1)
IUPAC name:	ammonium undecafluorohexanoate
Molecular formula:	$C_6H_4F_{11}NO_2$
Molecular weight range:	331.08 g/mol
SMILES notation:	[NH4+].[O-]C(=O)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F
Synonyms:	APFHx ammonium perfluorohexanoate
Structural formula:	

Table 4: Substance identity of NaPFHx.

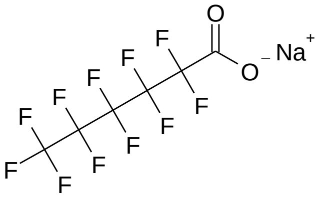
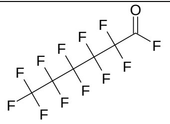
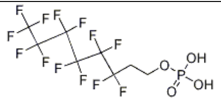
EC number:	220-881-7
EC name:	sodium undecafluorohexanoate
CAS number (in the EC inventory):	2923-26-4
CAS name:	hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-, sodium salt (1:1)
IUPAC name:	sodium undecafluorohexanoate
Molecular formula:	$C_6F_{11}NaO_2$
Molecular weight range:	336.04 g/mol
SMILES notation:	[Na+].[O-]C(=O)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F
Synonyms:	NaPFHx sodium perfluorohexanoate
Structural formula:	

Table 5: Non-exhaustive examples of PFHxA salts and related substances covered by the restriction proposal.

Name / Substance group	Structural formula	EC number	CAS number	REACH[2] (Pre-) Registration
perfluoroalkyl carboxylic acid halides				
perfluorohexanoyl fluoride		206-582-4	355-38-4	(X)
polyfluoroalkyl phosphoric acid mono/diesters				
6:2 fluorotelomer phosphate monoester			57678-01-0	(X)

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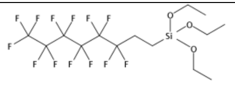
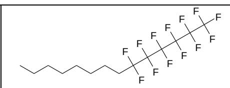
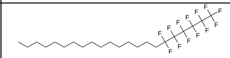
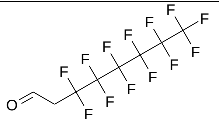
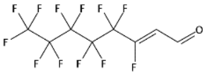
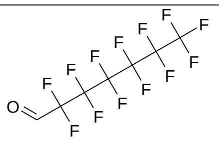
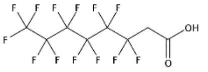
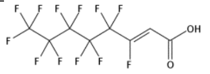
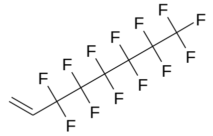
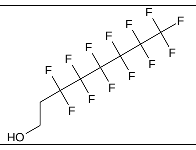
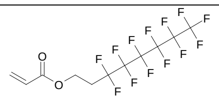
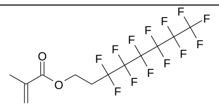
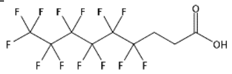
[2] Registration status reviewed: 29.01.2019

polyfluoroalkyl silanes				
triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silane		257-473-3	51851-37-7	X
semifluorinated n-alkanes				
(perfluorohexyl)octane		432-570-5	133331-77-8	X
(perfluorohexyl)hexadecane			133310-71-1	
(n:2) fluorotelomer aldehydes				
6:2 fluorotelomer aldehyde			56734-81-7	
6:2 fluorotelomer unsaturated aldehyde			69534-12-9	
perfluoroalkyl aldehydes				
perfluoroheptanal			63967-41-9	
(n:2) fluorotelomer carboxylic acids				
6:2 fluorotelomer carboxylic acid			53826-12-3	
6:2 fluorotelomer unsaturated carboxylic acid			70887-88-6	
fluorotelomer olefins				
6:2 fluorotelomer olefin		246-791-8	25291-17-2	X
fluorotelomer alcohols				
6:2 fluorotelomer alcohol		211-477-1	647-42-7	X
fluorotelomer acrylates				
6:2 fluorotelomer acrylate		241-527-8	17527-29-6	X
fluorotelomer methacrylates				
6:2 fluorotelomer methacrylate		218-407-9	2144-53-8	X
other transformation products of n:2 Fluorotelomer alcohols				
4,4,5,5,6,6,7,7,8,8,9,9,9-tridecafluorononanoic acid			27854-30-4	

B.1.2 Physicochemical properties

The physicochemical properties of PFHxA are listed in Table 6. PFHxA has not been registered yet.[3] Thus, the physical-chemical data rely on publicly available databases, which do neither provide detailed information on the software package nor on which form of the substance (dissociated vs. non-dissociated) or which relevant parameters were used for the calculation.

Table 7 summarizes the physicochemical properties of ammonium undecafluorohexanoate (APFHx), which are based on the registration[4] dossier.

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[3] Registration status reviewed: 29.01.2019

[4] Registration reviewed: 29.01.2019

Table 6: Overview of physicochemical properties of PFHxA.

Property	Description of key information	Value [Unit]	Reference/source of information
Physical state at 20 °C and 101.3 kPa		liquid	
Melting/freezing point	experimental	12-14 °C	(Huang, 1987) Huang, Bing Nan; Journal of Fluorine Chemistry 1987, V36(1), P49-62
Boiling point	experimental	157 °C	(Savu, 2000)Savu PM; Fluorinated Higher Carboxylic Acids. Kirk-Othmer Encyclopedia of Chemical Technology (1999-2015). New York, NY: John Wiley & Sons. On-line Posting Date: 4 Dec 2000
Vapour pressure	estimated (no experimental value available, unknown reliability of estimated value)	1.98 mm Hg = 264 Pa at 25 °C	US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.11. Nov, 2012. Available from, as of Jan 11, 2015
Density	experimental	1.762 g/mL at 20 °C	(Kauck, 1951) Kauck, E. A.; Industrial and Engineering Chemistry 1951, V43, P2332-4
Water solubility	experimental	15.7 g/L (ambient temperature)	Zhao L et al; Chemosphere 114: 51-8 (2014) (Zhao et al., 2014)
Partition coefficient n-octanol/water	estimated	Log K_{OW} = 4.06	calc., COSMOtherm (temp. not specified) (Wang et al., 2011b)
Dissociation constant	comparison of the sorption behaviours and mechanisms of perfluorosulfonates and perfluoro-carboxylic acids on three kinds of clay minerals.	pK_a = -0.16	Zhao L., Bian J., Zhang Y., Zhu L. and Liu Z.; Chemosphere 114, 51-58 (2014) (Zhao et al., 2014)

Table 7: Overview of physicochemical properties of Ammonium undecafluorohexanoate (APFHx).

Property	Description of key information	Value [Unit]	Reference/source of information
Physical state at 20 °C and 101.3 kPa		solid	
Melting/freezing point	experimental	decomposition at 135 °C	(Ota, 2017b) Ota, Y., (2017), Measurement of melting point for APFHx (C-1500N), Report No. 85024
Boiling point	experimental	decomposition at 135 °C	(Ota, 2017b) Ota, Y., (2017), Measurement of melting point for APFHx (C-1500N), Report No. 85024
Vapour pressure	experimental /calculated	0.005 Pa at 25 °C	(Ota, 2017c) Ota, Y., (2017), Measurement of vapor pressure for APFHx (C-1500N), Report No. 85027
Density	experimental	1.783 g/mL at 20 C	(Ota, 2017a) Ota, Y., (2017), Measurement of density for APFHx (C-1500N) Report No. 85026
Water solubility	experimental	57.61 g/L at 20 °C	(Takeda, 2017) Takeda, M. (2017), Measurement of Critical Micelle Concentration of APFHx (C-1500N), Report No. S414552
Partition coefficient n-octanol/water	calculated	Log K_{OW} = 2.06 (pH 4) 2.05 (pH 7) 2.05 (pH 9)	calc., ARChem SPARC. version 4.6, (2017)

The free undecafluorohexanoic acid (PFHxA) is in equilibrium with undecafluorohexanoate (PFHx), the conjugate base, in aqueous media in the environment as well as in the laboratory. The physico-chemical properties of PFHxA and PFHx are different. Therefore, the expected environmental fate will depend on the environmental conditions, which influence the equilibrium between base and acid (pH and pKa).

The ammonium salt (APFHx), which is for example used in some animal experiments, is very soluble in water. In aqueous solution it is present as the anion PFHx and the ammonium cation. The dissolved anion PFHx remains in equilibrium with the corresponding acid in aqueous media. With currently available analytical methods it is not possible to distinguish between PFHx and PFHxA in samples. In the literature reporting human and environmental monitoring studies the concentrations are referred to as PFHxA or APFHx, but always both species (PFHx and PFHxA) are included in the given concentration.

In the following PFHxA refers to the acid (PFHxA) as well as to its conjugate base PFHx. Only in cases where it is important to distinguish between both species and where species specific knowledge is available it is clearly indicated that either the acid PFHxA or the conjugate base PFHx is meant.

B.1.3 Justification for grouping

A grouping of substances in the scope of this restriction proposal is needed to eliminate the risks resulting from the exposure of humans and the environment to PFHxA. There is evidence on degradation of many PFHxA-related substances into PFHxA (for more details see chapter B.4.1.2). Therefore, these PFHxA-related substances also contribute to the exposure of humans and the environment of PFHxA. Besides the substances registered under REACH (see chapter A.1.1), further PFHxA-related substances are known which could be used within the EU and may also be imported into the EU via articles and mixtures. A grouping approach via chemical sum formula is therefore the most appropriate way to cover all relevant substances.

PFHxA belongs to the substance category of perfluorinated carboxylic acids (PFCAs). The substances in this group have a highly similar chemical structure: a perfluorinated carbon chain and a carboxylic acid group. They differ only in the number of CF_2-groups whereas all other fragments are the same within the group. As a result of comparing the experimental and estimated data of the PFCAs, it can be concluded that with increasing chain length water solubility decreases and the sorption potential increases (see Table 5 Section B.1.1). It can be stated with sufficient reliability that the behaviour of the PFCAs follows a regular pattern.

B.2 Manufacture and uses (summary)

For detailed information on manufacture and uses please refer to chapter E.2.

B.3 Classification and labelling

B.3.1 Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

PFHxA as well as their salts are not listed in Annex VI of CLP Regulation.

B.3.2 Classification and labelling in classification and labelling inventory/ Industry’s self classification(s) and labelling

The following industry self-classifications and labelling for PFHxA, its ammonium salt and selected related substances are available in ECHA´s C&L Inventory (query from December 2018).

Table 8: Industry´s self-classification and labelling (ECHA C&L Inventory).

Substance	**CAS No**	**Hazard Class and Category Code(s)**	**Hazard statement Code(s)**	**Number of Notifiers**
PFHxA	307-24-4	Skin Corr. 1B	H314	29
		STOT SE 3	H335	3
		Met. Corr. 1	H290	1
		Eye Dam. 1	H318	1
		Acute Tox 3	H301	1
		Acute Tox 3	H311	1
		Acute Tox 2	H330	1
APFHx	21615-47-4	Skin Corr. 1B	H314	1
		Skin Sens. 1	H317	1
		Eye Dam. 1	H318	3
6:2 FTOH	647-42-7	Acute Tox 4	H302	79
		STOT RE 2	H373	3
		Skin Irrit. 2	H315	42
		Eye Irrit. 2	H319	42
		STOT SE 3	H335	42
		STOT RE 1	H372	1
		Aquatic Chronic 2	H411	19
		Not classified		6
6:2 FTA	17527-29-6	STOT RE 2	H373	4
		Skin Irrit. 2	H315	25
		Eye Irrit. 2	H319	25
		STOT SE 3	H335	40
		Not classified		78
6:2 FTMA	2144-53-8	STOT RE 2	H373	12
		Skin Irrit. 2	H315	28
		Eye Irrit. 2	H319	28
		STOT SE 3	H335	27
		Not classified		35

B.4 Environmental fate properties

B.4.1 Degradation

B.4.1.1 Degradation of PFHxA

For PFHxA itself there are no studies on its degradation potential known that follow a standardised and generally accepted study design, such as the OECD test guidelines. The ammonium salt of PFHxA, is registered but information on degradation behaviour is only available from screening tests on ready biodegradation. Therefore, a read-across to the structural similar substance PFOA is applied where necessary.

PFCAs, like PFHxA and PFOA, are synthetic compounds, which contain a common structural feature: a perfluorinated carbon chain combined with a carboxylic group. The chemical structure of these compounds differs only in the number of perfluorinated carbon atoms in the carbon chain. There are no hints available in the literature that the length of the perfluorinated carbon chain has an influence on the degradability /stability of these substances.

A number of studies for the longer chain homologue PFOA shows that this substance is very persistent and does not undergo abiotic or biotic degradation at all in studies under environmentally relevant conditions (European Chemicals Agency, 2013b). The persistence of PFOA (fulfilling P and vP) as well as its ammonium salts was already confirmed by the Member State Committee that identified the substances as SVHC i.a. based on its PBT properties (European Chemicals Agency, 2013a).

Also C9-C14 PFCAs as well as the ammonium and sodium salts of C_9-PFCA and C_{10}-PFCA were included on the Candidate List as substances of very high concern (SVHC). All substances meet the P and vP-criteria of REACH Annex XIII based on a weight of evidence approach (European Chemicals Agency, 2012a; European Chemicals Agency, 2012b; European Chemicals Agency, 2012c; European Chemicals Agency, 2012d; European Chemicals Agency, 2015b; European Chemicals Agency, 2016b).

The structurally related substance PFHxS also contains this type of a stable fluorinated carbon chain. The conclusion that PFHxS fulfils the criteria for being “very persistent” was adopted by the Member State Committee in 2017 (European Chemicals Agency, 2017).

Abiotic degradation

The degradation behaviour of PFHxA in the atmosphere was assessed by using the QSAR model AOPwin v1.92 (EPISuite). AOPwin predicts degradation rates and half lives for direct and indirect photolytic degradation in the atmosphere. For the common preset of the model – assuming indirect degradation via OH-radicals, 12h-day, 1.5 10^6 OH radicals per m^3 - the tool predicts a degradation rate constant of 0.52 10^{-12} $cm^3/(molec\ s)$ which is equal to an atmospheric half-life of 20.57 days. These results can be seen as an estimate only because perfluorinated substances are not fully covered by the EPISuite models.

A slow indirect photodegradation in air with an atmospheric lifetime of 130 days has been reported for PFOA (European Chemicals Agency, 2013b; OECD, 2006). Hurley et al. studied the kinetics of the reactions of OH radicals with a homologous series of perfluorinated acids, $F(CF_2)_nCOOH$ ($n = 1, 2, 3, 4$), in 700 Torr of air at 296 ± 2 K. For $n > 1$, the length of the $F(CF_2)_n$ group had no discernible impact on the reactivity of the molecule. Atmospheric lifetimes of $F(CF_2)_nCOOH$ with respect to reaction with OH radicals are estimated to be approximately 230 days for $n = 1$ and 130 days for $n > 1$. Reaction with OH radicals is a minor atmospheric fate of $F(CF_2)_nCOOH$ (Hurley et al., 2004).

From the chemical structure it can be concluded that PFHxA will not undergo abiotic degradation via hydrolysis. The chain of fluorinated alkanes and the carboxylic acid are known to be stable against abiotic degradation via hydrolysis. This evaluation is backed-up by the registration dossier of APFHx where hydrolysis is not considered to be a relevant degradation pathway, too.

The analogue substance PFOA is hydrolytically stable under environmental conditions with a hydrolytic half-life greater than 92 years (European Chemicals Agency, 2013b).

No photodegradation in water of PFOA has been observed in studies conducted under relevant environmental conditions. The estimated DT_{50} for photolysis of the ammonium salt of PFOA in water is estimated to be greater than 349 days (European Chemicals Agency, 2013b). Because of the similar chemical structure, it is assumed that PFHxA will not be subject to photolytic degradation in water in relevant order of magnitude under environmental relevant conditions.

Biotic degradation

For PFHxA itself no biotic degradation study is available.

For the ammonium salt of PFHxA the results from a screening test based on test method OECD 301D (Closed Bottle Test) with modifications was provided in the registration dossier. The data is obtained from Saez et al. (2008). In this study PFHxA was tested in a mixture with other PFAS substances (PFOA, perfluorononanoic acid (PFNA), and PFOS). The concentration of the mixture was 4 mg/L. The test only showed 15 percent decrease in PFHxA concentration within four weeks (based on test material analysis), even after a prolonged test period of 15 weeks only 45 percent decrease was observed. The registrant concludes that the substance has to be assessed as “not readily biodegradable”. For interpretation of the measured degradation rates it has to be noted that the inoculum for the test was taken from a sewage treatment plant that is located in a highly industrialized area of the west harbour of Amsterdam. Therefore, it can be assumed that the sewage treatment plant is predominantly treating industrial waste water and that the inoculum was already subject to (low-level) preadaption to APFHx or structurally similar substances. Furthermore, according to Saez et al. (2008) there is no conclusive evidence for biodegradation of PFHxA in sludge under aerobic conditions. Although decreases in PFHxA concentrations were observed, the concentrations in the control bottles decreased to the same level, and it is therefore not possible to confirm that the decrease referred to biodegradation. The authors also stated that the concentration decrease could also be due to a non-biological degradation process, losses could occur not due to degradation or even due to incomplete sterilization of the control bottles (Saez et al., 2008).

In the study by Saez et al. (2008) also anaerobic tests were included. According to the authors, the anaerobic study did not show a significant decrease in the PFHxA concentration during 15 weeks. However, the presented figure shows a decrease of PFHxA-concentration of > 50% until week seven (both in experimental bottles and sterile control bottles).

For the structurally related substance PFOA ready biodegradability tests are available. In a 28-day ready biodegradability test according to test method OECD 301C using 100 mg/L PFOA, respectively, and 30 mg/L activated sludge non-biodegradability was demonstrated. Only 5 % (PFOA) and 7 % (ammonium salt of PFOA) degradation was observed by biochemical oxygen demand (BOD) within 28 days (MITI-List, 2002). In a further test of ready biodegradability according to test method OECD 301F no biodegradation of PFOA was observed in 28 days (Stasinakis et al., 2008). No toxicity control was done in this test.

For PFOA in the OECD SIDS Initial Assessment Report it was concluded that the substance is not expected to undergo biodegradation (OECD, 2006).

There are additional more complex studies available for degradation of PFOA in aquatic systems which are presented in the following. But these tests only provide information for dissipation of the substance from the test system, which does not necessarily represent biodegradation but for example might be the result of processes such as volatilization from open test systems, too. Therefore, it has to be considered that the half-life for biotic degradation may be higher than the dissipation half-life.

Hanson et al. performed a microcosm study in a water-sediment system. Microcosms were circulated for two weeks from a well-fed irrigation pond prior to the experiments. Nominal concentrations of 0.3, 1, 30, and 100 mg/L PFOA, as the sodium salt, plus controls were added to the microcosms. Over a 35-day field study PFOA showed no significant dissipation from the water column. However, at the highest concentration (100 mg/L) a partitioning from the water column into other compartments is suspected. In this field study only 32 % dissipation in 35 days was observed (Hanson et al., 2005). Since the documentation of the procedure was insufficient in the opinion of the Dossier Submitter the study is not reliable (reliability 3). A more detailed description of the study performed is available in the SVHC support document for PFOA (European Chemicals Agency, 2013b).

Liou et al. investigated the aerobic/anaerobic biodegradability of PFOA respectively its ammonium salt APFO in aqueous media by using a study design, which does not follow the stringent conditions of the OECD test guidelines for simulation tests in surface water or sediment (Liou et al., 2010). In a two-phase experiment (preliminary screening, hypothesis refinement) the use of PFOA as a physiological electron acceptor (electron donator: acetate, lactate, ethanol or hydrogen gas) was studied. Additionally, the possibility of co-metabolism of PFOA during reductive dechlorination of trichloroethene and during various physiological conditions (aerobic, nitrate-reducing, iron-reducing, sulfate-reducing, and methanogenic) was analysed. Five different inoculums were used (from a municipal waste-water treatment plant, industrial site sediment, an agricultural soil, and soils from two fire training areas). Soils and sludges were gathered from: the Ithaca sewage treatment plant; a water-saturated drainage ditch adjacent to the DuPont Chambers Works waste treatment facility in Salem County, New Jersey, previously shown to carry out reductive dechlorination; the Cornell agricultural field station (Collamer silt loam, Ithaca, NY), the Ithaca fire training facility, and the Rochester, NY fire training facility. The latter two sites were chosen due to potential contamination with fluorinated fire-retardant chemicals.

For the ^{14}C-PFOA experiments, Liou et al. utilized 15 mL serum bottles (50 % O_2-free N_2 headspace, 50 % inoculated anaerobic test medium) with non-radioactive PFOA and ^{14}C-PFOA (4.5 Ci/mL test medium) to give a final concentration of 100 mg/L PFOA. For establishing the various terminal electron-accepting processes, a standard anaerobic procedure was used. The samples taken were analysed for concentrations of PFOA, ^{14}C-PFOA, fluoride, nitrate, sulfate, and potential PFOA transformation products. Headspace gases were sampled with a gas-tight syringe (250 mL) and analysed for TCE, vinyl chloride and methane. PFOA quantification was performed by LC/MS/MS following a standard procedure. Potential PFOA metabolites were screened by applying LC/MS (Liou et al., 2010). For further description of the analytical approach please visit the SVHC support document for PFOA (European Chemicals Agency, 2013b).

In no combination of the inoculum source, electron donator or physiological conditions a significant percentage of the initial PFOA (100 ppm and 100 ppb, PFOA purity 96 %) was consumed (within test duration 259 days – phase 1). In addition the studies showed in the experiments for potential reductive defluorination, metabolism and cometabolism which the authors assign to "phase 2 considerations" that no significant concentration change compared to the initial PFOA concentration (100 ppm, 99.9 % PFOA purity, ^{14}C) occurred within a test period of 110 days. The authors found no indication of formation of radiolabelled transformation products. Part of these investigations was the biodegradation behaviour under aerobic conditions, too. In the aerobic test, at the end of the test period (110 days) no significant degradation was observed. Co-metabolism of PFOA during reductive dechlorination of trichloroethene was suggested by a drop in PFOA concentration in the 100 ppb treatment after a 65-day incubation. However, extensive analysis failed to determine corroborating transformation products (Liou et al., 2010).

The OECD SIDS Assessment Report also included studies for the soil compartment (OECD, 2006). Soils of various sites that were exposed to per- and polyfluorated substances – e.g. such as fire-training areas or industrial sites where applications of those substances occur – were analysed with regard to the concentration of PFOA in soil and groundwater. It was found that PFOA is still occurring in concentrations in the ppm-range in both environmental media.

Moody et al. investigated groundwater at a former fire-training area at Wurtsmith Air Force Base which was used between 1950s and 1993. Groundwater samples were collected from two types of monitoring wells. By using electron capture negative chemical ionisation (GC-MS) PFOA was found in ranges from 8 µg/L up to 105 µg/L, depending on the location of the sampling well. The authors estimated that perfluorinated surfactants had been in the groundwater for at least five years and possibly for as long as 15 years. This showed that degradation of PFOA was negligible under the environmental conditions at this site (for both soil and groundwater) (Moody et al., 2003). For further description of the analytical approach please visit the SVHC support document for PFOA (European Chemicals Agency, 2013b).

In conclusion, available studies on PFOA demonstrate the high persistence of the compound in various media, like sludge, soil, sediment and water. Due to the structural relationship between both substances it can be assumed that PFHxA will show high persistence in these environmental media, too.

Conclusion on degradation of PFHxA

The available information for PFHxA and the structurally related substance PFOA clearly show that PFHxA can be regarded as stable against abiotic degradation processes. Therefore, abiotic degradation is evaluated as a non-relevant pathway for removal of PFHxA from the compartments air, soil, waters and the related sediments.

A screening test with APFHx following test guideline OECD 301D, but with modifications showed only 15 percent decrease in PFHxA concentration in 4 weeks (Saez et al., 2008). This result is supported by available screening studies on ready biodegradation of the structurally similar substance PFOA. According to test guideline OECD 301C (MITI-List, 2002) and OECD 301F (Stasinakis et al., 2008) the degradation rate remained clearly below the threshold of 60 % within the standard test period of 28 days for concluding that the substance is "readily biodegradable".

No simulation studies according to standard test guidelines are known to be available for PFHxA. Hence, there are no relevant half-lives for biotic degradation under relevant environmental conditions available for the comparison with the persistence criteria of REACH Annex XIII. For the structurally similar PFOA the information from simulation and field data shows that the degradation rates for this substance under relevant environmental conditions will be negligible or very slow.

The stability of organic fluorine compounds has been described in detail by Siegemund et al. (Siegemund et al., 2000): "When all valences of a carbon chain are satisfied by fluorine, the zig-zag-shaped carbon skeleton is twisted out of its plane in the form of a helix. This situation allows the electronegative fluorine substituents to envelope the carbon skeleton completely and shield it from chemical attack. Several other properties of the carbon-fluorine bond contribute to the fact that highly fluorinated alkanes are one of the most stable organic compounds. These include polarisability and high bond energies, which increase with increasing substitution by fluorine. The influence of fluorine is greatest in highly fluorinated and perfluorinated compounds. Properties that are exploited commercially include high thermal and chemical stability".

Based on their molecular properties perfluorinated compounds can be expected to be poorly degradable. In accordance with this, in the studies considered for the SVHC identification of PFOA no degradation of PFOA was observed. PFOA was already assessed to fulfil the P and vP criteria (European Chemicals Agency, 2013a). Considering the organic chemistry of the substance group of perfluorinated carboxylic acids, it seems to be very likely that PFHxA is as resistant to degradation as it has been shown for PFOA and as it has been concluded on the basis of the data from PFOA for the C9-C14 PFCAs (European Chemicals Agency, 2012a; European Chemicals Agency, 2012b; European Chemicals Agency, 2012c; European Chemicals Agency, 2012d; European Chemicals Agency, 2015b; European Chemicals Agency, 2016b).

In summary, PFHxA is very persistent according to the criteria of Annex XIII to REACH. Moreover, its rate of abiotic or biotic degradation under relevant environmental conditions is expected to be slow. The degradation half-life is expected to clearly exceed the triggers for vP.

B.4.1.2 Degradation of PFHxA-related substances

PFHxA-related substances degrade to PFHxA under environmentally relevant conditions. Besides degradation studies for PFHxA-related substances, also degradation studies for PFOA-related substances and PFBA-related substances are shown. In general, the polyfluorinated substances are degraded to perfluorinated acids. It can be assumed that the degradation mechanism for PFHxA-related substances is similar to the homologues containing a carbon chain of eight carbon atoms. Using the weight of evidence approach it seems very likely that also similar substances may degrade in a similar way in the environment. At the end of a number of degradation steps PFCAs like PFHxA may most probably be the end product and persist in the environment.

In the following sub-chapters the degradation pathways of polyfluorinated substances (PFCA-related substances) are described.

Most of the following text was copied from the background documents of the restriction proposals on PFOA and the long-chain PFCAs (European Chemicals Agency, 2015a; European Chemicals Agency, 2018a).

B.4.1.2.1 Fluorotelomer alcohols (FTOHs)

Table 9: Summary of formed PFCAs during degradation of FTOHs and intermediate products (5:3 acid, fluorotelomer carboxylic acid and fluorotelomer unsaturated carboxylic acid (FTUCA).

Substance	**Compartment**	**Study duration**	**PFBA**	**PFPeA**	**PFHxA**	**PFHpA**	**PFOA**	**PFNA**	**PFDA**	**Reference**
6:2 FTOH	atmosphere		+	+	+	+				(Ellis et al., 2004)
	atmosphere			+	+	+				(Styler et al., 2013)
	soil (flow through)	84 d	0.8 %	4.2 %	4.5 %	-				(Liu et al., 2010a)
	soil (closed system)	180 d	1.8 %	30 %	8.1 %	-				(Liu et al., 2010b)
	mixed bacterial culture	90 d	< 0.5 %	< 0.5 %	5 %	-				(Liu et al., 2010b)
	WWTP-activated sludge	60 d	-	4.4 mol%	11 mol%	-				(Zhao et al., 2013b)
	aerobic river sediment system	100 d	1.5 mol%	10.4 mol%	8.4 mol%	-				(Zhao et al., 2013a)
	anaerobic digester sludge	90 d		-	0.2 mol%	-				(Zhang et al., 2013b)
		176 d		-	0.4 mol%	-				
	anaerobic sediment	100 d	-	-	0.6 mol%					(Zhang et al., 2016b)
8:2 FTOH	atmosphere		0.1 %	0.1 %	0.24 %	0.32 %	1.5 %	1.6 %		(Ellis et al., 2004)
	aqueous photolysis – H_2O_2 solution	10 h					40 %	+		(Gauthier and Mabury, 2005)
	aqueous photolysis – synthetic field water	140-146 h					1-8 %	+		
	aqueous photolysis – Lake Ontario						3	+ (but below LOQ)		

	mixed microbial system (sediment and groundwater	81 d				-	3 %	-		(Dinglasan et al., 2004)
	mixed bacterial culture	90 d			1 %	not evaluated	6 %	-		(Wang et al., 2005a)
	activated sludge	28 d				not evaluated	2.1 %	-		(Wang et al., 2005b)
	soil	197 d			1-4 %	-	10-40 % (average 25 %)			(Wang et al., 2009)
	anaerobic digester sludge	181 d			-	-	0.3 mol%			(Zhang et al., 2013b)
	anaerobic activated sludge	150 d	1.9 %	1.2 %	5.4 %	8.9 %	17 %			(Li et al., 2018)
8:2 FTCA	sediment-water system	50 d					21 mol% (water) 9.3 mol% (sed.)			(Myers and Mabury, 2010)
8:2 FTUCA	sediment-water system	35 d				12 mol% (water, at day 22)	27 mol% (water) 9 mol% (sed.)	< 1 mol%	< 1 mol%	(Myers and Mabury, 2010)

[+] detected, but not quantified; [-] not detected; [ ] not evaluated

Ellis and co-workers studied the kinetics of the reactions of Cl atoms and OH radicals with a series of fluorotelomer alcohols with differing chain lengths (4:2; 6:2, 8:2 FTOH) in 700 Torr of N_2 or air, diluent at 296 ± 2 K. Interestingly, the length of the perfluorinated carbon chain residue had no discernible impact on the reactivity of the molecules. The authors conclude atmospheric life-time of the FTOHs of 20 days by reaction with OH radicals (Ellis et al., 2003).

6:2-FTOH

The photooxidation of 6:2 FTOH was investigated at the surface of TiO_2, SiO_2, Fe_2O_3, Mauritanian sand, and Icelandic volcanic ash (Styler et al., 2013). At all surfaces the photooxidation resulted in the production of surface-sorbed PFCAs (PFHpA, PFHxA and PFPeA). These results provide evidence that the heterogeneous photooxidation of FTOHs at metal-rich atmospheric surface may provide a significant loss mechanism for FTOHs and also act as a source of aerosol-phase PFCAs close to source regions. The long-range transport of these aerosols is a possible source of PFCAs to remote areas.

The aerobic biodegradation of 6:2 FTOH was performed in a flow through soil incubation system (Liu et al., 2010a). After 1.3 days, 50 % of ^{14}C labelled 6:2 FTOH disappeared from soil, because of microbial degradation and volatilisation. The overall mass balance during the 84-day incubation averaged 77 % and 87 % for the live and sterile treatments, respectively. 16 % [^{14}C] 5:2 secondary fluorotelomer alcohol (sFTOH), 14 % [^{14}C] 6:2 FTOH and 6 % [^{14}C] CO_2 were measured in the airflow after 84 days. In soil the following stable transformation products were detected after 84 days: 5:3 acid (12 %), PFHxA (4.5 %), PFPeA (4.2 %), and PFBA (0.8 %). In soil-bound residues, the major transformation product was 5:3 acid, which may not be available for further biodegradation in soil. In a further study, the authors investigated the aerobic biodegradation of 6:2 FTOH (without ^{14}C-labelling) in soil (closed system) (Liu et al., 2010b). 6:2 FTOH primary degradation half-life was 1.6 days. The overall mass balance in aerobic soil was ~67 % after 180 days (e.g. due to irreversible bond to soil). After 180 days the following substances were accounted: 30 % PFPeA, 8.1 % PFHxA, 1.8 % PFBA, 15 % 5:3 acid, 1 % 4:3 acid, 3 % 6:2 FTOH, and 7.1 % 5:2 sFTOH. 5:2 sFTOH, 5:3 acid and the intermediate 5:2 fluorotelomer (FT) ketone were incubated with soil to elucidate the biodegradation pathway. 5:2 FT ketone yielded 5:2 sFTOH (78 %), PFHxA (4 %) and PFPeA (18 %) after 90 days. Incubation with 5:2 sFTOH for 60 days yielded PFHxA (12 %), PFPeA (85 %) and small amounts of 5:2 FT ketone (< 0.5 %). Incubating with 5:3 acid 4:3 acid (2.3 ± 0.4 %) was the only metabolite after 60 days. The concentration of the initial 5:3 acid concentration decreased to 63 %, this is likely due to the strong adsorption to soil (5:3 acid is becoming non-extractable).

Liu et al. also investigated the biodegradation of 6:2 FTOH in mixed bacterial culture (Liu et al., 2010b). Activated sludge was collected from an industrial wastewater treatment plant and was mixed with a nutrient medium. The sludge was pre-exposed to fluorinated chemicals. The bacterial culture itself was not pre-exposed to fluorinated chemicals. The primary degradation of 6:2 FTOH was rapid with an estimated half-life of 1.3 days. After 90 days, the overall mass balance was 60 % (low mass balance can be attributed to unidentified or unquantified metabolites). PFHxA (5 %), 6:2 FTCA (6 %), 6:2 FTUCA (23 %), 5:2 sFTOH (16 %) and 5-3 acid (6 %) were observed at the end of the study.

Zhao et al. investigated the aerobic biotransformation of 6:2 FTOH in activated sludge of two domestic WWTP (Zhao et al., 2013b). Primary biotransformation was rapid. More than 97 mol% converted within 3 days to at least nine transformation products. The most abundant transformation product was the volatile 5:2s FTOH. After two months 40 mol% 5:2sFTOH (30 mol% in the headspace) was detected. Further major biotransformation products were 5:3 acid (14 mol%), PFHxA (11 mol%), and PFPeA (4.4 mol%). PFBA and PFHpA were not observed within two months.

In an aerobic river sediment system similar biotransformation products as in soil and activated sludge were detected (Zhao et al., 2013a). The recovery of 6:2 FTOH and quantifiable transformation products ranged 71-88 mol% of initially applied 6:2 FTOH. The lower mass balance compared to sterile control (86-98 mol%) could be explained by formation of bound residues. After 100 days 22.4 mol% 5:3 acid, 10.4 mol% PFPeA, 8.4 mol% PFHxA, and 1.5 mol% PFBA were detected. PFHpA was not observed. Most of the 5:3 acid formed bound residues with sediment organic components, which can only be recovered by sodium hydroxide and ENVI-Carb™ carbon. In addition, 5:3 acid can be further degraded to 4:3 acid (2.7 mol%). Major intermediates during biotransformation of 6:2 FTOH were 6:2 FTCA, 6:2 FTUCA, 5:2 ketone, and 5:2 sFTOH. The 6:2 FTOH primary degradation half-life in sediment system was estimated to be 1.8 days. Figure 1 illustrates the proposed biodegradation pathway of 6:2 FTOH in aerobic sediment systems.

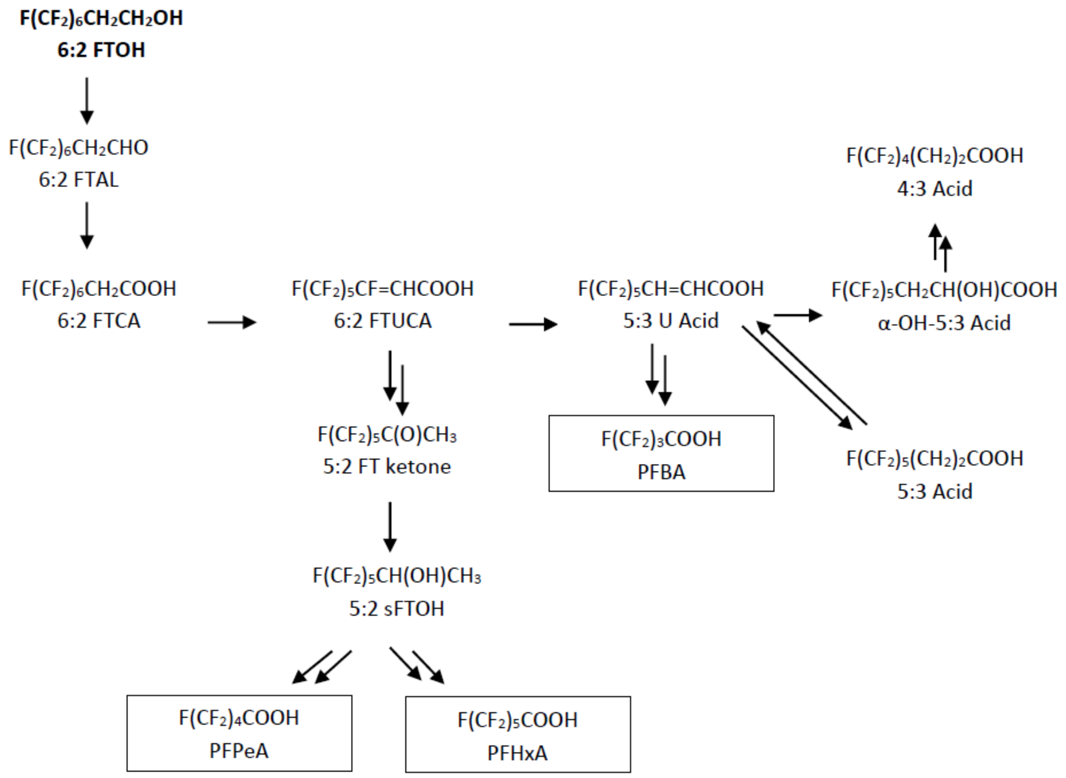

Figure 1: *Proposed 6:2 FTOH biotransformation pathways in aerobic sediment system. The single arrows indicate transformation steps based on observed transformation product and the double arrows indicate multiple transformation steps (based on (Zhao et al., 2013a)).*

Anaerobic degradation of 6:2 FTOH under methanogenic conditions has been analysed by Zhang et al., (Zhang et al., 2013b). Anaerobic digester sludge was incubated dosed with 6:2

FTOH in two studies one for 90 and the other for 176 days. The half-life of 6:2 FTOH (primary degradation) was about 30 days. PFHxA formation was much lower compared with the results of the aerobic sludge and soil studies (0.2 mol% in the 90d-study, 0.4 mol% in the 176d-study). Approximately 30 mol% and 6 mol% of the added 100 mol% 6:2 FTOH still remained at day 90 and day 176, respectively. An average of 43 mol% of intermediate transformation products (sum of 6:2 FTCA and 6:2 FTUCA) were detected in both studies. 5:3 acid was detected as a stable degradation product (average 21 mol%). The results on anaerobic degradation obtained by Zhang et al. may be relevant for conditions such as landfill leachate and anaerobic WTTP sludge.

8:2-FTOH

8:2 FTOH metabolism universally shows the formation of PFOA and, to a smaller fraction, PFNA and lower-chain-length PFCAs (Butt et al., 2014).

Dinglasan et al. investigated biodegradation of 8:2 FTOH using a mixed microbial system (Dinglasan et al., 2004). The enrichment culture was obtained from sediment and groundwater from a contaminated site. By day 81, PFOA was detected at 3 % of the total mass of added 8:2 FTOH. 8:2 fluorotelomer unsaturated carboxylic acid (8:2 FTUCA) was identified as the major metabolite at day 81 (~50 % of the total mass). Further degradation of 8:2 FTUCA may lead to an increase of PFOA concentration (see Figure 2). By day 81 only 55 % of products could be accounted. There may be a number of reasons for the loss: Volatile metabolites may have been lost during routine sampling (loss of initial 8:2 FTOH ~20 % in sterile control), volatile metabolites that were left unidentified or unsaturated metabolites, which are covalently bound to biological macromolecules.

Biodegradation of ^{14}C-labelled 8:2 FTOH has been investigated in mixed bacterial culture and in activated sludge (Wang et al., 2005a; Wang et al., 2005b). The mixed bacterial culture was obtained from sludge from an industrial wastewater treatment plant (WWTP). Meanwhile, the second study was performed with inoculums from a domestic WWTP (200-fold diluted). The results showed that 8:2 FTOH is adsorbed to sludge and degraded subsequently. A significant portion of the ^{14}C 8:2 FTOH had volatilized from the solid/aqueous matrix and deposited onto the PTFE septa of the experimental vessels. 36 % of ^{14}C 8:2 FTOH remained in the mixed bacterial culture at day 90 (Wang et al., 2005a) and 57 % of the parent still remained in the activated sludge system after 28 days (Wang et al., 2005b). In the mixed bacterial culture system, the concentration of PFOA increased over 56 days and levelled off to 6 % of the ^{14}C mass balance until day 90. Approximately 25 % of the sum of 8:2 fluorotelomer carboxylic acid (8:2 FTCA), 8:2 fluorotelomer unsaturated carboxylic acid (8:2 FTUCA) and 7:2 fluorotelomer secondary alcohol (7:2 sFTOH) were detected at day 90. These substances are degradation intermediates and can be further degraded to PFOA (see Figure 2) (Wang et al., 2005a). In the activated sludge system 2.1 % PFOA and 33 % sum of 8:2 FTUCA and 8:2 FTCA of the initial ^{14}C mass have been identified after 28 days (Wang et al., 2005b). Similar degradation pathways were observed in aerobic soil, whereby formation of PFOA was higher in the soil compared to mixed bacterial cultures and activated sludge. 10 – 40 % (average 25 %) of ^{14}C- 8:2 FTOH (half-life (primary degradation) < 7 days) was degraded to form PFOA (steady state after 7 – 56 days; test duration 197 days) (Wang et al., 2009). 10-35 % of total ^{14}C was irreversibly bound to soil, whereby PFOA was not irreversibly bound to soils.

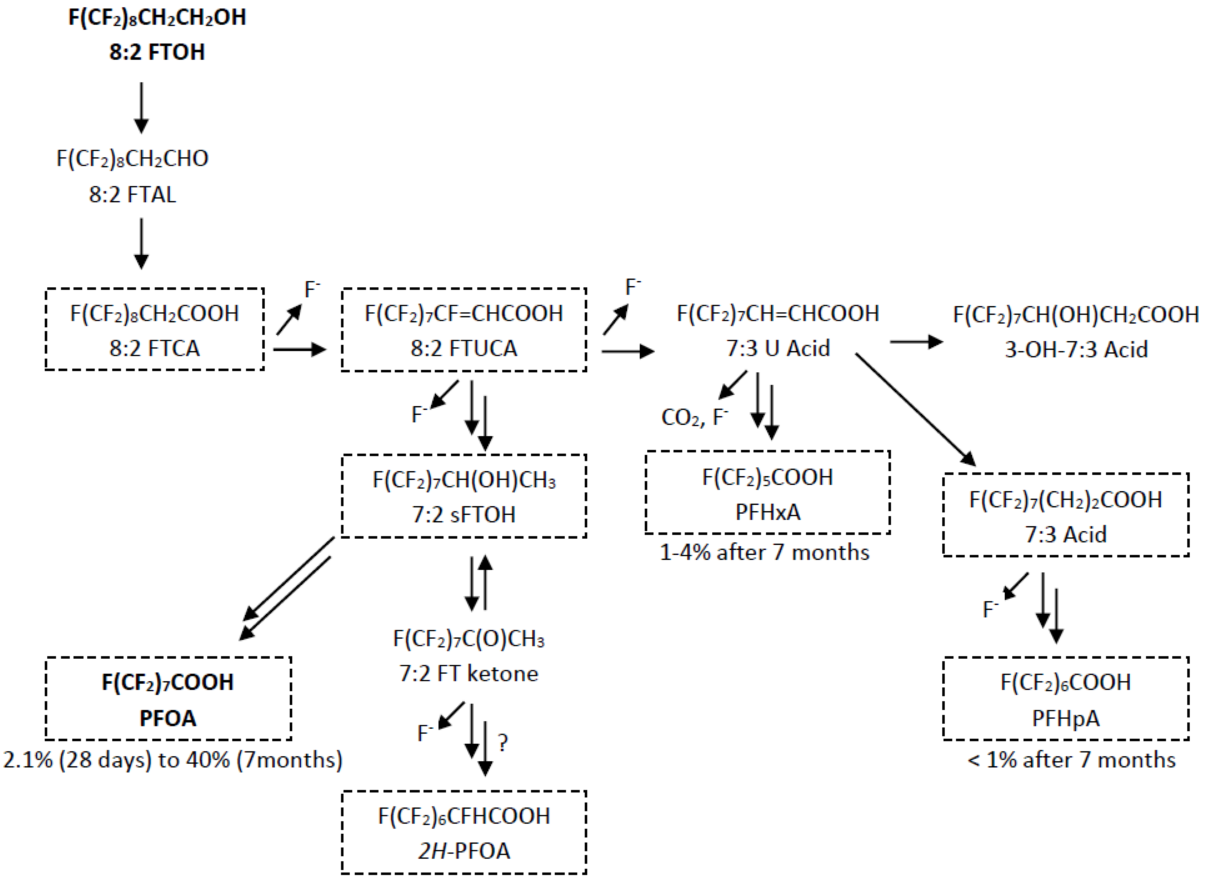

Figure 2: *Aerobic degradation pathways of 8:2 FTOH in soil and activated sludge (Figure based on (Liu and Mejia Avendaño, 2013). The double arrows indicate multiple transformation steps. Defluorination reactions are indicated by release of fluoride ions (F^-). Stable and semi-stable compounds are shown inside dashed boxes. 2H-PFOA has been proposed, but it has not been successfully validated as a PFOA degradation product. The percentages of the degradation products refer to studies by (Dinglasan et al., 2004; Wang et al., 2005a; Wang et al., 2009; Wang et al., 2005b)).*

Anaerobic degradation of 8:2 FTOH under methanogenic conditions has been analysed by Zhang et al., (Zhang et al., 2013b). Anaerobic digester sludge was incubated dosed with [3-^{14}C] 8:2 FTOH for 181 days. The half-life of 8:2 FTOH (primary degradation) is about 145 days. PFOA formation was much lower compared with the results of the aerobic sludge and soil studies (0.3 mol% of initially applied [3-^{14}C] 8:2 FTOH within 181 days). Approximately 39 mol% of the added 100 mol% [3-^{14}C] 8:2 FTOH still remained by day 181. 23 mol% of intermediate transformation products (sum of 8:2 FTCA and 8:2 FTUCA) were detected at day 181 2H, 2H, 3H, 3H-Perfluordecanic acid (7:3 acid) was detected as a stable degradation product (27 mol%). The results on anaerobic degradation obtained by Zhang may be relevant for conditions such as landfill leachate and anaerobic WTTP sludge.

Li et al. investigated the anaerobic biodegradability and metabolic pathways of 8:2 FTOH in anaerobic activated sludge (Li et al., 2018). In the influent of the sampled WWTP fluorine containing organic compounds (e.g. FTOHs or PFCAs) were detected at ppb level. Beside the anaerobic biodegradation of 8:2 FTOH the authors also studied the metabolic pathway of known metabolites (8:2 FTUCA, 8:2 FTCA, 7:3 acid, 7:2 sFTOH). After 150 days the following metabolites were detected during anaerobic biodegradation of 8:2 FTOH: 17 % PFOA, 8.9 % PFHpA, 5.4 % PFHxA, 1.9 % PFBA, 1.2 % PFPeA, 10 % 7:3 acid, 4.2 % 8:2 FTUCA, 1.4 % 8:2 FTCA, 1.2 % 7:2 sFTOH. The observed metabolites accounted for 57 % of initial 8:2 FTOH at the end of the study. The authors mentioned that neither conjugation nor volatilization losses could be contributed to the decline of the total molar recovery. Hence, unknown metabolites could be formed during the biodegradation process. The studies with 8:2 FTUCA, 8:2 FTCA, 7:3 acid, 7:2 sFTOH show that these substances are intermediates during the 8:2 FTOH anaerobic biodegradation as they were further transformed to the PFCAs.

Atmospheric degradation was further studied in a smog chamber (Ellis et al., 2004). Experiments were performed in 750 Torr of air at 296 K. Reaction mixtures were subject to 0.5 to 15 min UV radiation leading to a consumption of FTOH in the range of 66 to > 98 %. It was shown that 8:2 FTOH is oxidized, initiated by Cl atoms which represent OH radicals, and forms PFNA, PFOA (1.5 % C mass balance of 8:2 FTOH) and PFCAs containing a carbon chain of less than eight carbon atoms. The formation of PFOA is expected to be greater because intermediate transformation products were still observed (e.g. 26 % 8:2 FTCA, 6 % 8:2 fluorotelomer aldehyde (8:2 FTAL)). The authors stress that the formation of PFOA is small but significant and postulate that FTOH degradation is likely an important source of PFOA and other PFCAs in remote areas.

The aqueous phase photo-oxidation of 8:2 FTOH in aqueous hydrogen peroxide solution, synthetic field water, and water from Lake Ontario (Canada) was investigated by Gauthier and Mabury (Gauthier and Mabury, 2005). The half-lives of 8:2 FTOH were 0.83 ± 0.20 hours (10 mM H_2O_2), 38.0 ± 6.0 hours (100 µM H_2O_2), 30.5 ± 8.0 to 163.1 ± 3.0 hours (synthetic field water), and 93.2 ± 10.0 hours (Lake Ontario). The major products detected in the H_2O_2 study after 10 hours were 8:2 FTCA (~60 %) and PFOA (~40 %). During the experiment 8:2 FTAL was observed as a short-lived intermediate that underwent further photo-oxidation to - PFOA. 8:2 FTCA was shown to undergo aqueous phase photo-oxidation leading to PFOA as the major product. It therefore appears that aqueous phase photo-oxidation of 8:2 FTOH will result in 75-100 % PFOA with time. In the other test systems 1-8 % (after 140-146 hours; synthetic field water) and 18 % PFOA (duration not specified; Lake Ontario), respectively, were formed. Although the study is only of qualitative nature (no rate coefficients reported), it shows that fluorotelomer alcohols and other related compounds will undergo photo-oxidation in aqueous surface layers and in the atmospheric aqueous phases (cloud droplets and deliquescent particles). Since the PFOA yield from 8:2 FTOH photo-oxidation is 75-100 % in the aqueous phase (compared to 3-6 % in the gas phase), aqueous phase photo-oxidation may turn out to be very important in spite of the low solubility. Any quantitative statements will require multiphase modelling.

Kudo et al. (2005) investigated the biotransformation of 8:2 FTOH in male mice dosed via intraperitoneal injection and the diet. The PFOA levels in the animals continued to rise throughout the experiment. In the experiment where the male mice were exposed to 8:2 FTOH via the diet, the PFOA levels increased in a dose- and time dependent manner. The formation of PFOA was around ten times higher than that of PFNA (Kudo et al., 2005). Similar results were observed in a study by Martin et al. (2005) where the formation of PFOA was ten times higher than that of PFNA when measured plasma from rats after 8:2 FTOH injection (Martin et al., 2005).

Nabb et al. (2007) investigated the in vitro metabolism of ^{14}C labelled 8:2 FTOH in rat, mouse, trout and human hepatocytes, and in rat, mouse and human liver microsomes and cytosol fractions. The 8:2 FTOH clearance rates were highest in rat, followed by mouse, humans and lowest in trout. The yield of PFOA was low. However, the author found that the 8:2 FTOH volatilized from the aqueous fraction and into the headspace of the experimental set up and was not available for biotransformation (Nabb et al., 2007).

In a study by Himmelstein et al. (2012) biotransformation of 8:2 FTOH in rats exposed via inhalation was investigated. The most abundant metabolites were 7:3 FTCA > PFOA > 8:2 FTCA (Himmelstein et al., 2012).

Timed-pregnant CD-1 mice received a single dose of 8:2 FTOH (30 mg/kg bw) or vehicle by gavage on gestation day 8 (GD8). During gestation (GD9 to GD18), maternal serum and liver concentration of PFOA decreased from 789 ± 41 to 668 ± 23 ng/mL and from 673 ± 23 to 587 ± 55 ng/g, respectively. PFOA was transferred to the developing foetuses as early as 24 h post-treatment with increasing concentration from 45 ± 9 ng/g (GD10) to 140 ± 32 ng/g (GD18). The group of pups only exposed via lactation had a PFOA concentration of 57 ± 11 ng/mL at PND3 and 58 ± 3 ng/mL at PND15. 8:2 FTOH-intermediates were not assessed in this study (Henderson and Smith, 2007).

In a study by D'Eon and Mabury (2007) rats exposed to two doses of 8:2 FTOH (200 mg/kg bw) had increased concentrations of PFOA in blood with a peak of 34± 4 ng/g (D'eon and Mabury, 2007). Nilsson et al. (2013) measured the different metabolites FTCAs and FTUCAs of 8:2 FTOH in serum from professional ski waxers during the skiing season in addition to summer season without ski waxing. Several different polyfluorinated metabolites were detected in the serum, with PFOA (median of eleven ski waxers: 110 ng/mL) being the most abundant. Due to the findings of FTCs and FTUCAs in ski waxers blood after exposure to high levels of 8:2 FTOH via air suggest metabolism of FTOH to PFOA (Nilsson et al., 2013a). The downside with this study is the lack of a control group showing possible background levels of FTOH-metabolites.

Conclusion: Based on the available data it can be confirmed that n:2 FTOH will be degraded and transformed into C_x-PFCA (with x= n-2, n-1, n, n+1) in individual amounts greater than 0.1 % per year. For example, 6:2 FTOH will be degraded to PFHxA.

B.4.1.2.2 Fluorotelomer derivates

Table 10: Summary of formed PFCAs during degradation of fluorotelomer derivates.

Substance	**Compartment**	**Study duration**	**PFBA**	**PFPeA**	**PFHxA**	**PFHpA**	**PFOA**	**PFNA**	**Reference**
fluorotelomer iodide (FTI)									
6:2 FTI	soil	91 d	-	20 mol%	3.8 mol%	16 mol%			(Ruan et al., 2013)
4:2 FTI	atmosphere		+	+					(Young et al., 2008; Young and Mabury, 2010)
FTI	hydrolysis (modelling)		corresponding FTOHs and PFCAs						(Nielsen, 2014; Rayne and Forest, 2010)
fluorotelomer stearate monoester/fluorotelomer citrate triester									
8:2 fluorotelomer stearate monoester	agricultural soil	80 d			0.16 mol%	0.38 mol%	1.7 mol%	0.009 mol%	(Dasu et al., 2012)
8:2 fluorotelomer stearate monoester	forest soil	94 d			0.2 mol%	0.9 mol%	4 mol%		(Dasu et al., 2013)
8:2 fluorotelomer citrate triester	forest soil	218 d			0.2 mol%	0.8 mol%	4 mol%		(Dasu et al., 2013)
polyfluorinated olefins									
polyfluorinated olefins	atmosphere		corresponding FTOHs and PFCAs						(Nielsen, 2014; Sulbaek Andersen et al., 2005)
fluorotelomer (meth)acrylates (FT(M)A)									
n:2 FT(M)A (n=2-12)	hydrolysis (modelling)		corresponding FTOHs and PFCAs						(Nielsen, 2014; Rayne and Forest, 2010)
4:2 FTA	atmosphere		corresponding PFCAs						(Butt et al., 2009)
8:2 FTA	soil	105 d			< 0.4 mol%	1.3 mol%	8 mol%		(Royer et al., 2015)
8:2 FTMA	soil	105 d			< 0.4 mol%	3.4 mol%	10.3 mol%		(Royer et al., 2015)
polyfluoroalkyl phosphoric acid mono-/diesters (monoPAP/diPAP)									
n:2 diPAPs (n=4,6,8,10)	rats		Corresponding FTOHs and PFCAs						(D'eon and Mabury, 2011)

Substance	**Compartment**	**Study duration**	**PFBA**	**PFPeA**	**PFHxA**	**PFHpA**	**PFOA**	**PFNA**	**Reference**
6:2 monoPAP	wastewater and sewage sludge	92 d		0.7 mol%	2.1 mol%	8.4 mol%			(Lee et al., 2010)
6:2 diPAP	wastewater and sewage sludge	92 d		1.5 mol%	6.2 mol%	7.3 mol%			
n:2 monoPAPs (n=4,6,8,10)	wastewater and sewage sludge	92 d	corresponding FTOHs (1-2% after 92 days) and PFCAs						
6:2 diPAP	soil and plant	5.5 months	+	+	+	+			(Lee et al., 2014)
6:2 PAPs	activated sludge	30 d		0.47 mol%	2 mol%	0.04 mol%			(Lewis et al., 2016)
6:2 diPAP	soil	112 d	0.73 %	6.4 %	6 %				(Liu and Liu, 2016)
8:2 diPAP	soil	112 d			0.34 %	0.25 %	2.1 %		
6:2 diPAP	carp	14 d uptake; 14 d depuration			+	+			(Chen et al., 2019)
8:2 diPAP	carp	14 d uptake; 14 d depuration				+	+	+	
8:2 diPAP	gilt-head bream	7 d					+		(Zabaleta et al., 2017a)
8:2 diPAP	compost amended soil 2.4	108 d			+	+	10 %		(Bizkarguenaga et al., 2016)
	compost amended substrate				+	+	62 %		
	in presence of crops (carrot)	3 months	+	+	+	+	+	+	
	in presence of crops (lettuce)	1 month					+		

Substance	Compartment	Study duration	PFBA	PFPeA	PFHxA	PFHpA	PFOA	PFNA	Reference
8:2 monoPAP and diPAP	hydrolysis	14 d					8:2 FTOH		(D'eon and Mabury, 2007; Nielsen, 2014; Rayne and Forest, 2010)
8:2 monoPAP and diPAP	rats	15 d			-	+	+	-	(D'eon and Mabury, 2007)
polyfluorinated silanes									
Polyfluorinated silanes	atmosphere		corresponding PFCAs						(Nielsen, 2014)
perfluorinated amides/perfluoroalkane sulfonamides/perfluoroalkane sulfonamidoethanols									
N-ethyl-perfluoro-butyramide (N-EtFBA)	atmosphere		16 %						(Jackson et al., 2013)
perfluorobutane sulfonamidoethanol (N-MeFBSE)	atmosphere		+						(D'eon et al., 2006)
N-ethyl-N-(2-hydroxyethyl)perfluorooctaneamide (N-EtFOA)	hydrolysis pH14 pH 8.5	 24 h 8 d					 98 % -		(Jackson and Mabury, 2013)
N-ethyl perfluorobutanesulfonamide (N-EtFBSA)	atmosphere		0.33 %						(Martin et al., 2006)
fluorotelomer urethane (monomers)									
toluene-2,4-di(8:2 fluorotleomer urethane) (FTU)	agricultural soil	180 d					+ (from residual 8:2 FTOH)		(Dasu and Lee, 2016)
	forest soil	117 d			0.07 mol%	0.11 mol%	0.84 mol%		
hexamethylene-1,6-di(8:2 fluorotleomer urethane) (HMU)	forest soil	180 d			0.06 mol%	0.14 mol%	0.94 mol%		

Substance	**Compartment**	**Study duration**	**PFBA**	**PFPeA**	**PFHxA**	**PFHpA**	**PFOA**	**PFNA**	**Reference**
fluorotelomer ethoxylates (FTEO)									
(FTEO) with perfluorinated chain lengths between 4 and 12 and a degree of ethoxylation between 0 and 18	WWTP effluent	48 d	-	-	2.5 mol% (could have been formed from FTOH-residues)	-	0.3 mol% (could have been formed from FTOH-residues)	-	(Frömel and Knepper, 2010)
fluorotelomer sulfonate (FTS)									
6:2 FTS	WWTP-activated suldge	90 d	0.14 %	1.5 %	1.1 %	-			(Wang et al., 2011a)
6:2 FTS	aerobic sediment	90 d	-	21 mol%	20 mol%	0.55 mol%			(Zhang et al., 2016b)
	anaerobic sediment	100 d	-	-	-	-			
fluorotelomer thioether amido sulfonate (FTTAoS)									
n:2 FTTAoS (n=4,6,8)	soil amended with an AFFF solution	60 d	+	+	+	+			(Harding-Marjanovic et al., 2015)
perfluoroalkyl phosphinic acids (PFPiAs)									
PFPiAs			hydrolyse to PFPAs and $C_nF_{2n+1}H$ (further oxidation to PFCAs, when heated or alkalized)						(Wang et al., 2016)

[+] detected, but not quantified; [-] not detected; [ ] not evaluated

Fluorotelomer iodide (FTI)

The hydrolysis of fluorotelomer iodides was modelled with HYDROWIN module of EPI Suite software program (Nielsen, 2014; Rayne and Forest, 2010). At 20 °C the hydrolytic half-life is expected to remain constant at 126 days between pH 0 and 9 and then decrease to < 7 hours at pH 14. In marine system (pH = 8.1) the hydrolytic half-life decreased from about 8 years at 0 °C to about 130 days at 20 °C. The hydrolysis of fluorotelomer iodides may be contributing to substantial FTOH and PFCA inputs in aquatic systems.

The atmospheric fate of 4:2 fluorotelomer iodides was investigated in a smog chamber experiment by Young et al. (Young et al., 2008; Young and Mabury, 2010). Atmospheric lifetime of fluorotelomer iodides is expected to range from about 1 to 7 days (limited by photolysis), depending on time of year and latitude. Photolysis of fluorotelomer iodides occurs via elimination of the iodine atom leading to the formation of the fluorotelomer aldehyde. The fluorotelomer aldehyde will be further degraded (atmospheric lifetime ~4 days) to perfluoroaldehyde. Perfluoroaldehyde has an atmospheric lifetime of approximately one day with respect to photolysis and approximately 20 days with respect to reaction with OH-radicals. The oxidation of perfluoroaldehyde leads to the formation of PFCAs (e.g. for 4:2 FTI to perfluoropropanoic acid (PFPrA), PFBA and PFPeA). Because of their long-range potential fluorotelomer iodides contribute to the occurrence of PFCAs in remote areas.

Gas phase photolysis and hydrolysis of 8:2 FTI will lead to the release of 8:2 FTOH and thus PFOA (Rayne and Forest, 2010; Young et al., 2008; Young and Mabury, 2010).

Ruan et al. investigated the aerobic biotransformation of 6:2 FTI in soil (Ruan et al., 2013). Primary biotransformation was rapid with an estimated dissipation half-life of 4.5 days. The study showed that 6:2 FTI underwent biotransformation processes via 6:2 FTOH pathway to form PFPeA (20 mol%), PFHxA (3.8 mol%), 5:3 acid (16 mol%), and 4:3 acid (3 mol%). Furthermore, a significant level of PFHpA (16 mol%) was formed, perhaps via the intermediate 6:2 fluorotelomer unsaturated iodide (FTUI). Nevertheless, because of the lack of standard the authors could not verify their hypothesis.

Conclusion: Based on the available data it can be expected that n:2 FTI will be degraded and transformed into C_x-PFCA (with x= n-1, n, n+1) in individual amounts greater than 0.1 % per year. For example, 6:2 FTI will be degraded to PFHxA.

Fluorotelomer stearate monoester/fluorotelomer citrate trimester

The biodegradation of 8:2 fluorotelomer stearate monoester was studied by Dasu et al., in agricultural loam soil using laboratory microcosms within 80 days (Dasu et al., 2012). Although the microcosms were closed, the oxygen concentrations were comparable to aerobic conditions. The 8:2 fluorotelomer stearate monoester was degraded with a half-life (primary degradation) of 10.3 days (first-order kinetic model fit well up to day 20). At the end of the experiment 22 % of the initial 8:2 fluorotelomer stearate monoester was detected. The ester bond was hydrolysed and 8:2 FTOH was rapidly formed with a half-life of two days. Subsequent degradation was monitored. Similar reaction products as shown in Figure 2 were found. PFOA, which was the major terminal product, consistently increased over time reaching 1.7 mol% by day 80. PFOA concentration has not reached a plateau until day 80. Furthermore, PFHpA (0.38 mol%) and PFHxA (0.16 mol%) were detected as terminal product. PFNA was also observed and increased over time (0.009 mol% on day 80). PFNA is suspected to be from low residuals of 10:2 FTOH in the fluorotelomer stearate monoester. Approximately 14 mol% of intermediate transformation products (sum of 8:2 FTCA, 8:2 FTUCA and 7:2s FTOH) were detected at day 80. Therefore, further increase of PFOA concentration with time is possible. Total mass balance decreased over time to about 38 mol% by day 80. Reasons could be irreversible sorption and decreasing extraction efficiencies of degradation products over time and formation of unidentified products.

A similar study was performed with forest soil (Dasu et al., 2013). 8:2 fluorotelomer stearate was degraded with a half-life (primary degradation) of 28.4 days (first-order kinetic model fit well up to day 46), which was slower than in the previous experiment based on agricultural soil. The major terminal metabolite was PFOA (4 mol% at 94 days). Further terminal metabolites were PFHpA (0.9 mol%) and PFHxA (0.2 mol%). PFOA concentration has not reached plateau until day 94. Approximately 25 mol% of initial fluorotelomer stearate monoester remained at day 94. 13 mol% of intermediate transformation products (sum of 8:2 FTCA, 8:2 FTUCA, and 7:2 sFTOH) were detected at day 94. Total mass balance decreased over time to about 44 mol% by day 94.

Dasu and co-workers also studied the biodegradation of 8:2 fluorotelomer citrate in a similar experimental setup (Dasu et al., 2013). The citrate was degraded slower. Approximately 56 mol% of the initial fluorotelomer citrate remained by the end of the study (218 days). Formation of 8:2 FTOH and secondary metabolites were identical to those shown in Figure 2. 4 mol% PFOA, 0.2 mol% PFHxA, and 0.8 mol% PFHpA were detected at day 218 (sum of 8:2 FTOH, 8:2 FTUCA, 8:2 FTCA, 7:2sFTOH ~6 mol%).

Conclusion: Based on the available data it can be expected that n:2 fluorotelomer stearate monoester /fluorotelomer citrate trimester will be degraded and transformed into C_x-PFCA (with x= n-2, n-1, n) in individual amounts greater than 0.1 % per year. For example, 6:2 fluorotelomer stearate monoester/fluorotelomer citrate trimester will be degraded to PFHxA.

Polyfluorinated olefins

The atmospheric lifetimes of polyfluorinated olefins are around 8 days with 90 % removal via reaction with OH radicals and 10 % removal via reaction with ozone (O_3) (smog chamber experiment) (Sulbaek Andersen et al., 2005). The major product (~ 90 %) in the atmospheric photo-oxidation is the corresponding perfluoroalkyl aldehyde (PFAL). The atmospheric lifetimes of PFALs are estimated to be around 90 days with respect to reaction with OH. It is therefore likely that PFALs in part will partition to the atmospheric aqueous phase and undergo photo-oxidation there to form the corresponding PFCA (Nielsen, 2014).

Fluorotelomer olefins (FTO, $F(CF_2)_nCH=CH_2$), a sub-class of polyfluorinated olefins, can therefore be considered as a class of substances leading to release of PFCAs.

Conclusion: Based on the available data it can be expected that polyfluorinated olefins will be abiotic degraded and transformed into corresponding PFCAs.

Fluorotelomer (meth)acrylates (FT(M)A)

In general, carboxylic acid esters will undergo hydrolysis resulting in the corresponding alcohols and carboxylic acids. It is reported that hydrolysis of perfluorinated telomer acrylates (and methacrylates) may be fast in landfills (half-lives < 4 days; 40-50 °C and pH 4-9), but that they have half-lives in the range of years in marine systems (half-lives = 3-5 years; 15 °C and pH 8.1) (using SPARC software program). Hydrolysis of monomeric perfluorinated telomer acrylates may be a significant source to current environmental loadings of FTOHs and the corresponding PFCA. Under some saturated landfill conditions abiotic hydrolytic degradation of fluorotelomer acrylates could be occur resulting in significant fluxes of FTOHs and their degradation products into ground water and surface water (Nielsen, 2014; Rayne and Forest, 2010).

Butt el al. investigated the atmospheric chemistry of 4:2 fluorotelomer acrylate (4:2 FTA) (Butt et al., 2009). The atmospheric lifetime of 4:2 FTA is determined by its reaction with OH radicals and is approximately one day. The OH-radical-initiated oxidation in 700 Torr of air in the presence of NO gives HCHO with 4:2 fluorotelomer glyoxylate as the expected coproduct. The atmospheric fate of 4:2 fluorotelomer glyoxylate will be photolysis and reaction with OH radicals, which will lead to formation of 4:2 fluorotelomer aldehyde and ultimately perfluorocarboxylic acids. Hence, the atmospheric oxidation of FTA is expected to lead to the formation of perfluorocarboxylic acids (1-10 % molar yield) in approximately 10 days. Therefore, the atmospheric oxidation of FTA is a potential source of perfluorocarboxylic acids in remote areas.

Microbial transformation (microbially mediated hydrolysis) of 8:2 fluorotelomer acrylate (8:2 FTA) and 8:2 fluorotelomer methylacrylate (8:2 FTMA) in aerobic soils was investigated by Royer et al. (Royer et al., 2015). 8:2 FTA and 8:2 FTMA were rapidly degraded with half-lives of 3-5 days and 15 days, respectively. Both substances were hydrolysed at the ester linkage as evidenced by the formation of 8:2 FTOH. 8:2 FTOH was further degraded via the known biotransformation pathway (see Figure 2). 8 mol% PFOA was formed in FTA-amended soil, and 10.3 mol% PFOA was formed in FTMA-amended soil after 105 days, respectively. Besides the stable metabolites like PFOA, PFHpA (1.3-3.4 mol%), PFHxA (< 0.4mol%), and 7:3 acid (2.3-3.4 mol%), 38-47 mol% of intermediate metabolites (8:2 FTUCA, 8:2 FTCA, 7:2 sFTOH) were observed at day 105. Total mass balance decreased with incubation time with 50-75 % recovery at the end of 105-day incubation. Reasons for loss of mass balance could be reduced extractability, increased irreversibly bound metabolites over time, or additional metabolites that were not quantified or identified.

Conclusion: Based on the available data it can be expected that n:2 FT(M)A will be degraded and transformed into C_x-PFCA (with x = n-2, n-1, n) in individual amounts greater than 0.1 %per year. For example, 6:2 FT(M)A will be degraded to PFHxA.

Polyfluoroalkyl phosphoric acid mono-/diesters (monoPAP/diPAP)

Degradation of polyfluoroalkyl phosphates (6:2 monoPAP and diPAP) was studied by Lee and co-workers (2010) using raw wastewater and sewage sludge. It was shown that the ester bonds were cleaved (microbial hydrolysis) by the formation of monoPAP and thereafter 6:2 FTOH. In the end, the degradation of 6:2 monoPAP and 6:2 diPAP resulted in PFHpA (8.4 mol% and 7.3 mol% expressed as percent PAP present in the aqueous phase at the start of the experiment), PFHxA (2.1 mol% and 6.2 mol%), PFPeA (0.7 mol% and 1.5 mol%), and 5:3 acid (0.12-0.38 mol% and 1.5mol%). It should be noted, that only approximately 10 % of the initial 6:2 monoPAP and approximately 33 % of the initial 6:2 diPAP could be detected in the aqueous phase at the start of the experiment. The authors also performed a chain length study with n:2 monoPAP (n = 2,4,6,8). The production of FTOHs in the headspace and the production of FTCAs, FTUCAs and PFCAs in the aqueous phase of the bottles suggest that the monoPAPs were microbially transformed. Although the monoPAP congeners were observed to produce the corresponding FTOHs in relatively similar order (1-2 % after 92 days; conservative estimates), the rate of production was observed to decrease significantly as the chain length of the monoPAP increased. The short-chain monoPAPs fully degrade to the corresponding PFCAs, whereas the long-chain monoPAPs only partially degraded to the intermediates (FTCA and FTUCA). This difference may be explained by the steric constraint of the longer chain lengths to microbial attack and that the long-chain monoPAPs maybe preferentially associated with the various surfaces present in the experimental system (Lee et al., 2010).

D’eon and Mabury demonstrated in a study with rats that metabolism of 8:2 mono and diPAP in mammals leads to the formation of 8:2 FTOH, which is then available for oxidation to PFOA. The authors suggest that exposure in rats to either 8:2 monoPAPs or 8:2 diPAPs will result in increased PFOA blood levels (D'eon and Mabury, 2007). A later study by the same authors confirms these results and suggest that biotransformation of diPAP even with low exposure could over time result in significant exposure to PFOA (D'eon and Mabury, 2011).

Biodegradation pathways and plant uptake were elucidated in a greenhouse microcosm supplemented with high concentration of 6:2 diPAP (Lee et al., 2014). WWTP biosolids-amended soil sown with plant seeds (*Medicago truncatula*) and premixed with 100 mg of 6:2 diPAP from an ethanol-based standard were used for this study. The authors estimated a disappearance half-life in soil of ~2 months for 6:2 diPAP. The dissipation of the diPAPs in soil may occur through multiple pathways. The majority of 6:2 diPAP resided in the soil (99 %), with minor uptake observed in plants (1 %), leaching corresponded to < 0.1 %. Analyses of volatile substances like FTOH were not performed, as the vessels were open to the greenhouse atmosphere. For the same reason no mass balance calculation was performed. The following metabolites were observed after 5.5 months in soil: PFHxA > 5:3 acid > PFPeA > 6:2 FTUCA = 6:2 FTCA > PFBA > 5:3 Uacid = PFHpA. PFBA was the PFCA with the highest concentration in the plants after 5.5 months followed by PFHxA, PFPeA and PFHpA.

Lewis et al. investigated the biotransformation of 6:2 PAPs (mixture of 6:2 monoPAP, diPAP, triPAP, monopyro PAP and monopoly PAP = 11.5 % of 6:2 FTOH equivalent active ingredients) by three known FTOH-degrading *Pseudomonas* strains under different co-substrate conditions and compared the results with biotransformation by activated sludge (Lewis et al., 2016). The *Pseudomonas* strains (*P. butanovora*, *P. oleovorans*, and *P. fluorescens*) transformed 6:2 PAP to following transformation products after 30 days: 6:2 FTOH, 6:2 FTCA, 6:2 FTUCA, 5:2 ketone, 5:2 sFTOH, PFHxA, 5:3 acid and 5:2 Uacid. In the biotransformation study with activated sludge PFHpA (0.04 mol%/g cells basis at day 30) and PFPeA (0.47 mol%/g cells basis at day 30) were detected as additional transformation products. PFHxA was present with 2 mol%/g cells basis at day 30 in the activated sludge study.

Within 30 days more 6:2 PAPs were transformed by activated sludge (22 mol%/g cells basis) than by the FTOH-degrading *Pseudomonas* strains (*P. butanovora*: 1.5 mol%/ g cells basis, *P. oleovorans*: 1.1 mol%/ g cells basis, and *P. fluorescens*: 8.6 mol%/ g cells basis). Co-substrates (citrate and lactate) affected the amount of metabolites but did not have a major impact on total biotransformation yields.

The biotransformation of 6:2 and 8:2 diPAPs in aerobic soil was investigated in semi dynamics reactors (Liu and Liu, 2016). To investigate the phenomenon of solvent-enhanced hydrolysis, six different extraction solvents were compared. None of the six solvents was able to extract 6:2 and 8:2 monoPAPs with satisfactory recoveries and without causing solvent-enhanced hydrolysis. 6:2 and 8:2 diPAPs have exhibited higher stability and lower tendency to undergo solvent-enhanced hydrolysis. Acetic acid, which lowers the pH of the solution, seemed to play a more important role than the type of the solvents in achieving satisfactory recoveries and minimizing undesirable solvent-enhanced hydrolysis of diPAPs. The estimated half-lives for 6:2 diPAP were 12 days using a double first-order in parallel model and 15 days using single first-order model. After 112 days, 6 % PFHxA, 6.4 % PFPeA, 0.73 % PFBA and 9.3 % 5:3 acid were detected as stable transformation products. The biotransformation of 8:2 diPAP in soil proceeded much slower than the biotransformation of 6:2 diPAP. The estimated half-lives for 8:2 diPAP were > 1000 days using a double first-order in parallel model and 114 days using single first-order model. After 112 days, 2.1 % PFOA, 0.25 % PFHpA, 0.34 % PFHxA and 0.29 % 5:3 acid were detected as stable transformation products. The declining mass balances over 112 days (108 % to 40 % for 6:2 diPAP, 124 % to 69 % for 8:2 diPAP) could be attributed to the formation of soil bound residues.

Chen et al. investigated the biotransformation of 6:2 diPAP and 8:2 diPAP in common carp liver (*Cyprinus carpio*) (Chen et al., 2019). The carp was exposed to 6:2 diPAP or 8:2 diPAP at 8 nM in water during a 14-day uptake period. The uptake period was followed by a 14-day depuration period. No diPAPs were detected in the background water and control fish samples. DiPAPs could be quickly taken up by carp from water as these substances were detected in the fish liver on the first day of exposure and continuously increased with exposure time (no steady state during uptake period). During exposure period in the 6:2 diPAP study increasing concentration of several metabolites like 6:2 FTUCA, 5:3 FTCA, PFHxA (93.0 pmol/g ww on day 14) and PFHpA (2.01 pmol/g ww on day 14) were observed in fish livers (not detected in control fish). 6:2 monoPAP, 6:2 FTOH or PFPeA were not identified due to faster biotransformation or extremely low concentrations. During the depuration phase concentrations of PFHxA and PFHpA still increase, whereas concentrations of 6:2 diPAP, 6:2 FTUCA and 5:3 FTCA decrease. This suggests that biotransformation of the accumulated parent compound or intermediate metabolites continued. In the 8:2 diPAP biotransformation study 8:2 FTUCA, 8:2 FTCA, 7:3 FTCA as well as PFHpA, PFOA and PFNA were detected with increasing concentration during uptake period. PFOA and PFNA were detected in the control fish at relatively low concentrations, therefore concentrations in the exposed fish liver were corrected. After 14 days exposure, 7.39 pmol PFOA/g ww, 5.13 pmol PFNA/g ww and 3.96 pmol PFHpA/g ww were observed. The concentrations of the PFCAs further increased, whereas concentrations of the parent compound as well as the other metabolites decreased.

In the total, a higher transformation rate was observed for 8:2 diPAP (6.78 – 14.6 mol%) compared to 6:2 diPAP (0.49 – 0.66 mol%). According to the authors, a possible reason is that 8:2 diPAP contains more electron-withdrawing fluorine atoms, which makes it subject of stronger hydrolysis (Chen et al., 2019).

Zabaleta et al. studied biotransformation of 8:2 diPAP in gilt-head bream (*Sparus Aurata*) via dietary exposure (29 µg 8:2 diPAP/g) over seven days (Zabaleta et al., 2017a). 8:2 diPAP and potential transformation products were monitored in plasma, liver, muscle, gills, bile and brain. With the exceptions of 8:2 diPAP in the dosed feed, no PFASs were detected in blanks or feed. In control fish PFOA was observed in bile, brain (both with negligible concentrations compared to exposed animals) and liver. This observation was surprising, as PFOA concentration in water was below LOD. Nevertheless, the liver data for PFOA in this study were control-corrected. 8:2 FTCA, 8:2 FTUCA, 7:3 FTCA and PFOA were observed as intermediate or terminal metabolites. After seven days, 8:2 FTCA was the major metabolite in all tissues and biofluids, except for bile and brain, where PFOA concentration was the highest. No PFOA was detected in muscle and liver. In all other tissues/biofluids the PFOA concentrations at the end of the study were 0.12 ng/mL (plasma), 0.6 ng/g (gills), 3.7 ng/g (brain), and 1.32 ng/mL (bile), respectively.

The degradation of 8:2 diPAP in two amended soils (soil 2.4 and substrate) was investigated by Bizkarguenag and co-authors. A compost, fortified with 8:2 diPAP (500 ng/g), were mixed with the soils. Within the first six hours concentration of 8:2 diPAP decreased and remained almost constant until the end of the study (108 days). 8:2 mono PAP, 8:2 FTUCA, 8:2 FCA, 7:3 FTCA as well as PFHxA, PFHpA and PFOA were detected as degradation products. The major degradation product was PFOA. 10 % and 62 % PFOA were observed in compost-amended soil 2.4 and compost-amended substrate, respectively. All other degradation products were present at < 10 %. In the presence of crops (carrot and lettuce) different degradation products were observed. Whereas in the experiment with carrot PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA and 7:3 FTCA were detected in the soils, in experiment with lettuce PFOA was the only degradation product (Bizkarguenaga et al., 2016).

8:2 mono- and diPAPs are reported to undergo slow hydrolysis (lifetime of several years) at environmental conditions. D'eon and Mabury investigated the hydrolytic stability of 8:2 mono- and diPAPs under aggressive conditions (pH 9 and 50 °C) (D'eon and Mabury, 2007). Lifetimes of > 26 years were estimated. The reaction results in 8:2 FTOH and phosphoric acid (Nielsen, 2014). It is explicitly noted that the experimental hydrolysis rates cannot be reproduced by existing models (Rayne and Forest, 2010). Mono- and diPAPs of 8:2 FTOHs, including their polymers, can therefore be considered as a class of substances leading to release of PFOA by abiotic degradation processes.

Conclusion: Based on the available data it can be expected that n:2 monoPAP and n:2 diPAP will be degraded and transformed into C_x-PFCA (with x = n-2, n-1, n, n+1) in individual amounts greater than 0.1 % per year. For example, 6:2 monoPAP/diPAP will be degraded to PFHxA.

Polyfluorinated silanes

No relevant information concerning hydrolytic lifetimes of condensed or polymerized polyfluorinated silanes was found in the open literature.

Silanes have appreciable vapour pressures and may in principle evaporate and undergo photo-oxidation in the atmosphere. It is also conceivable that small siloxanes may partition to the atmosphere and undergo photo-oxidation there. As reaction product PFCA will be formed (Nielsen, 2014).

Conclusion: Based on the available data it can be expected that polyfluorinated silanes will be abiotic degraded and transformed into corresponding PFCAs.

Perfluorinated amides /perfluoroalkane sulfonamides /perfluoroalkane sulfonamidoethanols

Jackson and Mabury investigated the hydrolysis of the polyfluorinated amides *N*-ethyl-N-(2-hydroxyethyl)perfluorooctaneamide (NEtFOA) in 1 M NaOH solution (pH 14), in 5 mM tris buffer (pH 8.5), and in 50 mM borate buffer (pH 8.5) (Jackson and Mabury, 2013). No hydrolysis to PFOA was observed after eight days at pH 8.5. Rapid degradation was observed in the borate buffer, but not to PFOA. At pH 14 and at room temperature a quantitative (98 %) conversion of EtFOA to PFOA was observed after 24 hours. Hydrolysis from NEtFOA to PFOA under environmental conditions will be negligible. The environmental fate of polyfluorinated amides is suggested to be volatilized to the atmosphere followed by oxidation by hydroxyl radicals with a predicted lifetime of 3 – 20 days.

Jackson et al. studied the atmospheric photo-oxidation (smog chamber experiment) of N-ethyl-perfluoro-butyramide (NEtFBA, $C_3F_7C(O)NHCH_2CH_3$) as a more volatile surrogate for longer chained polyfluorinated amides and identified $C_3F_7C(O)NH_2$ as intermediate, and PFCAs and HNCO (isocyanic acid) as products (Jackson et al., 2013). They presented a general mechanism based on the observed product distribution. Atmospheric lifetime of NEtFBA, with respect to reaction with OH, was estimated to be 4.4 days. Primary oxidation products reacted further to PFCAs (16 % PFBA, 0.3 % PFPrA and 0.3 % trifluoroacetic acid (TFA)). The authors predict similar reaction kinetics for N-ethyl-perfluorooctanamide (NEtFOA) and NEtFBA since the length of a perfluorinated chain does not affect the reaction rate with OH. The primary oxidation products of NEtFOA are expected to have much longer lifetimes and could be capable of contaminating Arctic air. The primary oxidation products are expected to react further to form PFOA.

Martin et al. studied OH radical and Cl atom initiated atmospheric photo-oxidation (smog chamber experiment) of N-ethyl perfluorobutanesulfonamide (NEtFBSA, $C_4F_9S(O)_2NHCH_2CH_3$) (Martin et al., 2006). The atmospheric lifetime of NEtFBSA in the gas-phase (reaction with OH radicals) is estimated to be 20-50 days. The authors observed that Cl atoms are 23 times more reactive toward NEtFBSA than OH radicals. Therefore, Cl atoms were used in place of OH radicals for product experiments. Product formation experiments with OH radicals would be proceeded too slowly to produce secondary products in the experimental system. Nevertheless, Cl atoms and OH radicals are expected to react with NEtFBSA via hydrogen abstraction to give the same products (although not necessarily in the same field). Based on chlorine atom initiated oxidation, $C_4F_9S(O)_2NHC(O)CH_3$, $C_4F_9S(O)_2NHCH_2CHO$and $C_4F_9S(O)_2NHCHO$ were identified as intermediates, and SO_2, COF_2 and PFCAs as stable products. Three PFCAs were detected above the level of the blank: 0.33 % PFBA, 0.11 % PFPrA, and 0.09 % TFA of the molar balance, respectively. At the same time only 0.65 % COF_2 of the starting material had unzipped. Extrapolation of these results suggests that 45 % of the carbon in the perfluoroalkane chain will ultimately be incorporated into PFCAs upon complete oxidation, while the remaining fraction is expected to go to COF_2 (timeframe not given). PFBS was not detected in any sample. The authors suggest that it is evident that analogous perfluorooctane sulfonamide is a potential source for PFOA. They presented a general mechanism based on the observed product distribution.

D'eon et al. measured the gas-phase reaction of N-methyl perfluorobutane sulfonamidoethanol (N-MeFBSE) with OH radicals (D'eon et al., 2006). Experiments were performed in 750 Torr of air diluent at 296 K. An atmospheric lifetime of approximately two days was determined. The following products were identified by in situ FTIR spectroscopy and offline GC-MS and LC –MS/MS analysis: N-methyl perfluorobutane sulfonamide (NMeFBSA), COF_2, PFBA, PFPrA, TFA and PFBS. The concentration of PFBA and PFPrA increased with proceeding reaction. For quantification of PFCAs and PFBS a mass balance was carried out. After 50 % consumption of N-MeFBSE, the cumulative concentration of PFCAs and PFBS accounted for approximately 10 and 1 %, respectively. In addition, the authors performed Cl-atom initiated oxidation. The products of this oxidation were similar to those observed in the OH-radical initiated oxidation experiments. PFCAs and PFBS were detected with similar concentration profiles.

Conclusion: Based on the available data it can be expected that perfluorinated amides, perfluoroalkane sulphonamides and perfluoroalkane sulfonamidoethanols will be abiotic degraded and transformed into corresponding PFCAs in individual amounts greater than 0.1 % per year.

Fluorotelomer urethane (monomers)

Dasu and Lee studied the biodegradation of two 8:2 fluorotelomer urethane monomers in soil (Dasu and Lee, 2016). The biodegradation of toluene-2,4-di(8:2 fluorotelomer urethane) (FTU), containing an aromatic backbone, was investigated in a forest and an agricultural soil. While hexamethylene-1,6-di(8:2 fluorotelomer urethane) (HMU), with an aliphatic backbone, was investigated only in forest soil. In agricultural soil little to no biodegradation of FTU occurred (94 ± 15 % recovery at day 180). A production of PFOA was observed. Nevertheless, the authors assume that the PFOA was produced from residual 8:2 FTOH in FTU (0.56 mol%). In the experiments with forest soil biotransformation of FTU and HMU occurred. The authors mentioned that this activity may be due to fungal enzyme activity which may be more effective in urethane bon cleavage. Nevertheless, this assumption was not further investigated. For FTU half-lives of 126 days (first-order model) and 148 days (bi-exponential model) were estimated. The degradation of HMU was more slowly resulting in estimated half-lives of 478 days (first-order model) and 667 days (bi-exponential model). At the end of the study (FTU: 117 days; HMU: 180 days) 73 % FTU and 76 % HMU still remained. The addition of toluene-2,4-dicarbamic acid diethyl ester (TDAEE) to the FTU microcosms at day 52, a structurally similar non-fluorinated FTU analogous substance, enhanced the formation of terminal end products from 8:2 FTOH degradation. There was no clear evidence that TDAEE enhanced the cleavage of the urethane bond. Therefore, the authors appeared that TDAEE was only an additional carbon source. A second addition of TDAEE on day 74 appeared to retard subsequent degradation of FTU. The derogation of HMU was enhanced by re-aeration on day 106 indicating oxygen may have been limiting during some periods. Re-aeration of the FTU microcosms occurred during TDAEE addition. Based on the enhancements in the FTU microcosm 0.84 mol% PFOA, 0.11 mol% PFHpA, 0.07 mol% PFHxA and 0.11 mol% 8:2 FTOH were formed after 117 days. In the study with HMU 0.94 mol% PFOA, 0.14 mol% PFHpA, 0.06 mol% PFHxA, 0.88 mol% 7:2 sFTOH and 0.14 mol% 8:2 FTOH were observed at day 180. The authors estimated (KinGUI – Kinetic Graphic User Interface) final % PFOA yields from FTU and HMU are 1.5-1.9 % and 3-5.2 %, respectively. In the experiments with forest soil PFOA resulted from transformation of the 8:2 fluorotelomer urethane, since PFOA concentrations were well above what could result from residual 8:2 FTOH.

Conclusion: Based on the available data it can be expected that n:2 fluorotelomer urethane (monomers) will be degraded and transformed into C_x-PFCA (with x = n-2, n-1, n) in individual amounts greater than 0.1 % per year. For example, 6:2 fluorotelomer urethane (monomers) will be degraded to PFHxA.

Fluorotelomer ethoxylates (FTEO)

Biotransformation of fluorotelomer ethoxylates was reported by Frömel and Knepper (Frömel and Knepper, 2010). WWTP effluent was used under aerobic conditions. Zonyl FSH, a commercial mixture which contains fluorotelomer ethoxylates (8:2 FTOH residues = 0.29 %; 6:2 FTOH residues = 0.54 %) with perfluorinated chain lengths between four and twelve and a degree of ethoxylation between 0 and 18 was analysed. Fluorotelomer ethoxylates were rapidly degraded (half-life (primary degradation = 1 d). One significant metabolite was formed within the study duration of up to 48 days: Fluorotelomer ethoxylate carboxylate. The formation of 0.3 mol% PFOA and 2.5 mol% PFHxA was observed, but these PFCAs could have been formed from the FTOH-residuals. It can be assumed that studies with a longer time frame will result in higher PFCA concentrations.

Fluorotelomer sulfonate (FTS)

The aerobic biotransformation of 6:2 Fluorotelomer sulfonate (6:2 FTS) was investigated in closed bottles in diluted activated sludge from three WWTPs (Wang et al., 2011a). The biotransformation of 6:2 FTS was relatively slow, with 63.7 % still remained at day 90. The initial microbial aerobic desulfonation of 6:2 FTS may be the rate-limiting step. At day 90, 1.5 % PFPeA, 1.1 % PFHxA, 0.14 % PFBA and 0.12 % 5:3 acid were observed as stable transformation products. In addition, 2.6 % 5:2s FTOH and 0.8 % 5:2 ketone were detected. 6:2 FTOH and PFHpA were not observed during the 90-d incubation. The authors noted that a substantial fraction of initially dosed 6:2 FTS (24 %) may be irreversibly bound to diluted activated sludge catalysed by microbial enzymes. 6:2 FTS primary biotransformation bypassed 6:2 FTOH to form 6:2 FTUCA directly, which was then degraded via pathways similar to 6:2 FTOH biotransformation.

Zhang et al investigated the biotransformation potential of 6:2 FTS in aerobic sediment and the biotransformation potential of 6:2 FTS and 6:2 FTOH in anaerobic sediment (Zhang et al., 2016b). In aerobic sediment 6:2 FTS was rapidly bio transformed with a half-life of less than five days. The rapid transformation of 6:2 FTS suggests that 6:2 FTA de-sulfonation occurred readily in aerobic sediment, possibly using monooxygenases to catalyse desulfonation. After 90 days 20 mol% PFHxA, 21 mol% PFPeA, 0.55 mol% PFHpA, and 16 mol% 5:3 acid were detected as stable transformation products. 6:2 FTOH was detected at low levels (< 2.5 mol%) over the study period, suggesting that 6:2 FTOH is an initial transformation product of 6:2 FTS. After desulfonation, the biotransformation pathways of 6:2 FTS are the same as for 6:2 FTOH.

In the test with anaerobic sediment, no biotransformation of 6:2 FTS was observed over 100 days. In contrast, 6:2 FTOH was bio transformed to 60 mol% FTCA, 12 mol% 5:3 acid and 0.6 mol% PFHxA within 100 days in anaerobic sediment. These results confirm that the anaerobic experimental system was metabolically active and the molecular structure of 6:2 FTS hindered its biotransformation by microbes.

Conclusion: Based on the available data it can be expected that n:2 FTS will be degraded and transformed into C_x-PFCA (with x = n-2, n-1, n, n+1) in individual amounts greater than 0.1 % per year. For example, 6:2 FTS will be degraded to PFHxA.

Fluorotelomer thioether amido sulfonate (FTTAoS)

Harding-Marjanovic et al. investigated the aerobic biotransformation of Fluorotelomer thioether amido sulfonate (FTTAoS) in soil (Harding-Marjanovic et al., 2015). FTTAoS is a PFAS present in several widely used aqueous film-forming foam (AFFF) formulations. Beside 6:2 FTTAoS, which is the most abundant FTTAoS homologue, 4:2, 8:2, 10:2, 12:2, and 14:2 FTTAoS have also been detected in some AFFFs. In this study, the aerobic biotransformation of 4:2, 6:2, and 8:2 FTTAoS was investigated in soil slurries constructed with AFFF-impacted topsoil from a U.S. military base and enriched with an FTTAoS-containing AFFF formulation. The biotransformation of FTTAoS occurred in live microcosms over approximately 60 days and produced 4:2, 6:2, and 8:2 FTS, 6:2 FTUCA, 5:3 acid, PFBA, PFPeA, PFHxA, PFHpA and PFOA. An oxidative assay was used to indirectly quantify the total concentration of polyfluorinated compounds and check the mass balance. The assay produced near complete mass recovery of FTTAoS after biotransformation, with 10 % (mol/mol) of the amended FTTAoS accounted for in FTS, x:3 acid, and PFCA products (1.5 %). The transformation rates of identified products appear to be slow relative to FTTAoS, indicating that some intermediates may persist in the environment.

Yi et al. studied the biotransformation of 6:2 fluorotelomer thioether amido sulfonate (FTTAoS) under sulfate-reducing conditions (Yi et al., 2018). 6:2 FTTAoS is a component of several AFFF formulations. Pristine solids from the sediment of a creek and or AFFF-contaminated solids from a firefighting training area were used as microbial inocula. Approximately 75 % of FTTAoS had been transformed in in the pristine solid and AFFF-impacted solid microcosms after 270 days. Contrary to the study under aerobic conditions (Harding-Marjanovic et al., 2015), PFCAs and 6:2 FTS were not detected as transformation products under sulfate-reducing conditions within the test duration. In addition to the parent compound nine potential biotransformation products (e.g. 6:2 fluorotelomer thioether propionate) were observed. In addition, the authors used the TOP assay (total oxidisable precursor assay) for quantification of total PFASs. The complete PFAS mass balance (96 ± 8 % after 276 days) in the microcosms with pristine solids indicated that the remaining transformation products (other than 6:2 fluorotelomer thioether propionate) were converted into PFCAs (e.g. PFHxA) by the TOP assay. The mass balance in the AFFF-contaminated solid microcosm was incomplete (67 ± 6 % after 282 days) due to possible volatile transformation products or transformation products that were not converted into PFCAs by the TOP assay.

Conclusion: Based on the available data it can be expected that FTTAoS will be degraded and transformed into corresponding PFCAs.

Perfluoroalkyl phosphinic acids (PFPiAs)

In a review of Wang et al. available information on degradation of perfluoroalkyl phosphinic acids (PFPiAs) were collected and evaluated (Wang et al., 2016).

PFPiAs hydrolyse to yield perfluoroalkyl phosphonic acids (PFPAs) and $C_nF_{2n+1}H$. $C_nF2_{n+1}H$ can be oxidized to form corresponding PFCAs (e.g. via reaction with OH radicals at high temperature or with alkaline conditions). Similarly to PFCAs, PFPAs show high resistance to heat, oxidants, bases and aerobic biodegradation in surface water.

Formation of C6 and C8 PFPAs was also observed in rainbow trout after daily dietary exposure to C6/C6, C6/C8 and C8/C8 PFPiAs. A fast elimination from rat blood (half-lives: 1.8–9.3 days), low renal and faecal excretion (< 1 %) within 48 h after dosing, and low body storage (i.e. low to moderate liver-to-blood ratios) for C6–C12 PFPiAs were observed, which indicates that biotransformation likely occurred in rats, too. It is unknown if this biotransformation follows the same pathway as abiotic hydrolysis because $C_nF_{2n+1}H$ moieties were not measured. Furthermore, no degradation of C4/C4 PFPiA was observed in a 28-day OECD 301-F test on ready biodegradability. Thus, degradation of PFPiAs in a specific environment and biota, depends on actual conditions.

Conclusion: Based on the available data it can be expected that PFPiAs will be abiotic degraded and transformed into corresponding PFCAs.

Side-chain fluorinated polymers

The biodegradation potential of a fluoroacrylate polymer product was studied in four aerobic soils over two years (Russell et al., 2008). It was assessed whether the FTOH side chains covalently bonded to the polymer backbone may be transformed to PFCAs. The test substance itself was not directly measured. Instead, terminal transformation products like PFOA, PFNA, PFDA and perfluoroundecanoic acid (PFUnDA) were measured. The fluoroacrylate polymers contain the polymer itself and also residual raw materials and impurities ("residuals"). The fluoroacrylate monomer used for the polymer was prepared from 1 % 6:2 FTOH, 55 % 8:2 FTOH, 29 % 10:2 FTOH, 10 % 12:2 FTOH and 5 % 14:2 FTOH and larger. Major residuals present in the test substance were n:2 FTOH (n = 6, 8, 10), n:2 fluorotelomer acrylate monomer (n = 6, 8, 10), n:2 FTOH acetate (n = 6, 8, 10), n:2 fluorotelomer olefin (n = 8, 10). PFOA, PFNA, PFDA and PFUnDA were contained as impurities in the range of 2.3-9.9 ng/mg (0.004 – 0.02 µmol/kg).

Based on the rate of formation of PFOA in soil, estimated half-lives of the polymer ranged from 95 to > 2000 years (all soils combined 1160 years). The estimated half-lives of residuals were 12 to 43 days (all soils combined 27 days).

The maximum PFOA concentration ranged from 1.8 to 2.1 µmol PFOA/kg soil. The residual amount of PFOA in the test substance was 0.019 µmol PFOA/kg soil. Hence, PFOA is formed from degradation of residuals and possibly also from degradation of the side chains in the polymer. The maximum experimental PFOA concentrations are 24 – 28 % of the theoretical amount that could be derived from 100 % conversion of the residuals alone

(7.55 µmol PFOA/kg soil). If all 8:2 related analytes are summed 25 – 32 % of the theoretical amount of PFOA is formed from residuals.

Via an analogous degradation pathway to that for 8:2 FTOH, polymer side chains and residuals from FTOH with longer chains (e.g. 10:2 FTOH and 12:2 FTOH) are assumed to degrade to form PFCAs with longer chains. Similar to PFOA the concentrations of PFNA, PFDA and PFUnDA rise with time. The measurement of concentrations of higher PFCA-homologues (≥ C12-PFCA) was not included in this study. The maximum concentrations after 728 days ranged from 0.089 to 0.218 µmol PFNA/kg soil, 0.227 to 0.689 µmol PFDA/kg soil and 0.016 to 0.045 µmol PFUnDA/kg soil, respectively. Nevertheless, the amounts of longer chain FTOHs in the polymer were lower compared to 8:2 FTOH. Hence, lower concentrations of PFNA, PFDA and PFUnDA are not unexpected.

Detection of short-chain PFCAs like PFHxA was not in the scope of this study. Nevertheless, based on the observations for 8:2 FTOH and longer chain FTOHs an analogous degradation pathway is also expected for 6:2 FTOH residuals and polymer side-chains. Even if the amount of 6:2 FTOH (25 ng/mg; 0.07 nmol/mg) in the polymer was lower compared to 8:2 FTOH (1200 ng/mg; 2.6 nmol/mg) and 10:2 FTOH (650 ng/mg; 1.2 nmol/mg).

The study from Russell et al. was commented by Renner (Renner, 2008). She noted that the bottles, which were used for the experiment, leaked and may have released degradation products. Furthermore, FTOHs that were added to sterile control bottles could not be recovered. Russell et al. justified this with irreversible binding to the soil. However, no evidence exists for this claim. Furthermore, the soil experiments did not maintain mass balance. It is stated that it is very difficult to determine the breakdown rate for the polymer because of the relatively large amount of the residuals. A degradability test with a polymer (also containing fluoroacrylate ester linkage) from another manufacture shows relatively rapid fluorochemical polymer breakdown (Renner, 2008). Therefore, the study from Russell et al. should not be given too much weight.

In a further study Russell et al. evaluated the formation of PFOA from the biodegradation of a fluorotelomer-based urethane polymer product in four aerobic soils (Russell et al., 2010). The fluorotelomer alcohol raw material in the polymer synthesis was composed of 34 % 6:2 FTOH, 31 % 8:2 FTOH, 18 % 10:2 FTOH, 9 % 12:2 FTOH and 8 % 14:2 FTOH and larger. The degradation of the polymer begins with the enzymatic cleavage of the fluorotelomer side-chain from the polymer backbone followed by the fractional conversion of fluorotelomer side-chains containing eight fluorinated carbons through a series of intermediates reactions forming PFOA. The maximum concentrations of PFOA (modelled; first-order reaction) formed after two years ranged between 0.5 and 1.3 µmol/kg soil (initial concentration of polymer = 77.6 µmol/kg soil; initial concentration of intermediates and PFOA = 0.032 µmol/kg soil. Including all data until day 728 in kinetic evaluation the calculated half-lives of the polymer ranged between 79 and 241 years (geomean = 132 years). Including all data until days 728 except one soil through day 273 in kinetic evaluation the estimated half-lives ranged from 28 to 241 years (geomean 102 years). In contrast to Russell et al. 2008 the PFOA formation from residuals was negligible in this study. Hence, the PFOA formation resulted from biodegradation of the fluorotelomer-based urethane polymer. PFNA, PFDA and PFUnDA were also formed during the experiment, but modelling of the polymer degradation only considered PFOA formation. Detection of short-chain PFCAs like PFHxA were not in the scope of this study.

Washington et al. also investigated the degradability of an acrylate-linked fluorotelomer polymer in soil (Washington et al., 2009). The tested acralyte-linked fluorotelomer polymer contained e.g. impurities and residuals of n:2 FTOH (n = 6, 8, 10, 12), n:2 fluorotelomeracrylate (n = 6, 8, 10), Cn-PFCAs (n= 6-12), etc. The polymer can be degraded in soil through attack on the carbon backbone and /or the ester linkage connecting the backbone to the fluoroalkyl side chains resulting in PFCAs via the intermediate FTOH. Estimated half-lives of the tested coarse-grained polymers ranged from 870 to 1400 years. Modelling indicates much shorter half-lives (10-17 years) for more finely grained polymers assuming degradation is surface-mediated. The authors observed degradation of PFOA, PFHpA and PFHxA with an estimated half-life of 130 days, 37 days and 16 days, respectively. However, this result is contradictory to other studies which stated that PFCAs e.g. PFOA are not degradable in soil (Moody et al., 2003; OECD, 2006).

After extensive method development the authors investigated the degradation of two commercial acrylate-linked fluorotelomer-based polymers (containing ~ 50 % C8-fluorotelomer components, ~ 30 % C10-fluorotelomer components, ~10 % C12-fluorotelomer components and small amounts of larger fluorotelomer components) in four soils in a further study (Washington et al., 2015). The estimated half-lives ranged from 33 to 112 years. Compared with day 0, concentrations of C8-C14-PFCAs and FTOHs increased up to 12-fold and 28-fold until day 376. The authors estimated a half-life of 8:2 FTOH of ~ 1200 days. Due to discrepancy to literature values (half-lives < 28 days) a follow-up 8:2 FTOH degradation experiment was performed. After spiking microcosms with 8:2 FTOH a half-life of 210 days was estimated. Because the only design difference between the both experiments was the presence of the fluorotelomer-based polymer, the authors inferred the difference in half-lives to be due to presence of the fluorotelomer-based polymer. Furthermore, the authors performed a hydrolysis experiment with the fluorotelomer-based polymer. The results showed an increase of 8:2 FTOH in the pH 10 treatments, almost doubling over the 11-day experiment, while in the pH 3 treatments and dry controls the concentration remained constant. These results suggest that fluorotelomer-based polymer can undergo OH-mediated hydrolysis.

A further study on abiotic hydrolysis of a fluorotelomer-based polymer (containing ~ 50 % C8-fluorotelomer components, ~ 30 % C10-fluorotelomer components, ~10 % C12-fluorotelomer components and small amounts of larger fluorotelomer components) was investigated by Washington and Jenkins (Washington and Jenkins, 2015). The experiments were conducted at 25 °C and with eight pHs buffers over the range of 5-12. The concentrations of the hydrolysis products, 8:2 FTOH and 10:2 FTOH, were observed to increase until the end of the study (day 77) at each of the pH values. Compared to day 0, up to 34-fold concentration of 8:2 FTOH and 190-fold concentration of 10:2 FTOH were measured at day 77. In the range of pH 5 to 7 the rate of hydrolysis of the polymer is not a strong function of pH, whereas at higher pH, half-life decreased with increasing pH. For the fluorotelomer-based polymer hydrolytic half-life values of ~0.7 – 55 years based on 8:2 FTOH and 0.66 – 89 years based on 10:2 FTOH were estimated. Considering the large production volume of fluorotelomer-based polymers and the poor efficacy of conventional treatments for recovery PFCAs from waste streams, these results suggested that fluorotelomer-based polymers manufactured to date potentially could increase PFCAs fourfold to eightfold over current oceanic loads, largely depending on the integrity of disposal units to contain PFCAs upon hydrolytic generation from fluorotelomer-based polymers.

Rankin et al. investigated the biodegradability of a fluorotelomer-based acrylate polymer in soil-plant microcosm over 5.5 months in the absence /presence of wastewater treatment plant biosolid (Rankin et al., 2014). The biodegradation of the fluorotelomer-based acrylate polymer was observed via structural changes by direct analysis (matrix-assisted laser desorption/ionization (MALDI-TOF) time-of-flight mass spectrometry) and via determination of the degradation products by indirect analysis. A unique fluorotelomer-based acrylate polymer was synthesized by aqueous dispersion following two commercial patents. The polymer was determined to be solely a homopolymer of 8:2 fluorotelomer acrylate containing hydrogen and hexadecylthiol end groups and has primarily between two and 16 fluorotelomer appendages. The estimated half-lives ranged from eight to 111 years based on the 8:2 FTOH equivalent and summation of all intermediates and degradation products. Incubation of the fluorotelomer-based acrylate polymer results in the accumulation of PFHxA, PFHpA, and PFOA concurrently with the reduction of 8:2 FTCA and 8:2 FTUCA. PFOA was the dominant product, constituting 57, 70, and 80 % in all microcosm compartments in fluorotelomer-based acrylate polymer /soil, fluorotelomer-based acrylate polymer /plant, and fluorotelomer-based acrylate polymer /plant /biosolids, respectively.

Hydrolytic half-lives of 8:2 fluorotelomer acrylate polymer segments was estimated using SPARC software program (Rayne and Forest, 2010). The estimated half-lives were 170-270 years in marine systems (15 °C and pH 8.1) and < 1 year under landfill conditions (40-50 °C and pH 4-9). Under some saturated landfill conditions abiotic hydrolytic degradation of fluorotelomer acrylates could occur resulting in significant fluxes of FTOHs and their degradation products (e.g. PFCAs) into ground water and surface water.

Waste incineration of fluorotelomer-based polymers as a potential source of PFOA in the environment was investigated in a comprehensive laboratory-scale by Taylor et al. (Taylor et al., 2014). The fluorotelomer composition of the polymer was not further described. Experiments were performed with a gas-phase residence time of two seconds at a mean gas temperature of 1000 °C. No detectable levels of PFOA were produced from the combustion of the fluorotelomer-based polymer composites. Hence, the authors concluded that waste incineration of these polymers is not expected to be a source of PFOA in the environment.

Conclusion: Based on the available data it can be expected that side-chain fluorinated polymers will be transformed via n:2 FTOH into corresponding PFCAs.

Other potential PFHxA-related substances

Other potential PFHxA-related substances and UVCBs cannot in general be classified as classes of substances leading to release of PFHxA. However, substances containing $F(CF_2)_n(CH_2)_2$-groups will most probably result in release of n:2 FTOHs in the environment. Thus, using the weight of evidence approach they can be considered as a class of substances leading to release of PFHxA.

B.4.1.2.3 Prediction of biodegradation pathways of PFHxA-related substances

ECHA analysed potential PFCA-related substances (see chapters B.4.1.1.1 and B.4.1.1.2) with CATALOGIC to generate biotransformation pathways (European Chemicals Agency, 2018). Furthermore, ECHA compared in this project the degradability of the substances to investigate whether degradation mechanisms are independent from the chain length of the perfluorinated tail.

For the creation of degradation maps of potential PFCA-related substances CATALOGIC v.5.12.1 CATALOGIC 301C (v10.14) was used. Most of the substances were fully within the applicability domain or had only a small percentage of unknown fragments. Only for fluorotelomer iodide, incorrect fragments were identified, and the prediction may therefore not be reliable. Polyfluorinated silanes and perfluoroalkyl phosphinic acids were considered outside of the applicability domain after assessing the type of unknown fragments. The fluorotelomer citrate triester was above the molecular weight limit.

Predicted biodegradation of PFCA-related substances to corresponding PFCAs were in agreement with data from literature listed in chapters B.4.1.1.1 and B4.1.1.2 (exception fluorotelomer thioether amido sulfonate). All structures with n:2 elements (exception fluorotelomer thioether amido sulfonate) were predicted to be transformed via FTOH to PFCAs.

Furthermore, the length of the perfluorinated chain did not impact the biotransformation mechanism. The biodegradation pathways for the PFCA-related substances, which differ only in the chain length of the perfluorinated part, were similar.

In this project ECHA also screened potential related substances of PFHxA (European Chemicals Agency, 2018b). In a pre-processing step, all compounds with the substructure $CF_3(CF_2)_2$ were selected via the query tool in the QSAR Toolbox v4.1. Additionally, structures from a screening exercise (PFASs which are registered under REACH or being a constituent or impurity of a registered substance) were added to the list. Three profilers were created in QSAR Toolbox to identify the target structures within all transformation products (transformation via hydrolysis and biodegradation) of the pre-selected compounds. From 987 structures, 73 were identified as potential PFHxA-related substances (for more details see Appendix B.4.1).

B.4.1.2.4 Conclusion on degradation of PFHxA-related substances

In conclusion, all the presented PFHxA-related substances are degraded to PFHxA by abiotic and/or biotic processes in the environment. For those substances where no degradation studies are available it can be assumed that based on the chemical similarity (supported by modelling evidence) the substances will most probably be degraded in a similar way. Thus, based on the weight of evidence approach, PFHxA will most probably be released in the environment. Hence, these substances need to be considered as important sources of PFHxA in the environment.

B.4.2 Environmental distribution

B.4.2.1 Adsorption/desorption

For PFHxA no results from studies following one of the test guidelines commonly used under the REACH Regulation are known at the moment. Adsorption was tested in different laboratory or semi-natural set-ups.

Vierke (2014) investigated transit of PFHxA and other PFASs in a column (surface areas 1 m^2, length 1 m) under environmental conditions. The column was embedded in a natural slow sand filter basin and fed by the surrounding surface water. As it is supposed to represent riverbank filtration water was saturated. The water, which was checked daily, was pumped through the sediment at a filter velocity of 1.1 m d^{-1}. The column was filled with coarse-grained medium sand, followed by 30 cm gravel. The sand had a content of 0.02 % nitrogen N, 0.07 % organic carbon OC, 0.3 % carbonate C and a C/N-ratio of 16.1. PFHxA and other PFASs were spiked as one initial pulse in the supernatant of the column. Concentration of PFHxA was determined in samples from the supernatant, but also in depths of 40 cm and 80 cm in the column over a period of two weeks. The pH value of the water samples ranged from 7.4 to 7.9. The test substances were mixed with a tracer (here 25 % sodium chloride (NaCl) solution) to quantify the sorption process for every analyte. The sorption R was calculated for every analyte with

$R = t_{50(\text{analyte})} / t_{50(\text{tracer})}$,

with t_{50} (min) being the time at which half of the detected quantity of the tracer or analyte has passed the respective sampling point. The sediment-dissolved partition coefficient (Kd) takes sediment characteristics into account, acknowledging that partitioning in the sediment column is not expected to be at equilibrium. The Kd was calculated with equation

$Kd = \frac{ne}{\rho B} \cdot (R-1)$,

where ρB (in g cm^{-3}) denotes the density of the sediment and ne the effective porosity (dimensionless), which was calculated as ratio of the linear flow velocity (va, in m d^{-1}) and the filter velocity (vf, in m d^{-1}). To describe the relation between partition coefficients and OC content of the sediment OC normalised partition coefficients (K_{OC}) were calculated.

The equation used for this purpose was

$K_{OC} = Kd \cdot \frac{100}{f_{OC}}$,

with f_{OC} being the fraction of OC in the sediment. The distribution coefficient calculated for PFHxA based on the leaching was log K_d = -0.18/0.46 (in 40 cm / 80 cm) and log K_{OC} = 3.0/3.6 (in 40 cm/80 cm) for PFHxA. Furthermore, leaching of PFHxA through the column was faster than for long-chain PFCAs.

Gellrich et al. (Gellrich et al., 2012) also performed a column study. The columns were 60 cm long and 5 cm in diameter filled with loamy sand (LUFA standard soil no. 2.2; soil parameters: OC concentration 2.16 %, 13.9 %, particles < 0.02 mm, pH-value 5.4, cation exchange capacity 10 meq/100g). No distribution coefficient was calculated. But the results confirm the results of Vierke et al. when comparing the breakthrough of PFHxA to long-chain PFCAs: Leaching of PFHxA was always faster compared to longer-chain PFCAs indicating less sorption. Furthermore, long-chain PFASs can displace shorter PFASs from their binding sites in the soil.

For PFHxA, Guelfo and Higgins evaluated for the adsorption/desorption coefficient an average value of log K_{OC} = 1.31 (Guelfo and Higgins, 2013). In this study the adsorption behaviour of various PFAAs in three different soils which were loamy sand (OC content 1.7 %, pH 6.1), loam (OC content 4.5 %, pH 7.8), sandy clay loam (OC content 0.8 %, pH 5.2) were investigated. All soils were dry sieved (2 mm) prior use.

This assessment is supported by the work of Sepulvado et al. (2011) , who investigated the fate of perfluorochemicals in soil. They investigated the presence of various PFASs in sewage sludge of several municipal sewage treatment plants together with occurrence of these PFASs in soils on which the sewage sludge was applied on for agricultural purposes over several years. The investigated soil types were silty clay loam (OC content 4.1 %), fine sand (OC content 1.1 %) and silt loam (OC content 4.7 %). Sepulvado et al. investigated in a first stage the presence of PFASs in the samples, followed by desorption experiments over 14 days to determine the time necessary for the soil-water mixtures to reach equilibrium. The resulting data enabled them to calculate the desorption-based K_{OC} values. The equation used was

$$K_{des} = \frac{C_S}{C_W} = \frac{m_S^0 - m_V - m_W}{m_W} \cdot \frac{V_W}{M_{soil}}$$

where C_S is the concentration of the analyte in the solid phase, C_W is the concentration of analyte in the aqueous phase, m_s^0 is the analyte in the solid phase before desorption, m_V is the mass of analyte lost to the desorption reactor vial, m_W is the mass of PFASs in the aqueous phase at equilibrium, V_W is the volume of the aqueous phase, and M_{soil} is the mass of soil in the reactor. Resulting K_{des} values were then relevant to organic carbon normalized to calculate K_{OC} by

$$K_{OC} = \frac{K_{des}}{f_{OC}}$$

For PFHxA they found the log K_{OC} in the range 1.63 – 2.35.

Zhang et al. (2013a) showed that PFHxA adsorbs to a lower amount to sewage sludge compared to longer-chain PFASs (average distribution coefficient Kd PFHxA 14.8, PFOA 32.4).

Research by Ahrens et al. (2010a) showed that the log K_{OC} of PFCAs increases with the length of the carbon chain (C_8-PFCA: log K_{OC} = 1.09, C_{11}-PFCA: log K_{OC} = 4.8). This assessment is supported by the work of Higgins and Luthy. They also determined an increasing adsorption/desorption coefficient from C_8-PFCA (log K_{OC} = 2.06) to C_{11}-PFCA (log K_{OC} = 3.3) (Higgins and Luthy, 2006). For a more detailed overview please see the read-across information in Appendix A.1 of this document.

Li et al (Li et al., 2011) investigated perfluorinated compounds in the Haihe River and Dagu Drainage Canal in Tianjin, China. They found that PFHxA has a partition coefficient log Kd (sediment and overlapping dissolved phase) in the range of log Kd = 1.4 – 3.1.

Campos Pereira et al. (2018) investigated the effect of cation composition and pH on the sorption of 14 PFASs to an organic soil horizon. For this study a mono layer soil sample with pH 4.8, containing 45 % C, 1.3 % N and 3.4 % ash content on a dry weight basis was used. The sample was sieved < 2mm prior to homogenization, and then stored at 5 °C in its field-moist state with 69 % water content until further use. The sorption was investigated regarding dependence from pH and added concentrations of aluminium (Al^{3+}), calcium (Ca^{2+}) and sodium (Na^{+}) ions. It was found that PFCAs adsorb less strongly than PFAS. For PFHxA the averaged adsorption coefficient was approx. log K_{OC} = 1.3 from all values for the different pH-values and cations added.

In summary the log K_{OC} values for PFHxA reported in the literature range from 1.3 to 3.6. Because no standardised test guideline was followed, the matrices used for measuring the adsorption behaviour differ between the cited studies. Depending on the used matrix there was a varying content of potential adsorption surfaces available to PFHxA because matrices such as sewage sludge and soil differ in composition. They vary in parameters like water content, organic matter or ratio of clay minerals available. Therefore, it has to be kept in mind that adsorption does not only relate to the adsorption on organic matter, but also other binding mechanisms available need to be considered. This was shown by the study of Li et al. (2011).

The technical guidance documents of REACH define a range of log K_{OC} = 3.0 to 4.0 as threshold when a substance can be considered to have high potential for adsorption. In conclusion the available studies show that – compared to longer-chain PFCAs - PFHxA has a lower potential to be adsorbed on organic matter such as sewage sludge or on inorganic constituents that can be found in soil. This information indicates that PFHxA might be distributed more easily within and between the compartments of the environment compared to longer-chain PFCAs and therefore can be evaluated as mobile in the environment.

The environmental distribution of PFHxA especially with respect to a potential for long-range transport and for contamination of drinking water is further evaluated.

B.4.2.2 Volatilisation

Distribution processes are one of the reasons for removal of substances from a certain environmental compartment. Volatilisation describes the removal from the water phase to the overlaying air compartment and can therefore act as a source for emissions to the atmosphere. Depending on the substance properties and the resistance against direct and indirect degradation processes the atmospheric washout and (re-)volatilisation act as a motor for long range transport in air.

The Henry's Law constant describes the tendency of a substance to volatilise from water. It can be calculated by the following equation:

HENRY = VP · MOLW / SOL[5]

Whereas HENRY is the substance specific Henry's Law constant, VP is its vapour pressure, MOLW is its molecular weight and SOL is its water solubility.

Using the information for physical chemical properties from section B.1.2 (estimated VP = 263.93 Pa; measured SOL = 15.7 g/L) the Henry's Law constant of PFHxA is 5.279 Pa · m^3/mol.

For the structurally related substance PFOA the Henry's Law constant reads 0.183 Pa ·m^3/mol when using the equation above together with MOLW = 414.07 g/mol, VP = 4.2 Pa and SOL = 9.5 g/L from the SVHC support document on PFOA (ECHA, 2013b).

Compared to this value the siloxanes octamethylcyclotetrasiloxane (D4, CAS-No. 556-67-2, EC-No. 208-136-7) and decamethylcyclopentasiloxane (D5, CAS-No. 541-02-6, EC-No. 208-764-9) show a dramatically higher tendency for volatilisation. Whereas the Henry's Law constant for D4 siloxanes was determined to be $1.21 \cdot 10^6$ Pa·m^3/mol the value reads $3.34 \cdot 10^6$ Pa·m^3/mol for D5 siloxane (UK HSE, 2015).

This is an indication that PFHxA has a low to moderate tendency to volatilize from water when compared to the threshold for volatile substances (HENRY > 250 Pa·m^3/mol) from REACH Guidance R.16 (ECHA, 2016a). This shows that the aqueous environmental compartments are more relevant for PFHxA compared to the atmosphere. But it does not lead to the conclusion that volatilisation is unlikely.

As already indicated in the first paragraph of this section, (re-)volatilisation acts as a motor for long range transport. Because PFHxA has a photolytic degradation half-life of 20.57 days in the atmosphere the low to moderate volatility adds to the weight-of-evidence that PFHxA has the potential to undergo long-range transport via the atmosphere. Nevertheless, the majority of PFHxA will remain in the water phase. Long-range transport via this route therefore is also likely because the substance will not be subject to biotic or abiotic degradation processes (please see section B.4.1).

B.4.2.3 Distribution modelling

Distribution modelling covers several aspects of distribution of chemicals between different compartments. This covers both, natural and technical environments such as sewage treatment plants.

Wastewater might be treated within an industrial on-site sewage treatment plant and/or municipal sewage treatment plant in the follow-up before it is released into the

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[5] Equation R.16-4; REACH technical guidance document R.16: Environmental Exposure Assessment (ECHA, 2016a)

environment. It can be assumed that municipal sewage treatment plants contain various species of microorganisms that are normally not adapted to chemicals which are used within an industrial setting.

Different methods are available to evaluate the distribution of a substance within a municipal sewage treatment plant. This can be a simulation test in a laboratory with a downscaled sewage treatment plant but using mathematical models is more common. One of the models which is commonly used is the Simple Treat model (here Simple Treat v3.0 (debugged version), ©Dutch National Institute for Public Health and the Environment (RIVM), 1997). The model itself only provides values for the distribution and degradation of the substance in relation to the total amount contained in the influent wastewater, it does not use influent concentrations nor provides concentrations in specific media like effluent water or sewage sludge.

A measured log K_{OC} = 3.0 (Vierke, 2014) was chosen for further distribution modelling as this value represents the upper range of the measured K_{OC} values and therefore shows adequate conservatism for retention capacity in a sewage treatment plant. Using the physical-chemical properties water solubility and vapor pressure for PFHxA from section B.1.2 and the conclusion from section B.4.1 that PFHxA is "not readily biodegradable" the Simple Treat model provides the following distribution pattern:

Table 11: Modelling results for compartmental distribution pattern of PFHxA in municipal sewage treatment plants.

Summary of distribution pattern:	
Air	7.8 %
Water	80.9 %
Primary sludge	8.4 %
Surplus sludge	2.9 %
Degraded	0 %
Total	100 %

From this modelling results it becomes obvious that any PFHxA contained in the influent of municipal sewage treatment plants (or being a stable degradation product from the wastewater treatment process) will be predominantly released to receiving waters. The sewage treatment plant acts as a point source for emissions to the aquatic environment. This is supported by data from environmental monitoring where PFHxA can be found in effluents of wastewater treatment plants (see section B.4.2.4.1 Occurrence of PFHxA in effluents from wastewater treatment plants and landfills and occurrence in receiving waters).

About eight percent might be emitted to air. Therefore, sewage treatment plants may act as a source for releases of PFHxA to air in case PFHxA contained in the influent of municipal sewage treatment plants (or being a stable degradation product from the wastewater treatment process). The emissions will be distributed in the environment leading to indirect exposure of soil and the aquatic compartments, even on a continental or global level (please see section on long range transport potential).

As evaluated in section "B.4.2.1 Adsorption/desorption" the substance shows a moderate tendency to adsorb to sewage sludge. The model predicts that about 11 percent of PFHxA in the influent will adsorb on sewage sludge. Just because application of sludge from municipal sewage treatment plants for agricultural purposes still is common practise in several European countries, PFHxA will be transferred to the terrestrial compartment. Sludge application therefore is one pathway for indirect exposure of soil and groundwater.

B.4.2.4 Measured levels in environmental compartments

Field data

All monitoring studies summarized below and in Appendix B.4.2 have not only detected PFHxA but also its longer and shorter chained PFCA homologues as well as PFSAs and in some cases related substances compounds. A review on monitoring studies summarised that PFASs were ubiquitously found in the aqueous environment and that about 40 individual PFASs were detected (Ahrens, 2011).

B.4.2.4.1 Occurrence of PFHxA in effluents from wastewater treatment plants and landfills and occurrence in receiving waters

PFHxA is found by various studies in effluent and sludge of wastewater treatment plants (WWTPs) and landfill leachates. Some of the studies (Ahrens et al., 2009b; Loi et al., 2013; Nguyen et al., 2019) also looked for pre-cursors in influent, effluent and sludge of WWTPs. Though PFHxA was not detectable in influent and effluent and sludge in the analysis of (Loi et al., 2013) diPAPs could be quantified. As there is no industrial source in this area (Hong Kong), this result shows that pre-cursor containing consumer products are a source for PFHxA. Likewise, the study by Nguyen detected higher concentrations of the related substance 6:2 FTS than PFHxA in two Australian WWTPs. Only one study investigated influents over several years (Nguyen et al., 2019). Here daily influent samples were collected over one week at different seasons from 2014 to 2017. In this study for one of the two investigated WWTPs a significant positive trend for PFHxA was observed indicating a shift to short chained alternatives. Concentrations of PFHxA are lower in sludge than in effluent water. Concentrations of PFHxA in WWTP effluents range between < 0.25 to 57 ng/L with the hightest measuered value for WWTP at the River Elbe. Efluents were measured across Europe (e.g. Germany, Austria and Norway) aswell as in Nigeria, Australia and Hong Kong. Concentration found in sludge range between <0.0105 and 0.2458 ng/g d.w. Findings in landfill leachates are considerably higher ranging from < 0.37 ng/L to 4256 ng/L. All data compiled in Table 45 of Appendix B.4.2 are published in peer reviewed papers. The papers include a detailed description of the sample preparation, the analytical method used and analytical quality control and therefore are regarded as reliable. The table provides data from examples of currently available studies. In regard of its anticipated short history PFHxA has not been covered by monitoring studies as long as e.g. PFOA or PFOS.

B.4.2.4.2 Occurrence of PFHxA in surface water and oceans

PFHxA has been detected in several surface waters as well as oceans (see Table 46 in Appendix B.4.2). Concentrations in surface water is generally higher than in oceans. Nevertheless, the picture is relatively heterogeneous for surface water with concentrations from below the limit of quantification or detection up to 77 ng/L at different sites in the River Rhine and 3040 ng/L at different sites in the Moehne River and 1248 ng/lL in surface sample at different sites in the Ruhr area for instance (Skutlarek et al., 2006). This indicates a relatively high pollution with PFHxA. Concentration of PFHxA in Norwegian and Finnish rivers ranged between 0.1 – 7.97 ng/L ((Norwegian Institute for Water Research (NIVA), 2017c); unpublished data, available in database https://wwwp2.ymparisto.fi/scripts/kirjaudu.asp, 2018). In Guadalquivir and Ebro rivers (Spain) concentrations range between 9.6 – 31.4 ng/L. At the Ai River around a fluoropolymer plant within a 5 km radius of the plant in Osaka (Japan) 26.2 – 1130 ng/L PFHxA was measured. These results are comparable to the findings in the samples from the Ruhr area. Levels of PFOA decreased greatly, whereas those of PFHxA increased at the Ai river indicating a shift from longer chained PFASs to shorter chained PFASs. Samples were taken from 2003-2015 (Shiwaku et al., 2016). In comparison 40 river samples across the Hyogo prefecture, Japan showed concentrations from < 0.5 - 6.9 ng/L whereas in the same study 38 seawater samples across the Hyogo prefecture had concentrations ranging from 1.5 – 510 ng/L and therefore show higher concentrations (Takemine et al., 2014). Nevertheless, concentration in surface water is generally higher than in oceans.

Several samples taken during cruises into the Northern Atlantic, Canadian Arctic Ocean and Southern Atlantic Ocean show concentrations of PFHxA from < 0.0024 to 0.120 ng/L ((Benskin et al., 2012b); (Ahrens et al., 2010b); (Zhao et al., 2012)). Higher concentrations were found in the German Bight near human activities with concentrations ranging between 0.47 – 9.56 ng/L (Ahrens et al., 2009a). Together with findings also in the deep sea at Cap de Creus Canyon (north-western Mediterranean Sea) in sedimentary particles with concentrations of 0.89 to 4.47 ng/g (depth of 300 m) and 4.57 to 10.66 ng/g (depth of 1000 m) these data show a wide spread occurrence of PFHxA even in areas where human activity is expected to be low.

B.4.2.4.3 Occurrence of PFHxA in drinking water resources and drinking water

Several studies report findings of PFHxA in groundwater and drinking water (please see Table 47 and Table 48 in Appendix B.4.2 with findings in surface and groundwater). All data compiled are published in peer reviewed papers. The papers include a detailed description of the sample preparation, the analytical method used and analytical quality control and therefore are regarded as reliable. Drinking water is mainly obtained from groundwater as well as from surface water.

The study of Gellrich et al. (2012) shows higher concentrations and frequency of detection (FOD) for PFOA in surface water than the short-chain PFASs such as PFHxA and Perfluorobutanoic acid (PFBA). In groundwater, however, this study did not detect PFOA unlike the short-chain PFASs indicating a higher mobility of the short-chain PFASs (Gellrich et al., 2012). However, as monitoring data not only reflect the intrinsic properties of a substance but depend on its tonnage, uses and emmissions the results are not always this clear.

Having in mind the specific properties of PFHxA it is assumed that the substance will be able to pass natural barriers in the environment and further distribute from surface water via bank filtration into sources of drinking water respectively from sewage sludge applied on agricultural soil into ground water used for drinking water purposes.

The sources of raw water used for drinking water production differ between the Member States of the EU. In average about 50 percent of the water for drinking water production is taken from groundwater, whereas the amount from surface water is about 36 percent (European Commission, 2016). Bank filtration is used to a varying degree in several Member States. According to the European Commission report from 2016 in Hungary about 40 percent of the raw water is obtained from bank filtration whereas in the majority of the Member States no use of bank filtration was reported.

In Germany about eight percent of the raw water is obtained by bank filtration. Additionally, 13 percent of the raw water is taken directly from surface waters like rivers or basins whereas about 60 percent is pumped ground water (Statistisches Bundesamt, 2015). The use of surface water as drinking water source may be in some regions also significantly higher. E.g., the City of Helsinki, Finland, acquires practically its complete drinking water from lake water[6].

PFHxA is also found in drinking water or tap water in the low ng/L range between 0.31 and 6.4 ng/L. The reported percentages of concentrations above the limit of detection or quantification range for instance between 6.3 % in Germany outside Ruhr area and in the Ruhr area to 66.6 % in samples from 26 waterworks along the Ruhr River (Skutlarek et al., 2006). The highest reported percentage was reported for tap water samples from six European Countries (Sweden, Italy, Belgium, Netherlands, Norway and Germany). PFHxA was found in concentrations between < 0.38 – 5.15 ng/L in 86 % of the samples (Ullah et al., 2011). Austria reported drinking water /ground water concentrations of PFHxA up to 4.7 ng/L with a detection rate of 32.4 % (n = 37, limit of detection = 1 ng/L, sampled in 2018)

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[6] https://www.hsy.fi/en/residents/water/where-does-your-drinking-water-come-from/Pages/default.aspx (last access: 13.12.2019).

(personal communication). Concentrations of PFHxA in tap water range between 0.31 and 6.4 ng/L and are below the German guide value for drinking water (Trinkwasserleitwert) of 6 µg/L. However, in the light of the persistence of PFHxA and the difficulty to remove PFHxA from water, the concentration of PFHxA will increase if emissions to the environment – also from degradation of related substances – continue.

Concentrations in groundwater are below the limit of quantification up to 95 ng/L (von der Trenck et al., 2018). In observation wells downstream of potential PFAA sources in the Nethelands in a groundwater recharge area where sources are present (a former landfill, a military base and a small commercial /industrial area) concentrations ranged between 0.7 - 570 ng/L. In five pumping wells with a travel distance > 25 years approximately (based on hydrological modelling and tracers) concentrations ranged between 0.22 – 0.8 ng/L (Eschauzier et al., 2013). In comparison groundwater from an unlined firefighter training area at Ellsworth U.S. Air Force Base (AFFF used between 1970 and 1990) was especially highly contaminated with concentrations ranging between < 100 – 320 000 ng/L (Houtz et al., 2013). Well water of two wells near a fluoropolymer plant in Osaka, Japan had concentrations of PFHxA ranging between 64.3 - 220 and 110 – 970 ng/L (Shiwaku et al., 2016).

It has to be considered that not all of the groundwater dwells used for sampling in these studies are used for drinking water production. They might also be used for industrial or agricultural applications or even just for sampling (please see Appendix B 4.2. Table 48).

B.4.2.4.4 Occurrence in soil and sediment

In addition to the above given data on PFHxA in surface water, groundwater and drinking water, PFHxA is also found in soil and sediment. All data compiled are published in peer reviewed papers or reports. The papers include a detailed description of the sample preparation, the analytical method used and analytical quality control and therefore are regarded as reliable. Most reported findings of PFHxA in soil are from contaminated sites either former firefighter training area or accidental contamination. In soil (0.6 m below surface; n = 16) and aquifer solids (5 - 6 m below surface; n = 10) from an unlined firefighter training area at Ellsworth U.S. Air Force Base (AFFF used between 1970 and 1990) < 0.8 – 2 000 µg/kg and 16 – 210 µg/kg PFHxA were detected respectively (Houtz et al., 2013). Another study which investigated the same area reported a concentration range between < 0.05 – 2 761 µg/kg in soil and 0.445 – 297 µg/kg in aquifer solids (McGuire et al., 2014). With 0.18 – 18.5 µg/kg based on dry weight considerably lower concentrations were detected in soil from a fire-fighting training ground at Flesland airport, Norway (Klima- og forurensningsdirektoratet (KLIF), 2010). In comparison for soil of five stations in Oslo, Norway 0.00043 µg/kg based on dry weight are reported.

PFHxA is more water soluble than other PFASs and thus less likely to bind to sediment (Higgins and Luthy, 2006) and might be present mostly in pore water, rather than bound to the particles of the sediment (Ahrens et al., 2009c; Zhao et al., 2012). Therefore, in their study, (Codling et al., 2018) did not exclude pore water. This approach reflects the conditions in the sediment water interphase and thus the compounds that benthic organisms will be exposed to and might enter the food chain after contamination. In this study in sediment from Lake Erie with layers in the core corresponding to 1959 to 2013, concentrations of both PFOS and

PFHxA increased from earlier to more recently deposited sediments. More details are given in Table 49 in Appendix B.4.2.

B.4.2.4.5 Case example for agricultural soil and drinking water contamination with PFHxA

There are several examples of environmental contamination from the intentional (e.g. use of fire fighthing foam) or unintentional (e.g. use of contaminated soil improver) release of per- and polyfluoroalkyl substances like PFOA and PFHxA from all over Europe and also worldwide. One of these examples is from Rastatt, Germany. Concentrations of PFHxA at this contaminated site range between 3.1 to 32.3 µg/kg soil. The situation and problems in Rastatt have been summarised by Brendel et al. (2018). PFHxA is one representative of short-chain PFASs referred to in the following text quoted from Brendel et al. (2018):

"In the surroundings of Rastatt (Baden-Wuerttemberg, Germany), 480 hectares of former arable land are contaminated with short-chain PFAAs and precursors. The pollution was detected in 2013 and has probably been caused by the longstanding application of compost mixed with sludge from paper production, contaminated with various precursors. Over time, the precursors contained in the soil degraded to short-chain PFAAs and were enriched in plants. Local authorities derived thresholds for short-chain PFAAs in food (in the µg/kg range) [72], based on guidance values for drinking water [73]. Pre-harvest monitoring showed that the concentration of short-chain PFAAs in some crops exceeded these thresholds, preventing the use as food. Crops enriching high amounts of short-chain PFASs are recommended not to be cultivated for consumption on these contaminated fields (e.g. strawberries as well as asparagus and other vegetables). Despite the recommendations for cultivation, threshold values are in parts exceeded to date. This might be due to a strong influence of insufficiently predictable abiotic factors, such as organic carbon content, on the enrichment of short-chain PFASs in plants [74]. Over time, the very mobile short-chain PFASs and precursors in the soil also wash out into the groundwater. Irrigating crops with contaminated water are causing further emissions to soil and uptake into plants. Two groundwater wells for drinking water production had to be closed [72]. For several years, the dimension of the contamination and the problems arising with the contamination of short-chain PFASs has not been recognised. Estimations addressing all adverse environmental effects and socio-economic costs resulting from the contamination are not available, but according to information given by the water work solely the cost for water treatment with charcoal filters amounts to several million Euros. Until now, no practicable solution for removing the short-chain PFASs from the soil or groundwater has been found. Effective solutions, such as a removal and replacement of the top soil or "pump and treat" methods, would be far too expensive. Furthermore, there are still high concentrations of short-chain PFASs and unknown precursors contained in the soil and there is no applicable solution for stopping them from reaching the groundwater. Research to find an appropriate solution is ongoing. This Rastatt case clearly shows that once emitted to the environment, short-chain PFAAs cause irreversible contaminations, and thus causing high socio-economic costs and threats to man and environment." (Brendel et al., 2018)

Within this quote, cited references are:

72. Citizen information Rastatt. http://www.landkreis-rastatt.de/,Lde/PFC.html. Accessed 15 Jan 2018

73. German Environment Agency (2017) Fortschreibung der vorläufigen Bewertung von per-und polyfluorierten Chemikalien (PFC) im Trinkwasser (in German). Bundesgesundheitsblatt 60:350–352

74. Blaine AC, Rich CD, Sedlacko EM, Hyland KC, Stushnoff C, Dickenson ER, Higgins CP (2014) Perfluoroalkyl acid uptake in lettuce (Lactuca sativa) and strawberry (Fragaria ananassa) irrigated with reclaimed water. Envi-ron Sci Technol 48:14361–14368

B.4.2.4.6 Indirect exposure of humans via the environment and food

Sources of human exposure include food, drinking water, house dust, air and dermal contact to consumer articles. Apart from the exposure via the environment, also articles are a significant source of PFHxA for direct human exposure. Relevant articles such as furniture, textile and leather care articles or cosmetics are placed on the market and used in all EU Member States. A considerable share of articles containing PFHxA or related substances is imported from outside the EU.

Occurrence data were collected in the food surveillance programmes of Germany, in particular in the national monitoring and the federal control plan.

The national monitoring is a measurement programme in which foods from the German market are systematically examined for the presence of unwanted substances. It is performed jointly by the Federal Government and the Federal States. The national monitoring consists of pre-planned samples and thus aims on providing a realistic picture of the situation on the market.

The federal control plan is a risk-oriented monitoring programme. It consists of a yearly plan aiming at monitoring the compliance inter alia with food regulation. Therefore, it also consists of samples which were drawn based on some suspicion and may distort a realistic picture of the market situation. In the present evaluation these samples were not removed as they do not interfere with the aim of demonstrating the presence of PFHxA in food. The same is true for the very little number of risk-oriented samples that do not belong to one of the mentioned programmes.

The used data were collected between 2005 and 2018 and submitted by the Federal Office of Consumer Protection and Food Safety (BVL). In total, they consist of 3116 samples which were analysed for the presence of PFHxA. Of these, 3001 (96.3 %) were below the limit of quantification (LOQ) and 2933 (94.1 %) below the limit of detection (LOD). In the statistical analysis, these left-censored data were treated in the following way: Samples below the level of detection were replaced by zero. Samples below the level of quantification but above the level of detection were set to the level of detection. This approach is called the "modified lower bound" and gives the lowest possible value based on the available information. It was chosen here to only present non-zero values for samples where any amount of PFHxA was detected. The median LOD and LOQ for the samples is the same, being 1 µg/kg with an interquartile range of 0.5 µg/kg (LOD) and 1 µg/kg (LOQ).

Table 12: Overview of the PFHxA occurrence data from German food monitoring programmes.

Group	**N total**	**N > LOD**	**N > LOQ**	**Mean [µg/kg]**	**P50 [µg/kg]**	**P95 [µg/kg]**	**Max. [µg/kg]**
cereals	19	9	8	2.05	0	9.80	9.80
fish and seafood	1 180	107	71	0.17	0	1.25	15.00
fruits	173	4	3	0.03	0	0	1.80
meat and meat products	851	37	17	0.05	0	0	3.40
milk	70	1	1	0.006	0	0	0.006
mushrooms	78	3	0	< 0.01	0	0	0.12
potatoes and potato products	144	15	14	0.15	0	1.42	1.93
vegetables	601	7	1	0.02	0	0	3.10

Table 12 summarizes the monitoring data. Foods were grouped to general groups because of the low number of detects – for all groups except "fish and seafood" the number of detects is below 100, and below 20 for all other except "meat and meat products". Also, for some samples more detailed information to further specify the food category was not available.

Still, the groups consist mainly of foods that are regularly consumed by the German population (e.g. the vegetable group consists mainly of tomatoes, cabbages, carrots, salad, onions, etc.). The main exception is the "meat and meat products" group, which contains a large amount of liver and /or game samples and the "fruits" group of which about 100 samples are taken from strawberries.

In all food groups there is at least one value above the level of detection. The data from the German monitoring programme thus supports the presence of PFHxA in food. The percentage of detects is not very high, but it cannot be finally concluded whether this is due to the analytical limits or whether PFHxA is not that widely distributed up to now. Several detects are already from 2005 to 2010 and a time trend could not be derived by the underlying data.

Data from literature

A first search for the terms "PFHxA" or "Perfluorohexanoic" and "Food" or "Dietary Exposure" was performed on PubMed, Scopus, SciFinder, Web of Science and Science direct and yielded in total 89[7] sources. Each of the sources was further filtered using the following criteria:

1. Does the source contain occurrence data for PFHxA in food? (Exclude if no, 60 excluded)
2. Were the foods bought on markets inside the EU? (Exclude if no, 14 excluded)
3. Are any reported values above the LOD? (Exclude if no, 5 excluded)

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[7] For two sources the full text could not be obtained in time.

The first filter excludes references which are not relevant for PFHxA or dietary exposure. The second filter was applied, as a REACH restriction is only concerned with the European situation. The last filter was necessary because a large fraction of values is below the level of detection. Still, many sources opted to report upper bounded values (i.e. non-detects were set on the level of detection). This would compromise the aim of demonstrating the presence of PFHxA because most of the reported values would not be actual detects but reported upper bound concentrations. The five papers excluded due to criterion three might be interpreted as a further indication of low prevalence of PFHxA in food up to now. After applying these filters, ten sources remained and were further analysed. One additional source (Herzke et al., 2013a), was identified from the references of these screened sources and added to the analysis.

In a second search the first requirement was relaxed to the search term "perfluoroalkyl*" to also identify sources which did not list perfluorohexanoic acid explicitly but still measured it. From that second search, one additional source (Rivière et al., 2014) was classified as relevant. This source is referred to as (ANSES, 2011) because the latter document provides more detailed information on the results, which are from the Second French Total Diet Study (TDS).

The resulting references are summarized in Table 24 with the exception of (EFSA, 2012), which will be summarized separately. Only values above the level of detection were used in the summaries for the same reasons as explained above. Not all studies presented their results in the same way. Some reported single values for each food item, some only mean values. Some reported the values already aggregated to food groups, some provided detailed information of the specific food items. The latter ones were also aggregated to appropriate food groups for the sake of brevity. As it is the aim of this section to demonstrate the presence of PFHxA in food, this was not seen as an obstacle; however, the values cannot necessarily be compared from one study to another.

The heterogeneity of the studies also impedes the comparison with the results from the national monitoring. The literature generally reports lower values which is likely in large parts caused by lower detection limits (e.g. (Vestergren et al., 2012b) reports an MDL of 2.4 ng/kg and (Herzke et al., 2013a) a MQL between 2 and 50 ng/kg depending on type of PFAS).

One report, (EFSA, 2012), was excluded from the table because the data presented were collected from the national monitoring programmes of the member states of the European Union as well as from the PERFOOD project (Herzke et al., 2013b; Klenow et al., 2013; Vestergren et al., 2012a; Vestergren et al., 2012b). The former has overlap with the already presented data from the German monitoring program, the latter with some of the results presented in Table 24. In general, EFSA also reports large numbers of non-detects across all considered food groups. They also report lower and upper bound mean values. In comparison with Table 24 the reported lower bound values are lower and the upper bound values higher which is consistent with the different treatment of non-detects in the data analysis.

In general, also the data from the literature thus support the presence of PFHxA in food.

B.4.2.5 Summary and discussion of environmental distribution

PFHxA will not degrade under environmentally relevant conditions. The rate of degradation is unlikely to be measurable within the time frame of standard screening or simulation tests. Data from LC-PFCAs (longchain-perfluoroalkyl carboxylic acid/ perfluoroalkyl carboxylate) indicate that the tendency for adsorption increases with the length of the fluorinated carbon chain. Studies on adsorption behaviour of PFHxA show log K_{OC} values in the range of log K_{OC} = 1.3 to 3.6.

The data on the adsorption behaviour indicates that PFHxA is a substance with moderate tendency to adsorb on organic matter and desorption is likely to occur. Compared to substances like D4/D5-siloxanes the volatility of PFHxA from water is about six orders of magnitude lower. Once emitted to water PFHxA will predominantly remain in the water phase. Because of its higher water solubility compared to PFOA and LC-PFCAs PFHxA can be distributed more easily within aqueous phases. In conclusion PFHxA is mobile in the aquatic environment and capable to reach remote aquatic areas or groundwater which was already proven by monitoring studies.

Monitoring data and physicochemical properties show that PFHxA will preferentially distribute in the aquatic environment (Ahrens and Bundschuh, 2014), including ground water. Due to the low adsorption coefficient, PFHxA cannot efficiently be removed in conventional water treatment plants, resulting in direct emissions in the aquatic environment (Zhang et al., 2013a). The environmental distribution of PFHxA illustrates a high potential to reach drinking water resources. This has been supported by several studies reporting findings of PFHxA in for example tap water. PFHxA has also been monitored in food (see Table 12).

B.4.3 Data indicating potential for long-range transport

The physical-chemical properties of PFHxA together with the data on persistence and the calculated atmospheric half life of 20.57 days indicate that the substance is capable to be transported to remote areas. To substantiate this assumption, the long-range transport potential was modelled using the OECD tool for estimation of the Long-Range Transport Potential (LRTP-Tool; ©OECD, 2009) which is a spreadsheet formation containing multimedia fate models.

Using the adsorption coefficient log K_{OW} = 2.3 and the air water partition coefficient log K_{AW} = -2.66[8] as input parameters, the tool provides information for the characteristic travel distance (CTD, indicating the distance from a point source at which the chemical's concentration has dropped to 38 % of its initial concentration) and overall environmental persistence (P_{ov}) of PFHxA resulting in a CTD = 9598 km and a P_{ov} = 347 days.

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[8] calculated from HENRY constant (please see section B.4.2.2 Volatilisation), using equation R.16-5 from REACH Guidance R.16

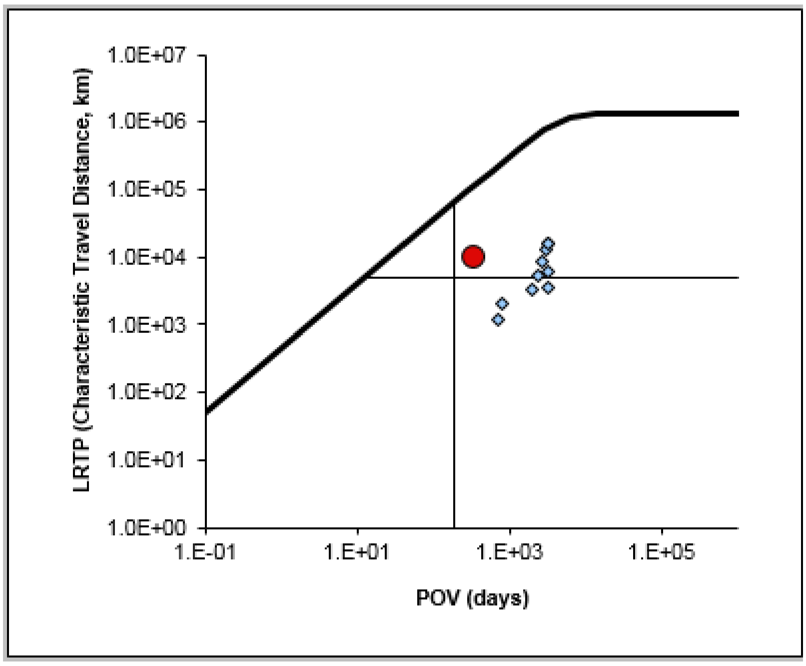

Figure 3: *Characteristic Travel Distance (CTD) and overall persistence (P_{ov}) of PFHxA and selected reference substances.*

Figure 3 shows the graphical output for the calculated CTD and P_{ov} for PFHxA (red dot) and seven chlorobenzenes which act as reference substances (blue squares). Substances with CTD and P_{ov} values of this magnitude are considered to show a high long-range transport potential.

Armitage et al. (Armitage et al., 2006) evaluated the oceanic long-range transport of perfluorooctanoate by using the GloboPOP model. The modelling provided a reasonable agreement to measured values in non-coastal areas where an impact from direct emissions can be assessed as negligible. This was especially true for areas in the north and the middle of the Atlantic Ocean, but also for regions in the northern polar zone. Armitage et al. concluded that long-range oceanic water transport is an important source for perfluorooctanoate that is found in the Arctic.

PFHxA has no known natural source. Nevertheless, different studies report findings of PFHxA also in remote regions which serve as evidence for long-range transport potential. Four examples are given in Table 50 in Appendix B.4.3. As shown in the literature (Kirchgeorg et al., 2013; Kirchgeorg et al., 2016), atmospheric decomposition is beside the transport via the water phase the major pathway of transport. Volatile related substances such as 6:2 fluorotelomer alcohol (6:2 FTOH) might contribute to a large amount to the long-range transport of PFHxA (Young and Mabury, 2010). PFHxA was also found in the air in remote regions such as the Norwegian Polar research station Zeppelin with a high detection frequency in 2013 but only detected in approximately 20 % of the samples in 2016 (Norwegian Institute for Air Research (NILU), 2014; Norwegian Institute for Air Research (NILU), 2015; Norwegian Institute for Air Research (NILU), 2016; Norwegian Institute for Air Research (NILU), 2017b).

For comparison PFOA has been found in the Canadian Arctic in concentrations ranging from 0.0065 ng/L to 0.047 ng/L in the Canadian Arctic (Benskin et al., 2012b). In snow samples from the European Alps PFOA has been found in concentrations ranging from 0.2 - 0.6 ng/L

(Kirchgeorg et al., 2013). Latest data from the Norwegian Zeppelin station ranged from 0.04 to 0.42 pg/m^3 (Norwegian Institute for Air Research (NILU), 2018a).

Even though the concentrations of PFHxA in remote areas are low they are a strong indicator for long range transport.

B.4.4 Bioaccumulation

In accordance with the numeric criterion as suggested in REACH Annex XIII (sections 1.3.2 and 3.2.2(a)) the potential for bioaccumulation is generally assessed by conducting a bioaccumulation test on fish. This approach, however, only addresses one compartment i.e. water and water breathing organisms i.e. fish. A comparative analysis of a homologues series of C7-C14 PFCAs and lipophilic organohalogens in an Arctic Marine Food Web by Kelly et al. (Kelly et al., 2009) shows an efficient respiratory elimination in water-respiring organisms due to high water throughput and high water solubility of PFCAs but very slow elimination and biomagnification in air-breathing animals of PFCAs. Acccordingly PFOA and PFHxS have been identified as PBT substances on the basis of their half-lives in humans (ECHA, 2013a; ECHA, 2017) and the C_9 and C_{10} PFCAs on the basis of biomagnification and trophic magnification in food webs including air-breathing homeotherms (ECHA, 2015b; ECHA, 2016b). Likewise, for PFHxA with its high water solubilty bioaccumulation in fish this may not be the most relevant endpoint to look at.

B.4.4.1 Bioaccumulation potential of PFHxA from laboratory and field studies

The biomagnification as well as the bioconcentration of short-chain PFAS in laboratory studies with fish is low. Martin et al. (Martin et al., 2003a; Martin et al., 2003b) conducted a bioconcentration and a biomagnification study with *Oncorhynchus mykiss*. Both studies investigated a homologous series of perfluoroalkyl carboxylates and sulfonates. Carboxylates and sulfonates with perfluoroalkyl chain lengths shorter than seven and six carbons, respectively, could not be detected in most tissues and were considered to have insignificant bioconcentration factors (BCFs). For detectable PFASs, carcass BCFs increased with increasing length of the perfluoroalkyl chain. Equivalenty the depuration rate constants in the dietary study decreased as the length of the fluorinated chain increased.

For the bioconcentration test juvenile rainbow trouts (*Oncorhynchus mykiss*) were exposed to a 1 000-fold dilution of the stock perfluorinated acids (PFAAs: C5 - C14) solution in a flow-through exposure design for 12 d, followed by 33 d of depuration in clean water. The water borne concentration in the bioconcentration study was 1.7 µg/L. Fish growth was monitored by weighing the total biomass. Three fish from the exposure tank and one from the control tank were sampled at each predetermined interval during the uptake phase of the experiment (4.5, 9, 18, 36, 72, 144, and 288 h). At 288 h, the remaining fish were transferred to new aquaria receiving clean water. During the depuration phase, three fish from the treatment tank and one from the control tank were sampled at each time interval (4.5, 9, 18, 36, 72, 144, 288, 456, and 792 h). During the uptake phase, water samples were collected below the surface at 0.25, 4.5, 12, 18, 36, 72, 144, 197, 244, and 288 h. Water samples were also collected at 48 and 96 h of the depuration phase from both tanks to check for contamination.

Sampled fish were anesthetized. The gut, consisting of esophagus, stomach, pyloric ceca, spleen, and intestines, was removed but not analyzed. The blood, liver, and carcass samples were analyzed separately for PFAAs at each sampling time to determine the kinetics of uptake and depuration. PFAAs were analysed by liquidchromatography–tandem mass spectrometry. PFAAs were not radioalabeled.

For the biomagnification study juvenile rainbow trouts (*Oncorhynchus mykiss*) for 34 days to PFCAs in the diet, followed by a 41 day depuration period were used. Though, the authors describe their results as bioaccumulation factor (BAF) the results of this study should rather be assigned as biomagnification factor (BMFs) as uptake only derived from the diet. During the uptake period, animals were daily fed with spiked food at a rate of 1.5 % food per body weight. Spiked food concentrations were 0.52 µg/g for PFHxA. Water samples collected before and after feeding revealed no traces of PFCAs in water. At six occasions during uptake period and during depuration period, fish were removed to determine the kinetics of uptake and depuration. The authors estimated the steady state to be reached after ten days. Carcass and liver concentrations were determined by using liquid chromatography-tandem mass spectrometry, and kinetic rates were calculated to determine bioaccumulation parameters. PFAAs were analysed by liquidchromatography–tandem mass spectrometry. PFAAs were not radioalabeled.

Both studies did not detect PFHxA in the investigated fish tissues and the biomagnification study concluded that the bioaccumulation potential of PFHxA was expected to be negligible, BAF < 0.1. The food borne concentration was 0.52 µg/g with uptake phases of twelve and 34 days respectively. No limits of detection in the studies are reported, otherwise the studies are regarded as reliable with a Klimisch code of 2.

Casal et al. (2017) reported bioaccumulation factors of 2.7 – 2.8 for oceanic plankton from the Indian Ocean for PFHxA. For comparison bioaccumulation factors ranged between 3.9 to 4.6 for PFOA and between 2.8 to 4.6 for PFOS. The BAF was determined from the concentration in plankton divided by the average seawater concentration.

B.4.4.2 PFHxA in biota and humans

Compared to some representatives of the long-chain PFAS there are very few monitoring data available for PFHxA in biota. Data on biota in Table 53 in Appendix B.4.5 and on humans in Table 54 to Table 58 in Appendix B.5 have either been published in peer reviewed papers or reports also containing of a detailed description of the sample preparation, the analytical method used and analytical quality control and therefore are regarded as reliable. The examined monitoring studies, with data from contaminated and uncontaminated sites, do not allow concluding on a possible bioconcentration or trophic magnification. In comparison with other long-chain PFASs such as PFOA, which is frequently found in biota and human serum, PFHxA concentrations in biota and human serum, urine and breast milk samples are more often reported below the limit of detection. In studies where PFHxA has been frequently detected (> 50 %) in human serum the arithmetic mean of PFHxA is either 0.9 ng/mL using ND = LOD/2 or 1.4 ng/mL using ND = LOD (Frisbee et al., 2009). This study has been conducted in the framework of the C8 Health Project: a population study created to gather data that would allow class members to know their own PFOA levels and permit subsequent epidemiologic investigations. Serum samples were analyzed for ten PFASs. PFHxS, PFOA, PFOS and PFNA were detectable in almost all (> 97 %) samples. Li et al. (2017b) report a median concentration of 0.01 ng/mL PFHxA and a mean concentration of 0.07 ng/mL PFHxA in serum. In this study, eight perfluorinated alkyl substances and five thyroid hormones were determined in 202 human serum samples of the general population of Guangdong, Guangxi and Hainan provinces in southern China. PFHxA was found in all urine samples in Austrian adults aged 25-46 with a median creatinine adjusted concentration of 1.6 ng/L (Environment Agency Austria, unpublished data (publication in preparation)). PFHxA was also found in breast milk with a high frequency in South Korea with a median of 0.047µg/L (Kang et al., 2016).

It should be noted that there are obvious differences in the distribution patterns of PFCAs. For instance, the proportions of short-chain PFHxA shows large differences between serum (2 %) and the non-invasive samples (urine: 23 %; hair: 76 %) in a study conducted by Kim and co-Workers (Kim et al., 2019). Similar compositions of PFCAs and PFSAs were found in serum (PFCAs: 46 %; PFSAs: 54 %), while relatively higher proportions of PFCAs were observed in urine (97 %) and hair (71 %) in this study. In addition, the concentrations and frequency of detection (FOD) values of short-chain PFCAs were higher in urine and hair than in serum. PFHxA concentrations in human serum are often reported below the limit of detection. However, urine might be a more appropriate matrix for biomonitoring of PFHxA.

PFHxA has been shown to occur in several human tissues (Perez et al., 2013). PFHxA was found in lung, brain, liver, kidney and bone. PFHxA represented the highest median PFAS-concentrations in brain and liver (brain: mean 180 ng/g and median 141 ng/g; liver: mean 115 ng/g and median 68.3 ng/g wet weight). The concentrations of 21 PFASs were analysed from 99 samples of autopsy tissues (brain, liver, lung, bone, and kidney) from 20 subjects who have been living in Catalonia, Spain. PFHxA showed the highest concentrations in the brain and liver. In brain, mean concentration of PFHxA was higher than all other PFAS and was detected in all the samples at concentrations ranging from 10.1 to 486 ng/g. In liver, PFHxA was detected in the samples at concentrations up to 353 ng/g. In general terms, the highest concentrations of PFASs were found in lung tissues (PFHxA mean: 50.1 ng/g and median 207 ng/g, ranging up to 559 ng/g). Mean concentrations of PFHxA in the bone and kidney were 36 and 6 ng/g. Results from this study support the conclusion that the substance is distributed to multiple organs of the human body.

19 PFASs were investigated in human milk collected in Stockholm (1972–2016) and Gothenburg (2007–2015), Sweden (Nyberg et al., 2018). A declining trend was observed for PFHxA.

Trend analysis of PFHxA in herring gull eggs from the North as well as the Baltic Sea show a negative trend from 1988 to 2017 (German Environmental Specimen Bank, unpublished data). However, there is a significant increasing trend for other short-chain PFAAs in the liver samples of cetacean species from 2002 to 2014 (Lam et al., 2016). For instance, the ratio of perfluorobutanesulfonic acid (PFBS) as an alternative to PFOS has significantly increased due to restriction /voluntary withdrawal of the production and use of PFOS. The concentrations of PFHxA in biota may increase in future if PFHxA is used as an alternative for restricted PFAAs. Due to the extreme persistence of PFHxA, newly emitted PFHxA will add to what is already there, leading to a build up of the substance in the environment over time.

Concentrations of PFHxA in biota are summarised in Appendix B.4.5 and concentrations in human body fluids are summarised in Table 54 to Table 58 (Appendix B.5). In the examined studies PFHxA was detected in biota mainly in the low nanogram per gram range (< 0.04 - 2.22 ng/g ww). Solely, Llorca et al. (2012b) reported higher concentrations in fish and algae listed in the table in Tierra del Fuego. In this study the highest concentrations of PFHxA were monitored in penguin dung (17.3 - 237 ng/L) and guano (< LOQ - 2480 ng/L). PFHxA was also the predominant substance in algae and guano.

B.4.4.3 Half-lives of PFHxA in humans and animals

Regarding the evaluation of the bioaccumulation potential, elimination half-lives have been proven to be of importance for long-chain PFASs. Elevated levels of PFOA in human blood and a half-life in humans of 2-4 years lead to the conclusion that PFOA is bioaccumulative (ECHA, 2013b).

In general, the reported half-lives for PFHxA in mammals are considerably lower when compared to PFOA. Half-lives of PFOA in mice, rats, pigs and monkeys are up to one order of magnitude higher compared to PFHxA, ranging from 0.08 days in female rat, 236 days in pig and several years in humans.

For further details see chapter B.5.1 Toxicokinetics (absorption, distribution, metabolism and elimination) and Appendix B.5.1.

B.4.4.4 Protein binding of PFHxA

The affinity of PFAAs to proteins is chain-length dependent and increases up to a certain number of perfluorinated carbons depending on the protein (Ng and Hungerbühler, 2014; Zhang et al., 2014; Zhang et al., 2013c). The relationship between structure (e.g. chain length) and affinity to proteins is complex and thus still a matter of research (Ng and Hungerbühler, 2014). Nevertheless, some toxicokinetic observations may be explained by certain protein bindings. The expression of organic anion transporters is gender as well as species specific. They function either as an aid for uptake or elimination and some are responsible for reabsorption from urine to blood. Binding to transporter proteins with a sex and species dependent expression may explain observed significant differences in the half-lives between sexes and species. The activity of human reabsorption transporters activity was far more pronounced than for rats (Weaver et al., 2010; Yang et al., 2010) and may explain the significant differences in the half-lives of PFAAs in humans compared to laboratory rodents.

Bischel et al., 2011, investigated with equilibrium dialysis the binding of PFCAs to bovine serum albumin (BSA). More than 99 % of PFHxA bound to BSA and the protein water distribution coefficient log K_{PW} was 4.05 (Bischel et al., 2011). An increase in K_{PW} with increasing chain length was observed for PFCAs with four to six fluorinated carbons. For PFCAs with greater chain length than six fluorinated carbons, K_{PW} values generally decreased. The authors suggest that increased rigidity associated with long-chain PFCAs may contribute to the observed nonlinear relationship of K_{PW} with the fluorocarbon tail length. The comparison with PFOA shows that the fraction bound to BSA is is equally high with > 99 % and that the K_{PW} of PFHxA is higher than for PFOA.

An important feature of PFAS including short chain compounds such as PFHxA, is a high affinity to human serum albumin (HSA). This might contribute to an efficient distribution into various organs and tissues. Recently, a substantially higher placental transfer efficiency was demonstrated for PFHxA, compared to longer chain PFAS including PFOA (Gao, 2019). This was linked to a higher dissociation constant (k_d) of HAS-complexes consisting of short-chain perfluoroalkyl acids. In the study by (Zhang T. et al., 2013), PFHxA was found above LOQ in 45% of the maternal whole blood samples (n=31)and in 87% of the cord whole blood samples (n=29). The median concentration in the cord blood samples was 0.14 ng/mL while the median concentration was <0.05 ng/mL for the maternal blood samples. Also, the max concentration in the cord blood samples was higher than the max concentration in the maternal blood samples, being 1.14 ng/mL and 0.43 ng/mL, respectively. In this study, placenta samples were also analysed, but due to limitations in the analytical method these results should be interpreted with caution. In the study by Gao et al 2019, 132 paired samples of maternal and cord serum were analysed. PFHxA was found above LOQ in 76 % of the maternal serum samples (median concentration 0.17 ng/mL) and in 78% of the cord serum samples (median concentration of 0.18 ng/mL). The authors calculated a placental transfer efficiency of 110% for PFHxA, which was lower than shorter chain PFCAs such as PFBA and PFPeA and higher than for example PFOA, PFNA and PFDA.

These studies clearly demonstrate transplacental transfer of PFHxA in humans, and the relative transfer seems to be higher for PFHxA compared to for example for PFOA, PFNA and PFDA. Importantly, this raises concerns whether an increased environmental exposure towards PFHxA might selectively affect foetal development.

According to previous studies, PFHxA displays a comparatively high affinity to serum proteins as PFOS (Bischel *et al.*, 2011), combined with a markedly higher K_d (Gao, 2019). Beside placental transfer, this might also affect other aspects of accumulation, such as passage of the blood-cerebral barrier. Notably, a previous comparative study demonstrated occurrence of PFHxA in human brain, using autopsies of various organs that had been sampled from 20 subjects. In contrast, detection of PFHxS and other PFAS was much lower in the investigated brain samples (Perez *et al.*, 2013). Again, further studies are required to clarify whether this effect is related to neurological or neurobehavioral health risks.

Protein binding which is one mechanism among others that explains PFHxA facilitated tissue distribution. This hypothesis is supported by the findings of Numata et al., 2014 who reported that PFHxA is effectively distributed to most organs in the body of pigs (see section B.4.4.3 Half-lives of PFHxA in humans and animals). Nevertheless, the potential to bind to BSA may not fully explain the toxicokinetics. Transporter proteins as described above may also have an impact on toxicokinetics. Apart from this, a study has shown that PFAAs binde to peroxisome proliferator-activated receptors. This plays a role in lipid metabolism, induces conformational changes of this receptor and may thus change the function of the protein (Zhang et al., 2014).

B.4.4.5 Summary and discussion of bioaccumulation

The biomagnification as well as the bioconcentration of short-chain PFAS in laboratory studies with fish is low. According to the BCF criteria outlined in REACH Annex XIII (sections 1.3.2 and 3.2.2(a)) the B criterion is not fulfilled. This approach, however, only addresses one compartment, i.e. water, and water breathing organisms, i.e. fish. Elimination half-lives have been proven to be of importance for long-chain PFASs such as PFOA. In general, the reported half-lives for PFHxA in mammals are considerably lower when compared to PFOA. Based on the considerably lower half-life reported for PFHxA in comparison to the half-lives of PFOA and PFHxS, it is concluded that PFHxA is less bioaccumulative. However, regardless of the half-life in mammals the non-reversible environmental background concentrations lead to long-term continuous human exposure. Substances that have a low bioaccumulation potential could potentially reach similar levels in biota to substances that are known to bioaccumulate, provided that they are sufficiently persistent and mobile in the environment (Peter Fisk Associates Ltd, 2018). For example, calculations in the study show that a substance with a half-life of 365 days and a BCF of 800 L/kg may reach comparable concentrations in a system as a substance with a half-life of 60 days and a BCF of 5000 L/kg, if time allows for steady-state to be reached (Figure 3 in reference). The authors of this report conclude: ”The longer the persistence of a substance is, the higher the concentrations that could be reached in an exposure medium, and the lower the bioaccumulation potential would need to be to reach a given concentration in biota exposed to that medium.” Based on their findings, the authors proposed screening criteria under the Stockholm Convention for substances that may be of concern in relation to their mobility.

PFHxA has a strong binding potential to proteins which may facilitate tissue distribution. Toxicokinetic studies show that PFHxA becomes well distributed within the organisms, mainly plasma, kidney and liver in rats and mice.

B.4.5 Enrichment in plants

As PFHxA has a good water solubility, high concentrations in the pore water are expected making it bioavailable for plants[9]. Several studies investigated the uptake of PFHxA and other PFASs from the surrounding environment into plants (see Table 13). These studies were conducted under strictly controlled laboratory conditions, under semi-natural conditions as well as under environmental conditions (field studies). Two studies of Felizeter ((Felizeter et al., 2012) and (Felizeter et al., 2014)) examined the uptake of PFAS by hydroponically grown lettuce, tomato, cabbage and zucchini plants. Especially in the edible parts and the roots the concentrations of PFHxA are considerably higher (ng/g) compared to the nutrient solution (ng/mL) with concentration factors between one and ten. Most of the PFHxA accumulates in leaves and fruits, which is attributed to the high water solubility and the resulting high potential for translocation. This is in line with (Krippner et al., 2014) reporting more than two times higher concentrations of PFHxA in maize shoots compared to maize roots. In another study with plants from biosolid-amended fields, PFHxA shows with a grass/soil accumulation factor of 3.8 the highest accumulation factor among all measured PFAS, indicating a high transfer potential from soil to grass (Yoo et al., 2011). Blaine et al. (2013) investigated the accumulation of PFHxA in lettuce and tomato grown on biosolid-amended soils and reported BAFs in lettuce up to 11.7 and in tomato up to 6.8. PFHxA does also accumulate in strawberry fruits (Blaine et al., 2014). A recent study by (Pi et al., 2017) reports uptake rates in submerged and free-floating aquatic macrophytes with whole-plant BCFs of 29.4 and 24.9 respectively.

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[9] Please see REACH Guidance on Chemical Safety Assessment, Chapter R.7c: Endpoint Specific Guidance (2017)

Table 13: Uptake of PFHxA and other PFCAs in plants.

Method	**Plant**	**Regarded PFCAs**	**Results**	**Reference**
field study (biosolid amended soils)	wheat (*Triticum aestivum L.*) (roots, straws, husks, grains)	C4-12 PFCAs	root concentration factor (RCF) PFHxA = 3.28 $(ng/g_{root})/(ng/g_{soil})$ straw concentration factor (SCF) PFHxA = 1.24 $(ng/g_{straw})/(ng/g_{soil})$ transfer factor from roots to straws (TF_{r-s}) **PFHxA = 0.392 $(ng/g_{straw})/(ng/g_{root})$** grain concentration factor (GCF) PFHxA = 0.311 $(ng/g_{grain})/(ng/g_{soil})$ transfer factor from straws to grains (TF_{s-g}) **PFHxA = 0.253 $(ng/g_{grain})/(ng/g_{straw})$** all concentrations are measured and based on dry weight without normalisation for OC.	(Wen et al., 2014)
climate chamber (100 µg/L of each individual PFCA per liter of nutrient solution at pH 5, pH 6 and pH 7) Analysis of plant material after 5 days of exposure.	maize (*Zea mays*)	C4-10 PFCAs	uptake rate by roots PFHxA = 0.35 µg/g root DW/d shoot:root ratios **PFHxA = 2.25** (transferred to shoot) all concentrations are measured and based on dry weight.	(Krippner et al., 2014)
pot experiment (soil was spiked with an aqueous solution of 0.25 mg individual PFCA/kg soil and 1.00 mg individual PFCA/kg soil). After 128 days	maize (*Zea mays*)	C4-10 PFCAs	straw transfer factor (TF_{straw}): PFHxA = 3.19 (0.25 mg/kg treatment) and 2.82 (1.00 mg/kg treatment) kernel: Transfer factor ($TF_{kernels}$) **PFHxA = 0.123** (0.25 mg/kg treatment) **and 0.216** (1.00 mg/kg treatment) all concentrations are	(Krippner et al., 2015)

Method	**Plant**	**Regarded PFCAs**	**Results**	**Reference**
straw and kernels were harvested.			measured and based on dry weight.	
field study (biosolid amended fields)	grass (from biosolid-amended fields)	C6-14 PFCAs	grass /soil accumulation factors (GSAF): PFHxA (mean) = 3.8	(Yoo et al., 2011)
greenhouse – hydroponic system (PFCA-spiked nutrient solution with nominal concentration of 10 ng/L to 10 µg/L of each spiked PFCA)	lettuce (*Lactuca sativa*)	C4-14 PFCAs	root concentration factor (RCF): **PFHxA ≈ 1.2** (lowest RCF of all PFCAs) foliage to root concentration factor (FRCF): PFHxA ≈ 0.98 transpiration stream concentration factor (TSCF): PFHxA ≈ 0.07	(Felizeter et al., 2012)
greenhouse – hydroponic system (PFCA-spiked nutrient solution with nominal concentration of 10 ng/L to 10 µg/L of each spiked PFCA)	tomato (*Solanum lycopersicum* var. Moneymaker), cabbage (*Brassica oleracea* convar. *capitata var. alba*) and zucchini (*Cucurbita pepo* var. Black Beauty)	C4-14 PFCAs	root concentration factor (RCF): cabbage: PFHxA ≈ 15.8 zucchini: PFHxA ≈7.5 tomato*:* PFHxA ≈ 3.6 stem concentration factor (SCF): cabbage: PFHxA ≈ 2.4 zucchini: PFHxA ≈ 5.5 tomato: PFHxA ≈ 2.3 leaf concentration factor (LCF) cabbage: PFHxA ≈ 6.9 zucchini: PFHxA ≈ 10 tomato: PFHxA ≈ 19 => leaves show the highest concentration factors compared to other above-ground parts of the plants, the leaves also store the largest mass of all of the PFCAs twig concentration factor (TCF) cabbage: (no twig)	(Felizeter et al., 2014)

Method	Plant	Regarded PFCAs	Results	Reference
			zucchini: PFHxA ≈ 1.7 tomato: PFHxA ≈ 5.3 edible part concentration factor (ECF) (cabbage head and tomato and zucchini fruit) cabbage: PFHxA ≈ 3.6 zucchini: PFHxA ≈ 0.9 tomato: PFHxA ≈ 4.4 transpiration stream concentration factor (TSCF) TSCF < 1 for all compounds in all plant species => transfer from the nutrient solution to the vegetative parts of the plants was inhibited cabbage: PFHxA ≈ 0.12 zucchini: PFHxA ≈ 0.06 tomato: PFHxA ≈ 0.12 edible part /leaf transfer factor: All factors were < 1, which indicates that leafy crops with open leaves (spinach or some lettuce) accumulate higher amounts in the edible part than fruit-bearing crops. Leafy crops pose a higher risk for human exposure	
semi-static mesocosm study. Uptake phase 15 days. Water concentration (nominal and measured): 20 µg/L	submerged and free-floating aquatic macrophytes: *Echinodorus horemanii* and *Eichhornia crassipes*		preferential translocation to leaf tissue: E. horemanii / E. crassipes: Leaf BCF_{ss}: 31.1 / 28.7 Root BCF_{ss}: 21.7 / 19.2 Whole-plant BCF_{ss}: 29.4 / 24.9	(Pi et al., 2017)
field and greenhouse study with	lettuce (*Lactuca sativa*) and		greenhouse, industrially impacted soil *L. sativa* / *L. lycopersicum*	(Blaine et al., 2013)

Method	**Plant**	**Regarded PFCAs**	**Results**	**Reference**
biosolids-amended soil.	tomato (*Lycopersicon lycopersicum*)		BCF: 11.7 / 2.9 Field trial *L. sativa* / *L. lycopersicum* BCF: < LOQ / 6.84	
greenhouse, water augmented with varying concentrations of PFAAs (nominal 0.2 - 40 µg/L).	lettuce (*Lactuca sativa*) and strawberry (*Fragaria ananassa*)		FCF (Fruit to soil concentration factor) for *F. ananassa* at 10 µg/L water concentration (0.4 % organic carbon content): 34.5 BAF for *L. sativa* at 10 µg/L water concentration (0.4 % organic carbon content): 415	(Blaine et al., 2014)

In conclusion PFHxA is taken up in plants, especially in leaves and fruits, often in the edible parts. This is of high concern, as the enrichment in plants might lead to an accumulation in other organisms. Plants, e.g. fruits and vegetables, are important nutritions for humans and are therefore a source for human exposure. Furthermore, agricultural land can be ruined when contaminated, as cultivated plants enrich PFHxA and can no longer be consumed (as it was the case in Rastatt Germany, see also (Brendel et al., 2018). PFHxA has been monitored in several food items in context of food monitoring programmes (see B.4.2.4.5).

B.4.6 Removal from the environment, decontamination and purification

Removal of PFHxA from different (environmental) media is important for example for lowering background concentrations in raw water used for the production of drinking water, for the purification of wastewater and also for the remediation of contaminated sites.

In general removal could either happen by using special removal, remediation or purification techniques such as reverse osmosis /electrochemical oxidation or by natural physical /chemical /biological processes. For PFOA marine waters, especially the deep sea and sediments were found to be a sink in a study addressing the mass balance of PFOA in the Baltic Sea (Filipovic et al., 2013). It can be assumed that deep oceans might also function as a sink for PFHxA (Sanchez-Vidal et al., 2015). Sanchez-Vidal et al. analysed PFASs in particles sinking to the deep sea at 300 and 1000 m depth in the Cap de Creus Canyon, north-western Mediterranean Sea. The dominant PFASs was PFHxA with 60 % of the total PFASs. The transfer of particulate matter down to the deep is enhanced by storms and dense shelf water cascading. The authors estimated a total transport of 34.5 kg of PFHxA to the deep of 1000 m during the whole cascading period of 43 days (referring only to PFHxA sorbed to particles; dissolved phase not considered).

Due to the lower adsorption potential of PFHxA compared to PFOA, it is less likely that sediments act as a sink even though it is unclear what happens over long-time windows, e.g. 50 to 100 years.

Data from wastewater treatment plants as well as from landfills as given in chapter B.4.2.4.1, already show that municipal wastewater treatment plants are only capable to remove PFHxA to some extent. They are emitting PFHxA via their effluents and sludge into the environment.

Several studies investigated the fate of PFASs including PFHxA in water treatment plants applying different treatment techniques:

Appleman et al. evaluated 15 full-scale treatment systems for the attenuation of PFASs in water treatment utilities through the U.S. using single or combined techniques for treatment of drinking water. The study demonstrated that full-scale conventional treatment processes in the U.S. which are also commonly used in the EU, such as coagulation followed by physical separation processes, and chemical oxidation, aeration and disinfection, and also anion exchange were unable to remove PFHxA in relevant quantities (Appleman et al., 2014). Granular activated carbon (GAC) filtration was able to remove 68 percent to 91 percent of PFHxA in the influent, but removal rate strongly depends on aging and reconditioning of the GAC. Breakthrough times depend on various parameters such as presence of dissolved organic matter in either the groundwater or surface water but also occurrence of longer chain PFASs because of the competitive effects with the sorbing species. It is expected by Appleman et al. that longer chain PFAS and dissolved organic matter lead to desorption and release of already adsorbed short-chain PFASs over time. Reverse osmosis is shown to be the most effective treatment technique. It was able to remove more than 97 percent of PFHxA in the water. Despite its effectiveness, reverse osmosis is the most costly method for removal. Also, disposal of the remaining concentrate, which will contain the rejected PFASs, adds to the cost of operation of these systems.

The work of Appleman et al. was taken up by Dickenson and Higgins, who investigated the local treatment and mitigation measures to remove PFHxA from water for about 20 sites. The averaged removal rates were only provided as broad ranges (less than ten percent, ten to 90 percent, above 90 percent) as this depends on the local situation, such as whether or not there is a cascade of treatment steps. For the different processes the observed remediation rates were (Dickenson and Higgins, 2016):

- Less then 10 % for aeration,
- less than 10 % for combination of coagulation /dissolved air floatation,
- less than 10 % for specific individual combinations of coagulation /flocculation /sedimentation /granular filtration /microfiltration,
- less than 10 % for anion exchange,
- less than 10 % for oxidation by chemical processes or UV photolysis with or without advanced oxidation (hydrogen peroxide),
- 10 to 90 % for granular activated carbon,
- above 90 % for nanofiltration (bench scale),
- above 90 % for reverse osmosis (bench scale).

Rahman et al. summarised several studies in a review on the fate and behaviour of PFASs in drinking water treatment (Rahman et al., 2014):

- Granulated activated carbon (GAC) failed to remove PFHxA (Eschauzier et al., 2012),
- powdered activated carbon at practical dosages would not achieve significant removal of PFHxA (Dudley, 2012),
- ion exchange in a full-scale drinking water treatment plant did not remove PFHxA (Dickenson et al., 2012),
- in full scale drinking water treatment plants removal of PFHxA ranged from 0 to 100 % ((Quinones and Snyder, 2009), ((Thompson et al., 2011)).

Thompson et al. (2011) investigated the removal of PFHxA in two Australian drinking water treatment plants. They sampled one plant twice (plant A), the other three times on different days respectively (plant B). For plant B the author themselves state that assessment of removal with the data is difficult, because grab sampling was performed and hydraulic retention times were not taken into account. Reversed osmosis is in this plant, the treatment step responsible for removing PFHxA from the water (enriching it in the reversed osmosis concentrate) (Thompson et al., 2011), leading to 100 % removal (Rahman et al., 2014). In treatment plant B removal ranged from +20 to -48 % (Rahman et al., 2014) making it hard to conclude.

Quinones and Snyder took influent and effluent samples from seven drinking water treatment plants in the US. The only removal observed in their study was in a plant with reversed osmosis (Quinones and Snyder, 2009).

The removal of PFASs (PFBA, PFOA, PFBS, PFOS from contaminated drinking water in batch and continuous pilot plants was investigated by (Zaggia et al., 2016) using strong anion exchange resins. The following dependency was shown:

1. The higher the hydrophobicity of the functional group of the resin the higher is the sorption capacity for PFASs;

2. the shorter the fluorinated chain the lower the sorption capacity;

3. the sorption capacity for carboxylic group is reduced to the stronger sulphonic group (Zaggia et al., 2016).

Boiteux et al. (2017) investigated the ability of three drinking water plants to remove per- and polyfluoroalkyl substances (PFASs incl. PFHxA) from the raw water. Different techniques in those plants like sand filtration, coagulation followed by sedimentation, chlorination and activated carbon filter, did not significantly remove perfluorinated carboxylic acids from the water.

In addition to those studies investing removal efficiency in full-scale treatment plant, several investigations were also performed on a laboratory scale. As it is difficult to state how such approaches would perform under real world conditions, only some of these studies are summarized in the following:

Lundgren (2014) investigated the removal efficiency of PFASs using four different treatment techniques. Removal of PFHxA from different types of water were (Lundgren, 2014):

- less than 20 % for anion exchange using MIEX® resins,

- less than 5 % for coagulation with iron (III) chloride ($FeCl_3$),
- less than 10 % for adsorption using powdered activated carbon (PAC) and
- less than 30 % for nanofiltration (NF) membrane.

Soriano et al. (2017) investigated in laboratory scale experiments how PFHxA can be treated efficiently by nanofiltration followed by electrochemical degradation of the nanofiltrate concentrate. They found that the specific membrane used for this experiment was capable to reach 96.6 - 99.4 % rejection of PFHxA. The achieved rate for electrochemical degradation was up to 98 %.

Also Steinle-Darling and Reihnhard (Steinle-Darling and Reinhard, 2008)) investigated the rejection of PFHxA and other PFASs by four nanofiltration membranes. Rejection of PFHxA and other ionic PFASs in deionized water was greater than 95 %.

Karnwadee (2015) investigated the adsorption of PFHxA from synthetic and industrial wastewater onto GAC, non-ion exchange polymers and anion exchange polymers. The study reports adsorption kinetics and isotherms. The results show that adsorption rates and capacities of PFHxA in synthetic wastewater were higher than those in industrial wastewater onto all adsorbents and that ionic strength and dissolved organic carbon (DOC) are the most relevant parameter influencing adsorption (increasing ionic strength and DOC lead to decreasing adsorption of PFHxA) (Karnwadee, 2015). Lindegren (2015) found close to 100 % PFHxA removal by nanofiltration in a pilot plant (using ground water which contained PFHxA). Furthermore, she tested the removal efficiency of PFHxA on GAC (47 ± 28 %) and anion exchange (21 ± 38 %) in a column study (by using spiked drinking water) (Lindegren, 2015).

(Bruton and Sedlak, 2017) investigated heat-activated persulfate chemicals oxidation in batch experiments. This technique was supposed to be applied *in-situ* in cases of contaminated groundwater due to exposure with PFASs-containing fire-fighting foams. Therefore, the batches contained two different foams in a water-sediment mixture. Results show the conversion of PFCA-related substances to PFCAs and further degradation of PFCAs. Nevertheless, in the end some short-chain PFCAs were still present. Also the production of potentially hazardous concentrations of HF could not have been excluded (Bruton and Sedlak, 2017).

Electrochemical mineralization was shown by Niu et al. in a laboratory scale with only PFHxA and four other PFCAs in aqueous solution using “Ce-doped modified porous nanocrystalline PbO_2 film anode” (Niu et al., 2012). Also Zhou et al showed degradation of PFHxA on a boron doped diamond (BDD) anode in a laboratory experiment (Zhuo et al., 2012). (Gomez-Ruiz et al., 2017) also used a BDD anode for the electrochemical treatment of eight PFASs (e.g. PFHxA, 6:2 fluorotelomer sulfonic acid). The authors investigated degradation of PFASs at environmentally relevant conditions in the effluent from a PFASs contaminated industrial WWTP at laboratory scale. 99.7 % PFASs removal was observed after ten hours and a current density of 50 mA/cm². At lower current densities initial degradation of 6:2 fluorotelomers into PFHxA were observed. For large scale implementation the high energy consumption is a challenge (Gomez-Ruiz et al., 2017).

Murray et al. (2019) investigated the removal of PFASs in a bench-scale system using super-fine powder activated carbon (SPAC, particle diameter < 1 μm) coupled with ceramic membrane filtration (CMF). AFFF-contaminated groundwater and diluted firefighting contaminated tank water were used in the study. No 10 % breakthrough (defined as 10 % of the influent concentration of individual PFAA present in the CMF permeate or column effluent) was observed for PFHxA after 77 hours of filtration in the experiment with the groundwater. Based on total PFAA mass loading, the authors compared the results with results from a GAC pilot-scale system - SPAC/CMF is at least 1.5 times more effective than GAC. In the experiments with the highly contaminated tank water 10 % breakthrough was observed for the short-chain PFAAs (e.g. PFHxA) after 42-196 hours (Murray et al., 2019).

Zhang et al. summarised in a review nanotechnologies applied in remediation of water contaminated by PFASs (Zhang et al., 2019). Deng et al. stated that adsorption of PFASs on carbon nanotubes was lower than on other conventional sorbents (e.g. activated carbon, resins) and that adsorption of PFASs on carbon nanotubes decreased with decreasing chain length (Deng et al., 2012). Unfortunately, most of the current research cited in the review focused on PFOA. (Zhang et al., 2019) concluded that most of the current studies were conducted in deionized water containing much higher PFASs concentrations than real contaminated water. Hence, performance of the applied nanotechnologies might be overestimated.

Ateia et al. reviewed removal techniques from water for short-chain PFASs (Ateia et al., 2019):

- lower removal efficiencies for short-chain PFASs compared to long-chain PFASs for adsorption on different carbonaceous material were confirmed (e.g. GAC, activated carbon filters, and carbon nanotubes) (Deng et al., 2012; Kothawala et al., 2017),
- > 80 % removal of short-chain PFASs by ion exchange resins; but desorption at lower PFASs concentrations (McCleaf et al., 2017; Zaggia et al., 2016),
- only very little data are available for removal of short-chain PFASs by membranes (e.g. reverse osmosis and nanofiltration) and advanced oxidation processes (studies are already mentioned/discussed above).

For these results from laboratory scale experiments it is not clear whether these results can also be achieved under real conditions where the water to be treated usually consists of a wide variety of constituents. At least the above summarized studies investigating full-scale water treatment plants indicate, that the situation is complex and PFHxA cannot be removed efficiently in all plants. Ross et al. investigated the potential of water treatment techniques to remove long-chain / short-chain PFCAs, but provided no quantitative removal efficiencies for PFHxA (Ross et al., 2018). By assessing a large number of available literature, they found that GAC is less effective for short-chain PFCAs and PFCA-related substances compared to long-chain PFCAs. The same general conclusion was drawn for injectable particulate carbon where proprietary products containing activated carbon are used for *in-situ* treatment of groundwater by injection of the product in the aquifer where it acts as a trap for the perfluorinated substances. The authors also mentioned that many ion-exchange resins on the market are more effective for long-chain PFAS than for the short-chain ones like PFHxA, but novel resins might have higher sorption capacities for both long-chain and some short-chain PFASs compared with GAC. Ion-exchange resins are an established technology for many common contaminants in both the municipal and groundwater treatment. It has to be kept in mind that co-contaminants such as chromates, chlorides or nitrates are within the wastewater stream or (naturally) within aquifers. Normally these are present at concentrations orders of

magnitude greater than PFASs, resulting in significant competition with PFAS for adsorption sites. For ozofractionation (e.g. via Ozofractionative Catalysed Reagent Addition – OCRA), effective removal of total PFASs was observed in full-scale. Nevertheless, this process represents only a part of a treatment train, and further technology to destroy the concentrated PFASs in the aqueous phase is necessary. Further effective removing processes for PFASs regardless chain length (including many types of related substances) are reverse osmosis and nanofiltration. In the context of groundwater treatment, it is important to assess the suspended solids and water geochemistry to prevent fouling or deterioration of the membranes.
The authors of the article mentioned that currently no treatment technologies for water and soil are available that can both remove and destroy PFASs (especially short-chain PFASs and related substances) simultaneously.

Full scale remediation installations are specifically adapted to local conditions and are facing several challenges and are shown by the following study: Bruton and Sedlak investigated the potential use of aqueous film forming foams (AFFF) for *in-situ* chemical oxidation. But this technique also requires the use of heat activated persulfates ($S_2O_8^{2-}$) and low pH-values ($pH \leq 3$). It was observed that the organic solvents in the AFFF and also aquifer sediments decrease the efficiency of the remedial process. The process is also challenged by the creation of acidic conditions in the subsurface, the potential for generation of undesirable transformation products and the release to toxic metals (Bruton and Sedlak, 2017).

The behaviour of PFHxA in treatment plants is triggered by its low adsorption potential (see chapter B.4.2.1) and the persistence (see chapter B.4.1.1). When looking on results from studies on a laboratory scale there seems to be some promising approaches which are able to remove PFHxA at least to some extent. But the investigation under real world conditions show that the situation is more complex. None of the investigated plants is capable to fully remove PFHxA. More effort would be needed, first in terms of research and second for applying such newly developed techniques on a broad scale, for being able to fully remove PFHxA from different environmental media. But for the current state of technology it can be concluded that it is very difficult to remove PFHxA from (waste) water or from the environment.

B.5 Human health hazard assessment

B.5.1 Toxicokinetics (absorption, distribution, metabolism and elimination)

The free undecafluorohexanoic acid (PFHxA) is in equilibrium with undecafluorohexanoate (PFHx), the conjugate base; however, due to its low pK_a (< 1), PFHxA primarily exists in the environment as an anion. However, some laboratories report results for the acidic form of PFHxA and the standards used by some laboratories to perform toxicity testing include various PFHxA salts, such as ammonium perfluorohexanoate (CAS-No 21615-47-4) and sodium perfluorohexanoate (CAS-No 2923-26-4). This is important, as the acid has been shown to be more irritating than associated salts. However, regardless of the administered compound, once absorbed into the bloodstream, the PFHx-anion will form. Additionally, when the salt or acid exists in liquids, it will dissociate and the salt or acid will break off, resulting in the anion (Luz et al., 2019).

In general, the main elimination pathway for PFHxA in mammals seems to be excretion via the urine (Chengelis et al., 2009b; Gannon et al., 2011a; Numata et al., 2014). Essentially 100 % of the dose was eliminated in urine in rats and mice (Gannon et al., 2011a). PFHxA was mainly found in plasma, kidney and liver in rats and mice with higher concentrations in male rats and female mice in kidney than in the liver but with a higher concentration in the liver in male mice (Gannon et al., 2016). Numata and coworkers report that accumulation in fattening pigs mainly occurs in plasma (48% of body burden), muscle meat (34%), fat (13%), liver (4.2%) and kidney (0.8%). The average elimination half-life for PFHxA in fattening pigs calculated by Numata et al. (2014) is 4.1 days. Chengelis et al. (Chengelis et al., 2009b) examined elimination half-lives of PFHxA in monkeys (intravenous administration) and rats (oral and intravenous administration) in the range of several hours (two to five hours) based on serum concentrations. The authors reported a gender specific difference in PFHxA serum clearance in rats, as female rats eliminated PFHxA about two to three times faster (0.42 h compared to 1.0 h). This would be in line with Gannon et al. (2011a) observing also serum elimination half-lives of PFHxA in rats and mice in the range of hours, with two- to three-fold faster elimination half-lives in female rats compared to male rats. However, there was no appreciable gender-specific difference in the extent or rate of urinary elimination and based on the short elimination time of PFHxA and the limited number of animals used. The gender difference in Sprague-Dawley rats remains to be established, especially in view of the conclusions drawn by Russell et al. (2013) who stated that "the half-lives of PFHxA in mice, rats, monkeys and humans were proportional to body weight with no differences observed between genders, indicating similar volumes of distribution and similar elimination mechanisms among mammalian species."

In general, the reported half-lives for PFHxA in mammals are considerably lower when compared to PFOA. For PFOA, half-lives of PFOA in mice, rat, pig and monkey are up to one order of magnitude higher compared to PFHxA, ranging from 0.08 days in female rat, 236 days in pig and several years in humans.

The shorter half-life of PFHxA in mammals is due to the rapid excretion via the urine (Chengelis et al., 2009b; Gannon et al., 2011a; Numata et al., 2014). Chengelis et al. (2009b) reported that after intravenous dosing of PFHxA approximately 80 % of the administered dose was recovered in the urine during 24 h post-dose. Following repeated oral dosing of PFHxA, approximately 90 % of the administered daily dose was recovered in the urine 24 h post dose in male rats, whereas in female animals, urinary elimination varied between 70 and 100 % of the administered dose during 24 h post-dosing.

For further details see Appendix B.5.1.

B.5.2 Repeated dose toxicity

One oral **subacute toxicity study**, two oral subchronic toxicity studies and one oral chronic toxicity study of PFHxA in rats are available. All studies show treatment-related effects. The subacute study showed an influence of PFHxA on clinical chemistry such as altered liver enzyme levels of AST, ASAT and ALP in both sexes. Additionally, altered organ weights were observed in males and females. The relative liver and kidney weights were increased in both sexes. Furthermore, PFHxA had an effect on haematological parameters: haematocrit, reduced levels of red blood cells and haemoglobin exceeded the 10 % level at doses of at 250 mg/kg bw/d. Degeneration and hyperplasia of the olfactory epithelium was observed in both sexes in dose-dependent manner, relevant increases in incidences were noted at 250 mg/kg bw/d and above. The most sensitive effect was a significant reduction of total T3, total T4 and free T4 at all dose groups of males justifying a LOAEL of 62.6 mg/kg bw/d (NTP, 2018).

The first **subchronic study** with PFHxA showed significantly lower mean body weights of males at 50 and 200 mg/kg bw/d group and similar (but not significant) trends in female rats at 50 and 200 mg/kg bw/d. Slight effects (< 10 % ranges) on haematological parameters were seen in 200 mg/kg bw/d-rats of both sexes. Furthermore, the liver enzymes ALT, AST and ALP were increased in 200 mg/kg bw/d in male rats. This was accompanied by minimal centrilobular hepatocellular hypertrophy in seven of ten animals. Kidney effects such as increased relative kidney weight at 50 mg/kg bw/d were not accompanied by other histopathological findings. Based on this subchronic study a LOAEL of 50 mg/kg bw/d could be derived based on lower body weight throughout the dosing peroid in male rats (NOAEL 10 mg/kg bw/d) (Chengelis et al., 2009c).

The second **subchronic study** was performed with sodium PFHxA and showed lower body weights in high-dose males in comparison to control values. Furthermore, liver weights (without any other abnormality) were increased in male rats at 100 and 500 mg/kg bw/d. The relevant adverse effect is the mild to minimal degeneration/atrophy of the olfactory epithelium in male and female rats at 100 and 500 mg/kg bw/d. The NOAEL was derived with 20 mg/kg bw/d (Loveless et al., 2009b).

After **chronic** gavage administration of PFHxA to Sprague Dawley rats a dose-dependent decrease in survival rate was observed in female animals only. In histopathological investigations the kidney and liver of female rats of the 200 mg/kg bw/d group showed tubular degenerative/papillary necrotic lesions. Thus, kidneys and livers represented the main targets for non neoplastic effects after chronic administration of PFHxA. Up to oral doses of 100 (males) and 200 (females) mg/kg bw/d over 104 weeks, no carcinogenic effects were observed. Thyroid hormone levels, shown to be sensitive effects in subacute studies, were not investigated in this chronic study. Histological examination of the thyroid was not performed. According to the protocol cited by the authors (Fiette and Slaoui, 2011) the thyroid gland with the parathyroids should have been weighed, but the results were not given in the publication (Klaunig et al., 2015b).

For further details please see Appendix B.5.2.

B.5.3 Mutagenicity

The Dossier Submitter concludes on PFHxA that the studies presented give no evidence for mutagenic properties of PFHxA.

For further details please see Appendix B.5.3.

B.5.4 Carcinogenicity

Based on the information available there is no indication for carcinogenic properties of PFHxA. However, this conclusion is based on the publication of study results available in public literature. The original study report was not available for evaluation.

For further details please see Appendix B.5.4.

B.5.5 Toxicity for reproduction

In an one generation reproductive toxicity study with sodium perfluorohexanoate (NaPFHxA) in rats no substance-related effects were observed on mating, fertility, gestation length, number of implantation sites, estrous cyclicity, sperm parameters, litter size, sex ratio, pup clinical observations, pup survival, or F1 adult developmental landmarks at any dose tested. Substance-related effects were observed during lactation at 500 mg/kg bw/d on mean pup weights (17-18 % decrease compared to controls) (Chengelis et al., 2009c; Loveless et al., 2009b).

In a study on prenatal developmental toxicity of NaPFHxA in rats, there were no substance-related deaths or gross post-mortem findings in dams at any dose. Maternal and developmental toxicity occurred at 500 mg/kg bw/d and consisted of reductions in bodyweight (Loveless et al., 2009b).

In a study on prenatal developmental toxicity of ammonium perfluorohexanoate in mice adverse effects on offspring occurred at 175 mg/kg bw/d and higher whereas no maternal toxicity was observed up to 500 mg/kg bw/d. The number of stillborn pups and pups dying on day 0 and from day 1-4 postpartum were significantly increased on day 0 postpartum at 500 mg/kg bw/d. The significant increase of stillborn pups furthermore indicated an effect from exposure of the fetuses during maternal treatment due to placental transfer of the compound. Additionally, the pup weight was reduced dose-dependently from 1.6 g to 1.4 g; the first effect was noted at 175 mg/kg bw/d.

A developmental NOAEL of 100 mg/kg bw/d was derived for lower absolute fetal body weights.

In comparison to the developmental LOAEL of PFHxA of 175 mg/kg bw/d, the restriction dossier of PFOA reported LOAEL values of 1.0 (maternal) and 3.0 (foetal) mg/kg bw/d (ECHA, 2015a) for developmental toxicity. In conclusion, there are indications that PFHxA has a considerably lower potency when compared to PFOA under the experimental conditions of the tests conducted so and thus presumably a lower potential to affect fertility and development.

For further details please see Appendix B.5.5.

B.5.6 Derivation of DNEL(s)/DMEL(s)

Table 14: Summary of animal studies and the estimated LOAEL and/or NOAEL for PFHxA.

Species and dose	**NOAEL mg/kg bw/d**	**LOAEL mg/kg bw/d**	**Effect at LOAEL/ NOAEL**	**Reference**
subacute studies				
Harlan Sprague-Dawley Rats 10 animals/ sex /dose were dosed via gavage with 0/ 62.6/125/250/500/1 000 mg/kg bw/d for 28 d	-	62.6	decreased level of free and total T4 and total T3	(NTP, 2018)
subchronic studies				
Crl:CD(SD) rats 10 animals/sex/dose were dosed via gavage with 0/10/50/200 mg/kg bw/d for 90 d	10	50	lower body weight*(11 % at 50 mg/kg bw/d and 8 % at 200 mg/kg bw/d)	(Chengelis et al., 2009b)
Crl:CD(SD) rats 10 animals/sex/dose were dosed via gavage with 0/20/100/500 mg/kg bw/d for 90 d	20	100	nasal lesions (degeneration/ atrophy of the olfactory epithelium)	(Loveless et al., 2009a)
chronic studies				
Crl:CD(SD) Rats 10 animals/sex/dose were dosed via gavage with 0/2.5/15/100 mg/kg bw/d (males) and 0/5/30/200 mg/kg bw/d (females) for 104 weeks	30 (females)	200 (females)	Kidney necrosis	(Klaunig et al., 2015a)
developmental and reproductive studies				
Crl:CD(SD) rats 10 animals/sex/dose were dosed via gavage with 0/20/100/500 mg/kg bw/d for 90 d	100 (maternal) 100 (fetal)	500 (maternal) 500 (fetal)	lower body weight gain* lower fetal body weight gain*	(Loveless et al., 2009a)
Crl: CD I (ICR) 20 females/dose were dosed via gavage with 0/100/350/500 mg/kg bw/d of APFHx from GD 6-18	- 100 (fetal)	500 (maternal) 175 (fetal)	no effects lower absolute body weight*	Hoberman (2011a) (Hoberman, 2011b)

*in comparison to the control group.

Table 15: Overview of DNEL-derivations for general population, long-term, systemic effects, all routes.

Effect at NOAEL/ LOAEL	**NOAEL mg/kg bw/d**	**LOAEL mg/kg bw/d**	**$DNEL_{oral}$ mg/kg bw/d (AF)**	**$DNEL_{inhalation}$ mg/m³ (AF)**	**$DNEL_{dermal}$ mg/kg bw/d (AF)**	**Reference of NOAEL and/ or LOAEL**
decreased level of free and total T4 and total T3	-	62.6	0.03 (1 800)	0.11 (450)	0.031 (1 800)	(NTP, 2018)
lower body weight*	10	50	0.03 (300)	0.1 (75)	0.03 (300)	(Chengelis et al., 2009b)
nasal lesions	20	100	0.067 (300)	0.21 (75)	0.06 (300)	(Loveless et al., 2009a)
Kidney (papillary) necrosis	30	200	0.3 (100)	0.94 (25)	0.27 (100)	(Klaunig et al., 2015a)
lower fetal body weight gain*	100	500	1 (100)	3.13 (25)	0.9 (100)	(Loveless et al., 2009a)
lower absolute fetal body weight*	100	-	0.57 (175)	4.80 (25)	0.51 (175)	Hoberman (2011a) (Hoberman, 2011b)

*in comparison to the control group

For further details please see Appendix B.5.6.

B.6 Human health hazard assessment of physicochemical properties

Not relevant.

B.7 Environmental hazard assessment

B.7.1 Aquatic compartment (including sediments)

B.7.1.1 Short-term toxicity to fish

Table 16: Summary of short-term effects on fish.

Substance	**Method/Organism**	**Results**	**Reference**
PFHxA	fish acute toxicity test (OECD 203) *Oncorhynchus mykiss*	LC50 (96h) > 99.2 mg/L	(Hoke et al., 2012)

(Hoke et al., 2012) are describing the study as follows: "The test was conducted in accordance with the OECD 203[10] guideline. Acute 96-h static testing with the rainbow trout, O. mykiss, was conducted in 26-L stainless steel tanks containing 15 L of test solution. A well water control and nominal test substance concentrations of 0.1, 1, 10 and 100 mg/L were tested using one replicate tank per concentration or well water control. Seven fish that were 28-68 d post-hatch were used per replicate tank. Testing was conducted in a waterbath maintained at 12 ± 1 °C with a photoperiod of 16 h cool white fluorescent light (approximately 250–500 lx) and 8 h darkness Measurements of pH, DOC and temperature were made at test start, at total mortality in a test concentration, and at test end. Observations of mortality and sublethal effects were made every 24 h until test end." (Hoke et al., 2012). The study is conducted in accordance with the OECD guideline and a detailed report is available. Hence the study is reliable without restriction.

B.7.1.2 Long-term toxicity to fish

Table 17: Summary of long-term effects on fish.

Substance	**Method/Organism**	**Results**	**Reference**
PFHxA	Fish early life-stage toxicity test (OPPTS Biological Effect Test Guideline No. 850.1400 *Oncorhynchus mykiss*	LOEC: hatching success, survival, length and weight > 9.96 mg/L	(Burke, 2008)

The study investigated the effect of the ammonium salt of PFHxA on growth and development of embryos and larvae of the freshwater fish species *Oncorhynchus mykiss* (rainbow trout) in a Fish Early-Life Stage (FELS) Toxicity Test. The study was performed in accordance with the OPPTS Biological Effect Test Guideline No. 850.1400, Fish Early-Life Stage Toxicity Test (1996). The test was conducted at nominal concentrations of 0.095, 0.304, 0.972, 3.110 and 9.960 mg/L active moiety, equivalent to 0.2, 0.641, 2.05, 6.56 and 21.0 mg/L in terms of

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[10] OECD Guideline for testing of Chemicals – fish, acute toxicity test; method 203; guideline adopted 1992

PFHxA ammonium salt with a purity of 50 % and a conversion factor of 1 054. These concentrations were based on the results of an acute toxicity test. Both solvent and dilution water controls were included in the test design, with duplicate test vessels at all exposure concentrations including the controls. The test was conducted with a flow through test design. Concentrated stock solutions and test media were analysed during the test. Measured concentrations of PFHxA active moiety in the concentrated stock solutions ranged between 98 and 100 % of the nominal concentrations, test media concentrations ranged between 94 and 108 % of nominal concentrations corresponding to geometric mean measured concentrations of 0.103, 0.310, 0.916, 3.14 and 10.1 mg/L. Hatching success in the control group was 74 %, satisfying the validation criterion for hatching success (> 66 %). The NOEC and LOEC for hatching success were determined as 9.96 and > 9.96 mg/L, respectively. Larval survival until day 28 post-hatch in the control group was 93 % thereby exceeding and satisfying the validity criteria for post-hatch survival (70 %). Posthatch survival across all remaining treatments ranged between 96 and 100 %. In terms of nominal concentrations, the NOEC and LOEC for post-hatch larval survival until day 28 were both considered to be equal to or greater than 9.96 mg/L. For fish total lengths, the NOEC and LOEC determined on day 28 post-hatch were 9.96 and > 9.96 mg/L PFHxA active moiety, respectively. For fish dry weights, the NOEC and LOEC determined on day 28 post-hatch were 9.96 and > 9.96 mg/L PFHxA active moiety, respectively. The study is described likewise in the publication. The study is conducted in accordance with the OECD guideline and a detailed report is available. Hence the study is reliable without restriction.

B.7.1.3 Short-term toxicity to aquatic invertebrates

Table 18: Summary of effects on aquatic invertebrates.

Substance	**Method/Organism**	**Results**	**Reference**
PFHxA	OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) *Daphnia magna*	LC_{50} (48 h) > 96.5 mg/L	(Hoke et al., 2012)
PFHxA	OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) *Daphnia magna*	EC_{50} (48 h) = 1 048 mg/L based on: mobility	(Barmentlo et al., 2015)

(Hoke et al., 2012) are describing the study as follows: ”The test was conducted following the OECD test guidelines 202 with minor deviations, e.g., 10 daphnids were used in a single beaker per treatment instead of four beakers each with five daphnids per treatment,The D. magna 48-h static exposures were conducted using 200 mL of test solution in 250 mL beakers. A well water control and nominal test substance concentrations of 0.1, 1, 10 and 100 mg L^{-1} were used for testing with one beaker per concentration or well water control. Each beaker contained 10 neonate daphnids that were <24-h old at test start. Daphnids were not fed during the test. A recirculating water bath was used to maintain mean temperature in the test chambers during the 48-h test at approximately 20.0 °C. A photoperiod of 16 h of cool-white fluorescent light (approximately 600–900 lx) and 8 h darkness was employed. Measurements of pH, DO, and temperature were made at study start and end. Immobility and behavioral observations were made daily. The statistical calculation of the EC50 was based on immobility at 48 h”. (Hoke et al., 2012)

(Barmentlo et al., 2015) tested acute immobility after 48 h of exposure also according to OECD guideline 202[11]. Daphnid neonates were exposed to the four compounds at five to eight concentrations (including control) in ISO medium. Four to six replicates per concentration were tested, each replicate consisting of a 50 mL polypropylene Greiner tube with the appropriate amount of the stock solution dissolved in 20 mL of ISO medium, containing five daphnid neonates (younger than 24 h). The uncovered vessels were randomly distributed in a climate controlled fume hood (20 ± 1 °C) with a 16:8 h light:dark photoperiod. The daphnids were randomly distributed over the test vessels and not fed during the experiments. After 24 and 48 h of incubation, the daphnids were checked for immobilisation. Daphnids were considered immobile when they were not able to swim after 15 s of gentle stirring, according to the guideline.

The studies are conducted in accordance with the OECD guidline and a detailed report is available. Hence the studies are reliable without restriction.

B.7.1.4 Long-term toxicity to aquatic invertebrates

Table 19: Summary of long-term effects on aquatic invertebrates.

Substance	Method /Organism	Results	Reference
PFHxA	OECD Guideline 211 (Daphnia magna Reproduction test) *Daphnia magna*	EC_{50} (21 d) = 776 mg/L based on: reproduction EC_5 (21 d) = 724 mg/L based on: reproduction EC_{50} (21 d) = 853 mg/L based on: population growth rate EC_5 (21 d) = 779 mg/L based on: population growth rate	(Barmentlo et al., 2015)

The chronic toxicity of PFHxA was determined in a 21 d daphnid reproduction test, following OECD guideline 211[12] (2008). Per test concentration 15 replicates were prepared, each consisting of one daphnid kept in 40 mL PFHxA containing Elendt M4 medium in a 50 mL Greiner tube. The tubes were randomly distributed in a climate controlled fume hood (20 ± 1 °C), with a light:dark regime of 16:8 h. The experiment was started by introducing one neonate (younger than 24 h) into each tube using a disposable transfer pipette. Each day the number of animals not responding to gentle stimulation by tapping on the tube was

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[11] OECD Test No. 202: Daphnia sp. Acute Immobilisation Test; guideline adopted in 2004

[12] OECD Test No. 211: Daphnia magna Reproduction Test, guideline adopted in 2008

scored. Juveniles and ephippia (winter eggs) were also counted and removed daily. The daphnids were fed daily with a suspension of the algae *Scenedesmus subspicatus*. The daphnids were transferred to new exposure tubes containing renewed test concentrations three times a week. The study is conducted in accordance with the OECD guideline and a detailed report is available. Hence the study is reliable without restriction.

B.7.1.5 Algae and aquatic plants

Table 20: Summary of effects on algae and aquatic plants.

Method/Organism	**Results**	**Reference**
OECD guideline 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test *Pseudokirchnerella subcapitata*	EC_{50} (72 h) > 100 mg/L based on: biomass EC_{50} (72 h) > 100 mg/L based on: growth rate	(Hoke et al., 2012)
Geitlerinema amphibium	IC_{50} (72 h) = 998.7 mg/L based on: optical densitiy	(Latala et al., 2009)
Chlorella vulgaris	IC_{50} (72 h) = 4032 mg/L based on: optical densitiy	(Latala et al., 2009)
OECD guideline 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test *Scenedesmus subspicatus*	EC_{50} (72 h) = 86 mg/L based on: growth rate NOEC (72 h) = 50 mg/L based on: growth rate	(ENVIRON, 2014)

The test by (Hoke et al., 2012) was conducted following the OECD test guideline 201 with minor deviations. Two instead of three replicates were used per treatment in the algae studies. Testing with *P. subcapitata* used an AAP control and nominal test substance concentrations of 0.1, 1, 10 and 100 mg/L prepared in AAP medium. The AAP medium was pH adjusted to approximately 7.5 and the medium was filter-sterilised. 50 mL of each test or control solution was placed in each of two replicate 250 mL Erlenmeyer flasks with foam stoppers for gas exchange. An appropriate aliquot of algal inoculum from a logarithmically growing stock culture was aseptically transferred to each replicate test flask to achieve the desired nominal concentration of 10000 cells/mL at test initiation. The test flasks were placed on a shaker table in an environmental chamber at 24 ± 2 °C using 24 h cool-white fluorescent illumination at 6000–10000 lx. The test solutions were not renewed and pH measurements were made of all test solutions at test start and end. *P. subcapitata* growth was determined by taking from a 0.2 mL sample from each flask approximately 72 h from study initiation. The statistical calculation of the ErC_{50} (growth rate) or EbC_{50} (biomass) was based on mean healthy cell counts.

The toxicity test on *Scenedesmus subspicatus* was conducted in accordance with OECD test guidelines 201 (ENVIRON, 2014).

The acute toxicity of PFHxA on Baltic microalgae was investigated by (Latala et al., 2009). The test algae were batch-cultured in f/2 medium prepared in distilled water. Salinity was similar to that in the southern Baltic Sea. All experimental parameters (pH, salinity and light intensity) were maintained unchanged throughout the study. The tests were carried out on the algae using modified versions of the methods recommended in the European Committee for Standardisation's guidelines (EN ISO, 1995; EN, 1993). The main modifications involved the use of an f/2 medium, selected test strains and a 16:8 photoperiod. The final batch cultures used in the experiments were obtained by mixing a known number of cells in the log growth phase with sterile medium. The initial cellnumber was constant and was measured as the optical density. 9.5 cm^3 aliquots of algal suspension were transferred to 25 cm^3 glass conical flasks, to each of which, in turn, 0.5 cm^3 of different concentrations of aq. PFCA or distilledwater (control) was added. All the toxicity tests involved three replicates per treatment plus controls. After 72 h incubation in culture chambers, the number of cells was determined by measuring optical density spectrophotometrically (Latala et al., 2009).

The studies are conducted in accordance with the OECD guideline and detailed reports are available. Hence the studies are reliable without restriction.

B.7.1.6 Other effects

B.7.1.6.1 Endocrine Disruption

Endocrine disrupting properties in the environment are currently investigated in the frame of the substance evaluation of two related substances of PFHxA: 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (EC-No. 241-527-8; CAS-No. 17527-29-6; 6:2 FTA) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (EC-No. 218-407-9; CAS-No. 2144-53-8; 6:2 FTMA).
Interaction with the hypothalamus-pituitary-thyroid axis

Regarding interaction with the HPT axis four *in vitro* assays are available:

Ren et al. (2015)

Method: using GH3 rat pituitary cancer cells a T-screen assay was performed to test for thyroid hormone dependent cell proliferation in order to identify thyroid hormone receptor active compounds. The competitive binding of 200-500000 nM PFHxA to the human TR ligand binding domain was tested in presence of fluorescein tagged T_3.

Results: PFHxA exhibited very low binding (0.06%) in comparison with T_3. PFHxA showed no agonistic or antagonistic activity in the T-screen assay in the concentrations tested (5-500 µM and 15 µM).

→ Klimisch reliability 2- well documented, non-guideline study without analytical determination of the test concentrations.

Naile et al. (2012)

Method: Rat H4IIE hepatoma cells were exposed for 72 h to 0.1-100 µM PFHxA and changes in mRNA abundance of thyroid-, cholesterol- and lipoprotein related genes were quantified by qPCR. Regarding thyroid-related genes PAX and HEX expression playing a role in thyroid development were tested. Cell viability was assessed visually.

Results: The cell viability was not affected by the treatment. An upregulation of the gene expression could be observed for PFHxA starting at 0.1 µM, although not in a concentration-dependend way. →

Klimisch reliability 2- well documented, non-guideline study without analytical determination of the test concentrations.

Vongphachan et al. (2011)

Method: A gene expression assay was performed on avian embryonic neuronal cells of domestic chicken and herring gull investigating key genes in the thyroid hormone pathway (iodothyronine 5'-deiodinase 2 and 3 –D2/D3, transthyretin –TTR, neurogranin –RC3, octamer motif-binding factor –Oct-1, and myelin basic protein –MBP). Primary cultures of chicken embryonic neuronal cells and herring gull embryonic neuronal cells were prepared from the cerebral cortices of day 11 or 14 embryos, respectively. PFHxA was administered at concentrations of 0.01, 0.1, 1, 3, 10, and 50µM (the latter was applied only for chicken neuronal cells) over 24h. Cell viability was estimated using the Calcein-AM assay. After RNA isolation and cDNA synthesis, qPCR was performed to investigate gene expression changes. In chicken cells, expression of genes of D2, D3, TTR, RC3, Oct-1, in herring gull cells, genes of D2, RC3, Oct-1 were investigated. As positive control for the gene expression analyses, T_3 was used.

Results: PFHxA decreased the cell viability in concentrations > 10 µM, therefore this was the highest applied concentration in the definitive test. PFHxA altered significantly the expression of MBP (LOEC 10 µM), D2 (LOEC 10 µM) and D3 (LOEC 3 µM) genes in chicken embryonic neuronal cells, although for D3 not in a concentration-dependent way (for MBP and D2 only the highest tested concentration exhibited significant expression changes). For the rest of the genes, no changes in gene expression were seen. The positive control, T_3 exhibited gene expression induction for D2, RC3 (LOEC 3 nM) but not for TTR, D3, Oct-1 and MBP. In herring gull embryonic neuronal cells changes were seen only for Oct-1 expression following PFHxA exposure (LOEC 3 µM). The positive control T_3 was effective for RC3 (LOEC 300 nM) but nor for D2 and Oct-1.

→ Klimisch reliability 2- well documented, non-guideline study without analytical determination of the test concentrations.

Weiss et al. (2009)

Method: using radiolabeled ^{125}I-labeled T_4 the competitive binding of PFHxA with T_4 to the human TTR was assessed for a concentration range of 10-10000 nM.

Results: PFHxA exhibited 0.7% of activity of T_4 with IC_{50} of 8220 nM (IC_{50} of T_4 = 61 nM) showing a concentration-dependent inhibition of T_4 bound to TTR.

→ Klimisch reliability 2- well documented, non-guideline study without analytical determination of the test concentrations.

More studies are available investigating thyroid disruption of other PFCAs. Both PFOA and PFNA altered the expression of genes playing a role in thyroid morphogenesis, TH synthesis, transport or metabolism and caused histopathological alterations in the thyroid follicles in fish (see annex).

Interaction of PFHxA with the hypothalamus-pituitary-gonadal axis

To assess the interaction with the estrogen signaling the following studies are available:

Benninghoff et al. (2011)

Method in vitro: An ER competitive binding assay was conducted by incubating liver cytosols from E_2 exposed trout in the presence of [3H]-estradiol and increasing concentrations of PFHxA (10^{-6}-10^{-2} M) for 24h.

Results in vitro: PFHxA exhibited an IC_{50} of 1.22 mM and a 0.0011% binding affinity relative to E_2 (LOEC and binding affinity for ethinylestradiol EE_2 were 0.0589 µM and 23.7 % and for 4-NP 842 µM and 0.0017 %, respectively). Higher homologues of PFHxA were also investigated. These showed similar IC_{50} values ranging between 0.234 - 2.89 mM. There was no correlation between fluorinated alkyl chain length and relative binding affinity.

Method in vivo: The same study investigated the *in vivo* VTG induction in blood plasma of juvenile trout in a subchronic dietary exposure (14 d) to 250 ppm PFHxA. VTG was determined using ELISA.

Results in vivo: PFHxA did not exhibit significantly the VTG induction compared to the control. However, a slight increase in VTG could be observed. Higher homologues of PFHxA were also investigated. Until 11 fluorinated alkyl chain, these homologues induced significantly the VTG expression, the magnitude of induction was dependent on the fluorinated alkyl chain length. Some of these homologues were assessed in more concentrations (2, 50, 250 ppm) showing concentration dependent VTG expression. Presumably, the low effect of PFHxA *in vivo* is related to the toxicokinetic characteristics of PFHxA (i.e. low internal concentration), as just slight and not fluorinate alkyl-chain dependent differences in affinity could be seen *in vitro* between C6-C11 homologues.

→ Klimisch reliability 2- well documented, non-guideline study without analytical determination of the test concentrations.

Gorrochategui et al. (2014)

Method: Aromatase inhibition of 500 µM PFHxA using human placental choriocarcinoma cell line (JEG-3) was assessed.

Results: PFHxA exhibited no effects in contrast to other PFASs tested (PFOS, PFOA and PFBS- see in the annex).

→ Klimisch reliability 2- well documented, non-guideline study without analytical determination of the test concentrations.

Wielogorska et al. (2015)

Method: A reporter gene assay using MMV-Luc cell line was used to assess the effects of PFHxA on estrogen nuclear receptor transactivation. Both agonistic and antagonistic (in presence of 10^{-10}M E2) activities were tested with a single concentration of 10 µM PFHxA (24h exposure). Cell viability was determined by comparing mitochondrial MTT activity.

Results: PFHxA exhibited neither agonistic nor antagonistic effects.

→ Klimisch reliability 2- well documented, non-guideline study without analytical determination of the test concentrations.

Higher PFCA homologues were shown to affect expression of genes, proteins and hormones in HPG axis in zebrafish. Histopatholgical alterations were observed followed by exposure to PFOA in gonads of rare minnows. Developmental effects in offspring of PFOA-exposed medaka were also noticed (see annex).

Table 21: Thyroid disrupting properties of PFHxA.

Test system	Endpoint	Effect concentration of positive control (µM)	Effect concentration of PFHxA (µM)	Reference	Reliability
Human TR binding assay	Competitive (with T_3) binding to TR	T_3: IC_{50}=0.3	IC_{50}~500*	Ren et al., 2015	2 – well documented, non-guideline study without analytical determination of the test concentrations
Rat hepatoma cells	Gene expression of PAX8 and HEX	Not measured	LOEC=0.1**	Naile et al., 2012	2 – well documented, non-guideline study without analytical determination of the test concentrations
Domestic chicken/ herring gull embryonic neuronal cells	Gene expression of D2, D3, MBP, TTR, RC3, Oct1	T_3 in Domestic chicken: $LOEC_{D2}$=0.003 $LOEC_{RC3}$=0.003 $LOEC_{TTR, D3, Oct-1, MBP}$ >0.03 T_3 in Herring gull: $LOEC_{RC3}$=0.3 $LOEC_{D2, Oct-1}$>0.3	Domestic chicken: $LOEC_{D2}$=10 $LOEC_{D3}$=3** $LOEC_{MBP}$=10 $LOEC_{TTR, RC3, Oct1}$>10 Herring gull: $LOEC_{Oct1}$=3 $LOEC_{D2, RC3,}$>10	Vongphachan et al., 2011	2 – well documented, non-guideline study without analytical determination of the test concentrations
Human TTR binding assay	Competitive (with T_4) binding to TTR	T_4: IC_{50}=0.061	IC_{50}=8.2	Weiss et al., 2009	2 – well documented, non-guideline study without analytical determination of the test concentrations

*Estimated by linear interpolation; **Not concentration-dependent

In summary, the available data show a concern for PFHxA interaction with the HPT axis based on *in vitro* data supported by *in vivo* fish data on homologues but are not sufficient to draw a definite conclusion.

For the moment, no conclusions can be drawn whether or not PFHxA is an endocrine disruptor in the environment.

B.7.1.6.2 (Sub)lethal effects

A study (Blanc et al., 2017) compared the gene expression induced by 3,3′,4,4′,5-pentachlorobiphenyl (PCB126) with mixtures of PCB126 + PFHxA, PCB126 + PFOS and PCB126 + PFOS + PFHxA in *Danio rerio* embryos. The results showed that PFHxA could enforce PCB126 toxicity in a mixture. A significant induction of *gpx1a* (involved in oxidative stress) for example only took place in a mixture of PCB126 + PFHxA and a mixture of PCB126 + PFOS + PFHxA. This means that PFHxA could be involved in a synergistic effect with PCB126 during the upregulation of *gpx1a*. A role in increasing cell membrane permeability induced by PFHxA and PFOS is dicussed by the authors as a probable cause for the synergistic effect. A recently published paper has studied the amphilic properties of PFASs and their potential to accumulate in phospholipid bilayers (Nouhi et al., 2018). Longer chain PFASs showed higher tendency to penetrate into the bilayer compared to the short-chain compounds. Nevertheless, the authors state that in dependence of the concentration PFHxA can also disturb the bilayer. This would support the assumption made by (Blanc et al., 2017).

B.7.1.7 Summary and discussion of the environmental hazard assessment

Standard tests on ecotoxicity are available for algae, daphnia and fish covering acute as well as chronic toxicity. In the study of (Hoke et al., 2012) no effects on fish and daphnia in the acute toxicity tests were observable up to > 99.2 mg/L and > 96.5 mg/L respectively. Also, no effects were observable for algae up to 100 mg/L.

Barmentlo and coworkers (2015) report an EC_{50}-value of 1 048 mg/L for acute toxicity on daphnia. The acute toxicity of PFHxA on Baltic microalgae investigated by (Latala et al., 2009) is 998.7 mg/L for *Geitlerinema amphibium* and 4 032 mg/L for *Chlorella vulgaris. Scenedesmus subspicatus* seems to to considerably more sensitive as an EC_{50}-value of 86 mg/L and a NOEC of 50 mg/L is reported (ENVIRON, 2014). Long term effects on hatching success, survival, length and weight of *Oncorhynchus mykiss* were not observable up to > 9.96 mg/L (Burke, 2008). The reported EC_{50} (21 d) value based on reproduction of daphnia is 776 mg/L. The EC_5 (21 d) value is not considerably lower (724 mg/L) (Barmentlo et al., 2015).

Likewise, there is no considerable difference between EC_{50} (21 d) and EC_5 (21 d) based on population growth rate (853 mg/L and 779 mg/L).

The studies described above all address the toxicity of PFHxA as a single substance. As Ahrens and coworkers (Ahrens and Bundschuh, 2014) concluded in their review on various monitoring studies of the aquatic environment, PFASs are continuously introduced into aquatic ecosystems and are ubiquitously present in complex mixtures. There is sufficient scientific evidence and a recently published paper has pointed out that neglect of mixture effects can cause chemical risks to be underestimated (Kortenkamp and Faust, 2018). In a multicomponent mixture of xenoestrogens experiment where each chemical was present at levels well below its NOEC and EC_{10} produced significant effects in a YES assay (Silva et al., 2002). Mixture toxicity are ecotoxicollogically relevant as for instance has been shown by (Junghans et al., 2006). 25 pesticides, which reflected a realistic exposure scenario in field run-off water, showed mixture effects on the reproduction of the freshwater alga

Scenedesmus vacuolatus. Chronic ecotoxicological tests do not take into account any cross generational effects as anticipated for PFASs. The exposure is continuous and even if releases would be regulated now, the mass already present in the environment will still cause exposure over a very long time period, even much longer than other substances being "very persistent" according to Annex XIII to REACH. The possible risk of extremely persistent organic fluorochemicals for humans and the environment has also been emphasised by leading scientists (Blum et al., 2015a; Scheringer et al., 2014).

B.8 PBT and vPvB assessment

B.8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

See section 1.3.7 assessment of PBT properties.

B.8.2 Emission Characterisation

Due to the considerable economic importance of PFCAs these synthetic compounds are ubiquitously present in the environment.

PFHxA and its salts are non-degradable as well in wastewater treatment plants (WWTP) as in the natural environment. However, many PFHxA-related substances like 6:2 FT(M)A or 6:2 diPAP may degrade fairly quickly to 6:2 FTOH, with a half-life of about 1.3 days (Liu et al., 2010b). PFHxA again is formed by degradation of 6:2 FTOH. The majority of 6:2 FTOH precursors and the degradation routs are unknown. For degradation of the sum of the unknown precursors, the formation ratio of 1 t 6:2 FTOH forms 39 kg PFHxA is used as a surrogate for further calculations (calculated based on data from Liu et al. 2010). These substances unrelieved getting to surface water and into the sewage sludge (Günther et al., 2009). A further source of water and soil contamination with PFHxA is landfilling. In her PhD-thesis (Vierke, 2014) investigated samples from WWTP as to the distribution of PFASs in the environment. Air-water concentration ratios were higher for short chain PFCAs compared to long chain PFCAs. But an enrichment of PFHxA and its related substances in water is likely, too.

The mobility of a substance in the environment depends on its occurrence in mobile environmental compartments, e.g. air and water and the mobility of these compartments (Ballschmiter, 1992). Diffusive and non-diffusive transport mechanisms are relevant for distribution of substances. Non-diffusive transport takes place as advection, e.g. in water or air currents and in rain or snowfall. Diffusive transport is the dispersion of a substance between different environmental media, e.g. from soil or water to air and from water to sediment (Mackay, 2001); (Schwarzenbach et al., 2003). For partitioning behaviour of substances the chemicals' properties, like vapour pressure or solubility, as well as the characteristics of the environmental media, e.g. sediment properties are decisive (Ballschmiter, 1992).

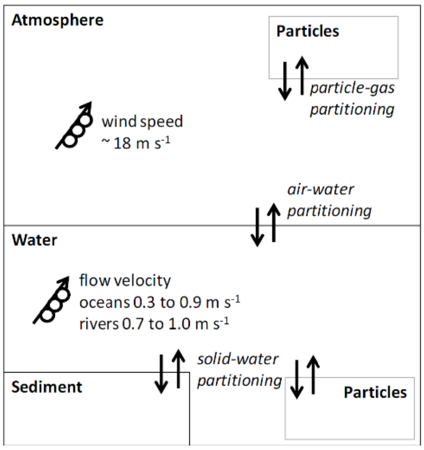

Figure 4: *Distribution of substances (equilibrium arrows) to mobile environmental media (circled arrows) (based on (Ballschmiter, 1992) and multimedia models ((Mackay, 2001); (Scheringer, 2002)).*

Concluding, PFHxA, its salts and related substances could be found as well in water and air as in sediments. Water and air are highly mobile compartments. Hence, a long-range transport of these PFCAs is likely. On the other hand, soil and sediments serve as depot for the persistent PFCAs.

Numerous direct and indirect sources of PFHxA, its salts and related substances contribute to the overall environmental emission of these substances. As described in chapter E.2, PFHxA, its salts and related substances are used in many applications and were detected in various consumer products such as textiles, carpets, upholstery, paper, leather, toner, cleaning agents and carpet care solutions, sealants, floor waxes, paints and impregnating agents. The substances are released into the environment during different life cycle steps via various emission pathways.

Direct sources include emissions from the manufacture and use of PFHxA or its salts and during the life-cycle of products that contain these substances as a constituent, impurity or residue. For example, fluoroelastomer-based products contain the ammonium salt of PFHxA as residue when the substance has been used as processing aid.

Indirect sources refer to the formation of PFHxA and its salts from their related substances (categorisation comparable to that of (Wang et al., 2014)).

Certain PFHxA-related substances, such as 6:2 FTOH, are volatile substances. They are released into air and wastewater during manufacture of the substances themselves, from side-chain fluorinated polymers and during use and disposal of consumer articles treated with PFHxA-related substances. When emitted to the atmosphere, they can be degraded to PFHxA, too. As well the related substances as PFHxA are deposited on soil or surface waters. They are also washed out from the atmosphere via precipitation.

Although due to the large number of uses it is not possible to elaborate on every single one, information on emissions of the selected sources is generally applicable to other uses as well.

Data on emissions are available on a top-down approach. However, large data gaps exist on the downstream user level. PFHxA and related substances are used in various applications which are wide dispersive.

Therefore, if a quantitative approach is not applicable, a qualitative approach has been chosen for the description of emissions and mainly worst case estimates of environmental emissions are given based on environmental release categories according to ECHA Guidance R.16 (European Chemicals Agency, 2016a).

B.9 Exposure assessment

RAC box

Based on the information available in the Background Document and submitted during the consultation, RAC performed a qualitative evaluation of the releases and effectiveness in view of the need to minimise the releases. This is because RAC concludes that the reported quantitative release estimates are unreliable due to numerous inconsistencies between different sections of the Background Document, insufficient justification for the assumptions made and significant gaps in the information presented or in the reporting of the underlying calculation methodology for the different use sectors. RAC, therefore, concludes that the Background Document provides insufficient information to draw firm conclusions on the central estimates and ranges of releases to the environment. At the same time, RAC notes that measured data in various environmental matrices convincingly demonstrates that emissions to the environment do occur.

The details and justification of of RAC's qualitative evaluation and of these concerns are reported in the RAC opinion.

B.9.1 General Discussion on releases and exposure

Not assessed.

B.9.1.1 Summary of the existing legal requirements

Not assessed.

B.9.1.2 Summary of the effectiveness of the implemented operational conditions and risk management measures

Not assessed.

B.9.2 General Assumptions made for environmental exposure estimations

Environmental releases are estimated in general by using standard emission factors for air, water and soil. These factors are defined for different uses in Environmental Release Categories (ERCs) and given in appendix A.16-1: Environmental release categories in Chapter

R. 16 of the ECHA guidance on chemical safety assessment. The ERCs describe the broad conditions of use from the environmental perspective. If necessary, sector-agreed data sets defined in Specific Environmental Release Categories (SPERCs) were used for environmental release estimations.

Manufacture:
PFHxA, its salts and related substances mainly not manufactured in the EU. In that case, the environmental release category ERC 1 - Manufacture of the substance – is not applicable for EU wide releases of substances. Further, industries provided reliable information for release mitigation measures. Therefore, when necessary, environmental releases at manufacturing are estimated based on provided information from industries.

Manufacture of C6 related side-chain fluorinated polymers (mainly polyacrylates):
A large amount of PFHxA, its salts and related substances is used in manufacturing of fluoropolymers and SFPs. For environmental release estimation ERC 6c - Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article) – was applied.

Industrial treatment of articles:
The vast majority of PFHxA, its salts and related substances is used for treating products and articles at industrial sites. The environmental release estimation occurs according ERC 12a - Processing of articles at industrial with low release. ERC 12a was applied to estimate releases from textiles and from paper and board.

Service life:
The use of products or articles from the point of sale to the point of discard is defined as service life. Articles containing PFHxA, its salts and related substances are used wide dispersively. Because there are no intended or high releases, the ERCs for widespread use of articles with low release indoor (ERC 11a) or outdoor (ERC 10a) are applied. The annual release of PFHxA, its salts and related substances is calculated dividing the estimated total release by the service lifetime.

When a different approach for environmental release estimation is used, this is described in the chapter of the respective use (like for inks and chrome plating).

To the Dossier Submitter's knowledge, PFHxA and its salts itself **only are used in one application** (use of APFHx as processing agent in fluoroelastomer manufacture). Consequently, **the only direct release is assumed by this use**. However, the estimated number of unreported releases could be higher. Therefore, PFHxA and its salts are considered as the main degradation product from many (unknown) related substances. The measured amount of PFHxA in various products and articles like in textiles is considered as transformation product from the used PFHxA related substances and lead on indirect releases. Due to the almost entirely use of PFHxA related substances, the emission estimation focuses on the release of the related substances. However, the estimated amount of PFHxA related substances was converted into PFHxA equivalents, finally using two different approaches.
Studying the scientific literature, only a few publications are available which consider detailed degradation processes of PFHxA related substances and which provide quantitative analysis as well of the precursors as of the degradation products. Mostly the degradation of 6:2 FTOH was investigated. Above that, other publications which are describing degradation of PFHxA related substances qualitatively (see chapter B.4.1 Degradation of PFHxA-related substances) demonstrate that one major metabolite is 6:2 FTOH which is further degraded. Therefore, the quantitative analysis of the degradation of 6:2 FTOH (mainly the publication from Liu et al

2010 and from Zhao et al. 2013) was used as a surrogate for the degradation of PFHxA precursors in general. Liu et al. published two investigations in 2010 regarding the degradation of 6:2 FTOH. One examination occurred in a closed system and the second in a flow through system. 6:2 FTOH seems to be degraded rapidly. After 1.3 to 1.6 days, 50 % of ^{14}C labelled 6:2 FTOH disappeared from soil, because of microbial degradation and volatilisation (Liu et al., 2010a). The overall mass balance during the 84-day incubation averaged 77 % and 87 % for the live and sterile treatments, respectively. Zhao et al. 2013 investigated the aerobic biotransformation of 6:2 FTOH in activated sludge of two domestic WWTP (Zhao et al., 2013b) and in an aerobic river sediment system. In both systems primary biotransformation was rapid. More than 97 mol% converted within three days to at least nine transformation products. The most abundant transformation product was the volatile 5:2s FTOH.

The DS resumes that most of 6:2 FTOH degradation occurs in some days by forming stable transformation products. Looking at the data gained in a flow-through soil incubation system provided by Liu et al. (2010), there was no further increase of PFHxA concentration of 4.5 mol% after day 20. So, the DS assumes that the concentration of PFHxA will not be increased further after 365 days. However, this number is low. The 4.5 mol% are the share which is released into water. Considering also the data gained in a closed system by Liu et al. (2010), the degradation of 6:2 FTOH yields in 8.1 mol% PFHxA. Liu herself interprets this difference in a loss to air. The numbers given in mol% are converted into mass% using the molecular mass of 6:2 FTOH and PFHxA. 4.5 mol% PFHxA from 100 mol% 6:2 FTOH reveal 3.9 mass% PFHxA and 8.1 mol% PFHxA reveal 7 mass%.

The resulting 70 kg PFHxA from 1 t/a related substances is used as a surrogate for the transformation of PFHxA related substances in general as a realistic worst case. Table 25 d in chapter B.9.17 summarises the equivalent PFHxA emission based on this scenario.

As worst-case approach it is assumed that 100% of low molecular PFHxA related substances are transformed into PFHxA over a long time. Again, 6:2 FTOH is used as a surrogate for all PFHxA related substances. The molecular masses of the fluorotelomer alcohol was proportioned to the molecular mass of PFHxA (1 t of 6:2 FTOH results in 0.86 t PFHxA).

Both approaches have a significant degree of uncertainty because the basis of the assumptions is a surrogate (6:2 FTOH). The fate and behaviour of many other (unknown) substances would be very different from the surrogate.

The numbers assumed by using the realistic worst case may underestimate the real formation of PFHxA. Many PFHxA related substances and its intermediates have to be considered as volatile and are detectable in products and articles only to a certain extent due to previous evaporation of the substances. That implies that large quantities of related substances have already been released into the environment from the investigated products and articles at the point of time when the measurement takes place. Therefore, it is not possible to cover these substances directly in the assessment of environmental releases of PFHxA and related substances.

Looking at the surrogate 6:2 FTOH, according to several authors like Liu et al 2010, Tseng 2012, He et al. 2013 described that large quantities of other substances like 6:2 fluorotelomer carboxylic acid (6-2 FTCA) and 6:2 fluorotelomer unsaturated carboxylic acid (6-2 FTUCA) occur during the degradation of 6:2 FTOH. The quality and the quantity of the intermediates are produced depends on many factors, like the presence or absence of UV radiation, or in which compartment (air, water, soil) the degradation occurs. The biotic degradation also depends on the microorganism community. Results from He et al. 2013 indicate that fungi are able to transform about 50% of 6:2 FTOH and 70% of 8:2 FTOH in 28 days. Major metabolites of 6:2 FTOH include 5:3 polyfluorinated acid (40%), 5:2 sFTOH (10%), PFHxA (4%), and others (about 1% each). The transformation rate and the formation of intermediates is significantly lower by bacterial degradation. Taking longer timeframes into account than the timeframes in standard degradation tests required and considering the further degradation of intermediates it could be assumed that higher quantities of PFHxA are formed than the surrogate calculation based on the degradation experiments from Liu et al. (2010) or Zhao et al. (2013) indicates. So, even the degradation rates and the degradation pathways of the surrogate 6:2 FTOH are already very variable. In addition, depending on the reaction conditions the degradation of every single definite related substance may produce different qualities and quantities of transformation products, too.

Concluding, depending on the substance degrading and the environmental conditions it is indeed highly likely that higher amounts of PFHxA are formed in longer time frames than estimated in degradation experiments.

On the other hand, as demonstrated before, during the degradation of PFHxA related substances also intermediates are formed, that not necessarily will be further degraded to PFHxA. Therefore, the worst-worst case approach, that 100% of related substances are degraded to PFHxA over time, may overestimate the formation of PFHxA in the environment and the actual percentage of degradation lies in between the realistic worst case and the worst-worst case scenario.

From the articles and products in use a global deposit of about 60 % in landfills is assumed (Geyer et al., 2017). Subsequently, together with the articles and products the containing PFHxA, its salts and related substances are also deposited in the same share.

Based on the assumptions made by the DS in the restriction dossier for PFOA, about one percent from total amount of SFPs could be released as PFHxA at service life. This value is used to describe the shared impact of SFPs on environmental PFHxA releases.

For further rough estimations environmental concentration at European level the following modified standard values from the Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 and values used in EUSES are considered.

Definition of default European area:
- Area of Europe: 4 476 000 km²,
- area fraction water: 10 % (scenario north – values representing Scandinavian countries),
- area fraction water: 1 % (scenario south – values representing countries like Spain),
- average water depth: 4 m.

That results in a freshwater body of 1 790 km³ (scenario north) and 179 km³ (scenario south).

Definition of default European marine surface water (coastal territorial waters):
- EU coastline: 68 000 km,
- width: 22.22 km (12 sm),
- average water depth: 10 m,

The regarded water body has a size of 15 110 km³.

- Area of North Atlantic (including the North Sea): 41 490 000 km², average depth 3 300 m,
- area of Mediterranean Sea 2 596 000 km², average depth 1 430 m,
- area of the Baltic Sea 413 000 km², average depth 52 m.

From manufacturing, formulating, using by several users and finally depositing the substances, the whole lifecycle of PFHxA, its salts and related substances (including its precursors and polymers) occurs widely distributed over the EU. According to the Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.16, in that case a fraction of 10 % of the whole used tonnage at EU level is attributed to the region by default while most of it (90 % by default) is attributed to the continental scale. Therefore, releases at continental scale will contribute as a background to the regional concentration. For further calculations it is assumed that about 80 % of PFHxA-related substances are found in water.

B.9.3 Manufacturing and uses at industrial sites

B.9.3.1 Environmental release

Due to their unique properties, perfluorinated substances are used for manufacturing of articles and products in large quantities in the EU. In general, two main methods are used for manufacturing perfluorinated substances: direct fluorination (electrochemical fluorination, ECF) and telomerising (Prevedouros et al. 2006). The perfluorinated substances produced may then react further, manufacturing different derivatives and polymers (Kissa 2001).

By passing an electrical current through a solution of dissolved or dispersed organic compounds and a liquid hydrogen fluoride, the organic compounds become fluorinated. This reaction is extremely vigorous and mixtures of perfluorinated substances are produced. The compounds in the mixture are varying in the lengths of carbon chains. Branched chains may also occur. Telomerising is a process in which a perfluorinated molecule reacts with an unsaturated molecule. The compound formed through this reaction is called telomere. Fluorinated telomers are characterised by the molecule containing a perfluorinated carbon chain bonded to a short carbon chain, usually two carbon atoms with hydrogen atoms. Telomers are produced and used commercially as mixtures. Because of the restriction of C8 to C14 perfluorinated substances, manufacturers shifted in using perfluorinated short chain substances (C6 and lower) and perfluorinated ethers, in addition to the existing uses. Chains shorter than eight carbon atoms represent approximately two percent by weight in the telomere mixture. Therefore, further processing and cleaning steps are necessary to concentrate the desired C6 telomere molecules. Large quantities of the perfluorinated C6 side chained substances are further used for polymer manufacturing.

A survey among manufactures carried out to collect data on tonnages and uses of perfluorinated substances. Mainly, the given tonnages were average values between 2016 and 2018. The substances, which may degrade to PFHxA were grouped into major classes of chemicals in use. The maximum given amounts for a substance / class of chemicals stated by manufacturers were summarised, respectively. Using these summarised tonnages, a tonnage band for manufacturing [t/a] in the EU was derived for each substance class. Additionally, these data were compared with the public available data from ECHA[13]. The registered annual tonnages of PFHxA, its salts and related substances are summarised in Table 22.

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[13] https://echa.europa.eu/de/search-for-chemicals (last access: 13.12.2019).

Several single substances, like some esters with C6 perfluorinated (side-)chains are manufactured in tonnages far below 10 t/a. The bulk amount of single low molecular perfluorinated substances (87 %) are precursors for manufacturing polymers or used as processing aids in polymerisation processes. Thereof, 36 % are monomers which are polymerised directly.

From the single low molecular substances recorded in these data, 7 % are used as surfactant in firefighting products (without dynax). Only a very small amount of these fluorinated low molecular substances directly is used as surfactants in surface coatings and lacquers (< 0.5 %).

Table 22: Used tonnages (= manufacturing + import – export) of substances with C6 perfluorinated (side-)chains in the EU.

	tonnage band [t/a] derived from max. tonnages manufactured in the EU	
	min	max
non polymeric low molecular substances		
PFHxA and its salts	10	100
perfluorohexanesulfonic acids	100	1 000
aliphatics with C6-perfluorinated (side-)chain	100	1 000
6:2 fluorotelomer iodides	1 000	10 000
6:2 FT-alcohols	1 000	10 000
esters with C6-perfluorinated (side-) chain	10	100
6:2 fluorotelomer sulphonamides	100	1 000
6:2 fluorotelomer phosphates	1	10
6:2 fluorotelomer acrylates	1 000	10 000
6:2 fluorotelomer substances (not further described)	10	100
further substances made with PF-C6	100	1 000
Polymers		
polyacrylates with C6 perfluorinated side-chains	1 000	10 000
further polymers made with C6 perfluorinated side-chains	10	100

For estimation of environmental releases of PFHxA, its salts and related substances at manufacture (ERC 1) the standard estimation according to REACH guideline Annex R.16 was used. In this standard scenario a release of the substance of interest to air of 5 %, to water (before sewage treatment plant) of 6 % and to soil of 0.01 % of the annual tonnage manufactured is assumed.

Currently, no registrations are available for PFHxA itself. Therefore, direct releases of PFHxA into the environment by manufacture in the EU could not be assumed.

Ammonium perfluorohexanoate, the ammonium salt of PFHxA (APFHx) is imported as watery solution into to the EU. Therefore, no data for manufacturing are available. APFHx is used at industrial sites as processing aid to manufacture fluoroelastomers, leading to inclusion into articles. According to the manufacturer of fluoroelastomers the environmental releases of APFHx is below 10 kg/a at elastomer manufacturing. This is realised by multiple reuse of monomer solution and by effective removal of APFHx from wastewater.

As well as 6:2 fluorotelomer iodides as 6:2 fluorotelomer-alcohols are intermediates to produce 6:2 acrylates (like 6:2 FTA as of 6:2 FTMA). According to industries, the reaction take place at one site in an enclosed system. The outcome of one production step, like the produced 6:2 fluorotelomer-alcohols, instantly is used in the next reaction step. Therefore, environmental releases of the acrylate precursors, the respective iodides and the alcohols are not expected. These 6:2 acrylates are monomers for manufacturing of acrylate polymers with C6 fluorinated side chains. Actually, the REACH guideline standard worst-case scenario has to be applied to calculate annual emission of 6:2 acrylate monomers. However, the production of these monomers occurs under strictly controlled and enclosed conditions and mitigation measures are applied. The majority of substances is regained and recycled at the production process. Residues in wastewater and air are captured e.g. with activated carbon or absorber resins. Due to release mitigation measure at production, the release of low molecular C6 fluorochemicals via WWTP and into the air is considered less than 10 t/a (according to industries). As well the absorber materials, the sludge from the WWTS, as the air from the processes are exhausted and incinerated. Consequently, for exposure estimations the release of C6 fluorochemicals at manufacture in the range of 1 – 10 t/a is assumed.

Concluding, the release of PFHxA, its salts and related substances seems to be low during manufacturing process of these substances.

The main purpose processing perfluorinated substances is the manufacture of homo- and copolymers with C6 fluorinated side chains. Acrylate polymers with C6 fluorinated side chains are produced in the EU in a range between 1 000 and 10 000 tonnes per annum. The majority of these polymers serve as repellent and finishing agent in textile and paper industries. 57 % of the manufactured polymers with C6 fluorinated side chains are used in textile treatment, and 18 % in paper treatment. For additives in surface treatment baths and in-home fabrics about 5 % are used. In fire-fighting products, as additive in lacquers and in a wide variety of not further specified products and articles below 1 % of these polymers are applied, respectively.

The release of PFHxA, its salts and related substances into the environment from polymers is discussed in the following chapters (polymers and plastic materials, textiles, paper).

B.9.4 Polymers and plastic material

B.9.4.1 General information

Polymers are an extremely large family of very different materials with different characteristics, properties and uses. These materials offer specialized solutions to a wide range of requirements in numerous products, applications and sectors. Among the polymers, fluoropolymers are high-performance materials.

The overall trend in global manufacturing and consumption of fluorotelomer and fluorotelomer-based polymers is a shift from ≥ C8 to C6 fluorotelomer chemicals (FluoroCouncil 2012 cited in Lassen et al. (2013)). Since the use of long-chain PFASs such as PFOA and its related substances has been restricted, manufactures shifted the production to short-chain fluorinated homologues (Luz et al., 2019). For fluorotelomer based products, this meant a shift to products that contained a six-carbon perfluoroalkyl moiety like 6:2 FTOH. In a recent survey (Ökopol, 2018), Europe-based manufacturers, formulators, article assemblers, and associations provided information on the establishment of the C6 fluorotelomer technology.

A large group of side-chain fluorinated polymers are polyacrylates with C6 perfluorinated side chains. Acrylates can be formulated as thermoplastic or thermosetting resins, or as water emulsion latexes. The use of C6 perfluorinated side-chain polyacrylates makes other materials water, oil and dirt repellent. Hence these polymers are used wide dispersively as textile and paper coatings and in surface coatings, lacquers and polishes, these acrylate polymers are also used as additives to give dyes more brightness and stability against UV radiation. They serve as wetting agents in waxes and polishes, as antifoaming compounds and as anti-stick substances in cosmetics, too (BUND, 2015). Polyacrylates with C6 perfluorinated side chains are manufactured up to 10 000 t/a in Europe. Impurities in the polymers and the partial degradation of the polymers may lead to an emission of PFHxA, its salts and related substances into the environment. Emissions occur during service life and at the lives end (deposition in landfills) of articles treated with or containing acrylates with C6 perfluorinated side chains.

APFHx is used at industrial sites as processing aid to manufacture fluoroelastomers. The annual consumption of APFHx in the EU amounts from 10 to 100 t/a. The ammonium salt may occur as impurity in these fluoroelastomers.

B.9.4.2 Exposure estimation

B.9.4.2.1 Environmental exposure

The annual tonnage of fluoropolymers and side-chain fluorinated polymers sold on the EU market results in the European manufacturing plus the import, minus the export from the EU. According to (Amec Foster Wheeler Environment & Infrastructure UK Limited, 2017), 51 000 t of fluoropolymers and SFPs were manufactured in the EU and 21 500 t were imported in 2015. Reducing this amount by 20 500 t fluoropolymers and SFPs exported from the EU, finally 52 000 t fluoropolymers and SFPs were sold on the EU market in 2015. This is about 20 % of the global annual demand on fluoropolymers and SFPs. However, North America and the Asia Pacific region are major consumers of fluoropolymers with a market share together of about 60 %. Several sources from industries report a market growing on this sector with a rate between five and eight percent. (Personal information from industries, (Amec Foster Wheeler Environment & Infrastructure UK Limited, 2017; European Chemicals Agency, 2015a). In this information it is not distinguished between fluoropolymers and side-chain fluorinated polymers. According to information gained in PC, the share of SFP-polyacrylates sold in the EU is about 10% and the share of fluoroelastomers is about 10% from total amount of fluoropolymers and side-chain fluorinated polymers. For the exposure estimation the release of PFHxA from C6 SFPs, mainly by polyacrylates with perfluorinated C6 side chains is considered only.

C6 side-chain polyacrylates (SFPs)
Based on data evaluated from 2016 to 2018, in the EU 1 000 to 10 000 t C6 side chain acrylates were manufactured annually. Assuming for the C6 side chain acrylates the same shares between manufacturing, import and export as for the whole group of fluoropolymers and SFPs in general, the amount of import and export is roughly in balance. However, there has been a geographical shift of manufacturing and industrial uses of perfluorinated substances from North America, Europe and Japan to emerging Asian economies. China has become one of the largest manufacturers and user of such substances (Liu et al., 2015b; Meng et al., 2017; Wang et al., 2014). Many articles made or treated with perfluorinated substances are imported into the EU in large quantities from the Asia Pacific region. Therefore, the import of articles containing C6 side chain acrylates is much higher than the manufacture of such articles in Europe. As a consequence, a higher release of C6 side chain acrylates than the release calculated using the above stated tonnage range is expected. The consequences of this gap are discussed in chapter B.9.4 for the textile sector exemplarily.

As well the C6 side chain acrylate polymers as their monomers may be released into the environment as well by manufacturing products and articles as using these treated articles and products at all life cycle stages. By degradation, the polymers and their monomers are a source for PFHxA release into the environment. For the use of monomers in polymerisation processes at industrial site (inclusion or not into/onto article) the default release factors according to ERC 6c can be applied for environmental release estimation. However, stakeholders reliable demonstrated a high reduction of environmental releases by effective mitigation measurement at C6 polyacrylate production. Therefore only 10% from the values calculated according ERC 6c are finally expected to be released into the environment. So, manufacturing 1 000 to 10 000 t/a of polymers with a C6 perfluorinated side chain, 5 to 50 t/a of PFHxA-related substances are released into air and water respectively. Concluding, **10 to 100 t/a of PFHxA-related substances** are released into the environment via C6 side chain (co-) polymers at manufacturing.

However, depending on the sector use, the amount of SFPs and the amount of related substances released during service life of products and articles made with C6 perfluorinated side chain polymers are very variable. But, for the life span of the polymer containing article an assumption using default worst-case release factors for the respective environmental release category is possible. About 75 % (treatment of textiles and paper) of the C6 side chain acrylate polymers are used wide dispersively for indoor products with low releases. Thus, a use of 750 – 7 500 t/a of these SFPs could be assumed in this sector. Applying the default release factors, for an average service live of 5 years for these articles, 0.15 to 1.5 t/a of the C6 side-chain polyacrylates are released to water and air, respectively (ERC 11a). At anaerobic conditions these polymers partially may degrade to PFHxA. Assuming the remaining 25 % of the manufactured polymers are used wide dispersively for outdoor products with low releases, the release factors for ERC 10a have to be applied. Following, annually 3.23 to 32.25 t/a polymers are released to water and soil respectively during an articles service life. In sum, 7 to 68 t/a of SFPs are released into the environment by articles containing these polymers during their service life. At its end-of-life every article becomes waste. Waste management includes sewage treatment systems, landfills, incineration and recycling. About 60 % of articles are deposited in landfills globally (Geyer et al., 2017). Applying this amount to articles containing or treated with C6 side chain acrylate polymers, together with the respective articles 600 to 6 000 t/a of these polymers are deposited in landfills.

According to several authors, the half-life of a C6 side chain acrylate polymer ranges from 870 to 1700 years. Later works indicates a half-life of the fluorotelomer based acrylate polymers between 20 and 60 years. Modelling experiments from (Washington et al., 2009) demonstrated that more finely grained polymers in soils might have half-lives of about 10-17 years. Additionally, the perfluorinated side chains may be dissociated from the backbone polymer partially. It is highly likely, that the formed fluorotelomer acrylate is subject to degradation to form n:2 FTOH, and further via a series of oxidation transitory intermediates to form n:2 fluorotelomer carboxylic acids (Russell et al., 2008). According to Washington et al. 2015, shorter perfluorinated side chains undergo a more rapid substitution in soil (see Chapter B.4.1). So, surface soils and landfills constitute a major global reservoir for PFAS (Washington et al., 2019). Consequently, these authors measured concentrations up to 4.26 µg PFHxA in leakage of landfills. For exposure estimations it is important to relate these results to the amount of source where the measured concentrations of PFHxA come from. Lang et al. 2016 composted carpet and clothing refuses treated with fluorinated acrylate polymers in bioreactors. The Dossier Submitter normalised these results to the average content of side chain fluorinated polymers in textiles. In average, per tonne acrylate polymers containing C6 side chains, up to 425 mg PFHxA are released mainly to water per year. However, this is far below from the release of 1% PFOA from C8 related SFPs. This assumption is a worst-case estimate. Due to the lack of other reliable studies describing the degradation of C6 related SFPs directly and not in combination with treated articles, the worst-case assumption of 1% release of PFHxA from C6 related SFPs was carried over from the restriction of PFOA.

Using this value for calculations, the annual release of PFHxA into the environment during service life of these polymers (about 5 years) is up to 150 kg. However, from landfills an emission of PFHxA up to 6 t/a could be expected from the 10 000 t of C6 side chain acrylate polymer used in the EU. Looking at these results, it is important to bear in mind that the estimated number of unreported releases could be much higher due to import of articles containing these polymers.

Conclusion: The partial degradation of C6 side chains from the acrylic polymers could be a source for release of PFHxA into the environment that should not be underestimated especially if large timeframes are investigated.

Fluoroelastomers containing Ammonium Perfluorohexanoate (APFHx)

Fluoroelastomers are rubbery materials based on several of the same monomers as used for manufacturing fluoropolymers. They are produced as highly viscous liquids and then cross-linked (or 'cured', or 'vulcanized') to harden them and impart their elasticity. For manufacturing a subset of fluoroelastomers, APFHx is used as processing aid. Therefore, APFHx could remain as a residual impurity in these elastomers. The APFHx containing rubbery material is used to produce e.g. seals and tubes in the transportation sector like in automotive or aviation. So, a wide dispersive outdoor use of these articles with a low release of APFHx could be assumed. Applying the default release factors for this release category (ERC 10a) and a service lifetime of 10 years, up to 0.65 t/a of the ammonium salt from the 10 to 100 t APFHx used in the EU are released to the environment. Assuming, a low release of APFHx by leachate from landfills (60 % of articles are deposited in landfills) up to 390 kg may be released into water annually. Concluding, **0.1 to 1.0 t/a APFHx** could be released into the environment by the use of APFHx in fluoroelastomers. However, the estimated number of unreported releases could be much higher. The number of articles imported into the EU containing fluoroelastomers or other products with APFHx as impurity is unknown.

B.9.5 Textiles

B.9.5.1 General Information

One of the largest sectors using perfluorinated substances is the textile manufacturing sector. In the European Economic Area (EEA) more than 61 000 installations that may use or emit PFAS working in this sector (Goldenman, 2019). The most important uses in the textile sector are uses for household textiles (e.g. furniture, carpets, curtains, awnings), for clothing including for occupational- and outdoor wear. Technical textiles including textiles for medical textiles are treated as well with C6 related side-chain fluorinated polymers (SFPs) as with low molecular PFHxA related substances. As far as DS knows PFHxA itself and its salts are not used for textile treatment. However, there are no, or only insufficient, reliable data available on volumes of PFHxA related SFPs and low molecular substances used to treat textile fibres, fabrics and garments. To close this information gap, estimations as described below were applied.

Estimation of used amount of SFPs in textile treatment and their related environmental releases:
In industrial finishing processes, the SFPs are applied as a thin film on the fabric surface by a so-called pad-dry-cure process (Gremmel et al., 2016). In this process, the untreated fabric is passed through an application bath containing the SFPs and is then squeezed between two rollers to remove excess liquid, followed by drying and curing in an oven at temperatures up to 180 °C. The curing promotes the cross-linking of the polymer to the fabric. Typically, 0.2 – 0.5 % (w/w) of polymer is applied to the fabric (BfR, 2012).
Two different approaches were applied to calculate the amounts of SFPs used in the treatment textiles.
a) The release estimation was conducted with data from perspective of production and the consecutive use of fluoropolymers and SFPs in the supply chain (see chapter B.9.4.2.1).
b) The above-mentioned concentrations from the BfR study were used to calculate the total volumes of PFHxA related SFPs processed in the respective number of textiles (see the following chapters describing some textile sub uses). The concentration-based approach finally was used for estimating the total SFP emission from textiles and thereof calculating the release of PFHxA from these polymers.

Estimation of used amount of PFHxA related substances in textile treatment and their related environmental releases:

As described for SFPs, also low molecular substances are tightly crosslinked to textile fibres to a certain extend. Above that, the used low molecular substances also may be bound covalently to the matrix. Emission calculation for low molecular PFHxA related substances in textiles was performed on the basis of measured concentrations in textiles of these substances provided by scientific publications (see summarising Table 37 "Reported concentrations of 6:2 FTOH and PFHxA in textiles" in chapter E.2.11.1).

Only data related to a "weak" extraction (mainly with methanol or water) and a subsequent quantitative analysis were used for the emission estimation. In contrast to data gained as the result of "harsh" extraction (measurement of total fluorine or total oxidizable precursor (TOP) assay), it is highly likely that crosslinked and covalent bound substances are not extracted with water or methanol and remain on the textile matrix. So, it could be assumed that the "weak" extracted substances are PFHxA related substances which have the potential to be released from textile products and articles wide dispersively used e.g. during processes like washing or by degassing (new textiles often have a specific odour). The median measured concentration of related substances ("weak" extraction) from literature data was correlated to the respective number of textiles. The so gained number is considered to be the amount of PFHxA related substances, which is released into the environmental compartments from the currently assessed sub-group of textiles.

Actually, releases into air, water and soil are calculated with default release factors starting using the total amount of substance. Default release factors are defined for several environmental release categories (ERC) (see Chapter R.16, Guidance on information requirements and Chemical Safety Assessment). To calculate releases from textiles which are "widespread used indoor with low release" - (ERC 11a – releases of 0.1%) or which are "widespread used outdoor with low release" (ERC 10a – releases of 6.45%) are applicable. Using the literature data as described above, the environmental releases are already estimated. However, especially for SEAC, the initially in textiles applied amount of PFHxA related substances (100%) is required. The provided default release factors from ERC 11a for indoor or ERC 10a for outdoor uses now were used to back calculate the initially used tonnage of PFHxA related substances for textile treatment.

Estimation of environmental releases of PFHxA:

As described for PFHxA related substances, the environmental releases of PFHxA are estimated also based on measured concentration from scientific literature. However, the measured concentration of PFHxA is considered already as transformation product from related substances. Therefore, the estimated share of PFHxA, which is formed by degradation of SFPs (1%) and by related substances (7%), finally is added to the literature-based estimate.

As a worst-case scenario, the assumption is made that all manufactured textiles are treated more or less with PFHxA related substances (as well with SFPs as with low molecular substances). This leads to an overestimate of environmental releases by textile treatment because only in 70% of the investigated textile samples as well PFHxA as the related substances are detected and in recent years the share of treated textiles has been reduced constantly.

This concentration-based approach is used for further calculations and for the prediction of use amounts in future.

B.9.5.2 Exposure estimation

B.9.5.2.1 Environmental exposure

European textile treatment – generic overview

The following assumption is made on the basis of data gained by a Stakeholder consultation by Ökopol using data from the perspective of the production and the consecutive use of fluoropolymers and SFPs in the supply chain. In contrast to this assumption, the assumption made in the following chapters for textiles and paper and boards uses data, taken directly from textile and paper industries and the measured concentration of PFHxA and related substances provided in literature. About 5 700 t/a of polyacrylates with C6 perfluorinated side-chains and 4 300 t of substances that fairly easy degrade to PFHxA (like 6:2 FTOH or polyfluoroalkyl phosphate esters) are used for textile treatment in the EU (derived from stakeholder consultations). Due to the large number of industrial sites for textile treatment in Europe, the release of PFHxA, its salts and related substances by manufacturing of fabrics, garment and textiles is wide dispersively.

The release of PFHxA from SFPs is considered low during the textiles service life of about five years (median from different sector of uses). However, the used low molecular PFHxA related substances may be released into air and water during articles service life. According Liu et al. 2010, 6:2 FTOH biodegradation in mixed bacterial culture was rapid with an estimated half-life of 1.3 d. The sum of the stable products at steady state in soil was significantly less in the flow-through system (23 %) than in the enclosed closed system (56 %) (occurrence of PFHxA in the flow-through system: 4.5 mol%; occurrence of PFHxA in the flow-through system: 8.1 mol%). Due to the volatile losses, more than the half of the initially used substances that fairly easy degrade to PFHxA may be lost to air and water during service life. Polyfluoroalkyl phosphate esters also may degrade to or via 6:2 FTOH. 6:2 FTOH itself is semi volatile. From textile articles manufactured in the EU, about 430 t/a low molecular PFHxA related substances are released into air and water during the service life.

Based on data from (Liu et al., 2010b) and assuming a low molecular PFHxA-related substance degradation following the first order kinetics, one tonne of the easily degradable substances may emit 70 kg PFHxA kg/a. Hence, by easy to PFHxA degradable textile treatment substances, 30 t PFHxA may be released to the European environment annually. Due to its high-water solubility the majority of this amount is getting into water, finally. From deposition of these textiles about 10 t PFHxA per year are released from indirect sources.

Clothing in general

Clothing are finished with durable water and dirt repellents (DWR), like polymers with perfluorinated side-chains or polyfluoroalkyl phosphate esters and n:2 fluorotelomer alcohols. Before the restriction of C8 perfluorinated substances was introduced, finishing agents with C8 side chain polymers were used. Exemplarily, Figure 5 summarises the possible mechanisms for diffuse emissions of DWR-related substances during the garment’s use-phase. This includes the wash-out of water-soluble residuals such as PFOA, the evaporation of volatile residuals such as 8:2 FTOH and the potential degradation of the polymer by UV-light, abrasion, and washing. C6 perfluorinated substances act in the same way.

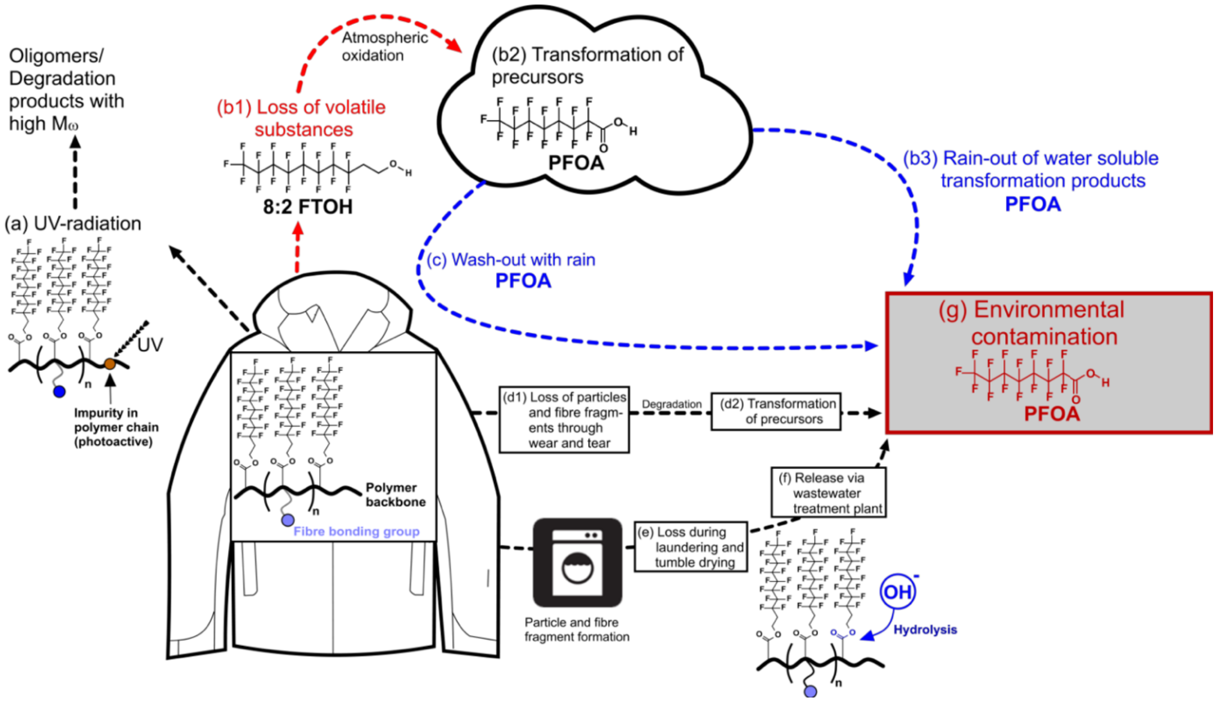

Figure 5: *Possible mechanisms for the diffuse emissions of DWR-related substances during the garment's use-phase. Modified and reprinted from Environment International 94, H. Holmquist, S. Schellenberger, I. van der Veen, G.M. Peters, P.E.G. Leonards, I.T. Cousins, Properties, performance and associated hazards of state-of-the-art durable water repellent (DWR) chemistry for textile finishing, 251-264., Copyright (2016), with permission from Elsevier.*

The following assumption on emissions of PFHxA and related substances based on data from a report of the European clothing action plan (ECAP) from 2017 (minimum values) and a study from the EC 2020 (maximum values). For release estimation the concentration-based approach using ERC 11a for indoor uses (see B.9.5.1 General Information) is applied. The release of related substances at wearing clothing outdoor is considered as negligible. The majority of PFHxA related substances is released at washing clothing.

In the last years between 1.2 and 3.6 million tonnes of clothing were manufactured in the EU annually. But, 4.2 to 14.6 million tonnes of clothing were used in the EU per year.
That implies, between 3 and 11 million tonnes were imported into the EU, mainly from the Asia-Pacific Region (China, Vietnam, Indonesia) (Rijkswaterstaat, 2017). The assumption of amounts for manufactured, imported and used clothing is uncertain. The EC report stated that the amount of imported clothing is much higher, even considering both, the EU internal use and the (re-)export from EU. Therefore, the share of 25% in the EU manufactured clothing and 75% into the imported share of clothing from the ECAP report was used for further assumptions. From the total used tonnages of clothing a share of about 1.5% t for professional apparel and about 2.3% for outdoor clothing is assumed (based on stakeholder consultation and on data from an EC study published in 2020).

Fabrics as well as the garments are frequently treated with perfluorinated substances to provide water and dirt repellency. Which finishing agents are being applied depends on the intended use and the design of the garment. Occupational wear and outdoor clothing are treated more intensely and preferably with perfluorinated side chain polymers than everyday clothes. For 95 % of the on the European market available textiles production steps are outsourced abroad partially or even entirely. So, emissions of PFHxA, its salts and related substances via manufacture of textile fibres and fabrics are considered as very low in Europe. Otherwise, the abroad use and finally the content of the perfluorinated substances is difficult to predict (Greenpeace, 2012).

For textile treatment both, substances that fairly easily could be removed from the fabric such as n:2 FTOHs or n:2 FTMA and on the other hand substances that are firmly connected to the fibres like polymers are in use. Several authors investigated the extractable content of perfluorinated substances in fabrics (see chapter E.2.11). The range of measurements goes from below the detection limits up to 8 500 µg 6:2 FTOH /kg garment and up to 546 µg PFHxA /kg garment. These values are strongly interlinked with the easily removable low molecular substances because, as mentioned above, curing with the polymers promotes the cross-linking to the fabric. Therefore, these substances are not as easy extractable. Typically, 0.2 – 0.5 % (w/w) of side chain fluorinated polymers are applied to the fabric (BfR, 2012).
Volatile substances like n:2 FTOHs are released into air and water entirely at the clothing's service life by washing and wearing the garments (Tissier et al., 2001). However, not all related substances are volatile at all. Therefore, based on the investigations from Liu et al. 2010, the loss during the service life is considered with 50 %.
For the further worst case estimations, the median value of the reported minimum and maximum concentration is used.
Under the category clothing different pieces of clothing, like socks, underwear, shirts and DWR are summarised.
At clothing manufacturing up to 137 t/a SFPs and up to 122 t/a PFHxA related substances resulting in up to 10 t/PFHxA are released into the environment. During the two-years service life of clothing manufactured in the EU, between 3 and 9 t/a C6 related polymers, 1 to 4 t/a related substances, resulting in 0.2 to 0.6 t/a PFHxA may be released into the environment. From landfills an annual release of low molecular PFHxA related substances is estimated up to 961 t. By degradation of PFHxA related substances in landfills a release up to 67 t/a PFHxA is estimated.
According to TEGEWA only 25% of clothing used in the EU are also manufactured in the EU. In contrast to that, making the same assumptions, from imported textiles 9 to 27 t/a polymers, between 4 and 12 t/a related substances resulting in 0.3 to 0.8 t/a PFHxA may be released into the European environment at two-years service life. Due to the short service life of clothing the majority of the environmental releases results from deposit of clothing. From imported clothing up to 2 882 t/a related substances mainly contribute to the releases of 202 t/a PFHxA from landfills. The numbers of imported clothing may be much higher, due to the unknown share of further export of clothing.

Professional apparel
There are no special investigations of occupational wear textiles regarding the content of PFHxA, its salts and related substances known. However, it could be assumed that more polymers than easy extractable substances are used for oil repellent clothes. However, the quality of clothes wearing in the medical sector are comparable to outdoor clothes. Therefore, the measured concentrations of the compounds in (outdoor-) clothes are used for environmental release estimation by occupational wear. It is assumed that about 60% of professional apparel is manufactured in Europe.
The typically to fabric applied polymer concentration 0.2 – 0.5 % (w/w) was used (BfR, 2012).

For this use a service live of two years is considered (Tissier et al., 2001). These data are related to the annual use of 194 000 t of –professional apparel used in Europe. So, 22 – 56 t/a PFHxA related substances are released into the environment. In summary, 2 – 4 t/a of PFHxA are released into the environment from professional apparel.

Home textiles

Up to 1 800 000 t of home textiles were used in Europe in 2018. This covers curtains and rugs, upholstery e.g. fabrics for soft-furnishings, including, large furniture items.

In 2018, about 380 000 tonnes of carpets were imported and about 180 000 t were exported.[14] So, about 200 000 t of textile floor coverings were used in Europe. The total demand on carpets in Europe shares into 55 % for residential buildings, 39 % for non-residential buildings and 6 % for other sectors like shipbuilding, automotive, trains, and aviation. Annually 1.6 million tonnes of carpets are becoming waste. Thereof 60 % are deposited in landfills, 37 % are incinerated and only 3 % of the textile floor coverings are recycled (European Public Health Alliance, 2016).

It is assumed that about 25% of home textiles are manufactured in the EU. The concentration of PFHxA related substances in carpets and other textile floor coverings reported by different authors (see chapter E.2.11). The measured low molecular PFHxA-related substances content is between 170 and 2 200 µg/kg and PFHxA was measured in concentrations between 0 and 11 µg/kg. At manufacturing home textiles in the EU 6 – 17 t/a SFPs and 1 – 4 t/a PFHxA related substances are released into the environment. That results in a PFHxA emission between 0.1 and 0.3 t/a PFHxA. The compounds are released from home textiles service life by degassing, by cleaning and by development of house dust. For home textiles a service life up to 15 years is considered. During service life of home textiles annually below 70 kg of PFHxA related substances are released, resulting in a release of about 0.1 t PFHxA, annually. Again, the majority of PFHxA, between 3 and 9 t/a is released from deposit.

Industrial fabrics:

An important sector of use for PFHxA, its salts and related substances are textiles for industrial uses. European producers are world leaders in markets for technical/industrial textiles and non-woven (industrial filters, hygiene products, products for the automotive and medical sectors, etc.), as well as for high-quality garments with a high design content. The tonnage used in Europe gained by back calculation using data for industrial textile fabrics for 2018 from UN comtrade database and the average prime costs for truck tarpaulin fabrics. So, the use of about 100 000 t/a could be assumed in Europe.

However, there are more kinds of technical fabrics, like filter membranes or fabrics for medical applications. The study from EC DG environment assumes an annual EU wide use of industrial technical fabrics up to 520 t. It is assumed that two third of industrial fabrics are manufactured in the EU. It is further assumed that more than 20% of industrial fabrics are used for medical applications. On behalf of the German Environment Agency various industrial fabrics (28 samples in total) were investigated for per- and polyfluoroalkyl substances like PFHxA, 6:2 FTOH and 6:2 FTS (Janousek et al., 2019; Knepper and Janousek, 2019). The samples included seat covers (furniture upholstering, bus /train seat upholstering, car seat

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[14] Comtrade, U. N. (2018). UN Comtrade database. *UN Comtrade Online*.

upholstering; n = 11), covers for truck trailers (n = 3), covers for maritime applications (e.g. boat cover, seat cover, bimini tops; n = 5), awnings and tarpaulins (e.g. marquee awning, party tent; n = 9). All samples were collected between October 2016 and August 2017 and analyzed as soon as possible. The following limits of quantifications were determined: for 6:2 FTOH 40 µg/kg, for PFHxA and 6:2 FTS 2 µg/kg. PFHxA was found in one seat cover, two maritime covers and five marquee awnings. Concentrations of PFHxA ranged from 2.4 – 18 µg/kg (average 7.7 µg/kg) in aqueous extracts and 2.6 – 18 µg/kg (average 9.9 µg/kg). 6:2 FTOH was found in one seat cover, one tarpaulin for truck trailers, two maritime covers and three marquee awnings with concentrations ranging from 40 to 790 µg/kg (average 350 µg/kg). 6:2 FTS was not detected above the LOQ in any of the samples.

At EU manufacturing of industrial fabrics, a release between 4 and 8 t/a SFPs and below 100 kg/a of related substances is assumed. That results in a release up to 0.13 t PFHxA.

Using the minimum and maximum values, from the study above and applying the default release factors for a wide dispersive use of outdoor products with low releases (ERC 10a) over a service life of ten years, 6 to 11 t/a C6 related polymers, up to 11 t/a related low molecular substances resulting up to 0.1 t/a PFHxA are released from industrial fabrics into air, water and soil.

B.9.5.2 Consumer exposure from textiles

To gain information on exposure levels of consumers to 6:2 FTOH and PFHxA, the scientific literature has been screened using search engines such as Scopus, PubMed and Web of Science. Key words used in the literature query included 6:2 FTOH, PFHxA, per- and polyfluoroalkyl substances, textiles, garments, waterproofing, surface treatment and consumer products. This approach identified several publications covering a broad spectrum of consumer product types ranging from outdoor textiles to swimming costumes. Additionally, data on the occurrence of PFHxA in clothing textiles sampled from the German market in 2010 – 2014 were included in the assessment as well. These data were obtained within the framework of the national monitoring program and were submitted by the German Federal Office of Consumer Protection and Food Safety (BVL).

The studies referred to below looked for the presence of residual non-polymeric PFASs (of different chain lengths) such as FTOHs, PFCAs, fluorotelomer acrylates, PFSAs and precursors. The spectrum of the detected and quantified substances in a given textile fabric provides a fingerprint that hints towards the underlying technology. For example, several products from more recent sampling campaigns contained 6:2 FTOH as the dominant residue, with PFHxA as degradation product sometimes being the second-dominant residue. This fingerprint indicates the use of state-of-the-art C6 fluorotelomer technology. There are, however, other examples showing, e.g., a distribution of 6:2 to 10:2 FTOHs with 8:2 FTOHs forming the peak of the distribution. It should be noted that products with such a fingerprint will no longer be on the European market because of the restriction of long-chain PFASs. These examples show that the concentrations of 6:2 FTOH and PFHxA reported below cannot be used as an indication that a C6 fluorotelomer technology was used, since alternative technologies can give rise to the occurrence of these compounds as by-product. Insofar, the data cannot be regarded as being representative for the C6 fluorotelomer technology unless confirmed by fingerprint.

Santen and Kallee (2012) analysed outdoor textiles purchased in 2012 for their PFASs content. Six and eight of twelve jackets were tested positive for 6:2 FTOH and PFHxA, respectively, with maximal concentrations of 3520 and 32 µg/kg of fabric.

Studies by Knepper et al. (2014) and Dreyer et al. (2014) also examined outdoor jackets for PFASs. Knepper et al. (2014) purchased the garments between August 2011 and March 2012. Whereas in both studies PFHxA is identified in nearly every jacket with comparable maxima of 120 and 147 µg/kg of textile, the 6:2 FTOH pattern is different. Only in two of the 16 jackets 6:2 FTOH was detected with a maximum concentration of 186 µg/kg of fabric by Knepper et al. (2014). The chemical analysis by Dreyer et al. (2014), on the other hand, revealed 6:2 FTOH in eleven of 14 jacket samples with concentration ranging from < 300 to 8 500 µg/kg of fabric.

More recent data by Greenpeace on the content of PFHxA and 6:2 FTOH in outdoor textiles purchased in 2015 are in good agreement with the findings by (Dreyer et al., 2014) regarding a higher prevalence of these substances (Brigden et al., 2016a). In seven of eleven jackets 6:2 FTOH has been extracted from the fabric with a peak concentration of 4 600 µg/kg. PFHxA was identified in eight jackets with a maximum concentration of 546 µg/kg of textile.

When comparing both Greenpeace studies, a shift from C8 to C6 substances is observed, as shown in Figure 6**Error! Reference source not found.**.

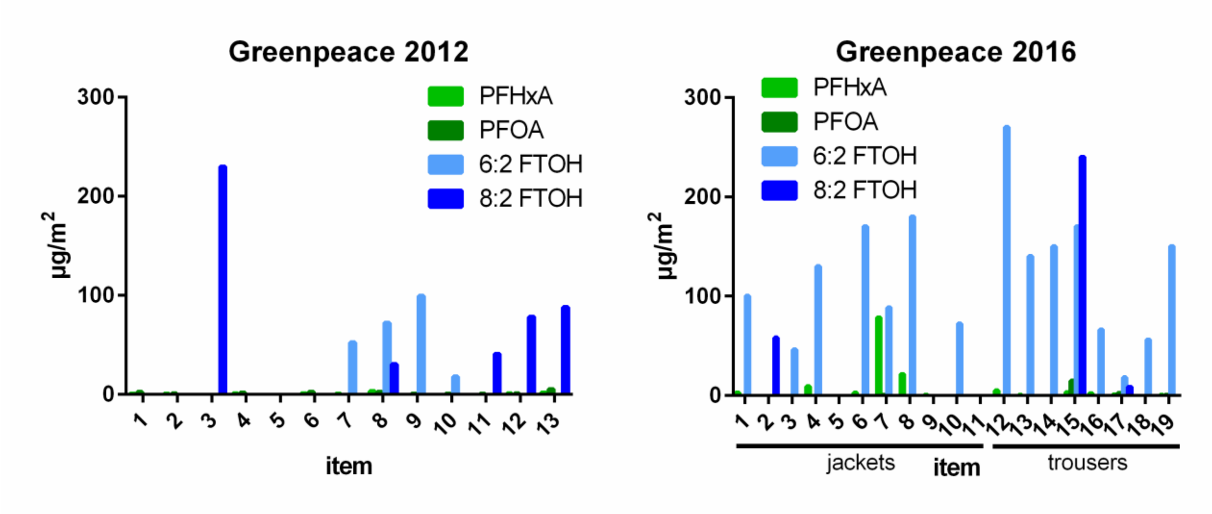

Figure 6: *Comparison of PFHxA, PFOA and fluorotelomers in outdoor clothing. Data were taken from Bridgen et al. (2016) and Santen and Kallee (2012).*

Analytical results by Borg and Ivarsson (2017) from textile samples purchased in the same year (2015), however, do not point to an increased usage of C6-perfluoralkyl substances to waterproof outdoor jackets. In their study, eight textiles samples (six jackets and two pair of shoes) collected in 2015 for a monitoring project by the Swedish Chemicals Agency have been analysed for their total organic fluorine content (TOF) and for 22 individual PFAS. The result of the targeted PFAS analysis showed that three jackets contained PFHxA albeit at much lower concentrations, nearly 30-fold less, than reported by Greenpeace. In contrast to the findings by Greenpeace, 6:2 FTOH was only identified (1400 µg/kg of textile) in one jacket. This would rather indicate a shift to PFAS free DWR alternatives.

There are few studies reporting on measurements of PFHxA or 6:2 FTOH in carpets or upholstery. Herzke et al. (2012) and Kotthoff et al. (2015b) analysed carpets purchased in 2009 in Norway and 2010 in Germany, respectively. Low levels of PFHxA were detected in some of the analysed samples with a maximal concentration of 11 µg/kg while 6:2 FTOH was detected in all carpets reaching up to 2000 µg/kg in one sample. A further study investigated PFAS in products imported to Norway from China (Vestergren et al., 2015). Several furniture textiles comprising towels, blankets, curtains and other products were investigated in addition to carpets, bathmats and rugs. Here, maximal PFHxA levels under 1 µg/m^2 were reported, but 6:2 FTOH levels were 2 - 3 orders of magnitude higher. These results confirm the general observation from the outdoor textile studies, that the fluorotelomer alcohol was also found in much higher concentrations than the corresponding fluorocarbon acid. In addition, Guo et al. (2009) analysed carpets and upholstery purchased between 2007 and 2008 in the USA. In these two product groups, maximal PFHxA levels reached 224 µg/kg and 238 µg/kg, respectively. It should be noted that levels of C7 and C8 PFCAs in the latter study were generally higher than the C6 values, suggesting long-chain based treatment of these products.

For the estimation of environmental release of PFHxA from textiles only few studies are available. Gremmel et al. (2016) re-analysed PFAS content in outdoor jackets after three years of storage and found a decrease of volatile FTOHs and a slight increase in PFCAs. Likewise, it has also been shown that FTOHs in textiles are not significantly decreased by washing (Liu et al., 2015a).

A study investigating textiles and carpets in experimental anaerobic landfill reactors shows a release of PFHxA in leachate, suggesting that degradation of these consumer products in landfills is a source of environmental exposure (Lang et al., 2016). However, to date there is a lack of data concerning the kinetics of long-term degradation of SFPs in DWR textile coatings during the textile's use phase and concerning the migration of PFAS from the textiles into aqueous media such as sweat.

A very recent study compared PFAAs and FTOHs in outdoor clothing before and after artificial weathering to simulate the products' life cycles (van der Veen et al., 2020). The products have been manufactured in 2012, 2013 or in an unknown year. In most samples PFHxA as well as 6:2 FTOH levels were higher after the lab-based weathering in comparison to the untreated outdoor textiles (up to 40-fold for PFHxA and up to 16-fold for 6:2 FTOH). In contrast few samples also showed decreased levels of both substances. It should also be mentioned that an increase of long chain PFAAs was also detected in some outdoor garments.

However, direct dermal exposure from outdoor textiles containing PFHxA is generally expected to be low for consumers during the garment's use phase, because the finishing is located on the outside of the garment.

For carpets or other household textiles, PFHxA-containing material released into house dust is the primary source for exposure, which is covered in B.9.15. For the volatile telomer 6:2 FTOH, transfer to indoor air is also to be expected. In addition, direct skin contact with carpets is very likely especially for toddlers, but data on dermal exposure of PFHxA are not available.

In conclusion, the consumers are being potentially exposed to 6:2 FTOH and PFHxA primarily via waterproofed outdoor textiles. Robust, statistically relevant and more recent marketplace data is lacking to support the working hypothesis that manufactures have substituted C8 with

C6 fluorochemistry on a large scale. Depending on the study, a shift from C8 PFAS either to C6 PFAS or to fluorine-free alternatives can be assumed.

Uncertainty

For a qualitative assessment of human exposure, several uncertainties need to be considered. First of all, in the listed studies only new products have been investigated. As mentioned before, 6:2 FTOH may occur as residual from the telomerisation process and PFHxA as oxidised product of the former substance. Thus, the PFAS concentrations measured in the studies represent maximal extractable levels in newly purchased textiles. These unbound residues might then be released and lead to human and environmental exposures. In addition, degradation of polymer side-chains by hydrolysis or UV light during the garments' life cycle is expected to lead to a constant release of PFAS, but systematic investigations on the release of PFHxA and 6:2 FTOH are still lacking.

The products analysed in the studies were purchased in different years ranging from 2007 to 2015. Thus, another uncertainty in the determination of human exposure is that the studies mentioned above might have contained C6 PFAS as by-product from C8-based PFAS treatment, because most products were purchased before the phase-out of C8 fluorochemistry has started. It is unknown whether C8 chemistry is substituted by non-fluorinated alternatives or by C6 chemistry. If the latter case holds true, there is also the concern that 'because some of the shorter-chain PFASs are less effective, larger quantities may be needed to provide the same performance' (Blum et al., 2015b). Thus, a higher content of PFHxA might be likely when today's products are analysed. However, it cannot be concluded from the data summarized here which scenario applies. Data from the most recent studies are controversial. While C6 PFAS are reported by Brigden et al. (2016b), only low levels of PFHxA and 6:2 FTOH have been reported by Lassen et al. (2015). While the former study investigated outdoor textiles from specialized stores the latter study focused on textiles for children which might have different requirements concerning water and stain repellence. In general, the different studies have to be compared with care since the methodology of analytical measurements is not standardized.

B.9.6 Paper

B.9.6.1 General information

Side-chain fluorinated polymers are used in the surface treatment of paper and packaging to impart grease, oil and water resistant properties, especially for food contact materials (plates, food containers, bags and wraps) but also for non-food applications (folding cartons, containers, glossy papers, carbonless forms and masking papers) (Federal Office for the Environment, 2009).

The most important application field is the production of paper and board for the packaging and preparation of food. The PFHxA-related substances are used in the paper pulp as well as for surface refining. They are applied to create water- and grease /oil-repellent paper products, which can be used at higher temperatures without burning and adherence to food or other materials. Typical articles are baking paper, packaging of pet food, packing of take away food, tablecloths, microwave popcorn bags, cupcake forms and sandwich papers (Blom and Hanssen, 2015; Borg and Ivarsson, 2017; Jensen et al., 2008; UBA, 2018).

An OECD study from 2020 stated that about 13 800 000 t of paper and board were produced for food contact from three main sectors: folding box board, corrugated boxes and paper sacks. According to industries, the content of side-chain fluorinated polymers is about 0.2 – 1.5%, depending on the specific purpose of the treated material (stakeholder consultation). Emission estimation was carried out as described in chapter B.9.5.1 using concentration-based approaches including ERC 11a.

B.9.6.2 Environmental exposure

The release of PFHxA and its related substances as well as perfluorinated side chain polymers at manufacturing of grease proof papers is considered as low, due to closed loop of materials and the recycling of treatment emulsions. According to industries, the content of C6 side-chain fluorinated polymers in paper is about 0.2 – 1.5%, depending on the specific purpose of the treated material (stakeholder consultation). Therefore, related to the volume of grease prove paper and board between 27 600 and 207 000 t of SFPs are used annually in these products and articles. It could be expected that 235 – 1 760 t/a of C6 side-chain fluorinated polymers would be released from paper and board.

PFHxA and 6:2 FTOH are measured in 70 % of the grease proof paper samples. The provided literature data have a very broad variation from 0.8 to >10 000 µg PFHxA related substances per kg paper matrix. The high variation of the values is due to the high variability of measured data and due to the very different kind of products. The median values from the literature described concentrations, are 5 000 µg/kg C6 related low molecular substances and 7 µg/kg PFHxA (summarising data from (Bokkers et al., 2019). The measured concentrations are based on non-oxidative sample preparation. Therefore, these measured values are considered as volumes of C6 related low molecular substances which have the potential to be released from the papers into the environment. In general, the service life of grease proof paper materials is very short – from days to a couple of weeks. Therefore, a share of 10 % from substances that have the potential to be released from the product (measured concentrations in scientific literature) is assumed for the release of C6 related low molecular substances per year. In total, the release of low molecular PFHxA related substances is assumed with 1 - 9 445 t/a, with the main releases from landfills and deposit. As far as the DS knows, PFHxA is not used in paper treatment. Therefore, the direct measured PFHxA concentration is assumed as a degradation product from SFPs and PFHxA related substances. Taking the measured data for PFHxA on the one hand and on the other hand the formation of PFHxA from related substances into account, about 18 to 849 t of PFHxA may be released from paper and board. Again, the vast majority is released from landfill.

B.9.7 Firefighting Foams

B.9.7.1 General Information

Firefighting foams are complex organic matrices with a mixture of solvents, hydrocarbon surfactants and other organic components. Some firefighting foams additionally contain fluorosurfactants. PFAS containing firefighting foams are usually used to extinguish liquid fires (class B), such as large storage tank fires and aviation accidents. For firefighting foams in general fluorosurfactants like perfluorinated sulfonic acids or substances with a perfluorinated moiety are in use. Only in a few cases polymeric substances may be added to the foam concentrate. In newer foams poly- and perfluorinated fluorotelomer alkyl betaines (PFAB) and other proteins are used (see Annex E.2.3.2 Use and functions). Additionally, several glycol ethers, probably with poly- and perfluorinated side chains, are added to concentrate. Between 240 - 400 t/a of fluorosurfactants are placed on the market in Europe within foam concentrates.

B.9.7.2 Environmental exposure

About 12 000 - 20 000 t/a foam concentrate are placed on the market. This quantity covers beside the uses on fire incidents, the use for testing and training purposes also amounts in new installations or in devices like in hand-held extinguishers. The replacement of aged foam concentrates also is included. The number is provided by the Norwegian Dossier Submitter in the PFHxS dossier (2019). Results from a study by the European Commission and ECHA suggest a market split as follows: Military 6%, civil aviation 9%, municipal fire brigades 13 %, chemical/petrochemical 59 % (there of 20% for large tanks assumed), marine applications 12%. According to EUROFEU, only about 10% of the annually on the market placed foam concentrates are deployed on fires. Above that, a large amount of concentrates is stockpiled in Europe. About 75 000 t are assumed to be on store, based on data provided by FOEN. Thereof, a range between 6 and 15% of used concentrates in fire incidents is assumed (see chapter E.2.3.5.). For release estimation an annual use of foam concentrates on fire of 2 000 t (10% of the maximum value of foams placed on the market, annually) is applied for calculating the minimum value. As maximum value 11 250 t (15% of stock) are used. For hand-held extinguishers the same conditions as for professional use of fire-fighting foams are assumed. The amount of fluorosurfactants containing foam concentrate filled up in hand-held extinguishers is considered as subset from total concentrate amount. Therefore, the overall estimation already contains the use in such devices.

In 2014, the Swedish Chemicals Agency investigated several fire-fighting foam concentrates from various manufacturers. Samples were taken from open containers from users as well as from distributors or intact containers and were diluted in water and methanol. The investigated samples had a broad concentration variety from 76 to 14 217 µg PFHxA / kg concentrate. The presence of PFHxA was associated with remaining residues from the manufacturing process or due to storage degradation of the related substances. The share of PFHxA from total fluorosurfactant content varies between 0.9 to 61 % (median 17 %). So, the foam concentrate includes 1 328 µg PFHxA / kg concentrate. PFHxA in fire-fighting foams is assumed to be a residue and occurs from PFHxA related substances and other PFCAs which are intentionally added as fluorosurfactants. Therefore, releases of PFHxA are presumably higher due to usage of fire-fighting foams as such related substances are assumed to degrade to PFCAs as PFHxA. Studies by Dauchy et al. (2017) and Larsson et al. (2018) used oxidation to transform PFCA-related substances into the end-stage products in samples of fire-fighting foams. The average PFHxA concentration of three oxidized foams was 314 880 µg /L (Dauchy et al., 2017; Larsson, 2018). Looking at the percentage of measured PFHxA concentrations, it appears that in protein free firefighting foams about 50 % of PFHxA related substances precursors are not detectable without the oxidation step. Investigating protein containing foams even 99 - 95% of the related substances are not covered without oxidation. These values are very low.

According to (Sontake and Wagh, 2014) the ready to use foam usually contains up to 0.45% surfactants. The ratio of carbon hydrate surfactants to fluorosurfactants in an average AFFF designed for a 3% proportioning in the foam solution is up to 2:1. Hence the maximum share

of fluorosurfactants is 0.15% in ready to use foams (EUROFEU). Foam concentrates are diluted with water for ready to use foams with the final concentration of 1 or 3% of the concentrate. So, the concentrate contains about 5% of fluorosurfactants. As a worst case it is assumed that 100% of the on fire used foam is released into the environment. Based on the data from Sontake and Wagh and from EUROFEU, this results in an annual release of PFHxA related substances between 100 and 563 t. This may be overestimated, considering further stakeholder information during PC: A lower content of fluorosurfactants in foam concentrates - between 1 and 3% instead of 5% - was indicated. The formulation of fire-fighting concentrates at industrial sites occurs under strictly controlled conditions. Therefore, the release of PFHxA and its related substances is assumed to be below 100 -250 kg/a during formulation. Applying the assumed 70 kg of PFHxA formed from related low molecular substances about 7 to 39 t/a of PFHxA is released into the environment.
In a survey German local volunteer fire brigades were asked for their use habits of firefighting foams in field operations (Keutel and Koch, 2016). Because only seven fire brigades answered the questions, the results can give only an indication for the local use of fire firefighting foams. However, personal communications with several volunteer firefighters support the data presented. The use of perfluorinated substances in the AFFF foams by volunteer fire brigades already has been reduced within in the last years from 3 or 1 % to even 0.1 % foam solutions. At their operations fluorinated foams mainly were used as surface-active agent in a concentration of 0.1 %. Above that, due to the PFOA restriction the vast majority of municipal fire brigades (professionals and volunteers) exclusively use fluorine free foam agents in Germany. For other European countries no data is available.

Concluding, **7 to 40 t/a PFHxA** could be released with extinguishing agents by professional and skilled workers into the European environment.

Fire-fighting foams will not be incinerated during an event of fire. As a worst-case estimate, 100 % of the remaining AFFF will be emitted into the environment. Therefore, large concentrations of the surfactants were found locally after fire-fighting operations, mainly in water. (Hähnle and Arenholz, 2011) studied per- and polyfluorinated surfactants in different water samples after cases of fire. The primary polyfluorinated substance used as fluorsurfactant and known as potential PFHxA-related substances were measured with concentrations of up to 6 900 µg/L in the extinguishing water. PFHxA was detected after the cases of fire in the discharge into the sewage treatment plant, in water bodies, in extinguishing water and in the treated effluent of a sewage treatment plant. After one case of fire PFHxA concentration was 3.3 µg/L in an effluent into water bodies.

A quantification of samples downstream of sites where AFFF were used showed the important impact of local sources. Dauchy et al. 2017 measured PFHxA concentrations in water samples from groundwater and surface water close to an oil storage depot, an international civilian airport, a military airport and a training centre for firefighters. In samples of all sites, PFHxA could be detected, within surface water close to the training centre for fire fighters and downstream of the discharge pipe showing the highest concentration (up to 178 ng/L).

As mentioned before, large amounts of AFFF are stockpiled and will only be used in exceptional cases. Presumably, only about 10% of AFFF coming on the market in Europe is used on fire. It is not always clear, whether concentrations of PFHxA and PFHxA-related substances originate from the use of old generation AFFF or new generation AFFF. Due to the long shelf life of the concentrates, the stocks often still contain PFOA and related substances. However, some manufacturers formulated their foams already with PFHxA related substances in the past. Therefore, even if it originates from old generation AFFF, it can be assumed that emission from new generation AFFF will exceed released concentration of PFHxA and PFHxA-related substances due to structural shift of fluorsurfactants based to C6 chemistry.

B.9.9 Building materials (incl. laqueurs)

B.9.9.1 General Information

Fluorinated substances are applicated in lacquers, coatings and paints to a large amount of very different building materials to improve flow, wetting, and levelling. It is primarily in water-based paints where these properties are required and PFASs can be present at concentrations of about 0.05 percent (European Chemicals Agency, 2018a).

B.9.9.2 Environmental exposure

There are currently no sufficient data available on tonnages used in those applications and for the release of perfluorinated substances from building and construction. In a stakeholder consultation the use of fluorosurfactants in coatings that are used in building material treatment were mentioned without further details and tonnages. Once, the use of 100 - 1 000 t/a in "manufacture of plastics products for including compounding and conversion in inks and films, for manufacture of furniture, for building and construction work, for manufacture of firefighting foams and paper finishing" was stated. But the shares of the different sectors of use are unknown. Therefore, a quantitative exposure assessment is not feasible. Coatings with fluorosurfactants especially are used outdoors. So, a direct release of perfluorinated surfactants from the sector building and construction into the environment is considered as very likely in significant amounts.

B.9.10 Cosmetic products

B.9.10.1 General Information

CosIng is the European Commission database for information on cosmetic substances and ingredients. A search using the database did not identify PFHxA as an intentionally added ingredient of cosmetic products. Instead, the search identified more than 70 perfluorinated substances e.g. polyfluoroalkyl phosphonic acids (PAPs) which according to CosIng, serve as emulsifiers and surfactants. Other PFAS (e.g. perfluorinated polymers, ethers and esters) are added to cosmetic products for binding, bulking and skin/hair conditioning purposes. According to a recent study by the Danish Environmental Protection Agency, 0.7 % (78 out of 11 108) cosmetic products contained fluoroalkyl substances or other fluorinated compounds (Brinch et al., 2018).

A literature search identified only a few studies which analysed the PFHxA content of cosmetic products, whereas no studies report on FTOH 6:2 concentrations. It is to note that product selection in all three studies focused on cosmetic products with declared PFAS content. A recent study by the Danish EPA found PFHxA in 15 of 18 products, whereas a study conducted in Sweden detected PFHxA in 10 of 31 products (Brinch et al., 2018; Schultes et al., 2018). An older study from Japan sampled cosmetic products in 2009 and 2011 (Fujii et al., 2013). In this study also sunscreens were analyzed and 18 of 23 products contained detectable levels of PFHxA. The studies had in common that high levels (> 1mg/kg) of PFHxA were measured in foundation make-up, which are leave-on cosmetic products with direct and prolonged skin contact. As it is very likely that PFHxA is dermally absorbed it has to be considered that cosmetic products may pose an additional relevant source for human exposure. Since PFHxA is not an ingredient of cosmetics, it is probably an impurity in and /or a degradation product of intentionally added PFAS. This assumption is in line with finding of the Swedish study in which a high PFHxA level in foundation make-up seems to be correlated with a high concentration of PAP (more than 100-fold higher). In addition, there is no data on the stability of PFAS such as PAP during dermal application under real-life conditions involving solar UV light radiation, skin bacterial metabolism, and skin metabolism (see Table 51 in Appendix B.4.4).

B.9.11 Chrome plating

B.9.11.1 General Information

For chrome plating 6:2 FTS is used as a surfactant mainly as a mist suppressing agent. Emissions of 6:2 FTS during plating processes originate e.g. from the rinsing steps between the electrolytes and from replacement of used solutions (Blepp, et al., 2017). In Germany up to 11.8 t/a of fluorosurfactants are used as well for decorative as for hard chrome plating (Willand et al., 2019). Based on Germanys share of the European GDP, for the EU a use up to 57 t/a was derived.

B.9.11.2 Environmental exposure

Chromate solution containing the mist suppressing agent has a limited usage lifetime and has to be changed regularly. The used solution is treated as chemical waste, where chromium is isolated. The wastewater is treated in WWTPs. After the ban of PFOS as mist suppressing agent 6:2 FTS is used as substitute among others. Due to the use of stronger acids for hard chrome plating the concentration of 6:2 FTS is about 2.5 times higher concentrated than for decorative chrome plating. For plastic products chrome plating two separated plating steps are necessary. For one step the low concentration of surfactants as for decorative plating is used. For the second step a similar high concentration is necessary as for hard chrome plating. Release of 6:2 FTS from chrome plating process into the environment is possible via industrial wastewater and air. 6:2 FTS has a low adsorption potential and is difficult to remove during water treatment processes and will be released in receiving waters. Furthermore, the substance will be degraded to PFHxA (see chapter B.4.1.2). Exposure to the environment is also possible via waste from the chrome plating processes (e.g. chromium hydroxide sludge), which may contain 6:2 FTS. Another, in the literature so far barely mentioned, emission source of 6:2 FTS could be the process of dechroming. 6:2 FTS was detected in demetalisation agent and degreasing agent (Willand et al., 2019). As these agents as well as the rinsing waters from these processes are mostly not treated PFAS-specific, 6:2 FTS will be released to wastewater. Due to the lack of information, a quantification of the 6:2 FTS release by dechroming is not possible.

In a project, initiated by the German Federal Environment Agency, the use of PFOS substitutes in surface treatment of metals and plastics (STM) was investigated (Willand et al., 2019). A survey among several plants being part of the German STM sector and information from German national metal plating association (ZVO) were collected in this study. Information from sectors of hard chrome plating, decorative chrome plating and plastics products chrome plating were obtained. As one important substitute the use of 6:2 FTS was investigated in this project, too. According to ZVO, about600 companies are working in the sector of hard chrome plating, about 800 in the sector of decorative chrome plating and about 30 in the sector of plastic products chrome plating in Germany. Germany's share of 21 % from the EU gross domestic product (GDP) in 2019 was used to extrapolate the data gathered for Germany in this project to EU-level. So, in total by the different chrome plating processes about 30 t (min 2, max 57 t/a) of 6:2 FTS are used in the EU, annually. For hard chrome plating 9 t/a (min 0.4, max 18 t/a), for decorative chrome plating 18 t/a (min 0.8, max 36 t/a) and for plastics products chrome plating 2 t/a (min 1.1, max 3 t/a) 6:2 FTS is used. The ZVO states that in the case of Germany 20% of the applied surfactant is lost in the plating processes annually (Brunn Poulsen et al., 2011). These losses are considered as environmental releases of 6:2 FTS. Based on this assumption about **5.9 t/a (min 0.5, max 11.4 t)** 6:2 FTS are released into the environment wide dispersevely. Calculating with the assumed surrogate for the annual degradation of related substances to PFHxA, it is assumed that about 0.45 t/a of PFHxA **(min 0.04 t/a, max 0.85 t/a)** are released into the environment. A subsequent service life is not relevant.

B.9.12 Inks and photographic uses

B.9.12.1 General Information

C6-based fluorinated surfactants are used in small tonnages in photographic equipment or in coatings when manufacturing conventional photographic films (Stakeholder Consultation, 2018).

Perfluorinated substances are added to printing inks for hydrophobisation of surfaces, for example of textiles, paper, and glass, building materials or adsorbents. In addition, it is possible for them to be used as interface promoter or emulsifier or viscosity reducer in paints, coatings or adhesives. (UNEP, 2012b). During stakeholder consultation it was confirmed that C6 based short-chain fluorinated surfactants are used in some water-based inkjet inks and latex inks. Only these fluorinated surfactants provided the required performance of the inks. The use of about 15 t/a of these substances in Europe is assumed as worst-case estimation.

B.9.12.2 Environmental exposure

The exact amount of the in photographic equipment used surfactants and the release rates at manufacturing and throughout the life cycle are unknown. However, due to small used tonnage in this sector the release of PFHxA and its related substances is considered as very low.

Many PFHxA-related substances show certain volatility. Therefore, for estimation of PFHxA release from printing inks, the CPA SpERCs for volatiles are used. According to SpERC CPE4 (formulation of water borne coatings and inks in large scale), 330 kg/a PFHxA-related substances (0.022 % of the used tonnage) are released to air during formulation. With the consumer applications (according CEPE 20) about 150 kg/a of the related substances are released into the air. When a loss of about 50 % of the surfactants during the life cycle of the imprinted papers is assumed, about 7.4 t/a of the related substances are released into air and from air into water in a further step. Considering a deposit of 60 % of the imprinted papers to landfills and a total release of the perfluorinated surfactants, an annual release of 4.5 t of the C6 based short-chain fluorinated surfactants (= 174 kg/a PFHxA) could be assumed. Considering a tonnage band from 10 to 100 t/a of C6 related substances used in printing inks an environmental release between **8 and 80 t/a** could be assumed.

B.9.13 Semiconductors

B.9.13.1 General Information

Short-chain PFASs are used as chemical processing agents in microchip production. Semiconductor manufacturing is performed in a cleanroom. However, they are possibly emitted from the process. Furthermore, short-chain PFAS materials are presumed to be contained in some fluoropolymers and fluoroelastomers which might become part of semiconductor manufacturing equipment and fabrication plant-related infrastructure (Stakeholder Consultation, 2018). Short-chain PFASs are included in anti-reflective coatings (ARC) and photoresist formulations.

B.9.13.2 Environmental exposure

The overall amount of PFASs used in semiconductor industry is assumed to be < 10 t per year (Stakeholder Consultation, 2018). Short-chain PFASs possibly may be emitted from the process of microchip manufacture. The into the environment released amount of PFHxA, its salts and related substances is unknown. However, the release is considered as very low. Most ARCs are solvent based and drained in a solvent collection system, which stream is treated off site via distillation to reclaim solvent constituents while the residue is incinerated. It cannot be excluded that fractions of PFASs are carried over into further steps along the subsequent (development, cleaning) processes and enter wastewater stream. Moreover, as some ARCs are water based formulations, they are drained into wastewater (Stakeholder Consultation, 2018). (Lin et al., 2010) studied effluents from a semiconductor plant in Taiwan and measured a concentration of 71.5 ± 16.5 ng/L PFHxA with concentrations of other PFASs being considerable higher (e.g. PFOS: 5663.3 ± 427.4 ng/L). Indicating a complete switch to short-chain PFASs not being implemented at that time (World Semiconductor Council (WSC), 2019). In a more recent study, analysing PFAAs concentrations in effluents, influents and sludge from industrial wastewater treatment plants in Korea, effluents of a semiconductor plant contained a sum of 65.9 ng/L PFAAs (eleven PFAAs measured including PFHxA) including 17.7 ng/L PFOA and 22.6 ng/L PFOS (Kim et al., 2016).

Worst case assumptions regarding concentration levels of perfluorinated substances in ARCs are 0.1 % wt/wt. The release of PFHxA, its salts and related substances from semiconductors during the service life is considered as very low.

B.9.14 Mixtures for consumer uses

Due to their advantageous characteristics, perfluorinated substances have been produced and used since the 1950s. PFCAs are not only used for industrial uses. These substances are used in various mixtures intended for end-use by consumers. Such consumer mixtures are, for example, (water)proofing agents, ski or floor waxes, car care and polishes and cleaning products ((Jensen et al., 2008); (Swedish Chemicals Agency, 2006); (Swedish Chemicals Agency, 2015b); (Knepper et al., 2014); (Posner et al., 2013)). The substances most commonly used in products are fluorotelomers as stated during stakeholder consultations. They are used either as independent active ingredients or as a component in more complex matrices (like in waterproofing agents).

Perfluorinated substances are used in low concentrations in cleaning agents such as floor polish, waxes, window cleaning agents, and car care products. In such products 6:2 FTOH up to 26 mg/kg and up to 1.5 mg/kg PFHxA were detected. Ski waxes that are used to improve slide properties of the skis on snow also contain PFCAs. In ski waxes up to 1.7 mg/kg PFHxA were reported. Further mixtures used by consumers are impregnating sprays to regain or to keep the water-, oil- and dirt repellency of shoes and textiles. In these sprays 6:2 FTOH was measured in concentrations up to 1 800 mg/kg (see also Table 35 "Reported concentrations of PFHxA and 6:2 FTOH in consumer mixtures" in section E.2.9.2). Typical concentrations in articles (e.g. impregnated textiles, treated skis) are below one percent. Polish agents contain fluorinated chemicals primarily to give them good flow properties. Surface improvement agents like spray polish are used after polish has been applied to improve the polish film. Products that maintain hard wax surfaces and also have a cleaning effect, may contain fluorinated compounds, too.

There is only limited information available about used tonnages of the mixtures and of the perfluorinated substances. However, the potential release of PFCAs from consumer mixtures should not be underestimated.

B.9.14.1 Environmental exposure

The manner of application of the several consumer mixtures leads to a direct release of the containing perfluorinated substances into air, water and soil.

For example, cleaning products and polishes are used wide dispersively and are directly released into wastewater and into WWTPs. In the WWTPs the perfluorinated C6 side chained substances are degraded fairly quickly. However, by degradation of these substances persistent PFHxA is formed. Due to the high-water solubility of PFHxA and the difficulties in removing it from water, PFHxA is released into surface water. The applied polish remains on flooring materials for three to four years. Polish layers may be rapidly worn and new polish layers are applied over this time. None volatile shares of the containing C6 PFCAs are released into soil by abrasion. Volatile residuals such as 6:2 FTOH may be released into air at application and during the service life of the polish layers.

Emissions to the environment by consumer mixtures can be significant due to the assumed large quantities of several consumer mixtures used in the EU.

B.9.15 House dust

Abrasion of fibres from carpets and furniture is a relevant source for the generation of house dust. In consequence, PFHxA is emitted to house dust from textiles and other consumer products.

A first search regarding the PFHxA content in house dust was performed in February of 2019 with the terms "PFHxA" OR "Perfluorohexanoic" AND "dust" in Pubmed, Scopus, SciFinder, Web of Science and Science Direct. In order to find articles that might report on PFHxA without mentioning it in their title, keywords or abstract, a broader search was performed with the keywords "Perfluoroalkyl*" AND "dust" in Pubmed, Scopus, Web of Science and Science Direct. 80 relevant articles were identified. As a counter check, the references in the review by Anderson et al. (2019) were evaluated. A further study known by experts from the BfR was added. All articles were further filtered by the following criteria:

1) Does the source contain occurrence data for PFHxA in house dust?
2) Were the house dust samples taken from European Countries?
3) Were the dust samples taken from private households?

The first filter excludes references that were not relevant for PFHxA or house dust, the second was applied because the restriction dossier refers to the European situation, and the third excludes offices and other working environments which may have different sources of exposure.

All in all, ten studies with measured data on PFHxA in dust from European households were found The median PFHxA contents range between 0.3 ng/g and 28 ng/g and the maximum contents between 2.9 ng/g and 96 ng/g. ((Huber et al., 2011), (D'Hollander et al., 2010), (Haug et al., 2011), (Ericson Jogsten et al., 2012), (Eriksson and Karrman, 2015), (Lankova et al., 2015), (Karaskova et al., 2016), (Winkens et al., 2018), (Bohlin-Nizzetto et al., 2015), (Padilla-Sánchez and Haug, 2016)) More information on these data can be found in Table 52 of Appendix B.4.4.

The house dust samples were taken between 2008 and 2015 and may still reflect PFHxA contaminations from C8-chemistry, as driving products for the contamination of house dust like carpets or decoration textiles have a long service life. However, in newer studies, there are indications for C6-chemistry, too. Due to the ongoing changes in PFAS uses, it is not possible to deduce future concentrations of PFHxA in house dust from these data.

The overall number of analyzed samples is small compared to the number of room types in the different regions of the EU. Also, the studies are limited to a few countries and far away from representativeness for the European situation. It should be noted that if the number of analyses for a certain product type is low, the observed maximum value may still underestimate the concentration in a realistic worst case.

Also, the reported studies differ in their sampling strategies. For example, higher surfaces may be cleaned less often than floors, and dust on these surfaces may absorb contaminants for a longer time. There is no harmonized method for the detection of PFAS in house dust, neither for sampling nor for analysis. The analytic procedures for detection of PFHxA are complex and they differ in the reported studies. This makes it difficult to compare the results, with reported medians ranging over two orders of magnitude.

Taken together the differences within the samples, the low number of samples with comparable conditions and methods, and the lack of data for many countries, the database gives indications on some orders of magnitude rather than the present distributions of PFHxA concentrations in European house dust.

B.9.16 Indirect exposure of humans via the environment: food

Direct exposure of humans to PFHxA results from direct contact to the mixtures and articles discussed above. The most relevant sources of additional indirect human exposure to PFHxA via the environment are drinking water (discussed under B.4.2.4.3), house dust (discussed under B.9.15) and food. In the following, data on the occurrence of PFHxA are discussed.

Occurrence data were collected in the food surveillance programmes of Germany, in particular in the national monitoring and the federal control plan.

The national monitoring is a measurement programme in which foods from the German market are systematically examined for the presence of unwanted substances. It is performed jointly by the Federal Government and the Federal States. The national monitoring consists of pre-planned samples and thus aims on providing a realistic picture of the situation on the market.

The federal control plan is a risk-oriented monitoring programme. It consists of a yearly plan aiming at monitoring the compliance inter alia with food regulation. Therefore, it also consists of samples which were drawn based on some suspicion and may distort a realistic picture of the market situation. Additionally, there are some indications that the data obtained from the monitoring programme might originate from places with elevated concentrations of PFHxA. These are mainly samples collected in the vicinity of Rastatt, where increased concentrations have been caused by contaminated sludge being used as fertilizer. In the present evaluation these samples were not removed as they do not interfere with the aim of demonstrating the presence of PFHxA in food. The same is true for the very little number of risk-oriented samples that do not belong to one of the mentioned programmes.

The used data were collected between 2005 and 2018 and submitted by the Federal Office of Consumer Protection and Food Safety (BVL). In total, they consist of 3116 samples which were analysed for the presence of PFHxA. Of these, 3001 (96.3 %) were below the limit of quantification (LOQ) and 2933 (94.1 %) below the limit of detection (LOD). In the statistical analysis, these left-censored data were treated in the following way: Samples below the level of detection were replaced by zero. Samples below the level of quantification but above the level of detection were set to the level of detection. This approach is called the “modified lower bound” and gives the lowest possible value based on the available information. It was chosen here to only present non-zero values for samples where any amount of PFHxA was detected. The median LOD and LOQ for the samples is the same, being 1 µg/kg with an interquartile range of 0.5 µg/kg (LOD) and 1 µg/kg (LOQ).

Table 23: Overview of the PFHxA occurrence data from German food monitoring programmes.

Group	N total	N >LOD	N > LOQ	Mean [µg/kg]	P50 [µg/kg]	P95 [µg/kg]	Max. [µg/kg]
cereals	19	9	8	2.05	0	9.80	9.80
fish and seafood	1 180	107	71	0.17	0	1.25	15.00
fruits	173	4	3	0.03	0	0	1.80
meat and meat products	851	37	17	0.05	0	0	3.40
milk	70	1	1	0.006	0	0	0.006
mushrooms	78	3	0	<0.01	0	0	0.12
potatoes and potato products	144	15	14	0.15	0	1.42	1.93
vegetables	601	7	1	0.02	0	0	3.10

Table 23 summarizes the monitoring data. Foods were grouped to general groups because of the low number of detects – for all groups except "fish and seafood" the number of detects is below 100, and below 20 for all other except "meat and meat products". Also, for some samples more detailed information to further specify the food category was not available.

Still, the groups consist mainly of foods that are regularly consumed by the German population (e.g. the vegetable group consists mainly of tomatoes, cabbages, carrots, salad, onions, etc.). The main exception is the "meat and meat products" group, which contains a large amount of liver and /or game samples and the "fruits" group of which about 100 samples are taken from strawberries.

In all food groups there is at least one value above the level of detection. The data from the German monitoring programme thus supports the presence of PFHxA in food. The percentage of detects is not very high, but it cannot be finally concluded whether this is due to the analytical limits or whether PFHxA is not that widely distributed up to now. Several detects are already from 2005 to 2010 and a time trend could not be derived by the underlying data.

Data from literature

A first search for the terms "PFHxA" or "Perfluorohexanoic" and "Food" or "Dietary Exposure" was performed on PubMed, Scopus, SciFinder, Web of Science and Science direct and yielded in total 89[15] sources. Each of the sources was further filtered using the following criteria:

4. Does the source contain occurrence data for PFHxA in food? (Exclude if no, 60 excluded)
5. Were the foods bought on markets inside the EU? (Exclude if no, 14 excluded)
6. Are any reported values above the LOD? (Exclude if no, 5 excluded)

The first filter excludes references which are not relevant for PFHxA or dietary exposure. The second filter was applied, as a REACH restriction is only concerned with the European situation. The last filter was necessary because a large fraction of values is below the level of detection. Still, many sources opted to report upper bounded values (i.e. non-detects were

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[15] For two sources the full text could not be obtained in time.

set on the level of detection). This would compromise the aim of demonstrating the presence of PFHxA because most of the reported values would not be actual detects but reported upper bound concentrations. The five papers excluded due to criterion three might be interpreted as a further indication of low prevalence of PFHxA in food up to now. After applying these filters, ten sources remained and were further analysed. One additional source (Herzke et al., 2013a), was identified from the references of these screened sources and added to the analysis.

In a second search the first requirement was relaxed to the search term "perfluoroalkyl*" to also identify sources which did not list perfluorohexanoic acid explicitly but still measured it. From that second search, one additional source (Rivière et al., 2014) was classified as relevant. This source is referred to as (ANSES, 2011) because the latter document provides more detailed information on the results, which are from the Second French Total Diet Study (TDS).

The resulting references are summarized in Table 24 with the exception of (EFSA, 2012), which will be summarized separately. Only values above the level of detection were used in the summaries for the same reasons as explained above. Not all studies presented their results in the same way. Some reported single values for each food item, some only mean values. Some reported the values already aggregated to food groups, some provided detailed information of the specific food items. The latter ones were also aggregated to appropriate food groups for the sake of brevity. As it is the aim of this section to demonstrate the presence of PFHxA in food, this was not seen as an obstacle; however, the values cannot necessarily be compared from one study to another.

The heterogeneity of the studies also impedes the comparison with the results from the national monitoring. The literature generally reports lower values which is likely in large parts caused by lower detection limits (e.g. (Vestergren et al., 2012b) reports an MDL of 2.4 ng/kg and (Herzke et al., 2013a) a MQL between 2 and 50 ng/kg depending on type of PFAS).

One report, (EFSA, 2012), was excluded from the table because the data presented were collected from the national monitoring programmes of the member states of the European Union as well as from the PERFOOD project (Herzke et al., 2013b; Klenow et al., 2013; Vestergren et al., 2012a; Vestergren et al., 2012b). The former has overlap with the already presented data from the German monitoring program, the latter with some of the results presented in Table 24. In general, EFSA also reports large numbers of non-detects across all considered food groups. They also report lower and upper bound mean values. In comparison with Table 24 the reported lower bound values are lower and the upper bound values higher which is consistent with the different treatment of non-detects in the data analysis.

In general, also the data from the literature thus support the presence of PFHxA in food.

Table 24: Occurrence of PFHxA in food.

Data Source	Countries	Foods with detects	Range of reported Detects [µg/kg]	N (no bracket: Samples, []: Groups)	N > LOD	LOD [µg/kg]	Remarks
Fromme et al. (2007)	Germany	whole diet	0.1 - 3.18	214	19	0.2	
Ericson Jogsten et al. (2009)	Spain	meat, vegetables	0.012 - 0.118	40	5	0.001	
Clarke et al. (2010)	UK	fish	2 - 7	252	3	1	
Haug et al. (2010)	Norway	vegetables, potato, dairy products, cereals, egg, fish	0.00098 - 0.014	16	7	0.0001-0.66	
ANSES (2011)	France	fish	0.002	591 [25]	1	0.0029-0.194	1 out of 25 groups had > 1 detect
Domingo et al. (2012)	Spain	fish and seafood, dairy products	0.031 - 0.007	40 [12]	2		2 out of 12 groups had > 1 detect
Vestergren et al. (2012a)	Sweden	oils, cereals, egg, vegetables, fruit, potatoes, sugar and sweets, soft drinks	0.0014 - 0.011	36	22	-	
Vestergren et al. (2012b)	Sweden	whole diet, vegetables, meat	0.0099 - 0.131	[5]	3	0.0024	3 out of 5 groups had > 1 detect
Gebbink et al. (2015)	Sweden	sugar and sweets	0.0156 - 0.107	14 / 22*	6	-	*14 Samples, of which 8 were measured unprepared and prepared
Herzke et al. (2013a)	Belgium, Czech Republic, Italy, Norway	vegetables	0.00289 - 0.099	62	19	0.002-0.05	
Yamada et al. (2014)	France	fish	0.03 - 4.01	481 [46]	36	0.007-0.95	36 out of 46 groups (all fish) had > 1 detect

B.9.17 Other sources

Natural sources for PFHxA are unknown. As far as we know, PFHxA itself is not used in Europe for manufacturing products and articles. But the PFHxA-related substances are used in large quantities and finally are released into the European Environment. As well as in the article's matrix as in the environment these related substances may degrade and form PFHxA. Further, PFHxA may occur as an impurity in articles and products containing PFHxA-related substances. As a consequence, the environmental exposure of PFHxA arises from the use and the degradation of related substances.

B.9.18 Overall environmental exposure assessment

PFHxA-related substances are used in Europe in large quantities. These substances are released into air, water and soil during all life cycle steps of an article or product. The tonnages of PFHxA and of the related substances that currently and in future will be released into the environment are summarised in ***RAC box***

RAC noted that the values presented in the following tables 25 a-d are not always consistent with the values presented in chapter 1.3.6. and in annexes B.9.1-B.9.17 of the Background Document.

The details of RAC's assessment are reported in the RAC opinion.

Table 25. PFHxA and the related substances are highly water soluble. By leaching from soil and landfills and by precipitation these substances are enriched in the water to the uppermost part. So, water is considered as the main target compartment into which PFHxA, its salts and related substances are released. The substances may be transported into remote areas by water and air.

Due to the only known use of PFHxA and its salts in fluoroelastomers, the only direct release of 0.1 to 1 t/a is assumed by this use. The remaining share of releases of PFHxA and its salts (up to 569 t/a) is considered as indirect release by the degradation of related substances.
Polymer particles are released into all environmental compartments for example by abrasion from articles. Currently, up to 120 t/a of polymers are released during the service life of articles. This amount contributes among others to microplastic.
With a calculated annual average release up to 2.55 kg/a PFHxA resulting from polymerdegradation from landfills, the release of PFHxA from polymer degradation is considered as very low. However, polymers with perfluorinated C6 side chains are a long-lasting constant source for PFHxA emissions over centuries.

For calculating environmental concentrations, the default values from R16, listened in chapter B.9.2 (General Assumptions made for environmental exposure estimations) are used. Due to the high-water solubility, the share accumulates in water, is assumed with 80%. Minimum values representing the northern- and maximum values the southern scenario. Based on the evaluated data, PFHxA precursors are released into the environment of about 6 600 t/a (measured values are converted with findings using the TOP-assay – only 50 % of compounds are detectable using water or methanol as extracting solvent). Based on this value, this may lead to an annual increase of regional concentration of the related substances in European waters between 4 and 37 µg/L. But the local concentration may be much higher for example in case of firefighting operations.

However, the related substances do not accumulate for long time in the environment. The related substances degrade at ambient conditions fairly rapidly and form PFHxA. There are no natural sources of PFHxA known and PFHxA itself is not used in the EU. So, it could be assumed that, in summary, about 1 000 to 5 000 t/a PFHxA (using different approaches like published experimental data or stoichiometrically calculated values) are currently released into the European environment as degradation product. This could result in a European PFHxA concentration of 3 – 28 µg/L water body. In contrast to the related substances, PFHxA accumulates due to non-degradability. PFHxA-related substances will be used in large quantities in the coming years, too. So, about 10 000 to 50 000 t PFHxA will have been released into the environment within the next 20 years without restriction. This is equal to a concentration of 28 – 279 µg/L in rivers and lakes.

However, the measured concentration in several European rivers and lakes is by magnitudes lower (in average below 10 ng/L). Due to high mobility of this substance, the amount of PFHxA reaches the surface water, is rapidly transported by the rivers into the oceans and seep into groundwater. Taking the by (Ahrens et al., 2009a) measured maximum concentration of PFHxA (9.56 ng/L) about 7 t PFHxA could be found in the German Bights surface water. Extrapolating this result to European territorial coastal surface waters, considering an average coastline of 68 000 km, about 144 t PFHxA already have been accumulated in this water body. The coastal waters are part of a larger system of seas and oceans. There are some publications available which report the PFHxA concentration in open sea surface water (see table 48 in appendix B.4.2). Assuming the measured PFHxA-concentration in the open sea surface water is equally distributed over the whole water body from surface to bottom, in the North Atlantic Ocean about 16 500 t PFHxA, in the Mediterranean Sea about 700 t and in the Baltic Sea about 6 t PFHxA are deposited. This assumption could only be a narrow regional snapshot. By main oceanic circulation the water globally is exchanged leading on a dilution on regional scale. However, PFHxA is distributed worldwide and is transported into remote areas.

Using PFHxA, its salts and related substances further without restriction, the PFHxA concentrations will increase as well in fresh- and marine water as in groundwater. Consequently, the chronic exposure of organisms will be increased, too. The increasing concentrations of PFHxA in groundwater will affect the drinking water quality and consequently a higher human exposure could be expected. Above that, PFHxA-related substances are used as constituents in many consumer products like cosmetics or outdoor clothes leading to dermal exposure of human.

RAC box

RAC noted that the values presented in the following tables 25 a-d are not always consistent with the values presented in chapter 1.3.6. and in annexes B.9.1-B.9.17 of the Background Document.

The details of RAC's assessment are reported in the RAC opinion.

Table 25: Overall exposure assessment: Overview of manufacture of articles and products (25a), the use and environmental release of SFP (25b), PFHxA-related substances (25c) and PFHxA (25d).

Table 25a Overview of manufacture of articles and products [t/a].

Sector of use	**Subsector**	**Current manufacture of products / articles**	
		min	max
1. polymers	1.1. manufacture of (acrylic-) polymers with C6 side chains	1 000	10 000
	1.2. manufacture of fluoroelastomers with APFHx	1 000	10 000
2. textiles	2.1. clothing manufactured in the EU	1 200 000	3 600 000
	2.2. clothing imported into the EU	3 000 000	17 000 000
	2.3. clothing used in the EU	4 800 000	14 600 000
	2.4. Professional apparel (PPE)	76 000	194 000
	2.5 Home textiles	620 605	1 800 000
	2.6. Technical textiles	270 000	520 000
	2.7. Medical applications	>54 000	>104 000
3. paper and cardboard	3.1. grease proof papers		13 800 000
4. extinguishing agents		12 000	20 000
5. chrome plating	5. chrome plating	no data available	
6. inks	6. inks	no data available	

Table 25b: Environmental release of C6 related SFPs by current use [t/a] and predicted cumulative releases over 20 years [t]

Sector of use	**Subsector**	**Used tonnages of C6 SFPs**		**Current release of C6 SFPs**		**Cumulative release SFPs until 2040 - [t C6 SFP from 2020 to 2040] (no restriction)**		**Cumulative release of C6 SFPs until 2040 (restricted)**	
		min	max	min	max	min	max	min	max
1. polymers	1.1. manufacture of (acrylic-) polymers with C6 side chains	1 000	10 000	7	68	135	1 350	41	405
	1.2. manufacture of fluoroelastomers with APFHx	no environmental release of C6 related polymers is expected							
2. textiles and leather	2.1. Clothing manufactured in the EU*	6 000	18 000	48	144	960	2880	54	162
	2.2. clothing imported into the EU*	15 000	85 000	8	43	150	850	23	128
	2.3. clothing used in the EU	24 000	73 000	50	174	990	3 470	71	247
	2.4. Professional apparel (PPE)	380	970	2	5	38	97	2	6
	2.5 Home textiles	3 103	9 000	6	18	124	352	9	27
	2.6. Technical textiles	1 350	2 600	13	25	254	495	140	272
	2.7. Medical applications*	>270	>520	>3	>5	>51	>99	>51	>99
3. paper and cardboard	3.1. grease proof papers	27 600	207 000	235	1 760	4 692	35 190	262	1 967
4. extinguishing agents		no environmental release of C6 related polymers is expected							
5. chrome plating	5. chrome plating	no environmental release of C6 related polymers is expected							
6. inks	6. inks	no environmental release of C6 related polymers is expected							
	summary:	**57 433**	**302 570**	**313**	**2 050**	**6 233**	**40 954**	**525**	**2 924**

*These numbers are not included within the overall sum, because the number are already included in other (sub-)categories

Table 25c: Environmental releases of low molecular C6 related substances by current use [t/a] and predicted cumulative releases over 20 years [t]

Sector of use	Subsector	Used tonnages of C6 related substances		Current release of C6 related substances		Cumulative release of C6 related substances until 2040 (no restriction)		Cumulative release of C6 related substances until 2040 (restricted)	
		min	max	min	max	min	max	min	max
1. polymers	1.1. manufacture of (acrylic-) polymers with C6 side chains	1 000	10 000	10	100	220	2 200	10	100
	1.2. manufacture of fluoroelastomers with APFHx	no environmental release of low molecular C6 related substances is expected							
2. textiles	2.1. Clothing manufactured in the EU*	5 340	16 020	362	1 085	7 256	21 768	3 569	10 707
	2.2. clothing imported into the EU*	13 350	75 650	807	4 572	16 137	91 446	8 822	49 993
	2.3. clothing used in the EU	21 360	64 970	1 161	4 034	23 227	80 686	12 344	42 907
	2.4. Professional apparel (PPE)	338	863	23	59	460	1.173	223	571
	2.5 Home textiles	735	2 133	45	132	903	2 640	486	1 408
	2.6. Technical textiles	2	3	0.1	0.2	1.62	3	1	1.6
	2.7. Medical applications*	>0.35	>0.7	>0.04	>0.07	>0.8	>1.5	>0.8	>1.5
3. paper and cardboard	3.1. grease proof papers	18	220 800	1	9 445	15	188 894	7	91.265
4. extinguishing agents	4. summary	100$^{\#}$	563$^{\#}$	100	563	2 002	11 265	560	4 440
5. chrome plating	5.1 hard chrome plating	0.4	18.2	0.1	3.6	1.6	73	0.3	12.5
	5.2 decorative chrome plating	0.8	35.5	0.2	7.1	3	142		
	5.3 plastics chrome plating	1.1	3.3	0.2	0.7	4.4	13		
6. inks	6. inks	10	100	8	80	160	1 604	13	131
summary:		**23 565**	**299 489**	**1 349**	**14 425**	**26 998**	**288 694**	**13 644**	**140 836**

*These numbers are not included within the overall sum, because the number are already included in other (sub-)categories

$^{\#}$ here use refers to the use during fire incidents

Table 25d: Environmental releases of PFHxA and its salts by current uses [t/a] and predicted cumulative releases over 20 years [t] estimated from related substances.

Sector of use	Subsector	Used tonnages or impurities of PFHxA and salts		Current release of PFHxA its and salts		Cumulative release of PFHxA and its salts until 2040 (no restriction)		Cumulative release of PFHxA and its salts until 2040 (restricted)	
		min	max	min	max	min	max	min	max
1. polymers	1.1. manufacture of (acrylic-) polymers with C6 side chains			0.6	6	12	123	1	13
	1.2. manufacture and use of fluoroelastomers with APFHx	10	100	0.1	1	2	20.6	0.22	2.17
2. textiles	2.1. Clothing manufactured in the EU*	329	988	22	67	448	1 343	220	660
	2.2. clothing imported into the EU*	824	4 667	50	282	995	5 641	544	3 084
	2.3. clothing used in the EU	1 318	4 008	82	285	1 790	5 446	881	2 679
	2.4. Professional apparel (PPE)	21	53	2	4	28	72	14	36
	2.5 Home textiles	3	10	3	9	65	188	34	99
	2.6. Technical textiles	0.04	0.08	0.14	0.26	2.74	5.27	1	1.96
	2.7. Medical applications*	>0.009	>0.016	>0.027	>0.053	>0.547	>1.054	>0.547	>1.054
3. paper and cardboard	3.1. grease proof papers	19	2 484	18	849	355	16 975	31	8 051
4. extinguishing agents	4.1 formulation and use by professional firefighting			7	39	140	789	39	311
5. chrome plating	5.1 hard chrome plating5. chrome plating			0.01	0.3	0.1	5	0.02	0.9
	5.2 decorative chrome plating			0.01	0.5	0.2	10		
	5.3 plastics chrome plating			0.02	0.05	0.3	1		
6. inks	6. inks			0.6	6	11	112		
	summary:	**1 371**	**6 655**	**113**	**1200**	**2 406**	**23 747**	**1 001**	**11 194**

*These numbers are not included within the overall sum, because the numbers are already included in other (sub-)categories

Due to the only known use of PFHxA and its salts in fluoroelastomers, the red highlighted numbers are considered as the only known direct releases of PFHxA and its salts.

B.9.19 Assessment of environmental releases from derogated uses

RAC box

RAC performed a qualitative evaluation of the releases and effectiveness in view of the need to minimise the releases. This is because RAC concluded that the Background Document provides insufficient information to draw firm conclusions on the central estimates and ranges of releases to the environment. Therefore, for the majority of the proposed derogated uses RAC does not support the Dossier Submitter's assessment of environmental releases and the proposals for derogations.

The details and justification of these conclusions are reported in the RAC opinion.

Due to those uses for which there are currently no reasonable alternatives available, the application of PFHxA, its salts and related substances still is necessary. Derogations are granted either time-limited until alternatives are available or higher thresholds are acceptable for a certain time (see chapter 2.2 Risk management option in BD part 1). Consequently, PFHxA, its salts and related substances could be released into the environment beyond this restriction will come into force. In the following, the releases of PFHxA and related substances are discussed for each proposed derogation.

General derogations:

Derogations of the restriction shall not apply to articles placed on the market before 18 months from entry into force of the restriction (referring to paragraph 4):
At cumulative emission estimation for different sectors of use (see chapters before) this aspect already is considered in applying the respective default service time of articles. This approach was applied as well for the prediction of possible emissions without and with a restriction of PFHxA its salts and related substances. Service times of articles are very variable and depend on the sector of use. There are very short service times e.g. for paper and boards (≤ 1 year). In contrast other products and articles like fluorinated polymers (including as well SFPs as fluoropolymers) or home- and technical textiles have a service life ≥ 10 years. In consequence, there are considerable amounts of PFHxA and related substances that could be released by articles beyond the date when measures of the restriction become effective.

Derogations related to manufacture:

Derogations of the restriction shall not apply to a substance that is to be used, or is used as a transported isolated intermediate (referred to paragraph 9 (a)).
As demonstrated in the previous chapters, industries already undertake major efforts to minimise releases of PFHxA, its salts and related substances in manufacturing products and articles for which these substances are required. This is also the case in manufacturing and use of transported isolated intermediates. These intermediates often are transported via direct pipeline connections between the site where the intermediates are produced and the site where these substances are further processed (see manufacturing of SFPs starting with perfluorohexyl iodide to manufacture C6 related acrylates and its further processing to respective polymers). Above that, for transportation enclosed containers are in use or the intermediates are transferred into states from which lower emissions are posed (like forming gelatinous blocks instead of transportation of liquids). Because the releases from

manufacturing are already considered as low this will not be changed after applying the provisions of the restriction and for derogated uses. A further reduction in environmental releases is expected due to an improvement of mitigation measures at manufacture and at transportation of isolated intermediates.

Derogations related to fluoropolymers:

The concentration limit for the sum of PFHxA related low molecular substances shall be 100 ppm in fluoropolymers (referred to paragraph 11(d)):
According to (Amec Foster Wheeler Environment & Infrastructure UK Limited, 2017), 52 000 t of fluorinated polymers (fluoropolymers, perfluoropolyether polymers and SFPs) were sold in the EU in 2015. A constant polymer production is assumed for the next 20 years. According to estimates, the share of SFPs is about 10% thereof. Following, for environmental release estimation of derogations 90% (46 800 t) of the fluorinated polymers are considered as "fluoropolymers" (containing fluoropolymers itself, fluoroelastomers and perfluoropolyether polymers). The proposed concentration limit is considered as extractable amount of PFHxA related substances ("weak extraction"). Referring to the assumption made for environmental emissions from textiles (see chapter B.9.5.1.), this amount is considered as the amount of PFHxA related substances which has the potential to be released. As worst case estimate it is assumed here, that the whole amount of extractable related substances is released via the average service life for polymers of about 10 years. On that basis it could be assumed that about 9.36 t of related substances are released by the use of fluoropolymers within 20 years.

The concentration limit for the sum of PFHxA and its salts shall be 2 000 ppb (2 ppm) in fluoropolymers (referred to paragraph 11(a)):
As estimated above, about 46 800 t fluoropolymers are sold in the EU annually. Again, the proposed concentration limit is considered as extractable amount of PFHxA which could be released into the environment over 10 years. It is assumed that due to this derogation about 0.19 t of PFHxA could be released by the use of fluoropolymers within 20 years. Applying the determined default degradation factor of 7% to the estimated amount of PFHxA related substances from above, this results in a release of 0.66 t PFHxA within 20 years. In sum, 0.85 t PFHxA could be released into the environment over 20 years, due to the threshold-based derogation for fluoropolymers in general.

The concentration limit for the sum of PFHxA related low molecular substances shall be 2 500 ppm in fluoropolymers used in the following usage groups: Engine parts in automotive, aerospace and shipping industry (referring to paragraph 11(e)):
The share of fluoropolymers used in engine parts in automotive, aerospace and shipping industry is unknown. However, due to information from stakeholders a majority of fluoropolymers used in engine parts are fluoroelastomers. Therefore, the emission estimation for this derogation is based on the share of fluoroelastomers. Fluoroelastomers represent about 10% from total fluoropolymers. Currently 4 680 t of fluoroelastomers are used in the EU. Stakeholders also provided shares of use for fluoroelastomers: about 70% use in automotive, 20% use in chemical industries and 7% of the elastomers are used in machinery in general. Based on this- and the assumption made previously in this chapter, 3 276 t of fluoroelastomers are used in engine parts in automotive, aerospace and shipping industry annually. The proposed concentration limit is considered as extractable amount of PFHxA related substances which could be released into the environment over 10 years from fluoroelastomers. As a consequence, 16.4 t of PFHxA related substances could be released within 20 years from fluoropolymers in engine parts.

The concentration limit for the sum of PFHxA and its salts shall be 150 ppm in fluoropolymers used in the following usage groups: Engine parts in automotive, aerospace and shipping industry (referring to paragraph 11(b)):
As estimated above, about 3 276 t fluoroelastomers are sold in the EU annually. The proposed concentration limit is considered as extractable amount of PFHxA which could be released into the environment over 10 years from fluoroelastomers. This finally results in a direct environmental release of 0.98 t PFHxA within 20 years. Additionally, about 1.15 t PFHxA are released from degradation of related substances. In sum, 2.13 t PFHxA from fluoroelastomers (fluoropolymers) in engine parts are released into the environment.

The concentration limit for the sum of PFHxA related substances shall be 500 ppm and for PFHxA and its salts shall be 10 ppm in fluoropolymers used in coating of electronic devices until 7 years after entry into force (referring to paragraphs 11(c) and (f)):
The amount of fluoropolymer-coatings in electronic devices is unknown. However, it could be assumed that the PFHxA releases are as there is only a small amount of such coatings in use. Based on stakeholder information electronic coatings used to be ultra-thin down to the nanometre scale and only small areas are coated. Further, fluoropolymers are mainly additives in the matrix. Therefore, environmental releases of PFHxA and related substances from electronic coatings are considered as not quantifiable.

Derogations related to textiles:

Derogations of the restriction shall not apply to personal protective equipment, high visibility clothing and to impregnation agents for re-impregnating such articles (referred to paragraphs 9 (b) to (d)):
The detailed composition of personal protective equipment (PPE) is unknown. However, it could be assumed that a large percentage of this equipment are textiles. Therefore, the emissions of PFHxA, its salts and related substances expected by this derogation are estimated for personal protective textiles exemplary. High visibility clothing is considered as subset from personal protective textiles. In evaluation of emissions of PFHxA, its salts and related substances from textiles a distinction between primary treatment of fibres and fabrics and a secondary treatment with impregnation agents did not occur. It is assumed that emissions from impregnation agents are also a subset of textiles. On the basis of stakeholder consultations, it could be assumed that about 50% of PPE (here including high visibility clothing and impregnation agents) need to be derogated from this restriction. There are partially alternatives available and above that, not all PPE has to fulfil the criteria of Regulation (EU) 2016/425, Annex I, Risk Category III. Based on this assumption it could be expected that from personal protective textiles between 223 and 571 t of PFHxA related substances and 14 to 36 t of PFHxA will be released into the environment within the next 20 years.

Derogations of the restriction shall not apply to textiles for the use in engine bays in the following usage groups: Automotive and aerospace industry (referring to paragraph 9 (e)):
The use of textiles in engine bays in automotive and aerospace industry is considered as subset of technical textiles. The share of technical textiles used in this area of use is unknown. According to the assumptions made for technical textiles in general, it is highly likely that to the uppermost part fluorinated polymers (fluoropolymers and SFPs) are used for textile treatment. In particular, considering that engine bays are highly stressed areas. The releases of PFHxA its salts and related substances are anyway already low from technical textiles. The

releases of these substances are much lower in this subset. A quantification of releases is not possible for this derogation.

Derogations of the restriction shall not apply to medical devices (referring to paragraph 9 (g)):
According to stakeholder information about 90% of medical devices specified in EU Regulation 2017/745 are textiles or textile related compounds. From these textile compounds a release of 0.8 to 1.5 t PFHxA related substances and 0.55 to 1.05 t PFHxA could be expected within the next 20 years (see chapter B.9.5.2.1).

Derogations of the restriction shall not apply to filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency (referring to paragraph 9 (h)):
For the use of PFHxA, its salts and related substances in filtration and separation media the same assumptions made above for textiles in engine bays are applicable. According to the assumptions made for technical textiles in general, it is highly likely that to the uppermost part fluorinated polymers (fluoropolymers and SFPs) are used for textile treatment in this area. The releases of these substances are considered as very low. A quantification of releases is not possible for this derogation.

Derogations related to firefighting foams:

Derogations of the restriction shall not apply to concentrated fire-fighting foam mixtures that were placed on the market before 18 months from entry into force of the restriction for five years (referring to paragraph 5 (c)):
Currently, an annual release of 100 t to 563 t of PFHxA related substances from firefighting foams is estimated (see chapter B.9.7.2). According to the proposed derogation for fire-fighting foam mixtures for 5 years, a release of 500 to 2 815 t over this time could be expected. Applying the estimated degradation factor of 7%, this results in an emission of 35 to 197 t PFHxA over five years. Due to the provisions made for fire-fighting foams used for training and testing purposes - all emissions to the environment have to be minimised and effluents have to be collected and safely disposed – releases from these uses are considered as negatable.

Derogations of the restriction shall not apply to concentrated fire-fighting foam mixtures for defence applications for seagoing units, air traffic facilities and storage of fuel (referring to paragraph 6 (a)):
Currently, an annual release of 100 t to 563 t of PFHxA related substances from firefighting foams is estimated (see chapter B.9.7.2). The share from defence applications is considered with 6%. It is assumed that thereof about 50% are from seagoing units, air traffic facilities and fuel storage (annual release of 3 to 17 t PFHxA related substances). So, a release of 60 to 338 t of PFHxA related substances is estimated by this uses over 20 years. Applying the estimated degradation factor of 7%, this results in an emission of 4 to 24 t PFHxA over this time.

Derogations of the restriction shall not apply to concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500 m^2 for 12 years from entry into force of the restriction (referring to paragraph 8 (a)):
Currently, an annual release of 100 t to 563 t of PFHxA related substances from firefighting foams is estimated (see chapter B.9.7.2). This estimation already considers the fact that only

about 10% of the foam concentrate in stock is used in fire incidents. The use of foam concentrates in chemical and petrochemical industries is used to demonstrate releases caused by this derogation. According to a study from the European Commission and ECHA, 59% of foam concentrates are used for class B fires in chemical and petrochemical industries. Thereof, about 20% are assumed for the use in large tanks. Applying the assumptions made above, it is assumed that 12 to 66 t of PFHxA related substances could be released by quenching fires of large tanks annually. Over the time of 12 years 142 to 797 t of related substances could be released into the environment. Applying the estimated degradation factor of 7%, this results in an emission of 10 to 56 t PFHxA over this time.

Derogations related to chrome plating:

Derogations of the restriction shall not apply to hard chrome plating five years after the entry into force (referring to paragraph 5 (a)):
Currently, an annual release of 1.8 t 6:2 FTS (minimal 0.1, maximal 3.6 t) is estimated (see chapter B.9.11.2). According to the proposed derogation for hard chrome plating for 5 years, a release of 9 t 6:2 FTS (min. 0.4, max. 18 t) over this time could be expected.
This results in an environmental release of 0.6 t PFHxA (min. 0.03, max. 1.3 t), applying the default degradation factor of 7%.

Derogations related to photographic applications and to printing inks:

Derogations of the restriction shall not apply to photographic coatings applied to films, papers, printing plates and inkjet photo media coatings five years after the entry into force and to latex printing inks seven years after the entry into force (referring to paragraphs 5 (b) and 7):
Current releases from photographic applications and from printing inks were calculated jointly. Therefore, the releases caused by these derogations were estimated over 6 years (median between five and seven). Currently, an annual release between 8 and 80 t PFHxA related substances are estimated for photographic applications and printing inks (see chapter B.9.12.2). So, within six years 48 to 480 t of related substances are expected to be released into the environment by these uses. This results in an environmental release of 3.4 to 34 t PFHxA, applying the default degradation factor of 7%.

Derogations related to semi-conductors:

Derogations of the restriction shall not apply to semiconductors and semiconductor related equipment twelve years after the entry into force (referring to paragraph 8 (b)):
Current releases from semiconductors and semiconductor related equipment already is considered as very low. By this derogation these low releases could be reduced down to 60% compared to having no restriction of PFHxA, its salts and related substances in place.

Derogations related to further uses:

Provisions of the restriction shall not apply to epilames used in watches (referring to paragraph 9 (f)):

Epilames are SFPs which are manufactured using PFHxA related substances. The tonnage produced in laboratory scale worldwide is in the lowest kg range. Therefore, possible emissions of PFHxA, its salts and related substances are considered as negligible.

Table 26: Environmental release of **PFHxA** **related substances** - predicted cumulative releases over the derogation time or over 20 years in case of derogation without time limit [t].

Sector of use	**Subsector**	deviant threshold	time limit for derogation	**Cumulative release of related substances [t] by derogation**	
		[ppm] = [g/t]	[year]	min	max
manufacture	transported intermediates		∞ (20)		low releases
polymers	fluoropolymers in general	100	∞ (20)		9.36
	fluoropolymers in automotive	2 500	∞ (20)		16.4
	fluoropolymers as coating in electronic devices	500	∞ (20)		not quantifiable, low releases
textiles	medical textiles		∞ (20)	0.8	1.5
	PPE, high visible clothing, impregnation agents		∞ (20)	223	571
	textiles in engine bays automotive / aerospace		∞ (20)		not quantifiable, low releases
	filtration and separation media		∞ (20)		not quantifiable, low releases
fire-fighting foams	firefighting foam produced before date entry into force		5	500	2 815
	firefighting foams military uses		∞ (20)	60	338
	firefighting foams > 500 m²		12	142	797
chrome plating	hard chrome plating		5	0.4	18
photographic applications	photographic coatings		5	48 (together)	480 (together)
printing inks	latex printing inks		7		
semi-conductors	semiconductors		12		not quantifiable, low releases
further uses	epilame monomers		∞ (20)		not quantifiable, low releases

Table 27: Environmental release of **PFHxA (including degradation of related substances)** - predicted cumulative releases over the derogation time or over 20 years in case of derogation without time limit [t].

Sector of use	**Subsector**	deviant threshold	time limit for derogation	**Cumulative release of PFHxA [t] due to derogations**	
		[ppm] = [g/t]	[year]	min	max
manufacture	transported intermediates		∞ (20)		low releases
polymers	fluoropolymers in general	2 (2 000 ppb)	∞ (20)		0.85
	fluoropolymers in automotive	150	∞ (20)		2.13
	fluoropolymers as coating in electronic devices	10	∞ (20)		not quantifiable, low releases
textiles	medical textiles		∞ (20)	0.55	1.05
	PPE, high visible clothing, impregnation agents		∞ (20)	14	36
	textiles in engine bays automotive / aerospace		∞ (20)		not quantifiable, low releases
	filtration and separation media		∞ (20)		not quantifiable, low releases
fire-fighting foams	firefighting foam produced before date entry into force		5	35	197
	firefighting foams military uses		∞ (20)	4	24
	firefighting foams > 500 m²		12	10	56
chrome plating	hard chrome plating		5	0.03	1.3
photographic applications	photographic coatings		5	3.4 (together)	34 (together)
printing inks	latex printing inks		7		
semi-conductors	semiconductors		12		not quantifiable, low releases
further uses	epilame monomers		∞ (20)		not quantifiable, low releases

B.10 Risk characterisation

There is currently insufficient information to derive a robust predicted no effect concentration (PNEC) as well as a predicted environmental concentration (PEC) that could be used to underpin a conclusion that risks are adequately controlled, either now or on the future. See also section1.3.7.

Annex C: Justification for action on a Union-wide basis

Based on the hazardous properties of PFHxA, its salts and PFHxA-related substances a union-wide restriction is needed to minimize the release to the environment and reduce human exposure to a minimum. These considerations are described below.

Perfluorohexanoic acid (PFHxA) and its salts have a combination of hazardous properties. The substance is extremely persistent and by far exceeds the trigger of being vP. Furthermore, the substance is mobile in the aquatic environment, can be distributed easily within and between environmental compartments by aqueous media, has a long-range transport potential and the potential to enrich in plants. In addition, the substance shows adverse effects in developmental toxicity studies. Though PFHxA does fulfil the P-criterion and vP criterion and even by far exceeds these, the data on bioaccumulation and ecotoxicity are not sufficient to identify PFHxA as a PBT or vPvB substance. Nevertheless, PFHxA shows characteristics which do comply to the concerns which are put forward to reason that a safe concentration of PBT/vPvB substances in the environment cannot be established with sufficient reliability due to unpredictable and irreversible adverse effects on the environment or human health over time. For vPvB substances this applies even if no toxicity is demonstrated. This similarity is in particular founded on the extreme persistence. In addition to the extreme persistence, the mobility and long-range transport potential of PFHxA leads to unpredictable and irreversible adverse effects on the environment or on human health over time. Therefore, PFHxA should be treated as a non-threshold substance for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment regarded as a proxy for an unacceptable risk.

A large variety of emission sources contributes to the exposure of humans and the environment to PFHxA (see chapter B.9). Several of its related substances as well as the ammonium salt are registered with tonnage bands from 1 to more than 1000 tonnes per annum. Use and production of these related substances are taking place in Europe. The use areas are broad and release into the environment cannot be excluded. Monitoring data for PFHxA and knowledge from other PFASs show that release into the environment is occurring.

Sources of human exposure include food, drinking water, house dust, air and dermal contact to consumer articles. Apart from the exposure via the environment, also articles are a significant source of PFHxA for direct human exposure. Relevant articles such as furniture or textile and leather care articles or cosmetics are placed on the market and used in all EU Member States. A considerable share of articles containing PFHxA or related substances is imported from outside the EU.

Therefore, any national regulatory action will not adequately manage the risks of PFHxA and related substances. Risk management measures need to be taken on a Union-wide basis.

An alternative for the restriction would be to list the substances in Annex XIV. However, this would a) enable companies to apply for an authorization, b) would make it difficult to set a threshold for unintended impurities and c) would not affect the import of articles containing these substances. In sum this could lead to ongoing emissions and therefore, to an unacceptable risk for human health and the environment. Moreover, a global regulation seems to be necessary since these substances are transported over global borders via air, water and articles. A European restriction could be the first step to achieve such a global action.

In conclusion, a restriction on PFHxA, its salts and related substances is the most appropriate way to limit the risks for human health and the environment on an EU level. Particularly import of articles containing these substances can be regulated this way.

Annex D: Baseline

Since the 1950s perfluorinated substances and the polymers made there of became more and more important for a wide range of uses. Mainly substances with C8 perfluorinated (side-) chains were used. Above that, the use of C4 and C6 substances was also very common. Due to their hazardous properties the C8 substances have been replaced by substances with shorter perfluoroalkyl chains by manufacturers in the USA, Canada, Europe and Japan step by step since 2002. Contemporarily the global market for fluoropolymers and SFPs was growing rapidly. Assuming a constant release of C6 related SFPs and of PFHxA over the last 50 years, about 6 000 t of polymers and about 19 000 t PFHxA have been released into the European environment.

So, PFHxA has been investigated in environmental compartments by several authors (e.g. Benskin et al. 2012b; Ahrens et al. 2010b; Zhao et al. 2012; Gellrich et al. 2012). PFHxA already is found ubiquitously as well in fresh- and marine surface waters as in groundwater. Compared to the estimated high annual release of PFHxA, the environmental load in European rivers and lakes is fairly low with about 2 t. However, PFHxA is extremely mobile in water. About 144 t PFHxA could be detected in European territorial coastal surface waters. Considering the whole water body, in the North Atlantic about 16 500 t PFHxA could be assumed. The waters of the world oceans are linked by the great currents which transport warm water at ocean’s surface like the Gulf Stream and transport cold water in the depth e.g. by the East Greenland Current. In the Arctic PFHxA is transported with the currents into deep waters and to the Antarctic. On the one hand this leads to a dilution of the PFHxA concentration in European waters, on the other hand PFHxA is transported to remote areas.

Caused by manufacturing, formulating and the use of articles and products containing PFHxA, its salts and related substances, PFHxA already could be detected in humans (see chapter B 4.4.2). PFHxA concentrations in human serum are often reported below the limit of detection. However, higher frequencies of detection are found in urine and hair than in serum.

Without restriction about 10 000 to 50 000 t PFHxA will have been released into the environment within the next 20 years. At the moment it is very difficult to remove PFHxA from the environment. PFHxA is extremely persistent. Consequently, the concentration of PFHxA will be increased in the environmental compartments and the exposure of organisms and humans will increase, too. Future generation will be faced with these contaminations. Effects will not only occur on the point of release of PFHxA but also far away from its point of release.

A restriction will decrease the release of PFHxA into the European environment within 20 years by a half. Supplementary mitigation measures, like the further replacement of PFHxA based products and the improvement of water cleaning methods will further reduce the release of PFHxA, its salts and related substances into the environment.

Annex E: Impact Assessment

E.1 Risk Management Options

E.1.1 Proposed option for restriction (phase out over 18 months with exemptions)

The proposed restriction is defined as a ban on the use of PFHxA, its salts and related substances. This includes a restriction on the manufacturing, placing on the market and use of PFHxA, its salts and related substances in the EU. The import of PFHxA, its salts and their related substances in articles to the EU is also included.

PFHxA is not registered under REACH and therefore most probably not intentionally used within Europe. Salts of PFHxA and related substances, however, are registered and used (see annex A.1.1). Imported articles are an emission source of intentionally used PFHxA, its salts and related substances as well. The substances are used for different purposes in the production of a large variety of mixtures and articles. Therefore, a broad restriction represents a sufficient way to emission reduction.

In terms of risk reduction capacity, a total phase out of manufacturing, use and contents in articles and mixtures (including imports) would be most effective. However, further criteria have to be considered: proportionality, implementability, enforceability and manageability /monitoring.

Proportionality: PFHxA, its salts and related substances are used in the production of a large variety of mixtures and articles. For most uses, alternatives are available and affordable. For some uses the availability of alternatives is unknown. For some articles and mixtures, the continued use of PFHxA, its salts and related substances is necessary, meaning that no alternatives are available for highly important purposes, for example health or safety or that alternatives are not economically feasible. For these uses a total ban on PFHxA, its salts and related substances is not proportionate considering that in relation to the expected emissions reduction large societal costs are to be expected.

Implementability: The proposed restriction is considered to represent an implementable option for the actors involved within the timeframe of 18 months for most uses. As described in Annex E.2 Impact Assessment for specific uses acceptable technology, techniques and alternatives are available and economically feasible. However, for some uses economically feasible alternatives that provide acceptable functionality are not available. For other uses alternatives are available but a longer timeframe than 18 months is needed for the adjustment to new technology, techniques and alternatives. Uses that are addressed by the restriction but for which no alternatives are available at the moment are e.g. in the production of semi-conductors or for textiles when dirt and oil repellency are required.

Enforceability: Enforcement authorities can set up efficient supervision mechanisms to monitor industry`s compliance with the proposed restriction. Methods can be easily adapted from the methods to analyse PFOA and longer-chain PFAS. Given that methods exist, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.

Manageability/monitoring: There are numerous analytical methods reported in the scientific literature to perfluorinated and some related substances in almost all environmental media, e.g. water, air, biota, and in humans.

Sweden has already initiated the development of a new CEN standard within the Technical committee TC248/WG26, "EC restricted substances in textiles" that specifies a test method for detection and quantification of extractable PFAS in textile articles, that includes PFHxA, its salts and related substances. Furthermore, at least in Germany, there is a norm (DIN 38407-42) for analysing PFCAs and PFSAs in water, sewage and sludge (Deutsches Institut für Normung e.V. (DIN), 2011). The method is applicable to concentrations higher than 0.01 µg L^{-1} in water (0.025 µg L^{-1} in treated sewage). Within that method unfiltrated water samples are spiked with mass-labelled internal standards and extracted with solid phase extraction. The instrumental analysis should be performed with liquid-chromatography coupled to a mass-spectrometer. A possibility to measure PFHxA-related substances without knowing every single substance, is the conversion of these substances to the corresponding acids and subsequent analysis of the PFCAs, for example in water samples. Oxidation can be performed with hydroxyl radicals (Houtz and Sedlak, 2012). These radicals can be produced in a water sample by thermolysis of persulfate under basic pH conditions.

Besides the availability of analytical methods, a sampling strategy is needed to monitor the restriction. There are different possibilities:

- time trend monitoring
- monitoring of emissions

For both strategies it has to be kept in mind that PFHxA is persistent. In consequence, PFHxA will remain in the environment for ages even if emission to the environment is stopped immediately. In addition, there will be continuing emissions from articles in use and from non-EU-countries via long-range transport. A time trend monitoring can be performed with samples from the environment, from animals or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring. Reductions of emissions of PFHxA and related substances in the environment should result in decreasing PFHxA concentration in such a trend monitoring. It might be sufficient to measure PFHxA in such a trend monitoring, because the related substances will be degraded to the corresponding persistent acid in the environment. Decreasing trends in emissions will then not be directly measurable in environmental samples because time is needed for degradation. Furthermore, it has to be kept in mind that release of PFHxA from environmental sinks, like sediment, might bias time trend in some cases.

SEAC box

SEAC notes that the RAPEX (Rapid Exchange of Information) system has been replaced by Safety Gate: the EU rapid alert system for dangerous non-food products.

A joint approach for different enforcement activities such as inspections and testing for the occurrence of several regulated PFASs as PFOS, PFOA, C9-C14 PFCAs and PFHxA, its salts and related substances at the same time would lower costs. Thereby, enhancing cost effectiveness and reducing enforcement costs for PFHxA, its salts and related substances. Regarding imported articles, border authorities can control compliance using the RAPEX system (Rapid Exchange of Information System) to report any violation of the restriction. A time trend monitoring can be performed with samples from the environment, from animals or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring.

This restriction proposal also includes recycled material and articles made from recycled materials. The Dossier Submitter demonstrated a concern resulting from the exposure to PFHxA, its salts and related substances. Subsequently there is a concern if recycled materials contain these substances. An exemption for recycled materials would potentially lead to higher emissions to the environment in comparison with an appropriate waste management. Recycling of contaminated wastes contributes to environmental releases and the contaminants may again circulate through use, disposal and recycling phase of articles.

The aim of the restriction is to end the emissions of PFHxA, its salts and related substances. Consequently, setting the concentration limit to 0 ppb would be the apparent approach. However, due to several reasons this is not feasible. When using 0 ppb as concentration limit even the slightest impurities would fall under the restriction and therefore increase the effort for the enforcement of the restriction distinctly leading to a disproportionate expense with regard to the effect on emissions. Besides the enforceability reasons also contradictions with the present restriction and with other regulatory measures needs to be avoided. It cannot be ruled out that alternatives for PFHxA, its salts and related substances might contain unintentional impurities e.g. due to trace contaminants in production facilities which switched from fluorine containing to fluorine free fire-fighting foams, as stated by an expert at the ECHA Stakeholders' Workshop on firefighting foams (2019). Also, derogations in other regulatory measures (e.g. restriction of PFOA, PFOA salts and PFOA-related substances) might include e.g. articles which contain unintentional impurities of PFHxA, its salts or related substances.

Hence, to prevent intentional use but allow usage of alternatives and prevent contradiction with other regulatory measures a threshold above zero was chosen.

Due to scarce information on unintentional impurities of PFHxA, its salts and related substances it was based on already existing concentration limits in previous restrictions.

Considering all aspects, the Dossier Submitter proposes a restriction that bans all manufacturing, uses or content in articles 18 months after entry into force of the restriction except for the uses specified in Table 5 of Part 1 of the restriction dossier, for which time-limited or total exemptions are proposed. It is concluded that the following thresholds are feasible for mixtures and articles placed on the market:

- 25 ppb for the sum of PFHxA and its salts
- 1000 ppb for the sum of PFHxA- related substances.

The proposed restriction does not cover the "second-hand" market (e.g. used textiles and textiles in the supply chain). One reason for this is that the second-hand market is difficult to control, in most cases one consumer donates /sells single articles to another consumer (directly or via a second-hand store). It would not be practical to remove single articles from the market. Also, to use e.g. a jacket as long as possible before it turns into waste is a sustainable management of resources.

E.1.2 Other Union-wide risk management options than restriction

Table 28: Other Union-wide risk management options than restriction.

Other relevant Instruments	**Community wide option for risk management**
Stockholm Convention	PFHxA might be proposed as POP in the future. However, it seems to be more effective to start with the assessment of concerns on PFHxA in the frame of an SVHC identification under REACH regulation first.
EU Drinking Water Directive	The not yet adopted draft of the EU Drinking Water Directive which will become effective in 2022 contains two different parameters relating to PFASs. One of the parameters is a sum parameter for a sum of single substances. This sum parameter shall not exceed 0.1 µg/L. PFHxA is listed as one of the relevant single substances of this sum parameter which shall be monitored when the risk assessment and risk management conclude that the listed substances are likely to be found in the water supply. As this regulatory measure focusses on a sum parameter in drinking water and addresses the consequences of an already passed emission the enforcement of the EU Drinking Water Directive will have a different effect than the restriction of PFHxA, its salts and related substances.
Further international regulatory activities	Given PFHxA might be present in imported articles, and due to its ubiquitous presence in environmental compartments, it is important to consider initiating world-wide risk management measures.

Voluntary industry activities	Voluntary measures to be initiated by industry might cover phase out of PFHxA and related substances from certain product categories and industrial uses. Furthermore, it might comprise the education of manufacturers, downstream users and consumers regarding the proper use of articles with PFHxA and related substances during its whole life-cycle. Emissions during manufacture might be as far as possible prevented. However, voluntary industry activities might address only certain sectors and applications, therefore they cannot completely prevent emission of PFHxA into the environment
Operational conditions implemented and recommended by the manufactures and/or importers	Measures such as improved containment in manufacture and use and increased use efficiency are possible for manufacturing to some extent. However, these measures address only a part of the problem: except for the use of alternatives, they are all associated with some level of discharge and they cannot influence contamination associated with goods used outside manufacturing or processing sites (Goldemann et al. 2019) i.e. diffuse source from consumer products. Furthermore, relevant emission sources as imported mixtures and articles, emitting PFHxA and PFHxA-related substances during the service life, are not addressed by this measure.

E.2 Impact Assessment for specific uses

SEAC box

SEAC noted that a conclusion on the magnitude of the overall socio-economic costs related to the restriction proposal is difficult to achieve and uncertain.

The justification for this consideration is explained in the SEAC opinion.

Table 29: Main applications, as well as benefits, of C6 related fluoropolymers and SFPs and fluorinated surfactants.

Industry	Application	Property	Benefit	Fluoro-technology
performance textiles and carpeting	interior textiles of cars /aircrafts	water, oil, stain, soil protection	improved cleanability, longer fabric life lowering overall maintenance costs	fluoropolymers and SFPs
	outdoor apparel and equipment	water, oil, stain, soil protection	durable, lifesaving protection in severe environments, longer useful garment life	fluoropolymers and SFPs
	professional protective textile	durable, high water and oil (solvent) repellency. Chemical resistance	life protection in severe environments, protection against hazardous chemicals, protection against water and liquids in a (fuel) fire.	fluoropolymers and SFPs
	non-woven (medical)	IPA repellency (isopropanol alcohol); repellency to blood, urine and other body fluids	prevention for medical work wear for the operating theatre; protection of hospital staff; departmental, ward and surgical clothing for nurses, nursing staff and doctors	fluoropolymers and SFPs
	non-woven	water- and oil	protection of	fluoropolymers and

	(automotive)	repellency; resistance to liquid chemicals (battery), diesel- and gasoline; heat resistance	components in the motor area; insulation	SFPs
	carpets /home textile	water, oil, stain, soil protection, reduced dirt pickup	easy clean, longer useful life	fluoropolymers and SFPs
food packaging		oil and grease resistance	enabling paper packaging for pet food, microwave popcorn, quick service restaurant, meals; reduces potential for burns from hot oil migration through the packaging or wrap; maintains aesthetics and integrity of packaging material	fluoropolymers and SFPs
electronics	semi-conductors (etching and resist materials, cleaning fluids)	wetting and levelling to control and improved chemical etching. High purity, pure drying cleaners	ability to manufacture semi-conductors.	fluorinated surfactant
	electronic grade coating	water and dust protection	fewer devices breaking down due to water or dust damages	fluoropolymers and SFPs
firefighting foams	airports, oil fields, fuel storage, defence applications	high efficiency oxygen starvation, faster extinguishment	quicker extinguishing of fires, resulting in saved lives,	fluorinated surfactant

		times, better burn back resistance	reduced asset losses; fire-fighter safety	
building and construction	paints, building materials protection	wetting, levelling, mould-releasing, anti-fouling	longer useful lifetime, lower repainting interval, reduced paint waste from recoat preparation	fluorinated surfactant
chrome plating	hard chrome plating, decorative chrome plating, plastic electroplating	wetting, lower surface-tension of plating solution	decrease aerosol emissions	fluorinated surfactant
printing inks	water-based printing inks, latex printing inks	reduction of surface tension	enhance picture quality, improves the working of modern printers	fluorinated surfactant
photographic applications	photographic materials (film, paper, plate), x-ray material	wetting, controlling spread, dirt repellence, static control and friction control agent	quality, improve coatability	fluorinated surfactant
filtration	medical devices, heating, ventilation and air conditioning (HVAC), coalesce, automotive fuel and oil, air-conditioning	water, oil, stain, soil filtration	improves service-life of devices, enhances filtration capacity	
watches	coating (epilames) for mechanical watch parts	reduction of surface tension	lubricant for mechanical parts stays in place, longer service life, fewer service intervals	fluorinated surfactant
medical devices	detergent proof, one-use,	provide detergent proofing	prevent cross infections and hospital	fluoropolymers and SFPs

	washbowls		acquired infections	
	ophthalmic applications	non-active medical device ("vehicle") in the application of eye drops	longer residual time on the eye and higher bioavailability of the active ingredient	semifluorinated alkane
	implantables and non-implantables	water- and oil repellency, altered surface properties	different health benefits through improved function and reduced complications (i.e. infections due to bacterial adhesion)	fluoropolymers and SFPs

E.2.1 Fluoropolymers and side-chain fluorinated polymers

E.2.1.1 Overview

PFHxA, its salts and related substances are used for the production of (per-)fluorinated polymers, either as monomers or as processing aid to control the polymerisation process. Fluoropolymers and SFPs provide vital performance characteristics to products or production processes. These polymers are used for several applications as finishing agents or as repellents. Therefore, fluoropolymers and SFPs are used in a wide range of sectors and a restriction would impact uses e.g. in building materials, FCM, electronic devices and cables, gaskets, seals, etc. – mainly as processing aid in the production of PTFE, ETFE and fluoroelastomers.

Proposed restriction elements for PFHxA and related substances in fluoropolymers and side-chain fluorinated polymers

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:
(a) another substance, as a constituent,
(b) a mixture,
(c) an article
in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.
Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction
Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.
The concentration limit referred to in paragraph 2 shall be
(a) 2000 ppb for the sum of PFHxA and its salts and 100 ppm for the sum of PFHxA related low molecular substances in fluoropolymers;
(b) 150 ppm for the sum of PFHxA and its salts and 2500 ppm for the sum of PFHxA

related low molecular substances in fluoropolymers used in the following usage groups: Engine parts in automotive, aerospace and shipping industry.

This derogation shall not apply to articles referred to in paragraph 2(c).

E.2.1.2 Use and functions

Structurally, fluorinated polymers belong to different polymer classes: side-chain fluorinated polymers (SFPs) and fluoropolymers. SFPs consist of a non-fluorinated polymer backbone with fluorinated side-chains. Non-fluorinated side-chains can be present as well. The fluorinated side-chain is typically composed of a terminal perfluoroalkyl moiety, a spacer and a linker. The backbone is attached to the fibre surface via physical or chemical bonding. Fluoropolymers such as polytetrafluoroethylene (PTFE) are used for the breathable membrane (Figure 8 (C)). They are distinguished by a carbon-only polymer backbone with fluorines directly attached to the backbone carbon atoms (Buck et al., 2011; Henry et al., 2018).

Several low molecular PFHxA-related substances are used as intermediate and as monomers for polymerisation. Most important for polymer production are numerous acrylates with a C6 perfluorinated side chain like the registered 6:2 FT(M)A. As well the acrylate (6:2 FTA) as the metacrylate (6:2 FTMA) are registered for 100 – 1000 t/a for use in the EU.

Fluoropolymers as such do not contain structural moieties like FTOHs and PFCAs. A potential source, however, could be residues of fluorinated processing aids. The ammonium salts of PFOA or PFNA have been historically used as fluorosurfactant in the manufacture of fluoropolymers by emulsion polymerisation (Buck et al., 2011). Many fluoropolymer manufacturers have discontinued the use of PFOA and PFNA salts as processing aids and are now using alternative fluorinated substances (Buck et al., 2011; Henry et al., 2018; Wang et al., 2013). Wang et al. (2013) mention that some producers may have used, or may use, the ammonium salt of PFHxA or a 6:2 fluorotelomer carboxylic acid (a low molecular PFHxA-related substance) as an alternative processing aid. The ammonium salt of PFHxA is a processing aid in the production of fluoroelastomers. Fluoroelastomers are predominantly used in highly critical combustion engine vehicles (gasoline, diesel). Their excellent heat and chemical resistance are necessary for smaller, higher performance engines necessary to meet the EU car emission standards (Euro6b). To our knowledge, fluoroelastomers are the only material combining excellent heat, oil, ozone resistance as well as fuel permeability. With the added amount of APFHx the quality of the fluoroelastomers is controlled. Fluorinated surfactants are required to achieve the intimate mixing of monomers in the polymerisation step to complete an efficient and safe reaction. The compound is registered for 10 – 100 t/a and is imported as 50 % water solution into the EU. Depending on polymer type, the residual content of unbound APFHx is varying.

Aqueous based products on the basis of side-chain-fluorinated polymer dispersions are used to impart functional oil and water repellency when applied to textile, leather, hard surfaces or paper fabrics (industrial and consumer application). The fluorochemical finishes can be applied by padding (foulard), spraying, foam applications, exhaustions or coating. During the manufacturing of synthetic fibres a fluorochemical polymer can be added during the polymer melt process to impart oil and water repellency to the finished fibres. A large quantity of the fluoropolymers and SFPs is further processed into a variety of specialized articles (fibres, tubes, sheets and tapes). Those articles are than further processed into the final products and offered for sale.

For side-chain-fluorinated polymers some information is available on uses from the public literature, too. For example textiles is one of the use areas of side-chain-fluorinated polymers (European Chemicals Agency, 2015a). Textiles are also mentioned by some registrants as one of the product categories for use of 6:2 FTMA in polymerization. Fluoropolymers and SFPs are used for making textiles water-, dirt- and stain repellent (Lacasse and Baumann, 2004). When extracting such textiles, e.g. outdoor textiles, non-polymeric fluorinated substances, beyond others, PFHxA and 6:2 FTOH, can be found (Greenpeace, 2016; Gremmel et al., 2016; Kotthoff et al., 2015a).

The fluorinated side-chains comprise an alcohol moiety which is bonded *via* ester linkage or other (e.g. urethane) linkages to the non-fluorinated polymer backbone (Figure 7). The alcohol moiety can typically be n:2 FTOHs or perfluoro-alkane sulfonamidoethanols. The former are related substances of PFCAs whereas the latter are related substances of perfluoroalkyl sulfonic acids (PFSAs). Polymer degradation and related breakage of the linkages can release the fluorinated alcohols as cleavage products. Degradation half-lives for fluorotelomer-based SFPs in soil and water are on the time scale of decades or longer (Holmquist et al., 2016; Li et al., 2017a). However, the ester linkages could be cracked partially, so that the polymeric structure itself seems to be a source for the occurrence of FTOHs and PFCAs, too. Most relevant sources are, however, residuals from production such as unreacted monomers and derivatives thereof. Impurities from the production process could be another source.

To better understand the structural identity of these residuals, it is useful to briefly mention the two principal technologies for the manufacturing of compounds containing perfluoroalkyl chains: electrochemical fluorination and telomerisation. The former produces a mixture of branched and linear isomers, whereas the latter produces primarily or exclusively linear compounds (Buck et al., 2011). According to information from manufacturers, telomerisation is the most frequently used technology. The telomerisation process usually starts with a perfluorinated C2 parent structure (tetrafluoroethylene) which is converted to a perfluoroalkyl iodide (Knepper and Lange, 2012). The addition of tetrafluoroethylene building blocks yields a mixture of perfluoroalkyl iodides with even-numbered fluorinated carbon chains. The mixture can be further purified by distillation to obtain compounds with desired chain lengths. The addition of ethylene finally yields fluorotelomer iodides which can be further transformed to, e.g., fluorotelomer alcohols (e.g., 6:2 FTOH, 8:2 FTOH) and (meth)acrylate monomers (Figure 7).

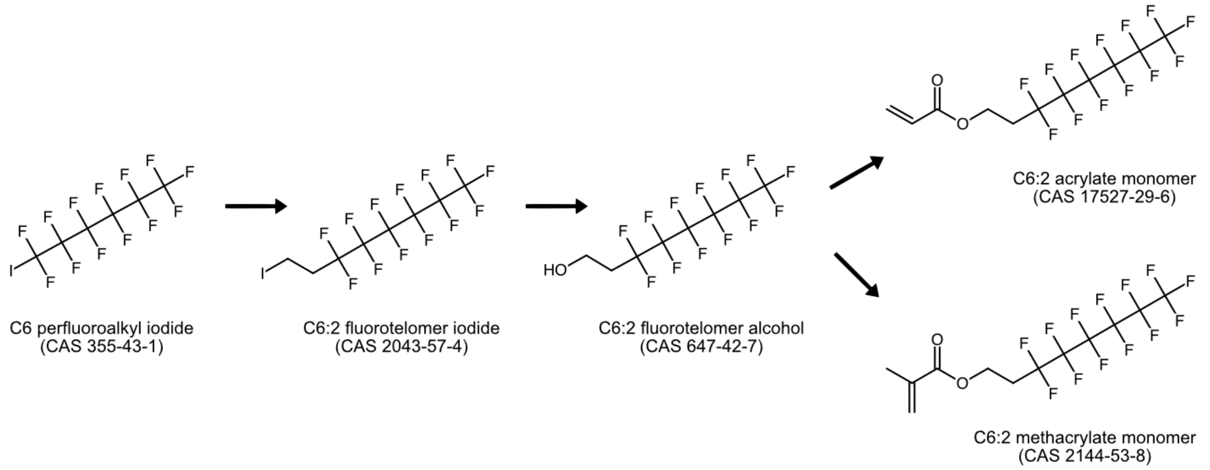

Figure 7: *Synthesis of fluorotelomer-based (meth)acrylate monomers as raw material for the manufacturing of side-chain fluorinated polymers (SFPs).*

The fluorinated (meth)acrylate monomers are copolymerized with one or more non-fluorinated acrylate monomers, and possibly other monomers. The SFPs contain, as a rule, 20 – 50 % (w/w) fluorine and are commercially available as water-based dispersions with a polymer content of 20 – 30 %.

The basic substances are manufactured in an integrated way as a production cascade where one reaction product serves as feed stock of the next stage. Alternatively at some stages the reaction products can be isolated and as such be sold to customers that perform further processing to manufacture fluorinated compounds of higher complexity (usually fluoropolymers or SFPs).

E.2.1.3 Baseline

Polymers are an extremely large family of very different materials with different characteristics, properties and uses. These materials offer specialized solutions to a wide range of requirements in numerous products, applications and sectors. Among the polymers, fluoropolymers are high-performance materials.

The overall trend in global manufacturing and consumption of fluorotelomer and fluorotelomer-based polymers is a shift from ≥ C8 to C6 fluorotelomer chemicals (FluoroCouncil 2012 cited in Lassen et al. (2013)). Since the use of long-chain PFASs such as PFOA and its related substances has been restricted, manufactures shifted the production to short-chain fluorinated homologues (Luz et al., 2019). For fluorotelomer based products, this meant a shift to products that contained a six-carbon perfluoroalkyl moiety like 6:2 FTOH. In a recent survey (Ökopol, 2018), Europe-based manufacturers, formulators, article assemblers, and associations provided information on the establishment of the C6 fluorotelomer technology.

SEAC box

SEAC considered that the reported figure on sales of 52 000 t in 2015 refers only to fluoropolymers, not to fluorinated polymers in general.

The justification for this conclusion is reported in the SEAC opinion.

According to (Amec Foster Wheeler Environment & Infrastructure UK Limited, 2017), 52 000 t of fluorinated polymers (fluoropolymers, perfluoropolyether polymers and SFPs) were sold in the EU in 2015. A constant polymer production is assumed for the next 20 years. According to estimates, the share of SFPs is about 10% thereof. The Dossier Submitter estimates that 90% (46 800 t) of the fluorinated polymers are considered as "fluoropolymers" (containing fluoropolymers itself, fluoroelastomers and perfluoropolyether polymers). As worst case estimate it is assumed here, that the whole amount of extractable related substances is released via the average service life for polymers of about 10 years. On that basis it could be assumed that about 9.36 t of related substances are released by the use of fluoropolymers within 20 years.

The share of fluoropolymers used in engine parts in automotive, aerospace and shipping industry is unknown. However, due to information from stakeholders a majority of fluoropolymers used in engine parts are fluoroelastomers. Therefore, the emission estimation for this derogation is based on the share of fluoroelastomers. Fluoroelastomers represent about 10% from total fluoropolymers. Following, currently 4 680 t of fluoroelastomers are used in the EU. Stakeholders also provided shares of use for fluoroelastomers: about 70% use in automotive, 20% use in chemical industries and 7% of the elastomers are used in machinery in general. Based on this- and the assumption made previously in this chapter, 3 276 t of fluoroelastomers are used in engine parts in automotive, aerospace and shipping industry annually. 16.4 t of PFHxA related substances could be released within 20 years from fluoropolymers in engine parts.

Manufacturing of polymers with perfluorinated C6 side chains is one of the most important uses of low molecular PFHxA-related substances. These polymers are used in the EU in quantities from 1 000 to 10 000 t/a. Further, the ammonium salt from PFHxA is used as processing aid for manufacturing of fluoroelastomers from 10 – 100 t/a. These polymers and fluoroelastomers mainly are designed for the special needs of the customers using these products.

Stakeholders demonstrated a high reduction of environmental releases by effective mitigation measurement at C6 polyacrylate production. Therefore, it is estimated that 10 to 100 t/a of PFHxA-related substances are released into the environment via C6 side chain (co-) polymers at manufacturing.

However, with regard to the whole life cycle the Dossier Submitter notes that the partial degradation of C6 side chains from the acrylic polymers could be a source for release of PFHxA into the environment that should not be underestimated especially if large timeframes are investigated.

Fluoroelastomers are rubbery materials based on several of the same monomers as used for manufacturing fluoropolymers. They are produced as highly viscous liquids and then cross-linked (or 'cured', or 'vulcanized') to harden them and impart their elasticity. For manufacturing a subset of fluoroelastomers, APFHx is used as processing aid. Therefore, APFHx could remain as a residual impurity in these elastomers. The APFHx containing rubbery material is used to produce e.g. seals and tubes in transportation sector like in automotive or aviation. So, a wide dispersive outdoor use of these articles with a low release of APFHx could be assumed. Applying the default release factors for this release category (ERC 10a) and a service lifetime of 10 years, up to 0.65 t/a of the ammonium salt from the 10 to 100 t APFHx used in the EU are released to the environment. Assuming, a low release of APFHx by leachate from landfills (60 % of articles are deposited in landfills) up to 390 kg may be released into water annually. Concluding, **0.1 to 1.0 t/a APFHx** could be released into the environment by the use of APFHx in fluoroelastomers. However, the estimated number of unreported releases could be much higher. The number of articles imported into the EU containing fluoroelastomers or other products with APFHx as impurity is unknown.

E.2.1.4 Economic and other impacts

Several stakeholders submitted information in the public consultation that PFHxA, its salts and related substances are required as process media to produce certain Fluoropolymers. Fluoropolymers are manufactured in various forms (resins, films, powders) and further processed by customers. Processing includes extrusion, molding, etc.

Based on the information from the public consultation no information is available which share of the approximately 52 000 t of fluoropolymers are manufactured with PFHxA, its salts and related substances. However, several uses are mentioned by the stakeholders.

Stakeholders mention inter alia the production of ETFE, PTFE micro-powders and certain fluoroelastomers as important applications where a derogation is justified with a view to societal benefits of continued use.

Stakeholders claim that fluoropolymers display outstanding chemical and temperature resistance, combined with mechanical and electrical properties. They are used in specific, high reliability/safety critical applications, but in a wide array of industries such as transport (automotive, shipping, rail), aerospace, energy (e.g. oil&gas, renewable, nuclear), chemical, telecommunications, semiconductor and electronics, pharmaceutical, food, etc. Furthermore, fluoropolymers are claimed to be key enablers for the decarbonisation of the EU economy, as critical components of fuel cells, batteries, renewable energies, digital technologies, as well as many efficient industrial processes.

ETFE resins are used for coating of cables and wire. Some stakeholders cite data from a report by Plastics Europe to illustrate the importance of fluoropolymers (Group, 2017). The report claims to be a socioeconomic analysis on Fluoropolymers. As it focuses only on benefits of fluoropolymer uses and not on available alternatives and emissions it is only of limited value for this dossier. Nevertheless, in this study many uses of fluoropolymers are described and obviously a lot of them generate high societal benefits.

Stakeholders in general did not provide detailed information on restriction scenarios. They did not provide information on alternatives for certain applications or detailed information on uses where costs from functional losses (when not using PFAS) are affordable.

The Dossier Submitter is not aware of further information that would help in identifying applications where technically and economically feasible alternatives are available or in development.

The Dossier Submitter notes that for several uses alternatives might be available (e.g. cookware, textiles, food processing) and for other uses it is prima facie not evident that society values the benefits of continued use as highly as stakeholders claim (e.g. construction materials, textiles). No information is available to differentiate for certain sub-uses whether a derogation is justified for all applications.

For example, there might be differences in societal benefits when assessing the impacts of a restriction for greases, oils and lubricants. The mixtures are presumably used inter alia in several industrial applications, transportation and leisure activities. The Dossier Submitter is not aware of any detailed information to categorize the manifold applications per sub-use by socioeconomic impact.

According to information from consultations with stakeholder's production sites for polyacrylates and polyurethane in the EU rely heavily on fluorinated compounds. One manufacturer claimed that a restriction would lead to complete reorganisation of his business and could entail a closure of the production site. The manufacturer claims that this might lead to the loss of a considerable number of jobs. However, this might be an overestimation as it is uncertain if and how the manufacturer could shift production to alternatives. Finally, the Dossier Submitter lacks information on whether the proposed derogations would enable the manufacturer to continue at least part of his business. Therefore, more detailed information is needed.

The Dossier Submitter has not enough information on the manufacturers that are already producing alternatives.

Fluoropolymers in automotive, aerospace and shipping applications

Fluoroelastomers are fluoropolymers that are produced with PFHxA-related substances and predominantly used in highly critical combustion engine vehicles (gasoline, diesel). Their excellent heat and chemical resistance are necessary for smaller, higher performance engines to meet the EU car emission standards. A stakeholder provided information that PFHxA-related substances remain as impurities in the product. Impurity levels have been measured up to 15 ppm.

Typical products are turbo charger hoses, fuel hoses, seals and gaskets. There is another way to produce fluoroelastomers called soap-free emulsion polymerization but the resulting fluoroelastomers do not reach the same performance levels. According to information received supply shortage of fluoroelastomers that are produced with C6 polymerisation aid would lead to considerable costs: massive requalification costs and time for downstream users and a considerably reduced competitiveness of the EU car industry.

The Dossier Submitter received information that the EU market for fluoroelastomers with C6 polymerisation aids is served by two producers. One of them demonstrated that emissions from the production process are in the very low kilogram-range. No information from the competitor(s) are available but the Dossier Submitter assumes that even if other manufacturers have higher emissions, these still will be considerably below 1 t/a. Releases from articles containing fluoroelastomers into water and soil have been calculated according to the expected use in automotive and aviation applications and are expected to be 120 – 160 kg/a.

The Dossier Submitter estimates loss of profit of the European (C6-)fluoroelastomer manufacturers in case of a restriction in the range between 2-16 million €/a. With no more details available a central estimate of 9 million €/a is assumed. A Cost-effectiveness ratio of 12 500 - 133 000 €/kg results, with a central estimate of approximately 64 300 €/kg. Additional costs for downstream users are to be expected in case they have to use non-C6 fluoroelastomers.

According to stakeholder information fuel lines, fuel hoses and turbochargers, o-rings, gaskets and seals play a vital role in boosting engine performance and reducing emissions in automotive and aerospace/aircrafts. They also contribute to the reliability of articles that have to withstand high temperatures and aggressive fluids. According to information received, the components suppliers in automotive industry have to supply according to requirements listed for example in ISO/TS 16949 (prepared by the International Automotive Task Force (IATF) and the "Technical Committee" of ISO). Stakeholders argue that these requirements can only be fulfilled with fluoroelastomers with C6 polymerisation aids.

One stakeholder reports that fluoroelastomers are used in the automotive sector to ensure the safe operation of vehicles, aircrafts and machines by preventing over-heat and leakage of oil/fuel which may cause serious accidents, to minimize emissions (CO_2, particle matters) to the environment, and to improve thermal efficiently. Therefore, the stakeholder argues that in case of a restriction and due to the lower performance of alternative materials, exhaust gas emissions from vehicles would increase and there would be a danger in terms of safety. Additional details were provided in a confidential attachment and taken into account by the Dossier Submitter in their analysis.

The Dossier Submitter cannot verify this claim and cannot verify whether all uses of C6-fluoroelastomers in automotive and aerospace industry are necessary to meet the requirements of ISO/TS 16949. The Dossier Submitter also could not obtain information on whether the norm would be adjusted in case of a restriction that covers C6-fluoroelastomers.

In summary, the stakeholders argue that continued use is beneficial with a view to emissions reduction in the concerned industries and that international competitiveness of components suppliers and automotive and aerospace industries would decrease. The Dossier Submitter agrees with these arguments but stresses the uncertainties with regard to a general derogation (higher limit-value) for all uses in engine parts in automotive, shipping and aerospace industries and with a view to the proposed limit value of 150 ppm (PFHxA and its salts in fluoropolymers) and 2 500 ppm (PFHxA related low molecular substances in fluoropolymers).

E.2.1.5 Cost-effectiveness, affordability and proportionality to risk

In sum, the Dossier Submitter notes that societal benefits of continued use of PFHxA, its salts and related substances are evident for some uses but ambivalent for others. Emissions from the use phase are significant but most likely very small in comparison to the positive impacts.

Cost-effectiveness cannot be calculated with the available information. The Dossier Submitter notes that reasonable worst-case scenarios in case of a restriction imply high societal costs. Industry claims for several uses that they are necessary to reduce severe risks for human health and the environment. Further industry claims that a restriction would pose a severe impediment to competitiveness of several important European industries in the world market.

With regard to the production of fluoroelastomers the Dossier Submitter recognizes the high costs in relation to the emissions reduction, the impacts on international competitiveness for the impacted European industries and the environmental benefits of using fluoroelastomers that are produced with PFHxA-related substances and therefore proposes a separate derogation with higher thresholds for the use of PFHxA, its salts and related substances.

In sum, cost-effectiveness cannot be calculated. Risks from further use (continuing emissions to the environment) and from a restriction are both poorly understood. However, it is plausible to assume that short-term risks of a restriction could be very severe and imply very high societal costs. Therefore, the Dossier Submitter proposes to first act and then learn (see 2.5.5 on this concept) by granting derogations (i.e. higher concentration limits) that enable the continued manufacture and use of fluoropolymers, incl. fluoroelastomers.

The Dossier Submitter proposes higher concentration limits and considers these concentration limits as adequate for continuing use in critical applications and also assumes that further emission reduction can be reached when all manufacturers have to consider identical limit values.

The European Commission and member states should take note of the very high uncertainties with regard to the justification for the derogations and should consider re-evaluation and further regulation in the future.

E.2.1.6 Impact of different transitional periods

No information has been received on the impacts of different transitional periods.

E.2.1.7 Uncertainties and sensitivity analysis

Major uncertainties have been discussed above.

Additional uncertainties concern the impacts from a restriction on production facilities. A manufacturer commented that it is uncertain if he can transition to fluorine-free production. Closing of a manufacturing plant is possible. Stakeholders claimed that the closure of production facilities might be a strategical disadvantage in general and especially in situations of crisis. The Dossier Submitter notes that the claims made in the public consultation in this regard are not substantiated by any evidence and should not be considered when justifying derogations.

Effects of closures are uncertain at the moment. However, in case of closure it would be highly likely that current producers release an unknown number of workforces, leading to costs of temporary unemployment.

No information is available if producers of alternatives within the EU would be prepared to meet the increased demand for non-fluorinated alternatives.

With regard to the derogation for the production of fluoroelastomers one manufacturer claims that emissions from end of life vehicles are low because shredder residues will be incinerated. It is unknown to the Dossier Submitter whether this is a high-temperature incineration process. Therefore, emissions might be much higher.

The estimated number of unreported releases could be much higher. The number of articles imported into the EU containing fluoroelastomers or other products with APFHx as impurity is unknown but might be very high.

The dossier submitter notes the ongoing discussions with regard to the question whether there is a scientific rationale for concluding that fluoropolymers are of low concern for environmental and human health. Recently, a group of scientists presented concerns with regard to the hypothesis that fluoropolymers are polymers of low concern (Lohmann R. et al., 2020). Discussing the whole group of fluoropolymers and not just those using PFHxA, its salts and related substances they conclude that

- Concluding that some specific fluoropolymer substances are of low concern for environmental and human health can only be achieved by narrowly focusing on their use phase;

- Ideally, the assessment and management of fluoropolymer products would consider the complete life cycle;

- mapping of all industrial activities that produce, process, and dispose/incinerate fluoropolymers is required to target protection of potentially exposed communities;

- It would anyway be impossible to verify if all fluoropolymer products were of low concern or not with the information available in the public domain. Assessment should be performed on a product-by-product basis because various grades and commercial products of fluoropolymers may or may not meet the polymer of low concern criteria. For example, a PTFE product made in China cannot be assumed to be equivalent to PTFE product from other regions

The authors recommend to move toward the use of fluoropolymers in closed-loop mass flows in the technosphere and in limited use categories, unless manufacturers and users can eliminate PFAS emissions from all parts of the life cycle of fluoropolymers. E.2.2 Electronic devices.

There are several uses of PFAS in the production of electrical devices and their components (e.g. semiconductors or printed circuit boards). In the following section the applications that the DS is aware of will be described. It should be noted, that there most likely are more applications that the DS was not informed about during the public consultation.

E.2.2 Electronic devices

E.2.2.1 Semiconductors

E.2.2.1.1 Overview

The semiconductor industry uses PFASs as process agents for the photolithography process, etching process and furthermore, in cleaning fluids and in fluoroelastomers. Besides surface activity, also purity and stability of PFASs are relevant properties for semiconductor industry. Furthermore, usage of PFASs in photo-acid generators (PAGs) allows the creation of strong acids and non-diffusive, highly soluble and non-agglomerating PAG molecules (Stakeholder Consultation, 2018).

Proposed restriction elements for PFHxA and related substances in semiconductors

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:
  (a) another substance, as a constituent,
  (b) a mixture,
  (c) an article
  in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.
Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction
Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.
Paragraphs 1 and 2 shall not apply to semiconductors and semiconductor related equipment until XX XX XXXX [twelve years after entry into force of the restriction.]

E.2.2.1.2 Use and functions

Four fundamental processes are involved when manufacturing semiconductors: Implant, deposition, etch/polish and photolithography. PFOS was used for Photo-resist and anti-reflective coatings (ARC) for semiconductors, as etching agent for compound semi-conductors and ceramic filters, photo masks in the semiconductor and liquid crystal display industries (UNEP, 2016). The industry eliminated PFOS and is eliminating PFOA and related substances. As replacement short-chain PFCAs and PFSAs are used. They are used in photoresists and antireflective coatings in the photolithography processes in semiconductor manufacturing (Stakeholder Consultation, 2018).

Photoresists are light-sensitive materials that allow transferring a pattern from a photo mask to a waver. In the photoresist coating process several critical issues exist: coverage over uneven surfaces, consistent coating thickness, controlling pattern defects and particle contamination. Short-chain PFASs are used as ingredients in photoresists as surfactants to achieve uniformity and change the absorption and refractive index. A photo-acid generator

(PAG) is contained in the photoresist, which decomposes by light into an acid. As a strong acid is preferred fluorinated substituents are used which increase the acidity of the acid. This is because PFASs are able to trap the hydrogen atoms liberated in the photolysis process. Additionally, the highly non-polar tail of PFASs, allows the molecule to stay in place when exposure occurs (Stakeholder Consultation, 2018).

Anti-Reflective Coatings (ARCs) reduce the reflectivity of the photoresist coating, e.g. by being spun onto the wafer prior to the resist coating stopping reflections from underlying layers. PFASs are used in ARCs chemical formulations to improve film forming properties and adjust the refractive index.

Furthermore, fluoropolymers are used in the etching process and in cleaning fluids in semiconductor manufacturing. In the etching process they are used due to their stability and their low surface tension for wetting and levelling to control and improve chemical etching. Fluoropolymers are used in cleaning processes as they provide purity as pure drying cleaners which is relevant to avoid trace contaminants in the production of the microchips.

Fluoroelastomers are used in the production of semiconductors mainly as seals with manifold applications. Besides the use for the production of semiconductors, fluoroelastomers are also part of the facility equipment of semiconductor production sites. In both applications fluoroelastomers fulfil functions that are critical for the functionality of the semiconductor (information received by stakeholder).

E.2.2.1.3 Baseline

Brooke et al. (2004) estimated a consumption of PFOS-related substances to be 470 kg/a for the year 2002 for the semiconductor industry in the EU (Brooke et al., 2004). Today the overall amount of PFASs used by semiconductor industry is assumed to be < 10 t/a (Stakeholder Consultation, 2018).

E.2.2.1.4 Uses, functions and alternatives

As non-fluorinated alternatives for both, photo-lithography and etching processes the following substances (photoresists, ARC and etching agents) were identified during the assessment of alternatives for PFOS:

- amyl acetate
- anisole
- *n*-butyl acetate
- ethyl lactate
- methyl-3-methoxypropionate
- propylene glycol methyl ether acetate (UNEP, 2018a).

It is however important to note, that these substances were identified from the product line of a single company (Dow Chemical Company, 2014) and may not be suitable for all companies and their applications within the semiconductor industry.

In 2010 IBM announced the invention of a fluorine free photo acid generator, which is used in photoresists, and the holding of several respective patents using this PAG (IBM, 2010). However, it is unclear if such products are used at the moment. Since 2010 no follow-up information on the fluorine free PAG was provided by IBM. Furthermore, Fujifilm USA describes a non PFOS/PFAS photoresist within its product line, which is applicable for a variety of processes, according to the products website (FUJIFILM Holdings America Corporation, n.d.).But no detailed information is given on the website with regard to the applicability or limitations of this photoresist.

A non-chemical approach to the elimination of PFAS from the semiconductor production could be the implementation of new production processes that omit the steps for which PFAS are necessary (photo-lithography and etching). This could be of special relevance to the semiconductor industry, since the technological development in this sector is fast. Continuous scaling, higher storage density (Wojtecki et al., 2018b), or the development of artificial intelligences (AIs) (Pedretti et al., 2017) are examples for processes that drive the demand for new semiconductor manufacturing processes.

Therefore, new `bottom up' methods are being developed, such as selective area atomic layer deposition (SA-ALD). This process bypasses the lithography and etching step and creates the patterned inorganic material, which defines the function of the semiconductor, trough depositing the inorganic film in a self-aligned process (Elinoff, 2018). In addition, atomic layer etching (ALE) is being investigated as an alternative for continuous etching in the semiconductor industry as it provides an important correspondent to ALD (Kanarik et al., 2015).

Fluoroelastomers fulfil functions in the production of semiconductors, that are critical for the functionality of the semiconductor and currently there are no alternatives available. However, substitution might be possible as one stakeholder presented a 3-step substitution plan with each step taking at least 1.5 years (information received by stakeholder). It has to be noted though, that the use of other PFAS than PFHxA was considered in the substitution plan which the DS considers as regrettable substitution that should be avoided.

It can be concluded that no single `drop in' chemical alternative is available which can substitute PFHxA in all production processes within the semiconductor industry. But with continuous technological development changes in production processes of semiconductors are inevitable (Elinoff, 2018, (Staff, 2018) and fluorine free alternative technologies are being developed. At this point a restriction with a twelve-year derogation could promote the development and refinement of PFAS free semiconductor production processes.

E.2.2.1.5 Economic and other impacts

Short-chain perfluorinated substances are used in very small quantities as ingredients at low concentrations in photoresist and ARCs chemical formulations in semiconductor photolithography. Short-chain perfluorinated substances are becoming part of the final product (the microchip) in very small quantities, estimated to be < 10 t/a.

A fluorocarbon surfactant /surface modifier is much preferred to available alternatives because the known alternatives all contain silicon. Etching and ashing photoresist (subsequent steps in production of semiconductor wafers) convert the silicon to silicon dioxide, which is a difficult residue to remove and interferes with product quality.

No single “drop-in” replacement is possible for all semiconductor applications where substitutes exist. Every use has to be re-engineered to see, if a replacement material will meet the technology requirements. Moreover, even within the semiconductor industry technologies are not consistent. Alternatives that work for one application, or one company's, will not necessarily work for another application or another company. A company use of PFAS is in many areas of photoresists specific to their individual process.

This substitution process takes also time and can only be done once the well-defined chemical structure, that is seen as the alternative, has been identified (hence, only after the step of an identification of a clear chemical alternative on a chemical level, real feasibility testing can be initiated). It is assumed that this process will take more than five years. If no such substitute is found to be available, R & D will have to look for alternative chemistry or processes and the time period needed for an invention cannot be estimated.

Currently the semiconductor industry does not see an option to substitute the fluorine chemistry from their processes immediately. If uses in the manufacturing of semiconductors are included in the scope of the restriction severe economic impacts are expected. Detailed information on impacts for European industry could not be obtained during the consultation or from research. Some general information is available: Global revenue of the semiconductor industry amounted to around 470 billion US $ in 2018. The share of Europe based manufacturers is estimated to be roughly nine percent.[16] However, it is unknown to the Dossier Submitter how many articles from European manufacturers are manufactured within the EU.

It has been reported that, in the US the cost of developing a new photo-resist represents 0.3 % of annual sales, indicating that cost is not a barrier to develop a new photo-resist system (UNEP 2018b).

Short-chain perfluorinated substances are sometimes becoming part of the final product (the microchip). According to stakeholder information (comment 3062) the PFHxA containing materials remains in the final product in the following cases:

(Note : Not all cases are listed below as there are so many semiconductor applications.)

CMOS image sensors have three color films (red, green and blue) which are formed by a photolithographic process and remain in the product. These films contain PFHxA as a surfactant. Some planarization films for semiconductors also contain PFHxA based surfactants and remain in the products. Therefore, the stakeholders strongly request exemption for semiconductors (including compound semiconductor) itself and no-time-limited derogation for the various use of semiconductor manufacturing processes such as process agents for the photolithography process, etching process and cleaning fluids.

If production is no longer possible in the EU it is expected that production will take place outside the EU and articles will be imported. The benefit of a restriction would be < 10 t/a emissions avoided.

In summary the Dossier Submitter proposes a time limited derogation for twelve years for semiconductors and semiconductor related equipment. The Dossier Submitter emphasizes that photolithography processes need to be covered by a derogation. In his view the current wording of the proposal is sufficient to account for this.

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[16] https://www.zvei.org/fileadmin/user_upload/Presse_und_Medien/Pressebereich/2018-89_Deutscher_Halbleitermarkt/2018-12_Pressekonferenz_Fachgruppe_Halbleiter_ZVEI.pdf (last access: 13.12.2019).

Alternatives are not available at the moment. Several stakeholders asked for a general derogation for semiconductors including manufacturing processes. The Dossier Submitter is hesitant to propose a complete derogation. The submitted information suggests a large variety of uses and it is not clear from the information which of these uses can be substituted in general and how long it would take to find suitable alternatives. Industry informed during the stakeholder consultation that efforts are undertaken to identify fluorine-free alternatives and to integrate them into production processes. The Dossier Submitter is aware that use quantities and emissions are comparatively low in comparison to the economic impacts that are possible when EU manufacturing or import of semiconductors would no longer be possible.

Therefore, the Dossier Submitter expects the Commission to monitor the situation closely after entry into force of the restriction. In the Dossier Submitters view an extension of the twelve-year derogation is only justified when manufacturers provide more detailed information on substitution efforts and prepare detailed substitution plans for the various applications.

E.2.2.2 Electronic grade coating

Proposed restriction elements for PFHxA and related substances in electronic grade coating

Shall not be manufactured, used or placed on the market as substances on their own; shall not be used in the production of or placed on the market in or used in:

(a) another substance, as a constituent,
(b) a mixture,
(c) an article,

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.

Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction

Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

The concentration limit referred to in paragraph 2 shall be 10 ppm for the sum of PFHxA and its salts and 500 ppm for the sum of PFHxA related substances in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force]

E.2.2.2.1 Overview

A C6 fluorinated polymer is used in a coating process to achieve high levels of water repellency to protect electronic devices from water and corrosion damage. More specifically there are two different applications reported by stakeholders:

- External protection – an ultra-thin protective coating is applied to a finished product. The key property for the functionality of the coating is liquid repellency.
- Printed circuit boards (PCB) protection – a thicker protective coating is applied to electronic circuit boards. The key property here is electrical resistance during immersion in liquids.

E.2.2.2.2 Uses functions and alternatives

With regard to the amount of PFAS used for this application, one stakeholder provided confidential information on the use tonnage of a C6 based monomer in Europe and worldwide.

The stakeholder also informed about his assessment of possible alternatives and reported that of the available non-fluorinated technologies none can mimic the full range of desirable properties found in their fluorinated counterparts. The main problem reported was water- and oil-repellency, the latter being particularly important for in-ear devices. Additional confidential information on the analysis of alternatives was provided. The Dossier Submitter considered this information in their analysis.

E.2.2.2.3 Economic impact

As alternatives are expected to not perform as good as current technology, it is estimated by stakeholders that a higher number of devices will break down due to water damage with a restriction of the use and manufacture of PFHxA and related substances. Therefore, a time limited derogation for at least 7 years is requested to allow for the development and synthesis of alternative chemicals able to deliver an acceptable performance. A derogation for this use may not be necessary as alternatives to achieve water repellency seem to be already available, although they may not perform as well as the current technology.

On the other hand, a time limited derogation for seven years might be justified under the consideration that for the use and production of fluoropolymers a general derogation threshold of 2000 ppb and 150 ppm for specific applications in engine parts in automotive, aerospace and shipping industry is proposed. Emissions from this use are expected by manufacturers to be low considering the closed loop recycling of electronic articles and the low amounts of C6 fluorinated polymers that are used for this application in Europe. The Dossier Submitter notes large uncertainties with regard to the question whether the materials can be recycled and reused in identical role as before or whether they are disposed of.

It should also be kept in mind, that the worldwide use of C6 fluorinated polymers in this application is higher and that a restriction for the European market could also influence the amounts used worldwide.

In absence of further information, the Dossier Submitter proposes a time limited derogation for seven years. The expected emissions in the EU most likely will be comparably low. Equally effective alternatives are only available for upscale articles at the moment, making it likely that these substitutes are not economically feasible as general substitute. Relying on the information from one stakeholder the socio-economic costs resulting from the use of less effective (cheaper) alternatives are potentially high.

E.2.2.3 Others

Further uses of PFAS in electronic devices that DS was informed about during the public consultation are different applications of fluorosurfactants. Fluorosurfactants are used due to their anti-corrosion and electrostatic properties in applications such as zinc batteries, plating bath aids, photoresists and low foam. Concerning the used amounts of fluorosurfactants for these applications, one stakeholder commented on individual use quantities, however gave no information regarding the overall market.. The Dossier Submitter assumes that this use will be covered by a derogation for semiconductors.

Amorphous fluoroplastics, are applied in electronic devices due to their ability to dissolve and their high transparency. A visible light transmission ratio of more than 95% can be achieved. They are used:

- as an organic gate insulator (OGI) in organic thin film transistors in organic electronics,
- in photonic integrated circuit (ICs), circuitry and as an interface material between photonic ICs and optical fibres,
- as a dielectric, hydrophobic surface in electrowetting based digital microfluidic devices or in low glare electrowetting displays (information received during public consultation).

Furthermore, DS was informed that fluorosurfactants are used as photoresists and coating solutions for polarization films in the production of Flat Panel Displays (FPD). In the view of the DS these uses are covered by the proposed derogation for semiconductor manufacturing and related equipment. However, due to missing information this view is fraught with some uncertainties.

E.2.2.4 Cost-effectiveness, affordability and proportionality to risk

Cost estimates could not be derived. Therefore, it was not possible to calculate cost-effectiveness. The yearly revenue of Europe based semiconductor industry is estimated to be 42 billion US $. Even considering that part of the production (and therefore part of the emissions) takes place outside the EU it is highly likely that the societal costs resulting from profit losses, the closure of manufacturing sites and release of workforce result in a very high cost-effectiveness ratio that indicates unproportionately high costs of a restriction. Semiconductors are integral parts of electronics, integrated circuits, computer industry and various other products. Stakeholders emphasized the high societal cost in case no alternative was available. They did not comment on the affordability of the substitution process in general but stressed that at the moment no alternatives are available for the various applications. The Dossier Submitter agrees that it is highly likely that emissions from the derogated uses are low in comparison to the expected costs in case semiconductors are no longer available.

With regard to the costs of the substitution process itself no information is available. However, considering that research and development (R&D) expenditure within the semiconductor industry can be considered the highest among all industries the additional costs for developing PFAS-free alternatives are probably affordable.

For electronic grade coating one stakeholder (comment 3007) predicts economic impacts of a restriction as follows:

"• Significant lost revenue for our client's operations for the 2021-2024 period if a restriction with no derogation is adopted and no alternative is identified.

- Significant lost profits for our client's suppliers in Europe
- Significant social cost of unemployment
- At least €315 million for replacement of broken-down devices in the EU for EU consumers in the 2021-2024 period.
- The sales of more than 9.5 million devices each year, with a value of at least €3.6 billion could be impacted. In addition to the monetised impacts for our client, its suppliers and the device users, it is expected that the restriction will also affect manufacturers of electronic devices, medical devices and other electrical equipment, as well as printed circuit boards."

The Dossier Submitter considers the economic impacts quoted as an overestimate as the possibility to repair broken-down devices as well as the fair value of the phone at the time of damage have not been considered adequately. It also has not been considered that alternatives are available at a higher cost. No information has been provided on the impact of using less effective alternatives which might be available.

In a confidential attachment, the same stakeholder predicts the cost for development of non-fluorinated alternatives to be significant.

In sum, the information available suggests that a time-limited derogation of 7 years for the continued use in electronic grade coating is justified. The stakeholder confirms that economically feasible alternatives will be available at that time. Information on total use quantities is not available but confidential information provided by the stakeholder on use quantities per device suggest that totally quantities used are reasonably low, if compared to other uses. On the other hand, costs are claimed to be larger than 70 million €/a. Although this might be an overestimation it is likely that a time-limited derogation is proportionate: If replacement cost amounts only to 20 percent of the claimed cost this would still result in a cost-effectiveness of >14 000 €/kg saved emissions.

E.2.2.5 Impact of different transitional periods

Semiconductor industry needs the appropriate amount of time to transition to fluorine-free production. A transitional period of less than twelve years would probably lead to a discontinuation of production and high costs for the industries manufacturing and using semiconductor related equipment. Stakeholders asked for considerably longer transition periods however failed to provide detailed information for which of the numerous applications alternatives could be available sooner.

A longer transitional period might be necessary for manufacturers to implement alternative manufacturing processes without PFHxA-related substances. However, the Dossier Submitter expects that manufacturers present detailed substitution plans within the twelve-year derogation period in case a different transitional period is required and the Commission to monitor this process.

For electronic grade coating stakeholder information suggests that substitution is possible within 7 years. It is uncertain whether a shorter transition period is justified.

E.2.2.6 Uncertainties and sensitivity analysis

Substitution for semiconductors depends on feasibility testing that needs more than five years. If these tests fail during the substitution process alternatives need to be identified which would result in much more time needed for substitution.

In general, the Dossier Submitter received information that the semiconductor industry and manufacturers of electronic devices are already investing in R&D activities to substitute fluorine-free substances. But it might be possible that a restriction with a time-limited derogation results in the need to invest considerably larger resources than expected, leading to costs that can be attributed to this restriction.

It is uncertain whether a derogation for electronic grade coating is justified. Alternatives are available in general but one stakeholder presented limited information that substitution is not economically feasible at the moment. Other alternatives need to be developed which takes up to seven years.

From information available the Dossier Submitter does not understand how competitors treat their electronic devices for water and oil resistance. The proposal for a time-limited derogation is based on one stakeholder information. No information is available if other devices are treated similarly or whether other manufacturers use PFAS-free alternatives and what the respective impacts would be. Therefore, it is uncertain if the derogation proposal is justified.

E.2.3 Fire-fighting foams

E.2.3.1 Overview

Fire-fighting foams are used for class B fires (flammable liquids) as well as in special cases for class A fires (combustible materials). Socio-economic impacts of a regulatory action under REACH on the use of PFHxA and related substances in fire-fighting foams are studied for five broad categories of uses:

- Aviation: Fluorinated fire-fighting foams are used in stationary fire extinguishing systems within buildings on the airport grounds as well as by the plant fire brigades to extinguish hydrocarbon fuel fires (de Vries, 2014).
- Petrochemical industry: Fluorinated fire-fighting foams are used in oil and gas platforms, refineries and fuel depots for e.g. in cases of mineral oil fires. They are used in stationary and non-stationary systems (IPEN 2018/POPRC-14, 2018; Stakeholder Consultation, 2018).
- Defence applications: Fluorinated fire-fighting foams are used for fire-fighting of class B fires in seagoing military units, fuel depots and airports. Also, for training purposes regarding fire-fighting on ships fire-fighting foams are used (information received by the Federal Ministry of Defence (Germany)).
- Other industrial uses: Fluorinated fire-fighting foams are used by plant fire brigades to protect e.g. production and in stationary fire extinguishing systems in warehouses e.g. in automotive industry in cases of fire of stored flammable liquids or tires (Stakeholder Consultation, 2018).

- Other uses: Hand-held fire extinguishers: Fluorinated fire-fighting foams are used in hand-held fire extinguishers for different operation sites such as indoor areas in public sectors or private sectors. They are used for Class B as well as Class A fires (MINIMAX, 2019).

No robust estimate is available with regard to the joint stocks of such firefighting foams of armed forces, of larger airports, of refineries, municipal fire departments and chemical industrial fire departments. Estimates available suggest stocks to be between 30 000 - 435 000 t. The Dossier Submitter estimates stocks of less than 75 000 t (see E2.3.5). Due to the enormous costs of AFFFs, it could be expected that this stock will be used until the use of perfluorinated surfactants will be forbidden in extinguishing agents.

Proposed restriction elements for PFHxA and related substances in fire-fighting foams

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:

(a) another substance, as a constituent,
(b) a mixture,
(c) an article

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.

Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction

Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

1. Paragraphs 1 and 2 shall not apply until XX XX XXXX [five years after the entry into force] to concentrated fire-fighting foam mixtures that were placed on the market before [date – 18 months after the entry into force of this Regulation] and are used or are to be used in the production of other fire-fighting foam mixtures for cases of class B fires;

   this shall not apply to:
   (i) use of fire-fighting foam for training; and
   (ii) use of fire-fighting for testing

   unless all emissions to the environment are minimised and effluents collected are safely disposed of.

Paragraphs 1 and 2 shall not apply to concentrated fire-fighting foam mixtures for defence applications – as long as no successful transition to military operable fluorine free foams can be achieved:

- for seagoing units, air traffic facilities and storage of fuel
- for training purposes provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely

Paragraphs 1 and 2 shall not apply until twelve years after entry into force of the restriction to concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500 m^2.

From (entry into force + 12 months), a natural or legal person benefitting from the derogation in paragraph 6 or paragraph 8(a) shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing:

(a) A description of their efforts on substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances;
(b) quantities they used in the previous year of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances per sector specifying:
    (i) share in training and in operation
    (ii) whether emission was contained, collected and disposed safely or emitted

into the environment.

The European Chemicals Agency shall consolidate and forward the data to the Commission by 31 March each year.

By (entry into force + 6 years), the Commission shall carry out a review of paragraph 6 and paragraph 8(a) in the light of new scientific information, including the availability of alternatives for articles referred to in paragraph 6 and paragraph 8(a), and proposing amendments if indicated by the outcome of the review. As long as the Commission concludes that there is still need for these exemptions this review shall be carried out every three years.

E.2.3.2 Use and functions

Different fire-fighting foams exist. Fire-fighting foams can be assigned to protein foams (P) and synthetic foams (S) as well as to their respective alcohol-resistant (AR) versions: P(AR) and S(AR), which are fluorine-free and the following foams which are fluorinated fire-fighting foams: Aqueous film-forming foams (AFFF, AFFF (AR)), fluorprotein foams (FP (AR)) and film-forming fluoroprotein foams (FFFP, AR-FFFP).
The listed fluorinated fire-fighting foams are often referred to as Class-B-foams, although they might be used for other classes of fires, e.g. Class-A, as well. In contrast to Class-B-foams these foams are not listed in EN 1568 as they are not developed to extinguish Class-B fires. They are chemically considered to be part of the synthetic foams (S) and are therefore considered as fluorine free fire-fighting foams. (CHEMGUARD, 2013; De Vries and Holemann, 2001; DIN EN 1658, 2018; Fire Fighting Foam Coalition (FFFC), 2016; Zwirner, 2010)

FP, FP(AR), P and P(AR) are not able to provide a film-forming effect on flammable liquids (Ulrich et al., 2018). However, users often state foams as AFFF but refer to it as a group which includes FFFP, FP and respective AR species, as AFFF and AFFF (AR) play the predominate role in fire-fighting compared to fluorprotein foams. Due to latter and the scarce information on FFFP and FP in the Stakeholder Consultation and in literature, the next paragraphs concentrate on AFFF and do not include fluoroprotein foams. However, it is not always transparent which definition was applied in respective studies and some of the listed points may also apply to fluoroprotein foams.

Fluorinated fire-fighting foams for extinguishing hydrocarbon-based fuel fires include fluorosurfactants to reduce the surface tension of the aqueous solution. The AFFF concentrates consist of water, surfactants, solvents and additives. The fluorinated surfactants contained in AFFF lower the surface tension and allow the formation of an aqueous film between fuel and foam, thereby cooling the surface, acting as a vapor barrier, allowing a fast spreading of the foam on the fuel and preventing re-ignition. Furthermore, fuel shedding is prevented as the oleophobicity of the fluorinated foam reduces the fuel contamination of the foam thereby preventing flammable foam (Ahrens et al., 2015; Kempisty et al., 2018; Laundess et al., 2011; Pabon and Corpart, 2002; Stakeholder Consultation, 2018).

AFFF are especially used for hydrocarbon fuel fires occurring in defence, industrial, aviation and municipal applications, but can also be used in firefighting trainings, in households and in public buildings. Different concentration ranges of fluorosurfactants in foam concentrates are reported, e.g. 0.6 – 1.5 wt% of total weight (Kempisty et al., 2018) or 1.5- 6.5 wt% (Moody and Field, 2000).

The composition of AFFF is divers and the structure of used fluorinated surfactants varies (D'Agostino and Mabury, 2014). In recent years a shift from long-chain PFASs to short-chain PFASs used in AFFF formulations could be observed (Houtz et al., 2016) due to several regulations regarding long-chain PFCAs, PFSAs and their related substances. Most fire-fighting foams are now manufactured with fluorochemicals /fluorotelomers based on a perfluorohexane (C6) chain (UNEP, 2016). Several short-chain alternatives used in AFFF are known, e.g. fluorotelomer surfactants like 6:2 fluorotelomer sulfonamide alkylbetaine (Moe et al., 2012), 6:2 fluorotelomer sulfonamide aminoxide (Jensen and Leffers, 2008) and 6:2 fluorotelomer thioamidosulfonate (Harding-Marjanovic et al., 2015).

However, the chemical structures of the fluorosurfactants are often trade secrets and many substances are difficult to analyze. (Dauchy et al., 2017) oxidized samples of fire-fighting foams to transform PFCA-related substances into the end-stage products. Thereby allowing conclusions regarding related substance concentrations in AFFF. PFHxA was detected in all three tested foams exceeding the concentration predicted based on prior analysis of related substances in the given samples. The highest concentration of PFHxA in an AFFF being 578 570 µg /L.

PFHxA can also be found in AFFF as unintended by-product (Cortina and Korzeniowski, 2008); (Favreau et al., 2017)). A chemical analysis of PFASs in Class-B-foams on the Swedish market in 2014 detected PFHxA in all seven foams showing the highest concentration of the analysed PFCAs for PFHxA (up to 14 000 µg/kg) (Swedish Chemicals Agency, 2015a).

In conclusion, a shift from long-chain to short-chain chemistry in AFFF could be observed in recent years with new fluorosurfactants being mainly based on a perfluorohexane (C6) chain, therefore being potential PFHxA-related substances. Some structures are known PFHxA-related substances, while further unidentified PFHxA-related substances are used as fluorosurfactants as well. Furthermore, PFHxA itself can be contained as impurity in aqueous fire-fighting foams. The application of fire-fighting foams will in most cases lead to considerable amounts released to the environment as it was shown by measured concentrations in the environment after such events.

E.2.3.3 Baseline

In B.9.8 it was estimated that for professional firefighting 12 000 - 20 000 t fluoro-surfactant containing firefighting foam concentrate are placed on the market annually. This estimate is based on personal communication with an expert (Blunk 2017) and the recent report from European Commission DG Environment/European Chemicals Agency (2020). Fluorosurfactants placed on the market in the area of firefighting foams are estimated to be in the range of 100 – 560 t/a. (European Commission DG Environment/European

Chemicals Agency, 2020) based on data provided by Eurofeu). Products that require these compounds are the AFFF and AR-AFFF products.

Results from the study by the European Commission and ECHA suggest a market split as follows: Military 6 %, civil aviation 9 %, municipal fire brigades 13 %, chemical/ petrochemical 59 %, marine applications 12 %.

Limited information is available on handheld and mountable fire extinguishers and fixed uses in other industrial manufacturing sites. The Dossier Submitter obtained expert information that AFFF for example is used in fixed systems in the automotive industry in storage sites. Another area of large uncertainty is ready for use products. Based on data by Eurofeu (European Commission DG Environment/European Chemicals Agency, 2020) the market share for these uses is estimated to be around 1 %. Using the same information as the Dossier Submitter EC/ECHA propose a high estimate that 60 - 90 million AFFF-based fire extinguishers might be in use EU-wide and a low estimate based on Eurofeu information of 15 million.

Within the last years a shift from AFFF to FFF took place. Many airports already have substituted AFFF with FFF. Data from European Commission DG Environment/European Chemicals Agency (2020) suggests that substitution with FFF can be observed for all uses. In municipal fire brigades, marine applications and airports FFF widely substitute AFFF. However, with a view to tonnages only for municipal fire brigades the share in the use of fluorine-free foams is larger than that of AFFF. Substitution progress is less advanced in the chemical/petrochemical uses and defence uses where the FFF still account for less than 30 percent of the total foam use. Information received in the public consultation (comment 3158) confirms these trends.

Personal information provided by an alternative's supplier suggests that substitution processes are also taking place in industrial manufacturing sites. The information suggests a decrease in the use of PFHxA-related substances in fire-fighting foams.

This trend (a decreasing share of AFFF in the market) will be counteracted when foams containing PFOA-related substances have to be replaced when the restriction under REACH becomes effective and the PFOA-related requirements from the Stockholm Convention are implemented in the EU. Without a restriction on PFHxA-related substances the Dossier Submitter expects substitution of PFOA mostly with C6-based foams. Considering these divergent trends, the Dossier Submitter expects a stable demand for AFFF in the future for the non-restriction scenario.

E.2.3.4 Uses, functions and alternatives

As already described several classes of fires exist in which fire-fighting foams are used. However, only in cases of fires with incinerated, non-polar liquids with an even liquid surface and an intensity and quantity not allowing the use of synthetic fire-fighting foams (S) the use of AFFF might be considered (Keutel and Koch, 2016; Ulrich et al., 2018). A Best practice guidance for use of Class-B fire-fighting foams published by FFFC (2016) states that the use should be limited to cases in which a significant flammable liquid hazard is present and only after investigating whether non-fluorinated techniques can achieve the required extinguishment and burn-back resistance. Furthermore, training foams not containing fluorosurfactants should be used in training situations. Surrogate liquid test methods without fluorosurfactants should be used for testing fixed systems and vehicle foam proportioning systems.

In recent years several fluorine-free fire-fighting foams meet the requirements of Class-B standard fire-fighting performance certifications (see Table 6 in UNEP/POP/POPRC.14/6) as alternatives to AFFF were developed. A project by the New York State Pollution Prevention Institute (Winnebeck, 2018) identified over 100 fluorine-free Class-B foams from 25 manufacturers.

Non-fluorinated alternatives are given in Table 30 and are e.g.:

- Hydrocarbon based foams,
- protein based foams,
- foams based on other detergents such as alkylsulfates.

Table 30: Examples for non-fluorinated foams.

	Substances /Product	**Manufacturer**	**Use**	**Reference**
Hydrocarbon based foams	2-6 % hexylene glycol (CAS No: 107-41-5, EC 203489-0); hydrolysed protein [70 – 80 %], metallic salt: $NaCl+MgCl_2$ [8 – 15 %]; $FeSO_4*7\ H_2O$ [0 – 2 %] /PROFOAM 806G	Gepro Group		(UNEP, 2018a)
	RE-HEALING	Solberg	foam concentrates (for class-B fires of hydrocarbon based burning material and fires of polar solvents, also useable for class-A fires)	(UNEP, 2018a)
Protein based foams	Sthamex F-15	Dr.STHAMER	synthetic foam concentrates (officially approved in accordance	(Sthamer, 2018; UNEP, 2016)

			with DIN EN 1568 for use as low, medium and high expansion foam for class A + B fires*, mainly used for training, but also has some marine uses)*	
Other Foams	sodium decyl sulfate (142-87-0), alkylpolyglycoside (132778-08-6) /trainol	Angus Fire	training foam concentrate	safety data sheet (ANGUS FIRE, 2018)
	Orchidex BlueFoam 3x3	Orchidee	foam concentrate for class A and class B fires	(Orchidee, 2019)
	Freedol	3F	different applications e.g. in industrial plants	data sheet (3F, 2019)

However, this is a non-exhaustive list and the market for fluorine free foams is fast moving regarding new developments, as stated by an expert at the ECHA Stakeholders' Workshop on firefighting foams (2019).

FFFC (2016) stated, that the use of class-B foams should be limited to institutions such as: airport operations, storage tanks, terminals and petroleum /chemical processing, highway and rail transportation, marine and defence applications, industrial facilities and some power generating facilities where situations may arise in which a significant flammable liquid hazard is given. Several establishments of the named industries shifted successfully from the use of AFFF to fluorine-free fire-fighting foams (see Table 31) showing the applicability of the developed alternatives.

Table 31: Examples for applications of non-fluorinated foams.

Place	Country	Area	Industry	Reference
Auckland	New Zealand	(major hub) airport	aviation	(IPEN 2018/POPRC-14, 2018)
Copenhagen	Denmark	airport	aviation	
Dubai	United Arab Emirates	(major hub) airport	aviation	

Edinburgh	Great Britain	(major hub) airport	aviation	
Gatwick	Great Britain	(major hub) airport	aviation	
London Heathrow	Great Britain	(major hub) airport	aviation	
Stuttgart	Germany	(major hub) airport	aviation	
Åre Östersund	Sweden	airport	aviation	(Goldenman, 2019)
Göteborg/Landvetter	Sweden	airport	aviation	
Kiruna	Sweden	airport	aviation	
Luleå	Sweden	airport	aviation	
Malmö	Sweden	airport	aviation	
Ronneby	Sweden	airport	aviation	
Stockholm/Arlanda	Sweden	airport	aviation	
Stockholm/Bromma	Sweden	airport	aviation	
Umeå	Sweden	airport	aviation	
Visby	Sweden	airport	aviation	
23 (out of 260) capital and major region airports	Australia	airport	aviation	(UNEP, 2018a)
Cologne /Bonn	Germany	airport	aviation	(de Vries, 2014)
40 offshore installations	Norway	offshore installation	petrochemical industry	(Ystanes, 2019)
Danish Armed Force			military	(Goldenman, 2019)
Royal Danish Air Force			military	-
Billund	Denmark	airport		-
Paris Charles De Gaulle	France	airport	aviation	(Ross, 2019)
Paris Orly	France	airport	aviation	-
Oslo	Norway	airport	aviation	-
Dubai	United Arab Emirates	airport	aviation	-
Dortmund	Germany	airport	aviation	-
Allgau	Germany	airport	aviation	-
Lyon	France	airport	aviation	-
Helsinki	Finland	airport	aviation	-
Lisbon	Portugal	airport	aviation	-
Leeds /Bradford	Great Britain	airport	aviation	-
London City	Great Britain	airport	aviation	-
Bristol	Great Britain	airport	aviation	-
Brussels	Belgium	airport	aviation	-
Manchester	Great Britain	airport	aviation	-
Stansted	Great Britain	airport	aviation	-
East Midlands	Great Britain	airport	aviation	-
Blackpool	Great Britain	airport	aviation	-

Bristol	Great Britain	airport	aviation	-
Newquay	Great Britain	airport	aviation	-

Furthermore, LASTFIRE tested six C6 pure AFFF and two fluorine-free fire-fighting foams on large-scale tanks. It was concluded that no ‘drop in’ replacement for previously used AFFF formulations by the new generation foams exist, independent from whether or not they contain fluorosurfactants. It was suggested that the performance capability of the alternative foams is specific to a formulation and the type of application equipment which is used (Ramsden, 2018).

At the ECHA Stakeholders’ Workshop on firefighting foams (2019) it was stated by several experts that for the successful transition from AFFF to fluorine foams several factors besides replacement of the product to a fluorine free foam concentrate have to be taken into account such as application rate, application technique, equipment, training, etc. It was also stated that requirements for fire-fighting foams are based upon fluorine containing foams but that known standards are already reviewed in regard of adaptions to test fluorine free foams.

PFCAs, PFSAs, fluorotelomer-based substances and perfluoroalkyl ether-based substances with a perfluorinated chain length of less than six carbons were identified as PFASs in PFAS-based foams (EC/ECHA (2020b)). Therefore, it cannot be ruled out that shorter chained PFASs will be used as alternatives in fire-fighting foams in the future. However, a distinct tendency can be observed to use fluorine-free alternatives.

During the public consultation it was reported by different stakeholders that the restriction of PFHxA, its salts and related substances will lead to a complete transition from fluorine containing to fluorine free foams as active substances in today’s AFFF are falling under the definition of PFHxA precursors. Additionally, it was reported that other PFASs that can be detected in AFFF have to be considered as unintentional trace contaminants.

E.2.3.5 Economic and other impacts

The Dossier Submitter intends to restrict the use of PFHxA-related substances in fire-fighting foams that are already placed on the market five years after entry into force of this restriction. Considering the large stocks held and the emissions of PFHxA-related substances when the stocks are used this proposal is justified.

The Dossier Submitter further identified two uses where derogations from the restriction on PFHxA-related substances are necessary. The DS proposes a temporary derogation for certain uses in the petrochemical industry and a derogation for certain uses in defence applications. Alternatives are currently not available. A restriction results in unacceptable risks for human health and the environment. The Dossier Submitter expects that alternatives will become available within twelve years for the derogated uses in the petrochemical industry. This is consistent with information obtained by European Commission DG Environment/European Chemicals Agency (2020), that up to ten years are required for testing of alternatives for large atmospheric storage tanks. The authors also report that Norwegian company Equinor required eight years from development and testing to full substitution with FFF.

During the public consultation DS was informed by several stakeholders, that the originally proposed derogation for the use of AFFF in cases of class B fires in storage tanks with a surface area > 500 m^2 is not feasible. It was claimed that also some process facilities have tanks with a similar size that are not used for storage but for processing of liquid fuels. Therefore, the word "storage" was removed from the original derogation proposal. Furthermore, DS received information, that a derogation is needed as well for class B fires in secondary containment areas (or so called bunded areas). As specified by the Seveso directive (Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances) tanks containing dangerous substances have to be placed within a secondary containment area to prevent possible spills form entering the environment. Such secondary containment areas usually have an area ten times bigger than the surface area of the enclosed tanks. In those cases, where a fire in a tank spreads from the tank into the secondary containment area (e.g. through breakage of the tank material) a significantly larger fire would be the consequence. DS was informed by fire-fighting experts, that such incidents are very rare. In the view of the DS, proposing a derogation for the use of AFFF in secondary containment area would undermine the intended narrow scope of the proposed derogation for large tanks, since it would also allow the use of AFFF for cases of fires in smaller tanks (< 500 m^2) or spill fires within a secondary containment area. Furthermore, DS is of the opinion, that a fire which started in a tank > 500 m^2 which than extends to a secondary containment area can still be extinguished with AFFF as the incident started as a tank fire.

At a Stakeholder Workshop on firefighting foam (24.09.2019, Helsinki) several experts confirmed, that alternatives are available for critical applications, for example for aviation. The Dossier Submitter is aware of two EU members, where the defence sector shifted to FFF: Denmark and Norway (IPEN 2018). The Dossier Submitter was informed by the fire-fighting services of the Royal Danish Airforce that alternatives were available to them on short notice and that extinguishing of JP-8 fuel (which is used by defence sector) is possible.

Other armed forces report challenges regarding a complete transition due to missing alternatives in the defence sector. One of the challenges reported is, that the available FFF do not fulfil the requirements of some defence-specific applications for fire-fighting foams. Due to some exceptionally high risks of defence-specific fire-scenarios (e.g. fire-fighting on seagoing units) a switch to FFF is currently not possible. Generally, the use of FFF for defence applications is desired and new alternatives are being investigated regularly. However, at the moment a restriction of the use of AFFF for defence-applications would lead to unacceptable constraints for fire-fighting in some defence-specific scenarios (Information received by the Federal Ministry of Defence (Germany)).

Another national authority confirmed these concerns in the public consultation (comment 3079) and additionally stated that NATO technical standards (see STANAG 3712 « Aircraft rescue and fire-fighting services identification categorie ») do not allow the use of FFF. Its updating is a prerequisite to allow its use by Member States' armies.

An exemption shall therefore apply for the defence-related use in fire-fighting foam mixtures for seagoing units, air traffic facilities and storage of fuel, furthermore, for training purposes relevant for these sectors provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely.

The market of fluorine free foams is rapidly developing and testing requirements for fire-fighting foams are already being reviewed with regard to the changing requirements when assessing fluorine free foams. Therefore, transition to fluorine free foams in the defence sector might be feasible for all armed forces in the foreseeable future. That is why the efforts on substitution will be closely monitored. Annual reporting on the quantities and efforts of substitution of fire-fighting foams that contain or may contain PFHxA, its salts and PFHxA-related substances will help the European Commission to gather data on the use of the substances in these sectors and to monitor the development of alternatives. The Commission shall re-evaluate the derogation in the light of new scientific information, including the availability of alternatives. The proposed action sends a signal that substitution of PFHxA, its salts and PFHxA-related substances is desirable.

The Dossier Submitter notes major uncertainties regarding the emissions resulting from the derogations. The DS has no information on emissions from training and testing. Wastewater might be disposed of via conventional wastewater treatment and not be incinerated potentially leading to significant emissions. Experts at the workshop (2019) explained that the market for FFF is expanding very fast and that new (and better products) are developed constantly. Therefore, it is likely that solutions for the derogated uses in the petrochemical industry will be available within the next years. The Dossier Submitter expects industry to monitor the developments closely and to inform the Commission in time in case no acceptable FFFs are available within twelve years.

The Dossier Submitter could not calculate total impacts of the proposed restriction. However, stakeholders provided extensive comments and additional information has been obtained from publicly available resources. Relevant costs for users of fire-fighting foams may arise from the following substitution activities:

- Price differences for fluorine-free fire-fighting foams,
- procurement costs for replacement with fluorine-free fire-fighting foams,
- incineration costs for replaced AFFF,
- cleaning of existing fire-fighting installations and vehicles,
- adjustments to existing extinguishing infrastructure,
- administrative issues, training with alternative foam,
- replacement of handheld fire extinguishers.

Price differences for fluorine-free fire-fighting foams

According to expert information "the price of F3 doesn't differ significantly compared to other foams like AFFF used in Western Europe" (IPEN 2018). However, AFFF foam concentrate is available in different qualities and concentrations. It has been reported that users in some parts of the EU are very price sensitive, resulting in higher cost for them if they are forced to buy fluorine-free products. Some sources claim that fluorine-free foams have to be used in higher quantities to achieve stable performance.

European Commission DG Environment/European Chemicals Agency (2020) reports weighted average prices for PFAS containing and fluorine free foams of 3 000 €/t. The reported price ranges are 2 000 - € 30 000 €/t for AFFF and 700 - 10 000 €/t for fluorine free alternatives. That study reports that fluorine free products might require larger use volumes. It reports information from one user that up to 100 percent more volume might be required and the authors calculate a central estimate of 50 percent more volume required on average. The Dossier Submitter notes that EC/ECHA additionally reports that many users indicated uses which do not require additional volumes. They also specify: “. Based on the available data, the range specified was between no change in volume and up to a maximum of 100% additional foam required. Note the 100% volume estimate was specified by just one consultee and it is understood that this relates to use in one application.”

The following further information is given for this foam: “Volumes vary depending on application. From no difference to up to double the volume required in some applications” (European Commission DG Environment/European Chemicals Agency 2020).

The EC/ECHA study reports on volumes required for four other alternatives, which seem to require between 0 and no more than 50 percent more volume. For the 5 foams for which information is available additional use volumes are given as follows: a) most likely 0%, b) 0%, c) 0-100%, d) 30-50%, e) 10% (European Commission DG Environment/European Chemicals Agency 2020).

Taken together the average additional volume needed is 20%. However, the Dossier Submitter needs to consider the information that for critical uses in chemical/petrochemical industries on average higher volumes are required and also consider that these industries use more than half of the AFFF placed on the market. Therefore, on average an increase in volumes required of 30 % for the concentrate is calculated when fluorinated foams will be restricted. This estimate is still very uncertain but reflects a) the maximum value reported of 100 percent increase in volume, b) the other reported values, which are all below 50 percent, c) the information, that one user in the oil/petrochemicals sector suggests that the alternative foams need 30 - 50% more volume for the same performance and d) the information from users from different other fields like airport firefighting, oil rig firefighting and municipal fire brigades that no additional volumes are required for their uses.

A 30 % increase in volume therefore would result in substitution costs of 0.9 €/kg foam concentrate when taking prices from the EC/ECHA study. Both AFFF and FFF cost on average 3 000 €/t. 30 % more volume results in additional costs of 900 €/t, i.e. 0.9 €/kg.

For professional firefighting an annual use of fluoro-surfactant containing firefighting foam concentrate of 12 000 - 20 000 t/a has been estimated, resulting in additional procurement cost of roughly 15 million €/a (central estimate) when all uses of AFFF are replaced with FFF. This number does not consider that some uses are derogated, i.e. it might be an overestimate.

Table 32: Annual procurement cost for fire-fighting foam.

	Quantity t/a (central estimate)	Additional volume required (central estimate)	Price €/t (central estimate)	Cost Million €/a (central estimate)

AFFF	12 500 – 20 000 (16 250)		2 000 – 30 000 (3 000)	25 – 600 (49)
FFF		0-50% (30%)	700 – 10 000 (3 000)	9 – 300 (63)

One aspect not considered in this calculation is the difference in disposal costs for AFFF and FFF. Stakeholders claim that large amounts of AFFF are never actually used but only disposed of after the expiration date. Fluorinated foams need to be disposed of safely when expired after roughly 10-25 years. As of today, this means that this is done most likely using high-temperature incineration. The Dossier Submitter calculates incineration costs to be 1 €/kg (see below). These costs will not apply to expired non-fluorinated foams in the future because they can be disposed of via less expensive methods. It is not possible to calculate the costs because the share of stocks that is never used is unknown. However, when considering the difference in costs of AFFF and FFF the corresponding difference in disposal costs for a significant share of the foams needs to be considered. Consequently, the cost difference in Table 32 is an overestimation.

Procurement costs for replacement of AFFF in stock with fluorine-free fire-fighting foams

Estimates for the EU-wide stock of AFFF foams are highly uncertain. For the restriction proposal on PFHxS, its salts and related substances (ECHA, 2019) an EU-wide stock of 31 240 t PFAS-containing fire-fighting foam has been calculated. European Commission – DG Env/ECHA (2020) estimate stocks to be between 210 000 t and 435 000 t.

Considering that 12 000 t - 20 000 t AFFF is placed on the market per year the number used by the Norwegian Dossier Submitter for ECHA (ECHA, 2019) might be an underestimate. But the authors also cite an estimate by the US Fire Fighting Foam Coalition for the United States that suggests that total US stocks for AFFF were below 37 710 t in 2011. It seems unlikely that EU stocks are 5-11 times higher than stocks in the USA. Another comparison would be data quoted in UNEP (2016), which states a stock of 19 000 t AFFF for Japan. Taken together, these numbers suggest that estimates from EC/ECHA (2020b) are an overestimate.

One stakeholder (Fire Fighting Foam Coalition, comment 3010) suggests to extrapolate EU-stocks from a 2004 US AFFF inventory report and estimates a stock of 66 000 t for the US in 2019 (using GDP growth as proxy for increasing foam stocks) and correspondingly a slightly lower stock for the EU (considering the slightly lower GDP). It could be discussed whether GDP changes are an appropriate proxy for changes in foam stocks (real GDP might be more appropriate and other information should be considered, e.g. that service industries were the main drivers of GDP growth in the recent past). However, to be able to give at least an idea on the possible procurement costs it is assumed that the stock in the EU is twice as high as in the USA in 2011, i.e. 75 000 t. While only an educated guess, the Dossier Submitter argues that this might produce a conservative estimate regarding the replacement costs. The EU’s population is less than 60 % larger than the US-population; the GDP is smaller and chemical/petrochemical industry is less than 30 % larger.

Not all stock needs to be replaced. The Dossier Submitter assumes that a share of the stock will be used or has to be replaced during the five-year transition period proposed for fire-fighting foam mixtures that are placed on the market before entry into force of the regulation.

It is realistic that nearly half of the stock will be used or has to be replaced during the five-year transitional period. Data on use rates of fire-fighting foams is limited. (European Commission DG Environment/European Chemicals Agency 2020) indicates a very low use rate of approximately 20 percent of annual sales per year. They base this claim on two sources that report usage rates for PFOS-containing foams in the UK. These sources, however, report usage rates as a percentage of stocks and not annual sales: In the UK, the fraction of the stock of foams (all types) used in 2002 was 15 % (Federal Office for the Environment, 2009). The same information from the UK was used by Bipro (2010) to calculate reduction of AFFF-stocks that contain PFOS ((BiPRO), 2011). However, Bipro then uses a usage rate of 0.5 percent, too.

This rate, however, assumes that municipal fire brigades actually have a usage rate of 15 % stock and on the other hand petrochemical industry does not use its foams. The reasoning is that larger fire incidents are very seldom in the petrochemical industry. This argument does not consider among others training and testing and smaller discharges. It also does not consider that during the infrequent large fires very high quantities of firefighting foam will be discharged.

Non-representative data on the use of fire-fighting foams in Germany has been submitted in the public consultation (comment 3158) suggesting use rates of approximately 2 - 6% of stock for AFFF in different sectors and partially higher use rates for FFF. This data, while not generalizable, suggests the possibility that use rates for AFFF decreased since 2002. A possible explanation would be that AFFF are mainly used for infrequent larger fire incidents. For more frequent discharges like training, testing and smaller fires FFF are increasingly used. However, this is only a possible interpretation by the Dossier Submitter. The data nevertheless suggests that using older data for the estimation of use rates might misrepresent current and future developments.

The Dossier Submitter for the restriction proposal on PFHxS (ECHA 2019) reports that use rate estimates for the USA in 2011 were 6 - 10 % of stock. No further information is available meaning the possible range of use rates is 6 - 15 % and the median represents the central estimate. At a 10.5 % use rate stocks would be reduced by 43 % after five years (the range for the 6 - 15 % use rate is 27 - 56 % used stock). For the conservative estimate of 75 000 t foam in stock this results in replacement of up to 43 750 t.

In that case transition from AFFF to FFF would still result in considerable replacement costs. Using the price of 3 000 €/t, replacement costs amount to nearly 130 million € when all foams that are placed on the market are replaced as a consequence of this restriction (which is an overestimate, considering that perhaps not all AFFF are PFHxA-related and that derogations for some uses will be in place). The numbers are very uncertain, but still demonstrate that replacement of PFHxA-related AFFF in stock with fluorine-free fire-fighting foams might be expensive.

However, stocks always have to be replaced after expiry. Therefore, replacement with new foams is just an early replacement. It is likely that a large part of unused stocks have to be replaced between 2025 and 2030 regardless of this restriction proposal. Stakeholders commented in the public consultation for the restriction proposal on PFOA that most foam stocks had been replaced between 2006 and 2011 to substitute from PFOS to PFOA. Expiry of unused stocks can be expected 2021 – 2031. Replacement and incineration costs would take place just a few years later. Therefore, the estimated replacement costs of 130 million € is an overestimate not considering the fair value of the foam stocks.

But the main argument why replacement costs related to this restriction will be considerably lower is the expectation that a large share of AFFF-users must replace their stocks latest in 2025 as a consequence of the amended Annex I to Regulation (EU) 2019/1021 which stipulates:

"By way of derogation, the use of PFOA, its salts and PFOA-related compounds shall be allowed in fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, including both mobile and fixed systems, until 4 July 2025, subject to the following conditions: (a) fire-fighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall not be used for training;

(b) fire-fighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall not be used for testing unless all releases are contained;

(c) as from the 1 January 2023, uses of fire-fighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall only be allowed in sites where all releases can be contained;"

According to information from stakeholders this results in the necessity to dispose of the large majority of foam stocks. Stakeholders communicated for the PFOA restriction (ECHA 2015) that 'significant and defined volume of firefighting foams is kept stored on industrial sites to supply mandatorily required fixed installed fire protection systems or as an emergency stock in moveable large volume containments (trailers, skids, etc.). Any consumption of that stored volume must be restored to the required minimum storage volume (in Europe typically defined by EN-Standards). Storage containments must be refilled with fresh foam agent in any case of partial consumption of the stored (old) foam agent.'

This means that an unknown but large share of existing stocks are mixtures containing PFOA-related and PFHxA-related substances. Industry stakeholders from the Fire Fighting Foam Coalition (FFFC) commented during the consultation for the POP listing: "A ban on the use of existing stocks of fluorotelomer-based foam with long-chain fluorosurfactant content would require more than 90% of the existing foam stocks in the world to be removed from service and disposed."

It is the Dossier Submitters understanding that most or all foams placed on the market after 2015 will not be affected by the POP regulation because newer fluorosurfactants comply with the Stockholm Convention concentration limits. However, most foams from 2014 and before have to be replaced. The Dossier Submitter assumes the common practice that remaining foam stocks are just refilled after partial use. Therefore, it is most likely that a large share of users use mixtures of pre- and past-2015 foams.

Information submitted in the public consultation confirms a high PFOA-content in AFFF from 2009-2011 (comments 2965 and 2992). Grey literature from 2020 from German Werkfeuerwehrverband states as a rule of thumb that pre-2015 foam likely needs to be replaced, post-2015 foam likely not.

Based on this information from industry and users the DS expects that a large part, likely to be more than half of the existing stock of AFFF containing PFHxA-related substances has to be disposed of as the mixtures contain PFOA and PFOA-related substances. Equipment must be decontaminated to ensure the concentration limits for PFOA and PFOA-related substances, which are identical to the limits proposed for PFHxA. If users act rationally they will switch to non-fluorinated alternatives where possible to avoid additional cost resulting from this restriction a few years later.

Whether the increased demand for FFF can be met by producers is not certain, but likely. EC/ECHA (2020) states (with regard to replacement of 100 % of the stocks) that "this may result in in a more sudden and potentially significantly larger demand for fluorine-free foams to replace existing stocks of PFAS-based foam. This heightens the risk of a shortfall in supply, - [...] As the largest single use, and with comparatively low current fluorine free sales volumes, the risks of supply constraints may be greater in the chemicals and petrochemical sectors."

Consequently, availability of foams may be an issue. But the risk of supply constraints in chemical/petrochemical industry is lower, when the time-limited derogation for large atmospheric tanks is granted, which has been proposed by the Dossier Submitter. The potential consequences from the restriction on the use of PFOA might lead to early substitution with non-fluorinated substances within the next years, thereby disseminating the demand for FFF over a longer time period.

The conclusion on procurement costs for replacement of AFFF in stock with fluorine-free fire-fighting foams is as follows: Without substitution activities resulting from the the listing of PFOA in the Stockholm Convention the Dossier Submitter estimates replacement costs of less than 130 million €. Up to 90 percent of these costs will not apply because fire-fighting foam will be disposed of as a result of requirements resulting from the Stockholm Convention.

Incineration costs for replaced AFFF

Fluorinated foams that are no longer usable must be disposed via a safe method. It is assumed that disposal happens via high-temperature incineration. Cost estimate for high-temperature incineration in Europe amounts to 0.83 €/kg (in 2019 prices) (Klein, 2013). European Commission DG Environment/European Chemicals Agency (2020) reports stakeholder information that incineration costs are 0.3 - 1.5 €/kg. The authors also report that the increased demand for high-temperature incineration can be met by existing incinerator capacities.

For illustrative purposes a cost of 1 €/kg is calculated. Not included in these costs are transportation and other handling costs. No information on the magnitude of these costs is available. Accordingly, for 42 750 t of stock (remaining stock after 5 years, assuming a usage rate of 10.5%) the costs would amount to approximately 43 million €.

Again, it is not possible to give a reliable estimate on quantities that need to be incinerated as a consequence of this restriction proposal. The Dossier Submitter expects that a share of up to 90% will already be replaced when mixtures with PFOA and PFOA-related substances must be replaced.

Cleaning of existing fire-fighting installations and vehicles

Substantial costs are connected to the decontamination of fire extinguishing systems. Both, for mobile and stationary fire extinguishing systems, it is difficult to remove contaminations after the fluorinated foam concentrate is discharged and before the fluorine-free concentrate can be used. Relevant parts have to be flushed and decontaminated flush water has to be disposed of safely.

Quantitative information on the number of stationary fire extinguishing systems, fire-fighting vehicles and foam tanks affected is uncertain. European Commission DG Environment/European Chemicals Agency (2020) cite the following numbers for exemplary purposes: for chemicals/petrochemicals, more than 10 000 establishments covered under the EU's Seveso III Directive; more than 600 offshore oil and gas platforms; more than 400 airports in the EU; more than 50 000 public fire brigades in the EU, more than 1 200 commercial seaports, more than 230 military airbases are covered.

Personal information from one stakeholder suggests that, for example, the cost for fire engine clean-up might amount to 50 000 € per vehicle. Another relevant information from the ECHA stakeholder workshop in Helsinki (Chatham House Rules) is that total costs for the substitution at one petrochemical plant amounted to 200 000 - 300 000 €. European Commission DG Environment/European Chemicals Agency (2020) cites costs for a specific decontamination process of 12 300 € per appliance.

Comment 2983 from the public consultation provides additional information that system cleaning cost (excluding disposal cost for foam concentrates but including disposal of flushing water) are about 1 €/L of system content (e.g. a 10 000 L tank requires 10 000 € to clean to the proposed threshold level). The cost for handling, cleaning and retrofitting can ramp up to 15 - 20 Mio € for a single one of Europe's biggest chemical sites.

Cleaning of stationary fire-fighting systems depends among other things on size, configuration and location. Therefore, average costs (per litre or per apparatus) cannot be estimated.

Due to the PFOA-related requirements decontamination costs resulting from the restriction on the use of PFHxA and related substances will be reduced. It is not possible to give a reliable estimate but costs, without considering the PFOA regulation, will most likely be between several hundred million and lower two-digit billion €. European Commission DG Environment/European Chemicals Agency (2020) provides a best estimate for cleaning of 1 billion €. The authors estimate 10 000 € per appliance with 100 000 appliances. The

Dossier Submitter likes to point out that this is an informed expert opinion that is not substantiated by reliable data and does not consider the PFOA regulation.

Adjustments to existing extinguishing infrastructure

The costs for the adjustment of existing extinguishing systems are expected to be comparatively low. According to information from a distributor of fluorine-free foams minor costs for example for the installation of different nozzles, pressure gauges etc. have to be considered depending on the existing system. It might be necessary for some users to install additional tanks to store larger amounts of foam (causing more significant costs). Some older equipment maybe has to be replaced. No detailed information is available.

However, information was submitted in the public consultation (comment 2983) that bund areas in tank farms may need to be retrofitted to cover a significantly higher volume of liquids. Additionally, significantly increased firewater retention capacity can be required, which can cause reasonable difficulties in retrofitting operating sites to the new demand. No information was submitted how likely and how frequent such demand is.

The Dossier Submitter expects the costs in general to be small in comparison to other substitution costs considered but notes uncertainties regarding bunded areas in tank farms.

Administrative issues, training with alternative foam

Additional costs are connected to the different properties of fluorine-free foams. It might be possible that some users have to consult external experts to prepare the conversion to fluorine-free foams. It might be possible that additional training is necessary to acquaint firefighters with the new foam. Costs cannot be estimated. One example cited by European Commission DG Environment/European Chemicals Agency (2020) is the transition to FFF in the Norwegian petrochemical sector. Labour costs of 360 000 € for the transition to FFF in 45 sites are indicated. Approximately 1.1 million litres of foam were replaced. This suggests that administrative costs are not negligible but also minor in comparison to other replacement costs.

Administrative costs for the reporting requirements will most likely be comparatively low. It is expected that procurement of fire-fighting foams for defence applications and larger companies in the petrochemical sector is highly centralized. The existing centralized structures most likely can be used when reporting to ECHA on uses of fire-fighting foams.

Handheld fire extinguishers

The Dossier Submitter received information that in handheld fire extinguishers, fixed foam fire suppression systems and trolley units AFFF cannot be replaced by fluorine free foams. Consequently, users must replace handheld fire extinguishers. It is expected that the fire extinguisher has to be decontaminated before being disassembled for recycling.

The Dossier Submitter is not aware of data on handheld fire extinguishers in use in the EU. But considering that in Germany roughly 600 000 handheld fire extinguishers containing

AFFF are placed on the market per year[17] it is possible that in Germany 6 - 12 million and EU-wide 40 - 80 million devices are in use. Only an unknown share of the extinguishers will be affected by the restriction. Eurofeu estimates that 15 million fire extinguishers use PFAS. For devices in private use a significant share of users will probably not comply with obligations resulting from this restriction (because of lack of awareness and enforcement).

Replacement costs are unknown but considering that handheld fire extinguishers are available for considerably less than 100 €/unit the replacement would be affordable for consumers and SME.

Calculation of avoided emissions

12 500 – 20 000 t/a AFFF concentrate are placed on the market in the EU. According to information from Eurofeu and extrapolation from European Commission DG Environment/European Chemicals Agency (2020) these contain 480 - 560 t fluorosurfactant. Usage rates

- according to Eurofeu are 10% of foam concentrate placed on the market. This results in PFAS emissions from 48 – 56 t/a.
- European Commission DG Environment/European Chemicals Agency (2020) state a best estimate of 26% of AFFF placed on the market. This results in PFAS emissions from 125 – 145 t/a.
- The Dossier Submitter estimates (cf. B.9.18) emissions of 100 – 563 t PFHxA-related substances per year. In order to narrow down this estimate he considers other information available for a high estimate of 15% of stocks used per year, i.e. 11 250 t. With a concentration of PFAS surfactants in the foam of 2.5% this amounts to approximately 280 t/a.
- As central estimate the Dossier Submitter considers the annual use of 10.5% of stocks that was discussed above with regard to the replacement costs for foam stocks, i.e. annual use of 10.5% of 75 000 t. With a concentration of PFAS surfactants in the foam of 2.5% this amounts to approximately 197 t/a.

The Dossier Submitter therefore estimates that, without a restriction, emissions to the environment amount to 48 – 280 t/a of PFHxA-related substances. With a restriction, emissions from military uses will continue and from chemical/petrochemical uses will continue for 12 years. Considering that not all uses in these industries will be derogated but also considering that these make up 65% of the current market a considerable amount of emissions will not be avoided. But most probably more than half of the emissions of PFHxA-related substances into the environment can be avoided. In case that alternatives for the derogated uses become available sooner than expected even more emissions can be avoided.

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[17] Personal communication with one stakeholder (28 May 2019). Information is based on data from bvfa - Bundesverband Technischer Brandschutz e. V.

Calculations in Annex B.9.19 are a very rough indicator for the environmental impact that can be expected when the proposed derogations are included in REACH Annex XVII. Significant emissions are expected but might be lower than calculated because replacement of significant amounts of stock might occur before the five-year transition period ends. The Dossier Submitter lacks crucial information regarding the emissions from large tank (>500m^2) and defence applications.

Therefore, the Dossier Submitter proposes not to take the calculations at face value but to use them as a rough indication that the derogations for firefighting foams will be responsible for a very large share of future emissions of PFHxA to the environment. As calculated in B9.19 emissions from foam will be responsible for more than 80 percent of future PFHxA-emission. When only considering environmental impacts from derogations that are not time-limited it can be expected that the derogation for defence applications will be responsible for the second largest quantities of remaining PFHxA-emissions (behind PPE), probably amounting to more than 30 percent.

E.2.3.6 Cost-effectiveness, affordability and proportionality to risk

It is not possible to calculate cost-effectiveness because important details on costs like the amount of fire-fighting equipment installations affected and the cost for cleaning are unknown. It is not known whether affordability could be an issue. Obviously larger airports, some manufacturers and the defence sector in general can afford the costs associated with substitution to FFF. No information is available how SME, smaller airports or municipal firefighting will be affected. However, the Dossier Submitter considers that some SME might face difficulties when forced to replace or clean-up their fire-fighting installations. As well it might be possible that smaller professional firefighting units still use very old equipment that is not suited for the use of FFF. Hence, such units would have to replace equipment to be able to replace AFFF with FFF. A large share of users will face the costs already when they need to comply with the amended regulation (EU) 2019/1021.

It is not possible to determine with certainty whether a restriction would be proportionate but using all the information available it is likely that a restriction is justified: Large parts of the costs will not be incurred when users act rational and replace AFFF with FFF when restrictions for PFOA come into effect. Other parts of the expenses are most probably just early replacement costs. Some users that are not affected by the POPs regulation and purchased foams recently will face higher costs resulting from a restriction on the use of PFHxA and related substances, especially for the replacement of existing foams. However, in the case of PFOA it already has been agreed that costs for the replacement of existing foams are affordable.

On the other hand, unknown but very high emissions of PFHxA-related substances into the environment will be avoided when AFFF containing PFHxA related substances will be replaced with FFF.

E.2.3.7 Impact of different transitional periods

Longer transition periods might reduce the cost of substitution substantially. More foam concentrates, firefighting vehicles and stationary extinguishing systems would meet their regular end of service life. Replacement of this equipment and the switch to non-fluorinated FFF could be combined, thereby realizing a reduction of the total cost. However, this argument might be wrong. In case of a shorter transitional period users will face restrictions for PFOA and PFHxA within a short period of time. Rational users will try to avoid regrettable substitution with PFHxA-related substances and consider immediate substitution with fluorine-free FFF. In case of a longer transitional period more users might consider substitution with PFHxA-related AFFF an option.

Additionally, the Dossier Submitter considers that a longer transitional period results in ongoing high emissions of PFHxA-related substances directly into the environment. Considering the large stock of AFFF a longer transition period for AFFF already on the market is not justified.

E.2.3.8 Uncertainties and sensitivity analysis

The major uncertainties are the largely unknown costs discussed in the impact assessment.

Further major uncertainties are:

- The impact of the ban of the use of PFOA-stocks resulting from the Stockholm convention.

Table 33: Possible impacts related to amended regulation (EU) 2019/1021 (best estimates).

	Expected costs of restriction on PFHxA-related substances in firefighting foams	
	before amendment	considering amendment
Additional procurement costs	15 million €/a	15 million €/a
Replacement costs	130 million € Over 20 years: 6.5 million €/a	Up to 90 percent shared with PFOA-related replacements. Replacement of uses with 12-year transition period will take place later, i.e. no synergies. Unknown share of users will not substitute with FFF immediately.
Incineration costs	43 million € Over 20 years: 2.15 million €/a	Up to 90 percent shared with PFOA-related replacements. Replacement of uses with 12-year transition period will take place later, i.e. no synergies. Unknown share of users will not substitute with FFF immediately.

Cleaning	1 000 million € Over 20 years: 50 million €/a	Up to 90 percent shared with PFOA-related replacements. Replacement of uses with 12-year transition period will take place later, i.e. no synergies. Unknown share of users will not substitute with FFF immediately.
Adjustments to existing extinguishing infrastructure	Unknown, but significant	no impact on costs
Administrative issues, testing, training	Unknown, but likely to be small compared to the other costs	no impact on costs
Avoided PFHxA-related emissions	Unknown, but most likely in the range of 48 – 280 t/a after transition period	Incentives for earlier substitution, i.e. reduced emissions

- Whereas most AFFF agents are compatible and different brands can be mixed in the same equipment, fluorine-free foams are generally not compatible and cannot be mixed with other types of foam agents. Mixing the foams may especially cause issues for fixed fire protection systems and defence applications. Stakeholders commented in the public consultation that this makes the five-year transition period meaningless because users cannot easily refill their stocks. While this argument is valid for some users, according to information from industry the majority of users does not use stocks because they face only rarely fire incidents. Therefore, for this majority of users the five-year transition period is not meaningless.

- The future availability of alternatives for firefighting in cases of class B fires in storage tanks with a surface area above 500 m^2 is uncertain.

- It is uncertain if and when certification and standards for the alternatives for defence applications are available.

- Environmental emissions are uncertain. Information is lacking on usage rates for the different applications and the resulting emissions into the environment. It is not known what disposal methods are used for contained releases from testing, training and use. Information is lacking whether expired/replaced foams are always disposed of via high temperature incineration.

- In the public consultation the issue was raised whether the restriction would lead to illegal disposal and therefore high environmental costs. However, according to stakeholders a large share of the stocked foams is not used during service life. It is not plausible to assume that all users are willing to pay for proper disposal at the end of shelf life but to assume that the same users are not willing to pay for proper disposal when the use of AFFF gets restricted. Therefore, if the argument that significant illegitimate disposal happens when foam needs to replaced is valid, then the continued use of PFHxA would lead to continuing significant emissions from illegal disposal, too – meaning that emissions from continued use of PFHxA are significantly underestimated.

- Thermal treatment is an energy-intensive disposal method with a high carbon footprint and the risks of potential air emissions. The effectiveness of incineration to destroy PFAS compounds and the tendency for formation of fluorinated or mixed halogenated organic by-products is not well understood. Continued use of AFFF leads to continued energy-intensive disposal and the continued risk of hazardous emissions to the environment. The same risks apply to disposal as a consequence of the proposed restriction, however not as a continuing risk.

- Impact on export is uncertain. Comment 3010 provided the following information: 20-25 manufacturers of class B firefighting foams in the European Union estimate that their export sales of foam agents account for about 60-70 million €/a. Currently, about 85- 95% of their class B foam sales are fluorinated foams. With the restriction in place as proposed, foam manufacturers in the EU would lose the ability to manufacture fluorinated foams, resulting in the loss of a significant percentage of their foam business as their sales into these markets would be replaced by foreign competitors. The stakeholder estimates that foam manufacturers in the EU could lose as much as 20 - 25% of their foam sales, with a resulting loss of as much as 10 - 15 million € annually.

  The stated loss seems to be the turnover. No further information is given on profit losses or loss of jobs and resulting costs. The socio-economic cost will be considerably less than 10 - 15 million €/a but might still be significant.

E.2.4 Printing inks

E.2.4.1 Overview

Adding fluorinated surface-active substances to inkjets improves the working of modern printers as well as enhancing picture quality with different media.

Proposed restriction elements for PFHxA and related substances in printing inks

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:
(a) another substance, as a constituent,
(b) a mixture,
(c) an article
in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA-related substances.
Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction
Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.
Paragraphs 1 and 2 shall not apply to latex printing inks until XX XX XXXX [seven years after entry into force of the restriction].

E.2.4.2 Use and function

The surface-active fluorinated substance improves surface wetting during the printing process (UNEP, 2012b). During stakeholder consultation it was confirmed that C6 based short-chain fluorinated surfactants are used in some water-based inkjet inks and latex inks. The main function is the reduction of the water surface tension, when applied on nonporous substrates. In absence of a surfactant the mixture would tend to form large unequal drops that would lead to a non-uniform surface coverage of the inks (Stakeholder Consultation, 2018).

E.2.4.3 Baseline

There is little data on the volumes of PFHxA-related substances used in inks. But results from the consultation with industry indicate that short chain PFAS are still commonly used in printing inks applications.

E.2.4.4 Uses, functions and alternatives

Various non-fluorinated surfactants were tested. Only the C6-based fluorinated surfactants provided the required performance, but research on non-fluorinated alternatives surfactants is continued. Some alternative technologies are solvent based or UV-curable mixtures (Stakeholder Consultation, 2018).

Stakeholders expect that a simple “drop in” substitution will not be possible. One stakeholder stated that it is not possible to present reliable timelines. Others estimated the time needed for substitution with 5 -10 years but were not giving an in-depth rationale for this timeline.

E.2.4.5 Economic and other impacts

Very little information could be gathered on the availability of alternative substances to be used in water-based printing inks. According to industry, fluorinated products are used in applications that require exceptional technical performance such as industrial coatings. In many coatings, siloxanes are commonly used instead, also because fluorine-based additives are comparatively expensive. It has been reported that C4 PFAS have partially replaced the long-chain PFAS. The Dossier Submitter therefore believes that alternatives are available.

In the public consultation stakeholders asked for derogations for certain printing applications and printing media. The Dossier Submitter is of the opinion that all derogation requests consider applications where alternatives are already available. The stakeholders argue that drop-in alternatives are not available at the moment, mainly citing difficulties with printing quality as a problem. However, it is unclear for which of the cited uses diminished printing quality would be relevant.

The Dossier Submitter cannot evaluate the decrease in printing quality and impact on user applications. Therefore, no additional derogations are proposed. The Dossier Submitter notes that with additional information on probable impacts use-specific derogations ranging from four to seven years might be justified considering the potentially disproportionately high costs when service life of a large share of printers is reduced substantially.

Considering the lack of additional information, a calculation of substitution costs was not possible but the following aspects have been considered:

- Regarding cost of substitution, some companies indicate similar ranges from 0.1 - 10 million Euro. Some stakeholders confirmed this cost range in the public consultation. Others assume higher costs of >10 million Euro (Stakeholder Consultation 2018). It was not possible to derive general substitution costs for the whole industry from this company related information.
- Information from industry suggests that printing inks are mainly produced outside the EU.
- The worst-case estimate for emissions of PFHxA-related substances is slightly above 10 t/a.
- Companies already undertake R&D irrespective of this restriction proposal. Therefore, these costs must not be counted as direct impact from the restriction proposal.
- Siloxanes and C4 PFAS (for example PFBS) have partially replaced longer chain PFAS. The Dossier Submitter assumes that this group of substances can be used as direct substitute but notes that C4 PFAS might pose a case of regrettable substitution.
- Other alternative technologies are solvent based or UV curable mixtures which are in the evaluation of one company. They are even less recommendable with regard to human health and environmental properties (during production and in final use) (Stakeholder Consultation 2018).
- Industry stated that slightly higher costs for the substitute substances in latex printing inks are expected.

Latex printing inks

For latex printing inks the Dossier Submitter proposes a temporary derogation. During the stakeholder consultation information was submitted that PFHxA-related substances are used in latex printing inks. One manufacturer claimed that a simple “drop in” substitution is not possible and a more extensive reformulation will be necessary to develop competitive products. The manufacturer estimated the time needed for substitution with five to ten years. Considering that research for substitution according to information submitted has already started the Dossier Submitter assumes that alternatives will be available in 2024. However, printers in use have to be equipped with the current generation of printing inks. These printers are expected to have a seven to ten-year service life. Hence, printing inks for the current printer generation need to be available after 2024 to avoid early replacement of the printers. The proposed exemption ensures that printer hardware can be used until the expected service life expires. Therefore, impacts from early replacement are not expected.

In summary, the Dossier Submitter proposes a temporary derogation for the latex printing inks. A manufacturer claims that alternatives are not available at the moment but in the process of development. Other information is not available. For the remaining printing inks, no derogation has been proposed. Stakeholders claim that for some applications (for example inkjet inks) printing inks with fluorosurfactants are needed to reduce the water surface tension. However, considering that printing inks without fluorosurfactants or with C4-fluorosurfactants are available, the Dossier Submitter would need more information to justify additional derogations in general and for which specific applications.

E.2.4.6 Cost-effectiveness, affordability and proportionality to risk

The Dossier Submitter expects the restriction to be cost-effective. Manufacturing most probably takes place outside the EU meaning that distributional consequences would not affect European companies and workers. Stakeholders did not indicate that prices for inks would be affected.

One stakeholder provided in the consultation confidential estimates of substitution costs for R&D and use quantities of PFHxA-related substances. Based on this information, the Dossier Submitter estimates that approximately 80% of used quantities will be emitted to the environment (see B.9.12) resulting in a cost-effectiveness of < 5000 €/kg for avoided emissions, if R&D costs are fully passed through to the EU-market and not worldwide. As this seems unlikely the cost-effectiveness ratio is an overestimate. Costs are affordable, based on the estimated number of printers affected, according to the same stakeholder. Over 20 years additional annually cost per printer amounts to <1 €.

Most likely the largest effect of a restriction would be the early obsolescence of the current printer generation. The temporary derogation ensures that printers for latex inks are in service for another seven to ten years, i.e. the expected service life.

E.2.4.7 Impact of different transitional periods

As explained a shorter transitional period would lead to a shortened service life of latex ink printers and therefore considerable cost which would most likely be unproportionate.

E.2.4.8 Uncertainties and sensitivity analysis

Functional losses are not expected but according to information from the stakeholder consultation possible.

E.2.5 Chrome plating

E.2.5.1 Overview

Identification of PFOS as persistent organic pollutant (POP) and the inclusion in Annex B of the POP regulation (EC No 850/2004) led to the substitution of PFOS with 6:2 fluorotelomer sulfonate (6:2 FTS also known as H4-PFOS) in chrome plating processes (UNEP, 2018a).

6:2 FTS degrades to PFHxA under environmental conditions (see chapter B.4.1.2). Furthermore, for 6:2 FTS itself not for all toxicological hazards sufficient data are available. Hence, a comprehensive assessment is not possible.

6:2 FTS is used in hard chrome plating processes as well as decorative chrome plating processes as surfactant to lower the surface tension of the plating solution. The differences between both chrome plating processes are reflected in thickness, hardness and deposition of the chrome layer on the plated object.

Aim of hard chrome /functional chrome plating (layer thickness > 0.2 mm) is to provide e.g. hardness, corrosion and wear resistance, lubricity and high resistance against chemicals. Hard metal plated parts are used e.g. in automotive industry, aircraft construction, shipbuilding and engineering like hydraulic cylinders and rods, railroad wheel bearings and couplers, moulds for the plastic and rubber industry (Blepp et al., 2017; UNEP, 2018a).

Decorative chrome plating is used for decorative surface finish. The thin layer of metal (layer thickness 0.05 - 0.5 µm) provides properties like aesthetically pleasing appearance or non-tarnishing and is used e.g. in sanitary industry, kitchen appliances, car and truck pumpers or motorcycle parts (Blepp et al., 2017; UNEP, 2018a).

A further electroplating process is the electroplating of plastics in combination with decorative chrome plating.

Proposed restriction elements for PFHxA and related substances for chrome plating

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:
- (a) another substance, as a constituent,
- (b) a mixture,
- (c) an article

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.
Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.
Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.
Paragraphs 1 and 2 shall not apply to hard chrome plating until five years after the entry into force of the restriction.

E.2.5.2 Use and functions

PFASs (e.g. 6:2 FTS) are used as wetting agents for numerous wet-chemical processes of surface finishing due to their properties with regard to process safety (Blepp et al. 2017). The wetting agents are used for chrome baths to lower the surface tension of the plating solution. The surfactants are also used to decrease aerosol emissions especially to reduce emissions of chromium VI (carcinogen) to the air (UNEP, 2018a; Willand et al., 2019). Due to reducing the surface tension, process gas bubbles become smaller and rise more slowly compared to larger bubbles. When the bubbles burst at the surface, mist is less likely to be emitted into the air because of the reduced kinetic energy of the slower bubbles (UNEP, 2017).

Fluorinated surfactants are only used in metal plating with chromium (VI) (Blepp et al., 2017; UNEP, 2018a).

For the process of plastic electroplating, firstly the plastics must be made electrically conductive. Therefore, microscopic pores are etched into the plastic surface by treatment with very strong oxidizing etchants. Mostly, a highly concentrated chromo-sulfuric acid solution is used as etchant. For achieving wettability of the hydrophobic plastic surface, a stable surfactant has to be added to the chromo-sulfuric acid (Blepp et al., 2017). As an alternative for PFOS predominantly polyfluorinated wetting agents (e.g. with 6:2 FTS) are used today (Willand et al., 2019).

E.2.5.3 Baseline

Based on an extrapolation (see B.9.11.2) up to 57 t/a 6:2 FTS (2 – 57 t/a; central estimate 30 t/a) are used for chrome plating in the EU, resulting in a central estimate of 5.9 t/a emissions (0.5 – 11.4 t/a) of PFHxA-related substances into the environment. This extrapolation is uncertain, however, is within the registered band for annual usage of 10 – 100 t/a 6:2 FTS. Accordingly, estimates for the emissions from the specific chrome plating processes are uncertain, too.

The ZVO states that in the case of Germany 20% of the applied surfactant is lost in the plating processes over time (Brunn Poulsen et al., 2011). The Dossier Submitter assumes that this share can be generalised for all manufacturers in the EU.

Without a restriction 9 – 228 t/a (central estimate 119 t/a) PFHxA-related substances will be emitted into the environment over 20 years. Considering a five-year derogation for hard chrome plating emissions would be reduced by 9 – 215 t to approximately 0.27 - 13 t/20 years as a result of the restriction.

The Dossier Submitter estimates that approximately 32 percent of the emissions are from hard chrome plating, 63 percent from decorative chrome plating and 5 percent from plastics products chrome plating.

E.2.5.4 Alternatives

Fluorinated alternatives could have similar risks to the environment like PFOS or 6:2 FTS (degradation to a substance with environmental concern). Therefore, these substances should not be used to avoid regrettable substitution.

Fluorine-free substances /products are not considered equally effective to fluorinated surfactants. Furthermore, additional risks with respect to safety, process stability and device preservation are mentioned by German electroplating industry association (UNEP, 2018a). Nevertheless, these substances have been partly used successfully in bright (decorative) chrome electrolytes (Blepp et al., 2017). The use in hard chrome plating is also possible, but according to the current state of knowledge the substances should be used on a case-by-case basis. Furthermore, fluorine-free surfactants oxidatively decomposed very rapidly in the process solutions and chromium (III) compounds are formed. This impairs the functional efficiency of the process solution (Blepp, et al., 2017).

Fluorine-free wetting agents contain higher concentrations on active substance (fluorine-free 1 – 50 %; 6:2 FTS 1 – 10 %). Reasons for this are, for example: a) these alternative substances reduce surface tension only at higher concentrations and b) higher consumption due to more or less rapid oxidation. Fluorine-free products often require a higher technical effort compared to the previous application with PFOS. In contrast to fluorinated products the fluorine-free products often have to be added diluted and in smaller dosages throughout the day. To achieve comparable surface tensions higher amounts of wetting agents are necessary (Willand et al., 2019).

As part of the assessment of alternatives for PFOS in chrome plating processes it was confirmed that non-fluorinated surfactants seem feasible for decorative as well as hard chrome plating (UNEP, 2019).

No surfactants (either fluorine-free or fluorinated) are necessary in closed coating reactors (UNEP 2018; Blepp et al., 2017). Chromic acid aerosols which are emitted to room air are significantly reduced. This is especially a technical alternative for hard chrome plating. Nevertheless, attention should be given due to explosion hazard of produced hydrogen gas (H_2) (UNEP, 2017). Due to highly diversified chrome plating processes it is impossible to describe a universal closed loop process technology for all of the various uses and process combinations (Blepp, et al., 2017).

For plastic electroplating non-fluorinated surfactants, which are not toxic and easily biodegradable, can be used successfully in the etching process if the production line is very constant. As a precondition, the plastic goods have to be dipped into the surfactant liquid before the etching process (UNEP, 2015). Successfully tested alternative immersion techniques include acidic permanganate solutions, nitric acid and trichloroacetic acid mixtures. The following disadvantaged were pointed out: problems with wastewater treatment due to organohalogen compounds; problems when searching for suitable rack insulation; risk of formation of nitrous gases during the use of nitric acid, and problems with the formation of manganese dioxide and fire safety issues when using permanganate solutions (Blepp, et al., 2017). Potassium permanganate, one of the alternatives, is harmonised classified as Repr. 2 (H361d).

Further fluorine-free alternatives and alternative processes are listed in Table 34.

Table 34: Examples for fluorine-free alternatives and alternative processes for chrome plating (UNEP, 2016; UNEP, 2018a; Willand et al., 2019).

Alternative	Hard chrome plating	Decorative chrome plating	Additional information	Reference
alkane sulfonates	x	x	not resistant to hard chrome plating; less effective in decorative chrome plating disadvantage: considerable data gaps of their chemical composition, hence environmental hazards cannot be assessed; general group of alkylsulfonates: commonly used degradable substances	(UNEP, 2016; UNEP, 2018a)
amine, C12-C14 alkyl, ethoxylated (CAS-No. 61791-14-8)	x	x	disadvantage: potential hazardous to the aquatic environment based on notified classifications in C&L inventory (impacts in mixtures unclear –	(Willand et al., 2019)

			specific amounts not known) self-classification for human health endpoints: Acute Tox 4 (H302), Skin Corr 1B, Eye Irrit 2	
oleo amine ethoxylates (e.g. mixtures with (Z)-octadec-9-enylamine, ethoxylated CAS-No. 26635-93-8)	x	x	disadvantage: (Z)-Octadec-9-enylamine, ethoxylated itself is potential hazardous to the aquatic environment based on notified classifications in C&L inventory (impacts in mixtures unclear – specific amounts not known) self-classification for human health endpoints: Acute Tox 4 (H302), Skin Irrit 2 or Skin Corr 1B, Eye Irrit 2	(UNEP, 2018a; Willand et al., 2019)
3-[dodecyl(dimethyl)ammonio]propan-1-sulfonat (CAS-No. 14933-08-5)		x	self-classification for human health endpoints: Acute Tox 4 (H302), Acute Tox 4 (H312), Skin Irrit 2 or Skin Corr 1B, Eye Irrit 2 or Eye Dam 1, STOT SE 3 (lungs)	(Willand et al., 2019)
paraffin oils, sulfochlorinated, saponified (CAS-No. 68188-18-1	x	x	disadvantage: potential hazardous to the aquatic environment based on notified classifications in C&L inventory (impacts in mixtures unclear – specific amounts not known) self-classification for human health endpoints: Acute Tox 4 (H302), Skin Irrit 2, Eye Irrit 2	(Willand et al., 2019)
other non-fluorinated alternatives	x	x	disadvantage: no information on chemical identity	(UNEP, 2018a)
physical covers (netting, balls) for metal plating baths (chromium (VI))	x	x	e.g. mesh or blankets (composite mesh pads) placed on top of bath or add-on air pollution control devices (packed bed scrubbers): advantage: high efficiency in removing chromium (VI) aerosols (> 98 %) (UNEP, 2016); no adverse health and environmental effects from control devices themselves; no factors limiting the accessibility e.g. PTFE coated balls on top of bath	(UNEP, 2016; UNEP, 2018a)

			disadvantage: PTFE coated balls will not reduce chromium emission from the bath (on the contrary: increasing chromium emission compared to using no mist suppressant)	
add-on air pollution control devices	x	x	e.g. packed bed scrubbers	(UNEP, 2018a)
novel plating processes	x	x	e.g. HVOF (high velocity oxygen fuel) process: advantages: process is globally available and is considered effective (high deposition efficiency and good quality finish) and with low costs; disadvantage: requiring high temperature application: layers may be more porous and less resistant to corrosion	(UNEP, 2018a)
chromium (III) plating		x	advantage: process does not require the use of fluorinated mist suppressants or wetting agents; disadvantage: potential for conversion of Cr(III) to Cr(VI) during plating process is unclear; potential contamination with other metals; potential formation of complexing agent	(UNEP, 2018a; Willand et al., 2019)
closed coating reactors	x	x	advantage: no fluorinated wetting agent necessary; limited aerosol emission to room air disadvantage: attention to possible explosion hazard	(UNEP, 2018a)

E.2.5.5 Economic and other impacts

For plastic electroplating non-fluorinated and non-toxic surfactants are available if the production line is very constant. As a precondition, the plastic goods have to be dipped into the surfactant liquid before the etching process (UNEP, 2015).

Fluorine-free substances /products are not considered equally effective to fluorinated surfactants. Furthermore, additional risks with respect to safety, process stability and device preservation are mentioned by German electroplating industry association (UNEP 2018). Nevertheless, these substances have been used successfully in bright (decorative) chrome electrolytes (Blepp et al., 2017).

The use in hard chrome plating is also possible but still under investigation.

An economic assessment for PFOS has been undertaken. Based on the price alone this was inconclusive. Some alternatives may be cheaper and some may be more expensive. This conclusion was related to PFOS and not 6:2 FTS. However, the POP Review Committee concluded: "Non-fluorinated surfactants are used during the production process for hard metal plating and decorative metal plating. Although they are degraded in the chromium electrolyte or etching bath and must be constantly dosed, the costs are not higher than using fluorinated surfactants" (UNEP/POPS/POPRC.12/INF/15/Rev.1).
This is based on data provided in a study by the Danish Ministry of Environment from 2011 that "suggests that the price of the PFOS products used as mist suppressant for non-decorative hard chrome plating is around 100 to 200 DKK (13 EUR to 27 EUR) per kg/litre. The price is dependent on the concentration of PFOS in the chemical. […] The price is not fully comparable as no information was received on the amounts to be used compared to a PFOS product. […] Other information about the price of the non-PFOS alternatives was sparse. One supplier informed that their non-PFOS alternative is more expensive than PFOS (but not how much more expensive)" (UNEP, 2013).

For decorative plating a shift to other electrolytes that are Cr(III) based is an available alternative. This would mean that the demand on surfactants and process fluids is considerably lower, and that PFAS are not required.

It has to be considered that in contrast to fluorinated products the fluorine-free products often have to be added diluted and in smaller dosages throughout the day. To achieve comparable surface tensions higher amounts of wetting agents are necessary (Willand et al., 2019). Therefore, it is possible that production processes need to be changed.

If an alternative is used where the goods have to be dipped into the surfactant liquid an additional bath has to be installed into the production facility. This means additional cost for the procurement of equipment as well as cost related to a reorganization of the production facility for some companies.

Information from industry suggests that "the costs of phasing-in alternatives varies per company. Tests with alternative products may cost a company €50 000 to €150 000 per test and a test cycle has a minimum length of at least 1 year. However, the representatives indicate that the costs are mainly related to the costs of phasing in the alternative in practice and not in the costs of testing. Most relevant for the cost is whether the alternative is a drop-in alternative or that new installations (tanks, baths, etc.) are required" (EU, 2016).

For decorative plating a shift to other electrolytes that are Cr(III) based is an available alternative. This would mean that the demand on surfactants and process fluids is considerably lower and that PFAS are not required. The Norwegian association of electroplaters (NGLF) has estimated the cost of replacing Cr(VI) in plating baths with Cr(III) to be approximately NKR 100 000 (US$ 15 000–16 000) per bath (UNEP, 2013). It is not clear whether this estimate would be lower for a bath replacement where the Cr(VI) in use is due for replacement at the moment of substitution.

According to the German national metal plating association (ZVO), in Germany about 200 companies are working in the sector of hard chrome plating, about 400 in the sector of decorative chrome plating and about 30 in the sector of plastic products chrome plating (see B9.10.2).

The association of the German plastic electroplating companies (FGK Fachverband galvanisierte Kunststoffe e.V.) reports that members ”plan the partly extensive modifications of the plating lines and to schedule them. This will take some years to complete depending on the company and the individual complexity and size of the machinery, but will be completed until 2024”.

The information that is available at the moment is not sufficiently detailed to derive a cost-effectiveness estimate. Information from Germany suggests that manufacturers in the sector of plastic product chrome plating have already started to replace Cr(VI) in plating baths with Cr(III). This substitution process has been set off by the listing of Cr(VI) as an SVHC under REACH Annex XIV.

However, for decorative chrome plating some users claim that Cr(III) use is not possible when high technical performance and strict aesthetic standards have to be met, as for example in the automotive industry (Steinhausen, 2019). Therefore, it is not clear how advanced substitution processes with regard to decorative chrome plating are.

The main missing information to derive costs for the chrome plating industry from this restriction proposal is the number of baths per manufacturer. The chrome plating industry is characterized by heterogeneity and a large share of small and medium enterprises. Large production facilities might use considerably more than 100 baths of different sizes. Small and medium enterprises might use single- to double-digit number of baths.

The cost estimate from the Norwegian association of electroplaters suggests that substitution of Cr(VI) with Cr(III) is affordable. Substitution costs mainly consist of one-time replacement costs that amount to less than 1 000 €/a (750-800 €/a) per bath when considering a time period of 20 years.

The quoted costs suggest affordability but information is not sufficient to evaluate proportionality of a restriction as information on emissions per bath are not available. Emissions depend on bath size, type of use and operating time.

It is not possible to derive sufficiently representative numbers from the literature to calculate use quantities and emissions for the industry as a whole or for individual baths. Non-representative information from Brunn Poulsen et al. (2011), Blepp et al. (2017) and other publicly available sources suggest large differences in the use of wetting agents. Used quantities among other things depend on recommendations from manufacturers, content of active ingredient, type of chrome plating and frequency of bath use.

For hard chrome plating where it is not possible to use Cr(III) a cost estimate cannot be derived. It is not clear to the Dossier Submitter how the quoted costs of 50 000 - 150 000 € translate into costs per bath or costs for avoided emissions.

Therefore, the following information was considered to evaluate the economic impacts qualitatively:

- PFHxA-related substances are used in non-negligible quantities in the EU (central estimate 30 t/a)

- A large share of the quantities used are emitted into the environment. The Dossier Submitters central estimate is that without a restriction nearly 120 t of PFHxA-related substances will be emitted to water in the EU until 2040.
- Alternatives are available and used for decorative chrome plating and plastic electroplating when using Cr(III) is possible. The substitution is economically feasible. As a positive side-effect the use of Cr(VI) which is identified as an SVHC and included in REACH Annex XIV will be reduced.
- As a response to the listing of Cr(VI) as an SVHC on Annex XIV manufacturers already prepare to use Cr(III) for plastic electroplating and when possible for decorative chrome plating.
- Alternative wetting agent fume suppressants for hard metal plating have been identified but not tested sufficiently by the industry. A time-limited derogation is needed to complete testing and procure new installations.
- Some alternatives proposed for hard metal plating might be costly. For example, control devices for air flow, additional baths or additional wastewater treatment could be needed. It is possible that manufacturing routines have to be changed.
- Of the various alternatives available some might have issues regarding performance, health and environmental impacts. Additional information is not available.
- The chrome plating industry is characterized by heterogeneity and a large share of small and medium enterprises.
- It is not possible to derive a generalizable restriction scenario for this diversified industry.
- The automobile industry is an important customer of hard metal plated parts and relies on these products. Suppliers have to deliver parts according to specifications over long time-periods (up to 20 years). Therefore, changes in the production process must not result in modified products.
- PFHxA-related substances are not present in the chromium-plated article. Therefore, no impacts are expected for imported articles.

Considering the scarce information, the Dossier Submitter proposes a temporary five-year exemption from the restriction for hard metal plating. The information suggests that the immediate substitution of substances falling under this restriction proposal is not possible. The European manufacturers of hard chromium plated articles would no longer be able to participate in the market and most likely their products would be replaced by imported articles. This could lead to supply shortages for downstream users who, like the automotive industry, depend on these products heavily. Five years is realistic to install the necessary production processes for continued manufacturing in the EU.

For decorative chrome plating and plastic electroplating alternatives are available and scarce information suggests that the cost of substitution is affordable. A recent report is inconclusive on the cost of additional investments and administrative burdens but emphasized that alternative processes are competitive in general: "It also has to be emphasised that substitution of chromium trioxide is connected with some financial and administrative burdens for the affected companies. The extent of efforts for investments, adaptations of process lines and administration for official permissions depends on individual conditions of the respective production facility. From an economic perspective, processes using trivalent chromium are in principal competitive, especially for new plants. There is a consensus within the branch of industry that a shift from chromium trioxide to trivalent chromium will not have a big influence on the costs of the whole coating process and the applications" (Müller et al. 2020).

E.2.5.6 Cost-effectiveness, affordability and proportionality to risk

Some uncertain evidence is available that suggests that in general the costs of substitution are affordable and proportionate to the risk (i.e. high direct emissions into the environment).

During the public consultation no additional information was submitted.

However, uncertainties regarding the reliability of the information which was used are high.

E.2.5.7 Impact of different transitional periods

Longer transitional periods lead to continued emissions. Only for hard chrome plating substitution is not possible immediately. Calculations in B9.19, although highly uncertain, indicate that the environmental impacts resulting from the 5-year derogation for functional hard chrome plating are non-negligible. Therefore, the transitional period for this application should be as short as technically and economically feasible. Longer transitional periods might affect economic feasibility when conversion of plants which restricts production is necessary.

E.2.5.8 Uncertainties

It is unknown whether data for German industry, provided by the German ZVO, and from the Norwegian association of electroplaters is representative for the EU. It is uncertain how robust the data collected by the POP Review Committee in the process of listing PFOS as a POP is.

The information on further costs is highly uncertain: Implementation costs might be a heavy burden especially for the large number of SMEs in the market. The Dossier Submitter notes that no additional information has been provided during the public consultation for this restriction proposal.

No additional transitional periods have been proposed for decorative chrome plating and plastic electroplating. As alternatives are available longer transitional periods are not seen as proportionate. For hard chrome plating a transitional period of less than five years would lead to high economic costs in case alternatives could not be installed successfully in that time period.

Some stakeholders claim that for decorative chrome plating the use of alternatives like Cr(III) will lead to limitations with regard to the aesthetic qualities of the final product. The DS has no information regarding the resulting magnitude of impacts. But it is uncertain whether customers will accept limitations or search for alternative suppliers outside the EU.

In a recent report on technical and economic feasibility of alternatives for chromium trioxide it was questioned whether alternatives are available for all applications in decorative chrome plating and plastic electroplating (Müller A. et al., 2020). No additional information has been provided in that regard in the public consultation.

E.2.6 Building material

Fluorinated substances are used in paints to improve flow, wetting, and levelling. The highly fluorinated substances are used to reduce surface tension in paints so that the surface on which the paint is applied is wetted. Fluorinated surfactants can yield in higher stability or resilience of foams for the formation of low-density concrete building blocks or adjustment of surface tension for better wetting behaviour of paints. Due to the good wetting property, fluorinated surfactants are also used as additives in adhesives and glues. Some sectors of building industry directly incorporate fluoropolymers as a construction material.

Proposed restriction elements for PFHxA and related substances for building material

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:
(a) another substance, as a constituent,
(b) a mixture,
(c) an article
in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.
Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.
Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

Compared with other wetting agents, such as silicones, PFASs are more effective in reducing surface tension which ultimately improves paint adhesion. It is primarily in water-based paints where these properties are required. Here, PFASs can be present at concentrations of about one percent. However, this figure is unreliable; in most cases there may be concentrations around 0.05 percent (European Chemicals Agency, 2018a).

Suppliers in the paint industry are of the opinion that surface-active fluorinated substances are generally significantly more expensive than alternative surface-active substances. They are therefore used only if such a low surface tension is required that this cannot be achieved with a fluorine-free alternative (UNEP, 2013).

The Swedish Chemicals Agency investigated a number of polymers and polymer appearing in raw materials in inventoried databases of paints and adhesives (Swedish Chemicals Agency, 2015b). These include perfluorinated and polyfluorinated (meth)acryl polymers, as well as several complex compounded side-chain fluorinated polymers (copolymers) which have not been categorized. Relevant for this restriction proposal are the following raw materials: silicones /siloxanes (C2-14), alkylammonium compounds (C4-7) and a smaller number of alkyl thiols (C4-20), phosphorus compounds (C6), (meth)acrylates (C6). Poly /perfluorinated (meth)acryl polymers (C-16), polyfluorinated silicones /siloxanes (C6-14), and poly /perfluorinated alkyl alcohols (C8-14) are used on the global market for printing inks.

On behalf of the German Environment Agency various building materials were investigated for per- and polyfluoroalkyl substances (Janousek et al., 2019; Knepper and Janousek, 2019). Prior to the analysis of the building materials a literature research on the use of PFASs in building materials was carried out. PFASs are used in coatings to achieve water, oil or dirt repellent properties and protect building materials from weather influence. Fluorinated surfactants can yield in higher stability or resilience of foams for the formation of low-density concrete building blocks or adjustment of surface tension for better wetting behaviour of paints. Due to the good wetting property, fluorinated surfactants are also used as additives in adhesives and glues (e.g. for production of derived timber products like oriented strand boards (OSB)). Some sectors of building industry directly incorporate fluoropolymers as a construction material. Application of polymers in building industry often involves ethylene tetrafluoroethylene (ETFE), which can be adopted for lightweight building shells (ETFE cushions), transparent roofing systems, greenhouses, covering of photovoltaic panels, or simply facade materials. Main superior properties of ETFE over glass or other conventional building materials are low dirt pick-up, corrosion protection, UV-light transparency, superior weight to surface ratio to glass builds, anti-fouling properties and long-lasting colour retention.

During the project selected building materials (total samples = 23) were analysed for various per- and polyfluorinated substances (e.g. PFHxA, 6:2 FTOH and 6:2 FTS). The samples included coatings, paints, lacquers, stain, foils (e.g. façade material), roofing material for flat roofs as well as sealants and glues. All samples were collected between October 2016 and August 2017 and have been analyzed as soon as possible. The following limits of quantification were determined: for 6:2 FTOH 40 µg/kg, for PFHxA and 6:2 FTS 2 µg/kg. C6 based PFASs were only detected in coatings (n= 3 of 4). Concentrations of PFHxA ranged from < 2 µg/kg to 360 µg/kg (aqueous and methanol extracts). 6:2 FTOH and 6:2 FTS were detected in one sample with a concentration of 1 700 µg/kg and 2.9 µg/kg respectively. Furthermore, 6:2 FTOH was detected in two further samples which had to be diluted. 6:2 FTOH concentrations were 520 mg/L and 4 300 mg/L. Due to high dilution factors, concentrations should be considered as approximative values. However, both, peak shape and retention time that were observed in dilutions matched standards. Nevertheless, since the used sample preparation technique was disadvantageous for volatile compounds, FTOH concentrations might be higher (Janousek et al., 2019; Knepper and Janousek, 2019).

Bečanová et al. investigated building materials including oriented strand board (OSB) and wood (n = 14), insulation materials (n = 16), mounting and sealant foam (n = 6), facade materials (n = 5), polystyrene (n = 5) and air conditioner components (n = 5) with the following resulting concentrations of PFHxA: OSB and wood: < 0.23 – 3.14 µg/kg (detected in twelve samples); insulation materials: < 0.23 – 5.79 µg/kg (detected in six samples). In all other samples PFHxA concentrations were below the limit of quantification of 0.23 µg/kg) (Bečanová et al., 2016).

During information collection one company reported the use of C6 fluorotelomer as oil and water repellent in special glass for construction (external glazing and interior decorative glass) as well as for the solar sector (Stakeholder Consultation, 2018). For water repellency the use of fluorine-free alternatives is possible.

The following further information regarding the use of PFHxA-related substances was submitted during Public Consultation:

One company mentioned the use of coated C6 fabric in reinforcement of roofing membranes to avoid any water absorption. Further information was not submitted.

The use of PFHxA-related substances for protection of surfaces and facades against water, molds, mosses, soil, solvents and oil-based stains (e.g. graffiti) was also mentioned in some comments. It was stated that the use of these substances leads to quicker cleaning as well as longer intervals between cleaning and painting intervals compared to fluorine-free alternatives.

Furthermore, C6 is used in non-woven fabrics for construction to bring weathering resistance. It was reported that C6 substances are not expected to be released during use.

Fluorinated polymers (not further specified) are used to make water- and oil-repellent penetrating sealers for natural stone, porous tile, grout and masonry. C6 fluorocarbons are used because of stain resistance, easy clean-up properties, hydro-repellence, protection from atmospheric agents, UV rays and pollutions.

Another use of C6 fluorinated substances is in textiles for flexible civil construction (e.g. flexible textile roofs or ceiling panels). It was mentioned that with fluorine-free alternatives a maximum dynamic water repellency and dirt repellency cannot be achieved and manufacture standards are failed to meet.

C6 fluorinated substances are also used in reinforcement fabric for wall plaster to ensure water and UV-resistant effects (e.g. for effective outdoor durability and low susceptibility). The company stated that no fluorine-free alternative is suitable for this use.

Economic Impacts:

The tonnage range for this application area is unknown. Sufficient information on specific uses is not available. But it is assumed that Coatings with fluorosurfactants especially are used outdoors. So, a direct release of perfluorinated surfactants from the sector building and construction into the environment is considered as very likely in significant amounts.

C4 or C6 PFAS have been introduced in this area as substitutes for the formerly used C8 substances. They are used in some special applications where water-based mixtures are intended to be applied to very non-porous surfaces like e.g. plastic films. Here the main function in the mixtures is the reduction of the water surface tension when the mixture is applied on nonporous substrates.

There is little data on the volumes of PFHxA-related substances used in paints. Comments from stakeholders indicate that short chain PFAS are still commonly used in paint applications (paints and varnishes). Suppliers in the paint industry commented that surface-active fluorinated substances are generally significantly more expensive than alternative surface-active substances. They are only used if a very low surface tension is required which cannot be achieved with a fluorine-free alternative (UNEP, 2013).

The concentration of the fluorinated substances in the paint can be up to 1 %, depending on the specific application. However, in most cases it is considered to be much lower, e.g. within the range of 0.05 %. There is little data on the volumes of PFHxA-related substances used in paint. Results from consultation for the preparation of the restriction proposal on PFOA with industry indicated that short-chain PFASs were already commonly used in paint applications. For that proposal it was estimated that PFOA-related substances were used (in 2015) in paints and inks within the range of 50 - 100 t/a within the EU. Considering that before the phase-out of PFOA, C6 substances were already in use and having received also information from industry that PFOA-related substances were substituted in the meantime at least partially with C6-substances, the Dossier Submitter estimates the same amount of use for PFHxA-related substances for the purpose of this restriction proposal: within the range of 50-100 t/a. This estimate is highly uncertain.

One company reported the use of C6 fluorotelomer as oil and water repellent in special glass for construction (external glazing and interior decorative glass) as well as for the solar sector.

For water repellency the use of fluorine-free alternatives is possible.

Considering that fluorinated substances are more expensive fluorine-free alternatives would be cost effective and available if only the water-repellent properties are needed and considered.

Stakeholders submitted information that dirt and oil repellent properties have considerable benefits: longer useful lifetime, lower repairing interval, reduced paint waste from recoat preparation. It might also be possible that the protective properties of anticorrosive paints can be enhanced by perfluorinated urethanes. No information is available on the magnitude of such effects. But it is possible that some uses would be affected considerably, for example maintenance intervals of constructions where maintenance and refurbishing is difficult in general. Stakeholders commented in the public consultation in this regard. The information provided was not sufficient to draw any conclusions.

As stated above several other stakeholders commented on various applications in the construction sector. However, no stakeholder provided sufficient information as a basis to calculate the impacts of a restriction.

Without further information the Dossier Submitter proposes a restriction on PFHxA-related substances in building materials. Benefits include lower-priced products and cessation of direct emissions into the environment from outdoor applications. However, costs might be considerable as well, when dirt and oil repellent properties are missing.

E.2.7 Photographic applications

E.7.1 Overview

C6-based fluorinated surfactants are used in small tonnages in photographic equipment or in coatings when manufacturing conventional photographic films (Stakeholder Consultation, 2018). These substances are applied for coating printing plates, coating of photographic layers for various applications (e.g. for medical applications) and for production of conductive screen inks and coating formulations. In these applications the substances are used as surfactants, as static control agents, as dirt repellents during coating operations and as friction control agents.

C6-based fluorinated surfactants are used in larger quantities for inkjet media coatings. The substances are applied to make the PE-coated paper more ink receptive and the coating evenly spread across.

Proposed restriction elements for PFHxA and related substances for photographic applications

Shall not be manufactured, used or placed on the market as substances on their own;

Shall not be used in the production of or placed on the market in or used in:

(a) another substance, as a constituent,

(b) a mixture,

(c) an article

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.

Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.

Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

Paragraphs 1 and 2 shall not apply to photographic coatings applied to films, papers, printing plates and inkjet photo media coatings until five years after entry into force of the restriction.

Paragraphs 1 and 2 shall not apply to inkjet photo media coatings until five years after entry into force of the restriction.

E2.7.2 Use and function

In the draft report on the assessment of alternatives to perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride (UNEP, 2018a) no C6 based fluorinated surfactants are mentioned as alternative for PFOS in the photo imaging sector. However, I&P Europe indicated that detailed information on alternatives in imaging products cannot be provided because it is considered as confidential business information. I&P Europe indicated that the search towards alternatives for C8 based substances typically involved a "preferred replacement hierarchy" favouring non-fluorinated hydrocarbon alternatives, followed by non-perfluorinated substances, further followed by per-fluorinated substances with shorter chain lengths (C3 or C4).

During stakeholder consultation it was commented that for some specific applications suitable non-fluorinated alternatives have not been found. Substances to be used in photographic applications require specific properties, e.g. lack photoactivity or colloidal stability (Stakeholder Consultation, 2018).

Nevertheless, at thirteenth meeting of the Persistent Organic Pollutants Review Committee (POPRC.13), representatives of the European photographic industry provided information that for specific photographic applications (photographic coatings applied to paper and for use in printing plates) non-fluorinated alternatives and the move to digital imaging have successfully replaced the use of PFOA and PFOA-related substances. These alternatives and alternative techniques should also be useable for the applications with C6-based fluorinated surfactants (UNEP, 2018b).

During Public Consultation representatives of the European photographic industry mentioned that PFHxA-related substances are still used in photographic coatings in some printing plates. PFHxA-related substances are used as an alternative of the C8 based substances but research to replace PFHxA-related substances is ongoing.

Stakeholders also asked for a derogation for the coating of photographic paper and provided confidential information on the technical function provided by PFHxA related substances and the related used quantities. This information was taken into account by the Dossier Submitter in their analysis and conclusions regarding derogations. .

Another stakeholder requested a longer transition period for coated inkjet photo papers to find, test and implement a non-fluorinated alternative. The stakeholder provided details on the reasons why short-chain perfluorinated surfactant (e.g. PFHxA-related substance) are used in certain water-based inkjet media coatings.

E2.7.3 Baseline

The exact amount of the fluorinated surfactants used in photographic coatings applied to films, papers, plates and inkjet photo media coatings and the release rates at manufacturing and throughout the life cycle are unknown. However, due to small used tonnage in this sector the release of PFHxA and its related substances is considered as very low. Stakeholder information from the public consultation suggests small used tonnages for photographic paper. The Dossier Submitter does not fully understand whether the stakeholder is the only manufacturer for this application for the whole EU-market. However, even if there are other manufacturers, emissions still should be very small.

For inkjet photo media coatings, one stakeholder reported confidential information on their use of PFHxA-related substances. Based on this information, the Dossier Submitter assumes that total use quantity for this use in the EU is <10 t/a. Considering the missing information the Dossier Submitter is not able to calculate a reliable baseline for emissions from this use. However, he assumes that the resulting emissions from this use would be <10kg/a when only indoor uses are considered. Outdoor uses might be possible, e.g. when printed posters are placed outside. Therefore, resulting emissions might be >10 kg/a, but <100 kg/a.

This rough estimate is very uncertain as data on use quantities is only available for one manufacturer. Use quantities, if any, for other manufacturers are unknown. No information is available on the exact use of the paper, e.g. how much is used for professional and private applications, indoor/outdoor use, etc.

E2.7.4 Alternatives

According to information received during the consultation for the PFOA restriction proposal remaining products for traditional photographic applications are mainly used by professional or hobby photographers, in medical or defence applications. Digital techniques will completely replace traditional photographic film within the coming ten years (information from 2015).

The stakeholder who asked for a derogation for inkjet photo media provided confidential information on their search for alternatives and concluded that it would not be possible to substitute within the 18 months transitional period.

E2.7.5 Economic and other impacts, uncertainties

As mentioned, remaining products are mainly used by professional or hobby photographers, in medical or defence applications. Digital techniques will completely replace traditional photographic film within the coming ten years. Owing to this strongly decreasing market demand and the significant investment that would be needed to switch to alternatives (0.5 - 1 million € for a single photographic material), it is likely that the manufacture of the photographic film could cease in response to the proposed restriction. It is reasonable to assume that cost would be high compared to the volumes of PFHxA and PFHxA-related substances used given the probability that no traditional photographic film might be available to consumers /downstream users anymore. The Dossier Submitter assumes that this business will phase out within the next years. Therefore, an exemption for five years after entry into force of the restriction is justified after which no more production is expected anyway.

For inkjet photo media it is estimated that inkjet photo media products are used by a large number of large format printers in print shops and home printers in Europe. One Stakeholder claims that premature obsolescence of these products would impact the ability of these small businesses and consumers to produce photo quality prints.

Based on information available the Dossier Submitter assumes that a restriction would not result in any direct cost to manufacturers or users. Manufacturers would produce without PFHxA-related substances resulting in articles with small repellences, cracks, and visual defects in the coating and consequently in photo prints with impaired visual quality. The Dossier Submitter has no information on how this functional loss impacts professional users or private users.

Considering the assumption that emissions will be comparatively small and that the derogation will be time-limited a derogation for five years is proposed. However, impacts are very poorly understood. Therefore, it is very uncertain whether this derogation would be justified.

E.2.8 Fragrance and flavour industries

During the public consultation regarding the SVHC-dossier for PFHxA, it was noted that PFHxA, its salts and related substances may be in use in fragrance and flavour industries. Fragrances are one of the key factors in consumer preference of cosmetic, home care or personal care products. In the past few decades, beside natural-, synthetic fragrance compounds have become ubiquitous components of consumer products. Fragrances are mostly apolar molecules with low water solubility and in the absence of substantial amounts of cosolvents such as ethanol, surfactants are needed to solubilize them in water-based applications. At equilibrium the solutes are distributed between the aqueous phase and the hydrophobic pseudo-phase formed by the micelles, respectively (Fieber et al., 2018). Microencapsulation has been widely used to encapsulate various core materials to protect them from the outside environment and provide long-lasting releases in the use of the products. Perfume oil, as an odour supplier is encapsulated to form perfume oil-filled microcapsules. These capsules have to be resistant against to several chemicals, like those essential oils containing high active unsaturated bonds on the structure such as clove oil, Litsea cubeba oil and lemongrass oil. Further, emulsifiers are necessary to stabilize oil droplets (He et al., 2018). Products made by PFHxA, its salts and related substances have properties that are necessary for handling of fragrance and odour compounds in products and articles, such as they are surface-active and inert to different chemicals. However, the use of PFHxA, its salts and related substances in this field of use is not clear so far.

E.2.9 Mixtures for Consumer Use

E.2.9.1 Overview

PFAS are used in various mixtures intended for end-use by consumers. These include impregnating agents, ski or floor wax, cleaning products, car care and polishes (Jensen et al., 2008; KEMI, 2015; Knepper et al., 2014; Posner et al., 2013). Only limited information is available regarding the use of PFHxA-related substances in these products. However, information is available that suggests availability of alternatives.

Proposed restriction elements for PFHxA and related substances in mixtures for consumer use.

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:
- (a) another substance, as a constituent,
- (b) a mixture,
- (c) an article

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.
Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.
Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

E.2.9.2 Concentrations of PFHxA and related substances in consumer mixtures

PFAS are used in various mixtures intended for end-use by consumers. These include (water)proofing agents, ski or floor wax, cleaning products, car care and polishes (Jensen et al., 2008; KEMI, 2015; Knepper et al., 2014; Posner et al., 2013). Some sources indicate a use of potential PFHxA-related substances in relevant products. For example, 6:2 fluorotelomer silanes or siloxanes (e.g. CAS No 51851-37-7 and 85857-17-6) are known to be used in nanofilm spray products on surface coatings with non-stick properties, which are applied to surfaces such as bathroom tiles, floors, windows and textiles (Kjølholt et al., 2015; NICNAS, 2016; Wang et al., 2013). According to the restriction proposal for TFDA's[18] in consumer products for spray application (RAC/SEAC, 2017), the *"…parent TDFAs will most likely predominantly [be] degraded/transformed to PFHxA".*

While the composition of the mixtures for consumer use (hereafter referred to as "consumer mixtures") is difficult to uncover due to lack of information in SDS and due to business confidentiality (BfR, 2014; Knepper et al., 2014), several studies have analysed the composition and contents of PFAS in these products. Historically, these investigations focused on PFOA, PFOS and potential related substances; however, several authors also reported on shorter chain PFAS content in consumer mixtures.

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[18] (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol tri-O-(alkyl) derivatives

For this restriction proposal the openly available literature was evaluated for reported levels of PFHxA in consumer mixtures.

The literature search included the keywords "perfluoroalkyl", "PFAS" and "perfluorohexanoic acid" /"PFHxA" in combination with relevant products as "impregnating agents", "waterproofing agents", "paints" and "consumer products" in general. The retrieved sources were manually filtered for relevance for this restriction proposal. The evaluation also included likely PFHxA-related substances (see section B.1.1). Among those, only 6:2 FTOH was reported in the available sources.

Herzke et al. (Herzke et al., 2012; Herzke et al., 2009) analyzed consumer products and preparations collected in Norway with supplemental samples from Sweden. A number of per- and polyfluorinated substances was analysed. PFHxA was found in two of five waterproofing agents and lubricants (23 and 25.6 µg/L), 6:2 FTOH in three of these products (523, 1 750 and 13 250 µg/L). In the three paints analysed, neither PFHxA nor 6:2 FTOH was found.

Fiedler et al. (2010) investigated impregnating agents, cleaning agents, lubricants /corrosion prevention agents, "conditioners" for wood or leather and other products. All products were sprays produced for private households and were samples from the German market (except one product from Brazil). Fluorotelomer alcohol 6:2 FTOH was detected in four of nine impregnating agents (max value 2.1 µg/mL) and two of four cleaning agents (72 and 148 µg/mL), PFHxA was not reported.

In a project regarding proofing products and technology, Knepper (Knepper et al., 2014) investigated five consumer impregnating agents. In two of five products PFHxA (0.1 and 0.13 µg/mL) and 6:2 FTOH (16.4 and 225 µg/mL) were found.

In a work by Liu et al. (2014b) investigating the increase or decrease of PFCAs in US household products a number of relevant liquid products was investigated. Including earlier results (Guo et al., 2009) in products purchased from 2007 - 2011 PFHxA was found in six of 13 carpets and fabric care liquids /foams (18.9 – 195 ng/g) and in four of eight "floor waxes and stone/wood sealants" (7.19 – 1 540 ng/g). In another study published by Liu and co-workers (Liu et al., 2015a) 6:2 FTOH was found in two of three carpet and fabric care liquids /foams (3 280 and 105 000 ng/g) and in one of five "floor waxes and stone/wood sealants" (754 ng/g).

In a study aiming at gathering more information on the use and the incidence of per- and polyfluorinated substances in every-day consumer products, Blom and Hanssen (2015) focused on shorter chain length polyfluorinated substances. While PFHxA was not detected, 6:2 FTOH was found in seven products from different categories (50 – 100 % of tested products) with concentrations of 0.114 mg/L (lubricant) to 0.741 mg/L (glider /glide wax for skis). In addition, the phosphate esters 6:2 PAP and 6:2 diPAP were included in the analysis but were not detected in the consumer mixtures.

Kotthoff and co-workers analysed a number of consumer mixtures purchased in Germany for different PFCA and FTOH (Kotthoff et al., 2015b). Three "Nanosprays" and impregnating sprays were investigated for PFHxA (max. 14.1 µg/kg, median 6.9 µg/kg) and 13 for 6:2 FTOH (max 440 000 µg/kg, median 1 900 µg/kg). In addition, 13 ski waxes were analysed for PFHxA (max. 1 737.1 µg/kg, median 17.9 µg/kg).

Borg and Ivarsson (2017) have focused on relevant consumer product types identified in the study from Blom and Hanssen (2015). The products were randomly selected from a number of Swedish retail stores. In several product types, including e.g. car wax, PFHxA and FTOH could be detected and quantified (PFHxA: 6/12 samples, 0.54 - 5.6 µg/L; 6:2 FTOH: 4/12 samples, 1 834 – 120 300 µg/L).

In a work including a relatively large number of samples Favreau et al. (2017) have reported on PFHxA in 7/60 proofing products (0.1 – 0.6 mg/kg, average 0.3 mg/kg). No PFHxA was reported in cleansers (n = 24), polishes (n = 18) or other products (n = 23). In the same study 6:2 FTOH was quantified in 30 impregnating agents (2 - 1 840 mg/kg, average: 194; median 2 mg/kg), in one cleanser (4 mg/kg) and one polish (26 mg/kg).

The available results, recalculated to µg/kg and µg/L respectively, are given in Table 35.

Table 35: Reported concentrations of PFHxA and 6:2 FTOH in consumer mixtures.

Reference	Products	PFHxA					6:2 FTOH				
		N	**Detects**	**Max.**	**Min.**	**Median**	**N**	**Detects**	**Max.**	**Min.**	**Median**
Favreau 2017			LOQ 0.5 ng/mL	**µg/kg**				LOQ 10 ng/mL	**µg/kg**		
	impregnation products	60	7	600	100	(300 "average")	60	30	1 840 000	2 000	(194 000 "average")
	cleansers	24	0	-	-	-	24	1	4 000	-	-
	polishes	18	0	-	-	-	18	1	26 000	-	-
	others	23	2	0.4	0.2	-	23	0	-	-	-
Borg 2017			LOD /LOQ not rep.	**µg/L**				LOD /LOQ not rep.	**µg/L**		
	rinse aid	2	0	-	-	-	2	0	-	-	-
	waterproof shoe treatment	2	1	2.5	-	-	2	1	120 300	-	-
	waterproof textile treatment	2	2	3.6	2.3	-	2	1	43 070	-	-

	waterproof textile /leather treatment	1	0	-	-	-	1	1	12 340	-	-
	shoe wax	1	1	4.7	-	-	1	0	-	-	-
	floor polish	1	1	5.3	-	-	1	1	1 834	-	-
	furniture polish	1	0	-	-	-	1	0	-	-	-
	car wax	2	1	0.54	-	-	2	0	-	-	-
Liu 2015								LOD 331 µg/g	**µg/kg**		
	carpet care liquid	n.a.	-	-	-	-	3	2	105 000	3 280	-
	household carpet /fabric-care liquids and foams	n.a.	-	-	-	-	2	0	-	-	-
	floor waxes and stone /wood sealants	n.a.	-	-	-	-	5	1	754	-	-

Kotthoff 2015			LOQ 0.5 μg/kg	**μg/kg**				LOQ up to 20 000 μg/kg	**μg/kg**		
	cleaning agents	6	0	-	-	-	3	n.r.	38 700	n.r.	3 800
	nanosprays and Impregnating sprays	3	n.r.	14.1	n.r.	6.9	13	n.r.	440 000	n.r.	1 900
	ski waxes	13	n.r.	1 737.1	n.r.	17.9	0	-	-	-	-
	wood glue	1	0	-	-	-	0	-	-	-	-
Bloom 2015			LOD 0.1 μg/L	**μg/L**				LOD 0.0001 μg/L	**μg/L**		
	car polish	2	0	-	-	-	2	1	263	-	-
	dishwasher liquid	2	0	-	-	-	2	1	391	-	-
	waterproofing product, shoes	2	0	-	-	-	2	1	2 410	-	-
	waterproofing product, textiles	2	0	-	-	-	2	1	259 000	-	-

			LOD 0.1 µg/kg	**µg/kg**				LOD 0.0001 µg/kg	**µg/kg**		
	glider for skis	1 to 2	0	-	-	-	1 to 2	1	741	-	-
	ski wax	1	0	-	-	-	1	1	623	-	-
	lubricant for bicycles	1	0	-	-	-	1	1	114	-	-
Liu 2014				**µg/kg**							
	household carpet /fabric-care liquids and foams	13	6	195	18.9	0	n. a.	-	-	-	-
	floor waxes and stone /wood sealants	8	4	48.3	15.3	21.4	n. a.	-	-	-	-
Knepper 2014			LOD 0.001 µg/mL	**µg/L**				LOD 0.01 µg/mL	**µg/L**		
	impregnation agents	5	2	130	100	-	5	2	225 000	16 400	

Herzke 2012, Herzke 2009			LOD /LOQ not rep.	**µg/L**				LOD/LOQ not rep.	**µg/L**		
	waterproofing agents	5	2	25.6	23	-	5	3	13 250	535	1 750*
	paint	3	0	-	-	-	3	0	-	-	-
Fiedler 2010				**µg/L**				LOQ 0.3 µg/mL	**µg/L**		
	impregnating agents	n. a.	-	-	-	-	9	4	2 100	600	1 250*
	conditioners for wood and leather	n. a.	-	-	-	-	4	0	-	-	-
	lubricants /corrosion inhibition agents	n. a.	-	-	-	-	4	2	148	72	-
	cleaning agents	n. a.	-	-	-	-	6	0	-	-	-

n.a.: not analysed; n.r.: not reported; LOD: limit of detection; LOQ: limit of quantification

Uncertainty:

The overall number of data on PFHxA contents in mixtures for consumer use is very limited compared to the number of products on the European market that, due to their function, could potentially contain PFHxA. The available studies report PFHxA in various product types, with the highest concentrations found in ski waxes and in proofing products.

While the studies focused on products where PFAS can be expected due to their function, the number of samples for a single product type was below 20, and the number of detects within these samples was even smaller (up to 7). Robust statistical distributions cannot be derived on this basis and even the maximum values found may not represent realistic worst cases.

In addition, the reported studies differ in their sampling strategies and analytical methods. This makes it difficult to compare their results. The reported concentrations range over four orders of magnitude. This may be the result of analytical difficulties or the diversity of the samples.

Taken to together the differences between the samples, the low number of samples with comparable product types and methods, and the lack of data for many products and countries, the database seems to be explorative, giving indications on orders of magnitude rather than the present distributions of PFHxA concentrations in European consumer products. Due to the ongoing changes in PFAS uses, it is not possible to deduce future concentrations of PFHxA in consumer products from these data.

E.2.9.3 Baseline

Information on current and future uses of PFHxA-related substances in mixtures for consumer use is highly uncertain.

Currently, the Dossier Submitter can only refer to uncertain and incomplete information regarding the market for mixtures for consumer use. The studies that are summarized in Annex ‘E.2.9 Mixtures for Consumer Use’ suggest that products are available with and without shorter chain PFAS content. Publicly available information (e.g. from Nordic ecolabel certification “Nordic Swan”) indicates that fluorinated as well as fluorine-free products are available to consumers for impregnating agents, ski or floor wax, cleaning products, car care and polishes. It remains unclear what the respective market-shares are and whether quantities will change in the future.

From the scarce information available it can only be assumed that use quantities and emissions are not negligible. The only respondent in the Dossier Submitter’s stakeholder consultation is present on the majority of the European markets but has no dominant market share.

Regarding emissions the DS assumes that a large share of quantities used will be emitted into the environment.

E.2.9.4 Uses, functions and alternatives

Additional information regarding specific uses and functions is not available. The manufacturer who responded indicates that substitution of fluorinated substances, technically and economically, is possible but would require some efforts. The area where they think that substitution could be possible the easiest is the impregnation of leather and textiles.

Publicly available information also suggests that alternatives are already available. A broad range of fluorine-free impregnating agents, ski and floor waxes and cleaning agents are on the market. There also seem to be manufacturers producing both fluorinated and fluorine-free products.

E.2.9.5 Economic and other impacts

Information on current and future use of PFHxA-related substances in mixtures for consumer use is highly uncertain. No information on quantities produced within and outside the EU could be uncovered. Only one manufacturer in the field took the opportunity to present information on uses of PFHxA and related substances. The manufacturer produces under established brand names cleaning and care products for private consumers as well as bulk for professional building cleaning.

This company reported that it produces mixtures that contain or are produced with fluorinated substances as well as fluorine free alternative products. The production costs when fluorinated substances are used compared to their non-fluorinated alternatives, are "somewhat higher costs than fluorine free alternatives (11-25 %)".

Besides this information, the Dossier Submitter can only refer to publicly available information and to cursory market research on the availability of alternatives. This publicly available information indicates that fluorinated as well as fluorine-free products are available to consumers for impregnating agents, ski or floor wax, cleaning products, car care and polishes. Fluorinated and non-fluorinated products are generally in a comparable price range. Several manufacturers produce fluorinated products as well as non-fluorinated alternatives. It is unknown what the respective market-shares are and if quantities will change in the future.

According to an older study from Kemi (Swedish Chemicals Agency, 2006) cleaning products, polishes and other mixtures for consumer use are widely used and are directly released into wastewater and water purification plants. They argue that in spite of the low concentrations used in products, emissions to the environment can be significant.

Fluorinated compounds are not added to the products for their cleaning characteristics but because they provide good spreading properties and an even surface (Swedish Chemicals Agency, 2006).

Additional information regarding specific uses and functions is not available.

Direct economic impacts for manufacturers and consumers are expected to be low. Alternatives seem to be available on the market from a number of manufacturers. As mentioned above, one stakeholder reported that non-fluorinated alternatives are slightly less costly than fluorinated mixtures. This information is highly uncertain as it is based on information from one manufacturer only, who produces some of the products falling under the category of mixtures for consumer use.

Impacts resulting from reduced or lost functionality of the mixtures are possible. For example, fluorine-free impregnating agents and floor polish might be less effective in protecting textiles and floors against oil and grease stains leading to a reduced service life or a loss of consumer-friendly cleaning properties. Fluorine-free ski waxes are less effective in optimizing the sliding properties of skiers. Such impacts cannot be further qualified or quantified by the Dossier Submitter. But it is assumed that not monetarizing reduced functionality leads to an underestimation of substitution cost.

In absence of more detailed information the Dossier Submitter argues that a restriction on the use of PFHxA, its salts and related substances in mixtures for consumer use will be proportionate. Alternatives are most likely less costly and already available on the market. Emissions most likely will be directly released into soil and wastewater: However, information is scarce on the possible impacts of functional losses and in addition it is possible that the Dossier Submitter is unaware of important uses in specialized products. No additional information has been provided in the public consultation.

E.2.9.6 Cost-effectiveness, affordability and proportionality to risk

The Dossier Submitter expects the restriction to be cost-effective. Alternatives are available in a similar price-range and therefore no additional costs are expected.

The restriction therefore is affordable and proportionate to the risk. It might even be possible that manufacturers are in a position to manufacture less expensive when the costs for non-fluorinated substances are lower as indicated by one stakeholder.

E.2.9.7 Impact of different transitional periods

Alternatives are already available on the market. Transition should be possible in a short timeframe. Therefore, a longer transitional period has no effect on affordability.

E.2.9.8 Uncertainties and sensitivity analysis

No additional information was provided during the public consultation.

Most of the information presented on PFHxA in mixtures for consumer use is highly uncertain.

- Products with and without PFHxA-related substances are available on the market for mixtures for consumer use.
- Highly certain is that the available fluorine-free products are direct alternatives to fluorinated products.
- Information regarding the substitution cost is highly uncertain, especially with regard to products like car polish and ski waxes. It might be possible that at least some reformulation processes are costly.
- Information regarding quantities produced in Europe and imported quantities is not available.
- Emission quantities are unknown but non-negligible.
- Functional losses have not been considered for the discussion on cost-effectiveness.

E.2.10 Cosmetic Products

E.2.10.1 Overview

PFAS are used in various cosmetic products. PFHxA concentrations have been reported in concentrations up to 6 500 µg/kg. PFAS serve as emulsifiers and surfactants and are added to cosmetic products for binding, bulking and skin /hair conditioning purposes. Studies suggest that PFAS are used in higher concentrations only in some product groups. Market research indicates that PFAS-free alternatives are available for all cosmetic products.

Proposed restriction elements for PFHxA and related substances for cosmetic products

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:
- (a) another substance, as a constituent,
- (b) a mixture,
- (c) an article

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.
Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.
Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

E.2.10.2 Use and functions

A search of CosIng, a database hosted by the European Commission, identified more than 70 perfluorinated cosmetic ingredients. According to the database, substances like polyfluoroalkyl phosphonic acids (PAPs) serve as emulsifiers and surfactants. Other PFAS (e.g. perfluorinated polymers, ethers and esters) are added to cosmetic products for binding, bulking and skin /hair conditioning purposes. According to a recent study from the Danish Environmental Protection Agency, 0.7 % (78 out of 11108) cosmetic products had declared contents of fluoroalkyl substances or other fluorinated compounds (Brinch et al., 2018).

There are only a few studies aiming to determine the PFHxA content in cosmetic products, whereas no studies report on FTOH 6:2 concentrations. It is to note that product selection in all three studies focused on products with declared PFAS content. A recent study from the Danish EPA found PFHxA concentrations in 15 of 18 products, whereas a study conducted in Sweden detected PFHxA in ten of 31 products (Brinch et al., 2018; Schultes et al., 2018). An older study from Japan sampled cosmetic products in 2009 and 2011 (Fujii et al., 2013). In this study sunscreens were analyzed, too, and 18 of 23 products contained detectable levels of PFHxA. In all three studies high levels (> 1 mg/kg) of PFHxA were detected in foundations, which are leave-on applications with direct and prolonged skin contact. Thus, it is reasonable to assume that cosmetic products contribute to human exposure in some cases, when high PFHxA containing products are used on a daily basis. The exact origin of the detected PFHxA is not known; however, both impurities in and degradation products of intentionally added PFAS seem plausible explanations. Indeed, foundations with high PFHxA levels also contained more than 100-fold higher PAP concentrations in the Swedish study. In addition, there is no data on the stability of PFAS such as PAP during dermal application under real-life conditions involving solar UV light radiation, skin bacterial metabolism, and skin metabolism.

Table 36: Reported concentrations of PFHxA in cosmetic products.

Data source	**PFHxA**		**µg/kg**		
Brinch et al. (2018)[a]	samples (n)	positive samples	max.	min.	median
all products	18	15	3 340.0	n.d.	4.9
facial scrub	1	1	6.3	5.4	5.9
BB /CC creams	3	3	397.0	12.0	16.5
body lotions	2	2	24.0	4.5	14.2
cream /lotion	2	2	2.6	1.1	2.1
eyeliner	1	0	n.d.	n.d.	n.d.
foundations	4	3	3 340.0	n.d.	178.5
concealer	1	1	1 940.0	1 930.0	1 935.0
highlighter	1	1	18.0	17.0	17.5
hair spray	1	0	n.d.	n.d.	n.d.
powder	1	1	34.0	30.0	32.0
eye shadow	1	1	5.5	5.4	5.5
Schultes et al. (2018)					
all products	31	10	4 640	< 3.35	< 3.35
cremes	7	0			
foundations	9	4	4 640	< 3.35	< 3.35
pencil	1	0			
powders	12	6	447	< 3.35	3.62
shaving Creme	2	0			
Fujii et al. (2013)					

all products	23	18	6 500	< 1.9	350
foundations	9	8	2 100	< 1.9	410
manicure	3	3	140	4.7	24
lip rouge	2	0	< 5.7	< 3.8	
sunscreen (milk)[b]	6	5	6 500	< 4.6	2 800
sunscreen (foundations)	3	2	350	< 2.3	180

[a] two individual products were analyzed per sample
[b] four different lots of a specific sunscreen milk were analyzed

E.2.10.3 Baseline

No information on use quantities and emissions is available. The highest concentrations of PFAS have been found in foundations, concealers and sunscreen. Emissions from these uses are at least partly emitted directly into environment and wastewater.

E.2.10.4 Uses, functions and alternatives

Market research indicates that PFAS-free alternatives are available for all cosmetic products: Some large producers have announced a phase-out of all PFAS from their products: L'Oréal, H&M, Lumene, the Body Shop, Isadora and Kicks. L’Oréal announced in 2018 that the reformulation processes are completed for all their trademarks (Chemical Watch, 2018).

The Danish retailer Coop eliminated all cosmetics containing PFAS from their product range.

E.2.10.5 Economic and other impacts

No cosmetics producer submitted information during the stakeholder consultation. However, the phase-out activities by the mentioned companies suggest that affordable alternatives are available and functional losses of products are not to be expected. It can be assumed that alternatives are available for the whole scope of cosmetics on the market. For example, L’Oréal is the world’s largest cosmetics company and serving various market segments with different brands (e.g. mass, professional, luxury, and active cosmetics markets).

E.2.10.6 Cost-effectiveness, affordability and proportionality to risk

Cost effectiveness cannot be demonstrated due to the lack of data. However, the voluntary phase-out activities demonstrate that the transition to a PFAS-free production is affordable and therefore the Dossier Submitter proposes to restrict the use of PFHxA-related substances in cosmetic products.

E.2.10.7 Impact of different transitional periods

The Dossier Submitter has no information on possible impacts of a longer transitional period.

E.2.10.8 Uncertainties and sensitivity analysis

No additional information was submitted by stakeholders in the public consultation.

Uncertainties regarding functional losses are minor. The manufacturers that phase-out PFAS from their products serve large parts of the cosmetics market and have alternatives available for all their products.

Some uncertainties remain regarding the affordability of a restriction on PFHxA-related substances. Obviously, some large companies are in a position to reformulate their products at reasonable costs. However, according to information from the restriction proposals on microplastics and D4, D5 and D6 several participants on the cosmetic market are small and medium enterprises. No information is available how these companies would be affected by a restriction on PFHxA-related substances. Uncertainties remain on whether such companies are prepared to reformulate at affordable costs, i.e. whether scientific expertise and financial resources are always available to substitute their products without functional losses.

E.2.11 Textiles

E.2.11.1 Overview

Proposed restriction elements for PFHxA and related substances in mixtures for textiles

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:
(a) another substance, as a constituent,
(b) a mixture,
(c) an article
in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.
Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction
Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.
(a) Paragraphs 1 and 2 shall not apply to personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d),

(e), (f), (g), (h), (l) [19];
(b) High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3
(c) impregnation agents for re-impregnating of articles referred to in paragraph 9(b), (c), (g);
(d) textiles for the use in engine bays in the following usage groups: Automotive and aerospace industry

From (entry into force + 12 months), a natural or legal person placing a mixture or an article specified in paragraph 9(b)- 9(i) on the market for the first time and benefitting from the derogation therein shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing:
(a) the identity of the substance(s) used in the previous year;
(b) the quantity of PFHxA, its salts and PFHxA-related substances used in the previous year.

The European Chemicals Agency shall forward the data to the Commission by 31 March every year.

The occurrence of fluorotelomer alcohols (FTOHs) and PFCAs in textiles is (primarily) related to the DWR finishing that imparts water, oil and stain resistance to the textile. Textiles treated are apparel, personal protective equipment (PPE), technical textiles and home textiles. Some technical textiles, namely filters, membranes and non-woven and woven medical textiles will be discussed in the chapters on filtration and medical devices.

DWR finishing finds important application in functional clothing such as performance outdoor textiles, which provide weather protection and body moisture management to the wearer (Schellenberger et al., 2018). This is achieved by a multi-layered fabric system, in which a water-repellent outer fabric is combined with a waterproof breathable membrane inside (Figure 8 (A)).

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[19] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. Category III includes risks that may cause very serious consequences such as death or irreversible damage to health. The categories mentioned above relate to the following: III(a) substances and mixtures which are hazardous to health, III(c) harmful biological agents, III(d) ionising radiation, III(e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C, III(f) low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less.

E2.11.2 Use and functions

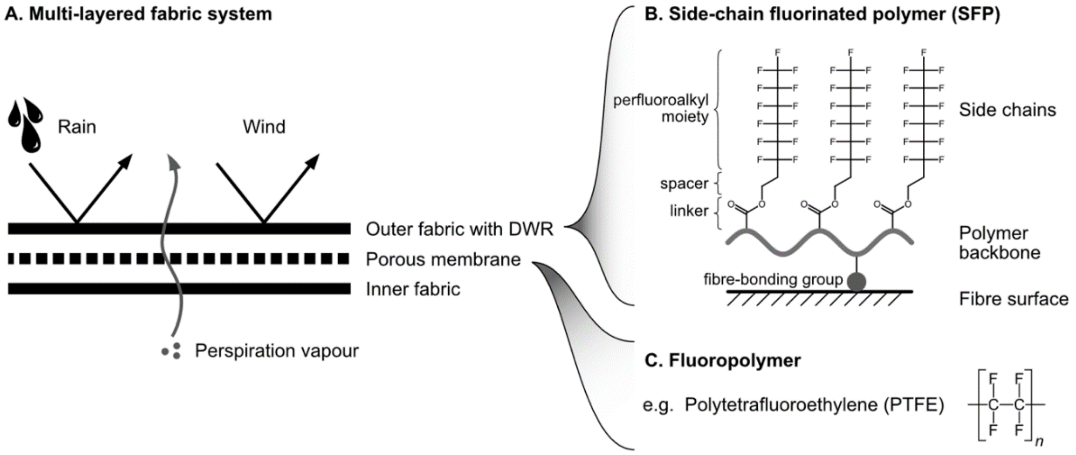

Figure 8: *Schematic representation of a multi-layered waterproof and breathable fabric used in performance outdoor textiles (A) as well as general structure of a side-chain fluorinated polymer (B) for durable water repellent (DWR) finishing and a fluoropolymer (C) for a vapour permeable porous membrane. Adapted from Holmquist et al. (2016).*

Both the DWR finishing and the breathable membrane can be made of fluoropolymers and SFPs (Figure 8 (C)).

Table 37: Reported concentrations of 6:2 FTOH and PFHxA in textiles. Values given as µg/m² were converted to µg/kg on the basis of 1 m² of fabric weight equals 100 g.

Data source	samples (n)	Positive samples	**µg/kg**			samples (n)	Positive samples	**µg/kg**		
Outdoor textiles										
			Max.	Min.	Median			Max.	Min.	Median
Santen and Kallee (2012)	**6:2 FTOH**	LOD/LOQ not rep				**PFHxA**	LOD/LOQ not rep			
outdoor clothing jackets (12) trousers (1) purchased 2012	13	jackets (6)	3 520	176		13	jackets (8)	32	3	
Brigden et al. (2016b)	**6:2 FTOH**	LOD/LOQ not rep				**PFHxA**	LOD/LOQ not rep			
Hiking & camping equipment purchased 2015	29	21				29	19			

jackets (11)		jackets (7)	4 600	270			jackets (8)	546	1.2	
trousers (8)		trousers (7)	1 500	400			trousers (6)	27.8	1.8	
footwear (7)		footwear (6)	1 300	470			footwear (4)	18.8	0.5	
sleeping bags (2)		sleeping bags (1)	1 100				sleeping bags (1)	18.6	n/a	
gloves (1)		gloves (0)		n/a			gloves (0)			
Kotthoff et al. (2015b)	**6:2 FTOH**	LOQ 0.3 - 0.8 µg/m^2				**PFHxA**	LOQ 0.5 µg/m^2			
outdoor textiles (5) purchased 2010	**4**	outdoor textiles (4)	158	65		19	outdoor textiles (3)	171		15
leather (13)							leather (13)	45		
gloves (3)		gloves (1)	90	82			gloves (3)	26		13
Borg and Ivarsson (2017)	**6:2 FTOH**	LOD/LOQ not rep				**PFHxA**	LOD/LOQ not rep			
jackets (6) purchased 2015	8	jacket (1)	1 405	<LOD		8	jacket (3)	11.6	0.33	
shoes (2)		shoes (0)	<LOD	<LOD			shoes (0)	<LOD	<LOD	

Lassen et al. (2015)	**6:2 FTOH**	LOD 0.6 µg/m^2				**PFHxA**	LOD 0.001 µg/m^2			
children's clothing snowsuits (5) purchased: not reported	15* (22)	snowsuits (3)	41	0.2			snowsuits (3)	9.9	0.0	
jacket (4)		jacket (1)	2.5	n/a			jacket (1)	0.5	n/a	
softshell suits (2)		softshell suits (1)	6.1	n/a			softshell suits (1)	32.6	n/a	
rain suits (4)		rain suits (3)	4.8	4.4			rain suits (3)	2.2	0.1	
gloves/mittens (3)		gloves/mittens (3)	830	17.3			gloves/mittens (3)	5.4	0.7	
infant sleeping bags (4)		infant sleeping bags (4)	61.9	8.3			infant sleeping bags (4)	2.5	0.0	
Knepper et al. (2014)	**6:2 FTOH**	LOQ 0.2 µg/m^2				**PFHxA**	LOQ 0.02 µg/m^2			
jackets purchased 2011-2012	16	2	186	< LOQ		16	13	147	0.1	

Gremmel et al. (2016)	**6:2 FTOH**					**PFHxA**				
jackets (15) purchased 2011-2012	11	< LOQ				13	13	147	0.1	
Dreyer et al. (2014)	**6:2 FTOH**	LOD/LOQ not rep				**PFHxA**	LOD/LOQ not rep			
outdoor jackets (14) purchased: not rep.	16	jackets (11)	8 500	~ 300		16	jackets (12)	120	2	
gloves (2)		gloves (2)	11 900	306			gloves (1)	12.5	2	
BVL (2018b)						**PFHxA**	LOD 1 µg/kg			
underwear purchased 2010–2014						48	48	60.9	1.5	4.3
outerwear						4	3	9.7	<LOD	2.3
gloves						5	2	3.7	<LOD	<LOD
other products						32	13	19.2	<LOD	<LOD

Other Textiles										
			Max.	Min.	Median			Max.	Min.	Median
Herzke et al. (2012)	**6:2 FTOH**	LOD/LOQ not rep				**PFHxA**	LOD/LOQ not rep			
carpet (2) purchased 2009	4	carpet (2)	2 200	170		carpet (1)	carpet (1)	11		
tablecloth (2)		tablecloth (2)	191	540						
Kotthoff et al. (2015b)	**6:2 FTOH**	LOQ 0.3 - 0.8 µg/m^2				**PFHxA**	LOQ 0.5 µg/m^2			
carpet (14) purchased 2010	8	8	21.2	?		6	2	0.8	<LOQ	<LOQ
Guo et al. (2009)	**6:2 FTOH**					**PFHxA**	LOD 0.05 µg/kg			
pre-treated carpet (9) purchased 2007/2008						23	3	224	<LOQ	<LOQ

treated home textiles and upholstery (14)							9	238	<LOQ	2.96
Vestergren et al. (2015)	**6:2 FTOH**	LOD 0.5 μg/m^2				**PFHxA**	LOD 0.005 μg/m^2			
furniture textiles (27) purchased 2012-2013	36	14	3 737	<LOD	5.50	36	10	8.12	<LOD	<LOD
carpets/mats (9)		6	744	<LOD	252.0		5	1.53	<LOD	0.14

On behalf of the German Environment Agency various industrial fabrics (total samples = 28) were investigated for per- and polyfluoroalkyl substances like PFHxA, 6:2 FTOH and 6:2 FTS (Janousek et al., 2019; Knepper and Janousek, 2019). The samples included seat covers (furniture upholstering, bus /train seat upholstering, car seat upholstering; n = 11), covers for truck trailers (n = 3), covers for maritime applications (e.g. boat cover, seat cover, bimini tops; n = 5), awnings and tarpaulins (e.g. marquee awning, party tent; n = 9). All samples were collected between October 2016 and August 2017 and have been analyzed as soon as possible. The following LOQs were determined: for 6:2 FTOH 40 µg/kg, for PFHxA and 6:2 FTS 2 µg/kg. PFHxA was found in one seat cover, two maritime covers and five marquee awnings. Concentrations of PFHxA ranged from 2.4 – 15 µg/kg (average 7.7 µg/kg) in aqueous extracts and 2.6 - 18 µg/kg (average 9.9 µg/kg). 6:2 FTOH was found in one seat cover, one tarpaulin for truck trailers, two maritime covers and three marquee awnings with concentrations ranging from 40 to 790 µg/kg (average 350 µg/kg). 6:2 FTS was not detected above the LOQ in any of the samples.

Technical textiles are mainly used in automotive and aerospace applications, as filtration media (see the separate chapter E.2.13.4), construction (see separate chapter E.2.6) and medical applications (see separate chapter E.2.13.6).

In vehicles like cars, trains, busses, aircrafts and marine vehicles, textiles are mostly used for interior trim (e.g. seating, carpets, trunk, side panels). Safety items (e.g. seat belts and air bags), engine bay items and filters are also manufactured with technical textiles.

Stakeholders (e.g. comment 2996) explained that textiles in the engine bay provide sound and heat isolation: PFAS are used as a part of the flame-retardant system to prevent the build-up of flammable deposits / liquids in the substrate's lattice. Without fluorocarbon the deposits of flammable materials can overload the flame-retardant properties of the substrate when ignited (comment 2996).

Outdoor technical textiles are e.g. canvas, awnings, tarps, tents, sails, rope, tarpaulins, sacks. PFAS are mainly used for the water, oil and dirt repellent properties.

Home textiles include e.g. carpets and rugs, curtains and blinds and textile-based coverings (European Commission DG Environment and European Chemicals Agency, 2020). PFAS are mainly used for the water and oil repellent properties.

E.2.11.3 Baseline

Information on relevant uses and their quantities in the textile sector is scarce. The Dossier Submitter obtained only some basic information: In 2015 approximately 6.4 million t of clothing (estimated range 4.8 -14.6 million t) were used in the EU of which approximately 75 percent were imported (Rijkswaterstaat, 2017). In addition, about 95 000 t professional apparel (76 000 – 194 000 t/a) 1.2 million t home textiles and 400 000 t technical textiles were placed on the market in Europe.

A recent report by European Commission – DG Environment ((European Commission DG Environment and European Chemicals Agency, 2020)) presents different numbers but – considering the very high uncertainties – is mostly in line with these estimates. The report mostly relies on PRODCOM data but the Dossier Submitter is not of the opinion that these numbers are more reliable than the data used here for risk assessment and socio-economic analysis. Data differs as follows:

Table 38: Use quantities in the background document and comparison with European Commission – DG Environment (2020).

Use	Background document – central estimate of tonnages	European Commission – DG Environment (2020) - Estimate of tonnages
(1) Home textiles	1 200 000	2 900 000
(2) Consumer apparel	6 400 000	5 150 000
(3) Professional apparel	95 000	190 000 (incl. 90 000 professional sports wear and footwear)
(4) Technical textiles	400 000	520 000
(5) Leather		720 000

Leather has not been considered separately by the Dossier Submitter. The one use with significantly different estimates is home textiles where it is possible that the estimates in the background document are significantly underestimated.

For 95 % of the on the European market available textiles production steps are outsourced abroad partially or even entirely. So, emissions of PFHxA, its salts and related substances via manufacture of textile fibres and fabrics are considered as very low in Europe. Otherwise, the abroad use and finally the content of the perfluorinated substances is difficult to predict (Greenpeace, 2012) but should be kept in mind when discussing proportionality of a restriction.

The Dossier Submitter estimates (see B.9.5 Textiles) that the use of PFAS remains constant in the future. Without a restriction, constant releases of PFHxA-related substances from textiles amount to 1 500 – 4 600 t/a. Accordingly, emissions over 20 years are expected to add up to 30 400 – 92 300 t. Additionally release of C6 related fluoropolymers and SFPs of approximately 300 – 810 t/a (5 900 – 16 100 t over 20 years) has to be considered. These numbers are highly uncertain.

Estimates for the releases from major sub-uses are as follows:

Table 39: Releases from use in textiles.

Subsector	**Release of C6 side-chain fluorinated polymers (min – max t/a)**	**Release of C6-related substances (min – max t/a)**
Clothing used in the EU	50 – 174	1 450 – 4 410
Professional apparel	2 – 5	23 – 59
Home textiles	6 – 18	50 – 140
Technical textiles	–13 - 25	0.2 – 0.5

E.2.11.4 Uses, functions and alternatives

To identify alternative technologies a literature search was performed. The focus was on coating technologies which allow fabrication of water-, oil- and dirt-repellent textiles and fabrics.

According to present knowledge, no alternatives allow an encompassing replacement with a performance of equivalent quality. Especially development of alternatives for properties such as oil and dirt repellency are challenging.

For DWR a progress in development of alternatives can be observed. Several chemical processes are available, which show comparable results for water repellency. An example is shown in Figure 10. In the field of industrial textiles, which are designed and produced for professional uses and have to withstand harsher conditions, limitations exist.

Information on durability of textiles faced with physical and chemical stress (e.g. rain, washing, abrasion) are scarce in the screened literature. Also, regarding the renewability of coatings, the stability and the wear comfort of textiles limited information are available. Furthermore, it cannot be determined whether the identified alternatives can be used in the same manner as the PFASs based substances for textiles, leather, carpets and impregnation sprays.

Information in more detail on coating technologies, processing chemicals and substance identity of *active ingredients*, are confidential and therefore not available.

Following technologies were identified (non-exhaustive list):

1. Paraffin-based repellent.
2. Silicon-based repellent.
3. Dendrimer-based repellent.
4. Polyurethane-based repellent.
5. Stearic acid – melamine repellent (melamine resin).
6. Stearamidomethylpyridinium chloride.
7. Nanomaterial-based repellent.

Some examples of fluorine-free DWR alternatives are shown in Figure 9.

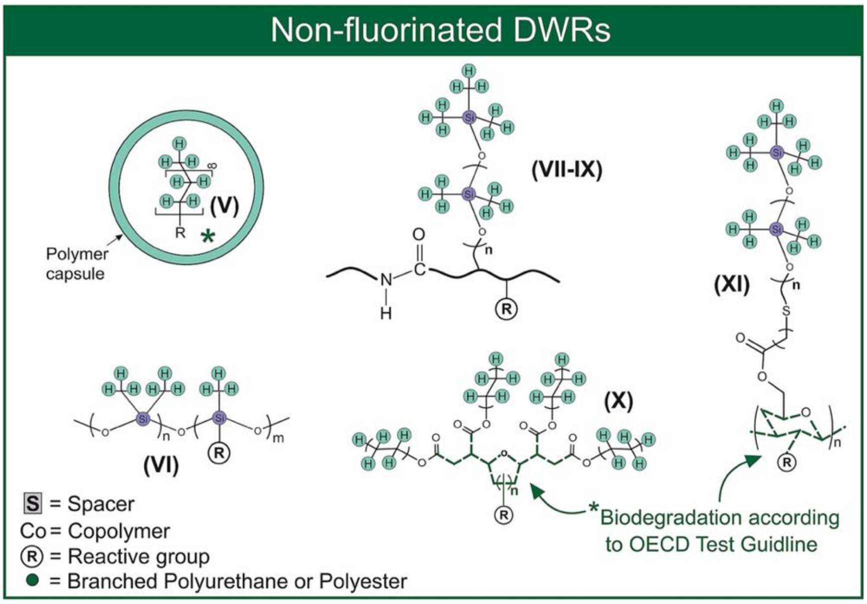

Figure 9: *Simplified structures of non-fluorinated durable water repellents (DWRs) (Schellenberger et al., 2019). The examples comprise an encapsulated wax-based polymer (V), a polymer based on polydimethylsiloxane (VI), silicone functionalized polyurethane (VII–IX), a fatty acid-modified saccharide (X), and a silicone-modified saccharide (XI). Licensed under Creative Commons Attribution-NonCommercial-No Derivatives License (CC BY NC ND).*

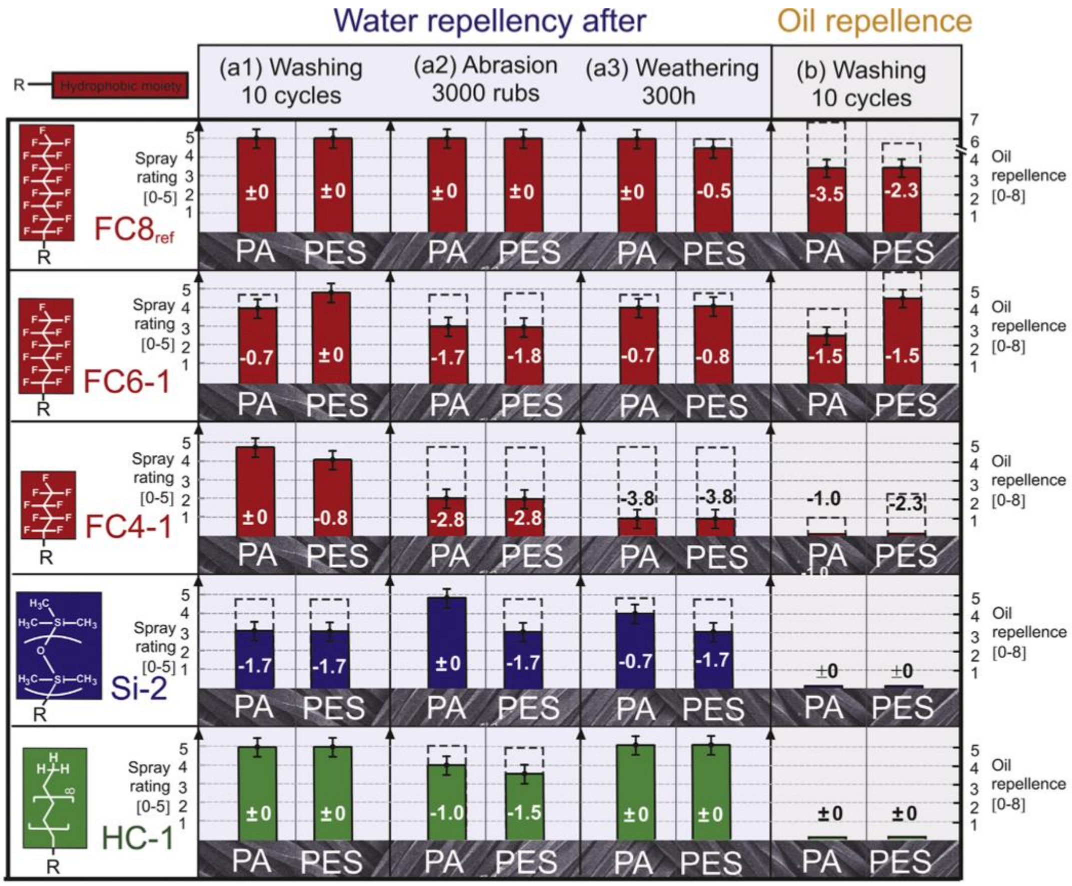

Figure 10: *Results of durability tests for fluorinated and non-fluorinated DWRs applied on polyamide (PA) and polyester (PES) fabrics (Schellenberger et al., 2018). The fluorinated DWRs comprised a C8-based side-chain fluorinated polymer (SFP) as reference (FC8$_{ref}$), C6- and C4-based SFPs (FC6-1, FC4-1), a silicone-based DRW, and an encapsulated wax-based polymer (HC-1). Water repellency was tested after ten washing cycles, abrasion tests and artificial weathering. Oil repellency was tested after ten washing cycles. Reprinted from Chemosphere, 193, S. Schellenberger,P. Gillgard,A. Stare,A. Hanning,O. Levenstam,S. Roos,I.T. Cousins, Facing the rain after the phase out: Performance evaluation of alternative fluorinated and non-fluorinated durable water repellents for outdoor fabrics, 675-684, Copyright (2018), with permission from Elsevier.*

According to a recent report (commissioned by European Commission – DG Environment, 2020, overview in Table 1) alternatives are available and already in use that provide good water repellency. These include alternative technologies (woven fabrics) and alternative substances. The report analyses alternatives according to chemical groups: Dendrimers, hybrids (silicon/carbon), hydrocarbons, nanotechnologies, polyurethanes, silicones and other alternatives without substance information available. Human health and environmental hazards and risks of most alternatives are according to the report not fully understood. Some alternatives might be problematic with regard to human health, ecotox or fate properties. However, according to the Commission report the properties of some substance groups (e.g. dendrimers, hydrocarbons) are most likely less hazardous than PFAS.

Alternatives to provide equivalent oil and dirt repellence properties are not available. The loss or reduction of these properties might induce a significantly reduced service life and increased cleaning efforts for home textiles (e.g. carpets, awnings, seating furniture), textiles used in automotive and aerospace sectors and other public places (e.g. seats and carpets). However, more specific information on impacts is not available.

E.2.11.5 Economic and other impacts

Apparel:

According to the consulted industry substitution is possible for water repellence. There is a general trend in the sportswear and outdoor industry to phase out PFAS-related substances and move to fluorine-free alternatives, due to increasing pressure from the public to phase out hazardous substances. This demonstrates that substitution is technically feasible. Alternatives are available that can be used without specific new investments (unchanged machinery). For applications, "where repellence against oil, alcohol and oil-based dirt is not required, the alternatives are considered to provide acceptable properties at costs at the same level as the costs of using the PFAS-based agents (MIDWOR-LIFE, 2017).

Limited information is available with a view to the costs of the alternatives. Industry information from the consultation and review of publicly available information suggests that treatment with non-fluorinated substances in general is not more expensive than with PFHxA-related substances. Additional information from publicly available resources indicates that the cost change when using non-fluorinated alternatives is negligible.[20]

Literature reviewed and experts interviewed by European Commission – DG Environment (2020a) confirm that alternatives might be similarly priced or are slightly more expensive. The purchasing costs for some alternatives are up to 50 percent lower. However, alternatives might use 30-50 percent more volume compared to C6-related chemicals (European Commission – DG Environment, 2020).

Considering the various applications and the confidentiality of price information, it was not possible to identify generalizable market prices. The Dossier Submitter concludes that alternatives might cost from 50 percent less to 30 percent more than PFHxA-related substances. The upper price range seems likely only for applications were very high water

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[20] See for example information provided by the company Levi-Strauss (2016): http://www.levistrauss.com/wp-content/uploads/2016/05/160311_Case-Story_Levi-Strauss_May252016final.pdf (last access: 13.04.2020). The company took steps "to eliminate short chain, C6, perfluorinated chemicals (PFCs) from its Commuter™ line of denim and non-denim apparel." Main results of this phase-out were described by the company as follows: a) it was concluded that the cost differential between the C6-related and the non-fluorinated substance was negligible; b) the alternative was able to meet the performance standards; c) The company successfully transitioned away from short chain PFCs to similar performance using PFC-free technology for its denim and non-denim apparel.

repellency is required. The cheaper alternatives most likely require considerably higher quantities (European Commission – DG Environment, 2020, overview in Table 5.22).

The Dossier Submitter estimates that industry might face slightly higher costs, albeit in an affordable range. Some non-fluorinated substances are cheaper and require higher loading and most are similar priced. Some uncertainty remains whether some applications require higher loading from similar priced alternatives to achieve the required performance. Stakeholders in the public consultation confirmed that prices of alternatives are similar and therefore affordable.

A minor uncertainty concerns required machinery and equipment alterations. Some companies transitioned to non-fluorinated alternatives and report that application methods are similar with only minor modifications (for example Levi-Strauss, see footnote 20). The report from European Commission – DG Environment (2020) confirms that application methods are very similar.

Reduced stain and oil repellence might lead to costs, mainly caused by a reduced service life, for example of textiles that are used in strongly frequented public places. But also, for apparel it is plausible to assume higher costs for textile cleaning and a reduced service life. The magnitude of the resulting costs is unknown. The Dossier Submitter is not aware of any studies that quantitatively substantiate claims of significant costs for apparel, home textiles or technical textiles resulting from reduced functionality. Hence, substitution costs will be underestimated when not considering the cost of functional losses. The magnitude, whether the effects are negligible or significant, is completely unknown. No additional information was provided in the public consultation.

Information from stakeholders suggests that increased reimpregnation frequency of textiles might lead to additional costs for end-users because PFAS-free finishing chemicals withstand household laundering much less. This could have implications which lead to more frequent replacement or re-impregnation of the goods by the user/consumer (European Commission – DG Environment, 2020).

Personal protective equipment:

Regulation (EU) 2016/425 of 9 March 2016 on personal protective equipment (the PPE regulation) defines PPE as (a) equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety; (b) interchangeable components for equipment referred to in point (a) which are essential for its protective function; (c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use.

Generally, the same considerations regarding cost apply to PPE and apparel. Costs of alternatives and C6 are comparable. Reduced stain and oil repellence might lead to costs, mainly caused by a reduced service-life and more frequent textile cleaning. However, some PPE protects against risks where reduced oil, dirt and soiling properties might endanger the needed protective function. In the medical sector repellency to bodily fluids is necessary to avoid the transmission of diseases. In other sectors (e.g. defence, firefighting, oil and gas industry) repellency towards non-polar stains is also part of the hazard management (Schellenberger et al., 2019).

The lack of these properties might lead to unacceptable health risks for certain groups, possibly leading to high societal costs. Therefore, derogations are proposed by the Dossier Submitter:

- Personal protective equipment intended to protect users against risks as specified in regulation (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l).[21]

Category III includes the risks that may cause very serious consequences such as death or irreversible damage to health. Only qualitative information is available on the probable effects of a restriction. Information submitted by stakeholders suggests that Cat. III(a), (c), (d), (e), (h), (l) are required for uses where water repellency is not sufficient to substantially mitigate the risks. No further quantitative information is available. According to information from the public consultation a derogation for Cat. III(g) is needed for belts and ropes where UV-resistance and strong resistance against weathering are important safety concerns. No further information on the availability of alternatives has been provided. Cat. III(f) includes the risks caused by very low-temperature environments. Stakeholders argue that maximum water-repellency is required to effectively protect the wearer from such risks. In absence of any further information the Dossier Submitter notes that he agrees with this argument in general. However, he also notes the risk that this derogation might become a legal loophole for uses where in his view no derogation is justified, e.g. seasonal clothing or sports clothing. No further information is available to better understand this risk.

An additional risk with regard to PPE is the visibility of a wearer in certain situations. One stakeholder explained (comment 3011): C6 based textile finishes protect workers along the roads and on the construction sites through a good visibility. These garments require oil repellent materials to not impair the fluorescent colour and luminance stains such as bitumen asphalt (sticky, black and highly viscous mixture of hydrocarbons). An impairment of the garment's fluorescent ability contributes to a greatly impaired visibility of workers, and thus an increased risk of accidents (especially at night). C6 based fluorocarbon treatments help to keep garments cleaner for a longer period of time which ultimately increases working safety.

Again, no quantitative information is available, but the Dossier Submitter agrees that soiling of high visibility PPE can impair the intended function severely. Therefore, a derogation is proposed for

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[21] REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. Category III includes risks that may cause very serious consequences such as death or irreversible damage to health. The categories mentioned above relate to the following: III(a) substances and mixtures which are hazardous to health, III(c) harmful biological agents, III(d) ionising radiation, III(e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C, III(f) low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less, III(g) falling from a height, III(h) electric shock and live working; III(l) bullet wounds or knife stabs;.

- High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3.

Class 3 high-visibility clothing is mandatory when visibility in the dark is required at traffic speeds up to 90 km/h. The norm stipulates minimum areas of visible material in m^2 for reflective tape, fluorescent material and contrast material.

Derogations for woven and non-woven medical textiles are discussed in the chapter on medical devices. Uncertainty remains regarding the necessity of the proposed exemptions. The Dossier Submitter has no information on actual risk reduction from using C6-treated textiles as PPE. Considering that the risks of equipment failure, need of early replacement and other unwanted consequences could be potentially high, precautionary use of textiles treated with PFHxA-related substances is justified as long as uncertainties with regard to the technical availability of alternatives are high.

Several other derogations for PPE have been proposed by stakeholders in the public consultation. A non-exhaustive list of requests has been provided with confidential comment 3133. The Dossier Submitter will not propose further derogations. In contrast to the proposed derogations there is no serious risk to be expected when alternatives are used. Not using C6-related substances might lead to functional losses comparable to those for apparel, i.e. shortened service-life or reduced ease of use might be possible. But in order to consider such costs the Dossier Submitter needs more evidence that they could be significant.

Technical textiles

Technical textiles are mainly used in automotive and aerospace applications, as filtration media (see the separate chapter), construction (see separate chapter) and medical applications (see separate chapter).

In vehicles like cars, trains, busses, aircrafts and marine vehicles textiles are mostly used for interior trim (e.g. seating, carpets, trunk, side panels). Safety items (e.g. seat belts and air bags), engine bay items and filters are also manufactured with technical textiles.

Stakeholders (e.g. comment 2996) explained that textiles in the engine bay provide sound and heat isolation: PFAS are used as a part of the flame-retardant system to prevent the build-up of flammable deposits / liquids in the substrate's lattice. Without fluorocarbon the deposits of flammable materials can overload the flame-retardant properties of the substrate when ignited (comment 2996).

Outdoor technical textiles are e.g. canvas, awnings, tarps, tents, sails, rope, tarpaulins, sacks. PFAS are mainly used for the water, oil and dirt repellent properties.

A derogation is proposed for certain textile uses in the automotive and aerospace sector. It has been reported that products are used for sound absorption, climate regulation within vehicles and reduction of fuel among other things. Stakeholder commenting in the public consultation was too generic to be able to determine the actual risks resulting from a restriction on the uses. However, in accordance with other derogation proposals for PPE the Dossier Submitter proposes a derogation with a view to the potentially life-saving functions the treatment with C6-related substances provides:

- Textiles for the use in engine bays in the following usage groups: Automotive and aerospace industry.

Also, in accordance with previous considerations no derogations are proposed for further transport-related uses. Not using C6-related substances might lead to functional losses, e.g. shortened service-life or reduced ease of use. But in order to consider such impacts the Dossier Submitter needs more evidence that they could be significant.

Home textiles, outdoor home textiles and awnings

In the public consultation derogations have been requested inter alia for the use in carpets and rugs, textile wall covers, upholstery, curtains and blinds, outdoor cushions and seating. Information provided did not demonstrate significant impacts from a restriction for these uses. Impacts cited include visual impairments and reduced service-life as a consequence of reduced dirt, oil and soil resistance. However, the significance of such impacts was not demonstrated.

Emission estimates resulting from the proposed automotive and aerospace derogations are not available. No further information is available on end-of-life treatment of the derogated articles. The Dossier Submitter notes that stakeholders proposed to ensure proper disposal of derogated articles via the EU Directive on End-of Life Vehicle 2000/53/EC.

Substitution costs

Owing to the vast number of textile and leather products and applications, in which PFHxA-related substances are used, it is not possible to give a robust estimate of substitution costs, which is representative for the entire industry. Therefore, the estimation below is considered to be an illustrative calculation only.

European Commission – DG Env (2020) reports regarding the cost of substitution: 'Regarding the effective price of alternatives, manufacturers of alternatives consider that the overall price is more or less the same. In some cases, the unit price of the fluorine-free alternatives that provide water repellency is lower but the amount required during application can be up to 50% more compared to the C6 technologies to achieve comparable water repellence[22].

It has been reported that water-repellent alternatives might cost from 50 % less to 30% more. Additional amounts of products that are needed are reported to be in the range 0 - 50%. Considering the high use quantities and the price of PFHxA-related substances a theoretically possible range of substitution costs from -7.6 billion – 10 billion € results.

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[22] However, there is uncertainty over what exact level of performance is really needed in some applications (whether it is the level currently provided by PFAS or it can also be lower).

However, based on the expert opinion quoted above the Dossier Submitter assumes that these large ranges and especially the extreme negative and positive values are misleading. The Dossier Submitter therefore expects that during application more product is required when using cheaper products. Non-fluorinated products in a similar price range as fluorinated products most probably do not require larger use quantities. In sum the cost of substitution will be negligible.

It was not possible to obtain specific price levels of the PFHxA-related substances and the respective alternatives. Hence, a general price range for PFHxA-related substances has been derived based on information provided in the background document to the Opinion on the Annex XV dossier proposing restrictions on PFOA, PFOA salts and PFOA-related substances (ECHA/SEAC/RES-O-0000006229-70-03/F).[23]

Considering the information available annual substitution costs of PFHxA-related substances in textile treatment are estimated as follows. The central estimates are derived as follows: 4.6 million t is minimum estimate for clothing used in EU. According to

EURATEX data 6.4 million is a best estimate. Therefore, all minimum data for general clothing have to be multiplied by factor 1.33 for the central estimate.

For professional apparel the DS has a best estimate of 95 000 t. Minimum estimate is 76 000 t. Therefore, a factor 1.25 has to be applied to the minimum estimates. For home and technical textiles, the DS assumes in absence of better information that the median of the range quoted is the central best estimate:
For home and technical textiles, we assumed in absence of better information that median of the range quoted is the central best estimate.

Table 40 illustrates the theoretically possible range of costs. However, as discussed above, expert opinion from stakeholders suggests that costs for treatment of textiles with C6-related and alternative substances are comparable.

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[23] Numbers provided in that document have not been challenged by stakeholders or SEAC and are therefore considered to be best estimates (inflation adjusted by 4 percent based on HCPI 01/2015 – 01/2019). In the restriction proposal for PFOA the price for PFOA-related substances was estimated to be in the range 20,000 – 80,000 € (central estimate 50,000 €). It was estimated that prices for short-chain PFAS alternatives are 0 – 20 percent higher (central estimate 10 percent). The estimates are highly uncertain and do not differentiate between different PFHxA-related alternatives (e.g. polyacrylates with C6 perfluorinated side-chains. 6:2 FTOH or polyfluoroalkyl phosphate esters).

Table 40: Substitution costs of PFHxA-related substances in textile treatment (central estimates in brackets)

Current Use	Volume t/a	Additional amount of product to be used	Cost increase per unit	Price of PFHxA-related substances 1,000 €/t	Substitution costs Million €
clothing used in the EU	45 360 – 137 970 (60 500)	0 – 50 %	-50 – 30 %	21 – 100	-6 900 – 8 970
professional apparel	720 – 1 830 (900)				-90 – 120
home textiles	3 840 – 11 130 (7 490)				-560 – 720
technical	1 350 – 2 600 (1 980)				-130 - 170
Sum	**51 270 – 153 540 (70 870)**				**-7 680 – 9 980**

A yearly reporting requirement has been proposed for the derogated uses. Information on the derogated use quantities is scarce and monitoring future use quantities will lead to sufficient information if further EU action is required. The costs associated with this requirement are expected to be affordable. Costs include:

- A one-time cost to develop the reporting format and software to submit and process the information for regulators;
- ongoing costs for industry to gather the required information and submit it annually.

The costs for industry are difficult to estimate as it would depend on the complexity of company structure and the number of products with reporting requirements. However, the Dossier Submitter notes that derogations are proposed for very specific applications where manufacturers already have to conform to certain norms (e.g. DIN EN). Technical knowledge on required PFAS-quantities to fulfil the required norm should be available within the supply chain. Manufacturers of impregnation agents for re-impregnation should also be able to provide the necessary information.

The one-time costs to ECHA are unlikely to exceed 50 000 €, especially when considering the possibility to develop the functionality under existing tools such as REACH-IT or Article 66 notifications. Considering the comparatively low costs for reporting requirements a yearly reporting is proportionate, providing detailed information for possible further actions.

In sum it is expected that costs related to the restriction proposal for textiles will mainly be direct substitution costs. The Dossier Submitter assumes that these costs are negligible considering various information that cost for alternatives and PFAS substances are comparably high. Uncertainties remain whether different product groups face different substitution costs, i.e. whether costs for e.g. apparel are considerably lower than for e.g. awnings.

A restriction on PFHxA, its salts and related substances for all textiles results in emissions reductions over 20 years of approximately 21 100 – 62 500 t, on average a reduction of 1 100 – 3 100 t/a. The central estimate results in emissions reductions of approximately 28836 t over 20 years or on average 1 440 t/a.

Information from the MIDWOR-project (see above) suggests that existing machinery can be used unchanged (MIDWOR-LIFE, 2017).

Some information from industry claims that certain functional properties will not be available for end-users any longer when articles (i.e. home textiles, apparel) are not treated with fluorinated substances. Especially the loss of stain and oil repellent properties might lead to higher cost for textile cleaning and a reduced service life for textiles. More frequent reimpregnation of articles might lead to additional cost. Further, stakeholders argued that reduced water-repellent properties lead to loss of comfort for example for outdoor home and technical textiles. However, the Dossier Submitter could not obtain generalizable information on economic effects of such performance losses. On the contrary, in a recent consumer survey on important purchasing factors to consumers of outdoor apparel, 'green' chemical use was three times more important as purchasing factor than stain resistance. The latter has been named as purchasing factor only by five percent of the survey respondents. 57 % of respondents did not consider repellency to oil, soil or dirt essential to the garment (Schellenberger et al., 2019). In a study on PFAS coatings in school uniforms in the United Kingdom, the author concludes that no reduction in wash frequency is associated with stain resistant finishes and that no reduction in purchase frequency is associated with stain resistant finishes (Dinsmore, 2018).Stakeholders commented that derogations are needed for home textiles that are mainly used outside as well as for awnings. However, water repellence can be provided by non-fluorinated alternatives and stakeholders did not provide reliable data if and how service life of their articles would be affected when oil and dirt repellence are reduced. They also failed to provide data on the availability of non-chemical alternative solutions, e.g. replaceable textile covers for chairs or cushions.

In summary there are indications that functional properties with regard to stain repellency are not valued as highly by consumers as is claimed by industry. An unknown number of consumers might even prefer not having to pay for these properties when buying new clothes. Nevertheless, the loss of stain and oil repellency leads to a reduced service life for some articles. The severity of this impact is unknown, but substitution costs will be underestimated when not considering the cost of functional losses.

E.2.11.6 Cost-effectiveness, affordability and proportionality to risk

Cost-effectiveness cannot be calculated quantitatively. The Dossier Submitter assumes that direct costs of substituting PFHxA-related substances with alternatives are negligible. The cost for machinery and equipment alterations will also be very low. Not considered in this estimate are costs for the reporting requirement, costs of functional losses, testing and other administrative costs. Functional losses are expected and their main economic input would be early replacements and loss of some user-friendly properties (e.g. easy-to-clean properties).

According to EURATEX, total household consumption for textiles and clothing amounted to 520 billion € in 2018. With approximately 15 – 20 percent additional consumption (mainly for industrial and technical textiles) by industry and governments total consumption in Europe for textiles and clothing amounts to at least 600 – 650 billion €. Not all articles are treated with PFHxA-related substances. Therefore, potential additional costs from this restriction might affect consumers and industry differently. However, overall for industry and consumers the costs from this restriction are affordable, with the central estimate being no price increase.

For sensitivity purposes it is assumed that 20% more product is needed on average and that the alternatives are 10% more expensive. The Dossier Submitter stresses that considering stakeholder information such a price increase is very unlikely to happen. Applying central estimates for use quantities and price of C6-substances the resulting additional cost would amount to approximately 0.2% of total yearly consumption (or less than 3 €/a per capita).

It might be possible that for some unknown niche applications functional losses are relevant. The Dossier Submitter identified categories of uses that would be affected severely from a restriction, where the functional losses would potentially lead to high social cost. Therefore, derogations have been proposed. A yearly reporting requirement has been proposed for the derogated uses. Information on the derogated use quantities is scarce and monitoring future use quantities will lead to sufficient information if further EU action is needed. The cost associated with this proposed requirement are expected similar to the proposal for the restriction on microplastics to be comparatively low.

E.2.11.7 Impact of different transitional periods.

Alternatives are available and affordable. Therefore, a longer transitional period is not required. In the public consultation stakeholders proposed a longer transition period of 24-36 months to account for production lead time and stock keeping. In the Dossier Submitter's view, a longer transition period is not needed in general. Drop-in alternatives are available for the majority of uses enabling the manufacturers to comply with the restriction. Stockkeeping might be an issue for textiles that are less fashion oriented. Information submitted was very general. Detailed information on specific product groups would be necessary to justify differentiated transition periods.

E.2.11.8 Uncertainties and sensitivity analysis

Owing to the vast number of textile and leather products and applications, in which PFHxA-related substances are used, it is not possible to give a robust estimate of substitution costs, which is representative for the entire industry. The socio-economic impact on the companies that provided information varies with their role in the supply chain but also with their product portfolio. Some stakeholders reported that costs for alternative substances might be similar. However, they expect that application volumes will be considerably larger. Therefore, it cannot be excluded that some sectors of the textiles and clothing industry face comparably higher substitution costs than others.

The Dossier Submitter as well as European Commission – DG Env (2020) demonstrate that several alternatives are available. Both conclude that some of the several alternatives might be regrettable substitutions resulting in additional risks to environment or human health. However, several other substitutes are technically and economically feasible. Stakeholders did not submit information that suggests economic or technical incentives to use the more hazardous substitutes. Therefore, it can be expected that the risk for regrettable substitution is small.There are some indications that a part of the market for carpets and rugs is moving away from using PFAS (information submitted in the public consultation). If this is true, emissions and costs are overestimated. With a view to proportionality and affordability, the over- or underestimation of the share of textiles treated with PFHxA-related substances does not impact conclusions. Direct cost of substitution (i.e. cost of alternative), cost of functional losses and emissions are directly dependent on the share of textiles treated.

During public consultation stakeholders claimed that a derogation is needed for the manufacture of sun protection and outdoor furniture fabrics in order to make them water and oil repellent, resistant to the formation of dirt and to the exposure to all kinds of atmospheric agents. Stakeholders argue that products will have more limited performance and last less over time. As a consequence textile covers might be increasingly replaced by permanent structures where the fabric is not used.

DS notices that there are no fluorine-free alternatives to date for outdoor furniture and solar protection fabrics regarding dirt or oil repellence. However, some functions, especially water repellency, can be substituted by non-textile alternatives. Stakeholders did not describe impacts resulting from dirt or oil soiling in detail but mentioned that the products would have a more limited performance and last less over time. The Dossier Submitter cannot verify these claims but notes that alternatives providing water repellency are available. Stakeholders did not claim that alternatives like manual cleaning are not possible.

Stakeholders also did not provide further convincing information why dirt and oil repellency is needed for outdoor furniture textiles.

High concentrations of PFHxA-related substances have been measured in awnings that offer a high hazard potential for the environment. Due to the specific uses manifold entry pathways into the environment are likely (Janousek et al., 2019).

Therefore, considering that alternatives are available and environmental risks are potentially large, the Dossier Submitter proposes no derogation for these articles.

In general, the uncertainties with regard to the cost generated by functional losses have been discussed above. Valuation of certain functionalities by consumers and with regard to shortened service life are not well understood, neither by the Dossier Submitter nor by stakeholders. Some stakeholders claim that the loss of functionality which resulted from the substitution of PFOA-related substances with PFHxA-related substances led to customer complaints. However, no stakeholder provided any robust evidence (e.g. lower turnover over time or increasing warranty cases, etc.).

Supply chains and production steps are diverse and largely unknown to the Dossier Submitter. Therefore, no robust estimate can be derived on impacts to import and export. For clothing the EU is a net importer. It might be possible that some additional cost (if any arise) will not be passed through to consumers. For industrial and technical textiles, it might be possible that competitiveness on non-EU markets decreases when products are no longer oil and/or dirt repellent.

Minor uncertainties have to be considered with regard to the reporting requirement. It is expected that significant quantities are imported into the EU and no information is available whether importers are prepared to provide the required information. Production of the derogated articles might happen in several stages outside the EU and it might be difficult for the importing company to obtain complete information on quantities and identity of the relevant PFHxA-related substances through the supply chain. However, as has been noted above, derogations are proposed for very specific applications where norms have to be fulfilled. Technical knowledge should be available along the supply chain.

The EU PPE-regulation does not apply to PPE specifically designed for use by the armed forces or in the maintenance of law and order. The Dossier Submitter assumes that manufacture and use of this PPE is also covered under the proposed derogation. A major uncertainty is the justification for derogations. The Dossier Submitter undertook a sensitivity analysis to demonstrate that under pessimistic assumptions a general restriction on textiles is still affordable. No robust information is available on the probable impacts if no derogations for certain PPE and technical textiles are considered. However, considering that potentially high risks for human health and the environment are addressed with the uses a potentially disproportionate socio-economic risk arises. For example, more than 250 000 professional firefighters and probably even more people working in the health sector would be potentially affected by the restriction.

With regard to regretful decision-making the Dossier Submitter argues that the maximum potential negative socio-economic cost from not granting a derogation might be considerably higher than the cost which has been deemed proportionate for past restrictions.

Nevertheless, the difference with regard to expected continued emissions resulting from the uses for PPE and technical textiles respectively should be considered when justifying the derogations. Calculations in B9.19 are very uncertain. Nevertheless, it is highly likely that emissions resulting from the automotive and aerospace uses will be very small in comparison to other continuing uses. On the other hand, it is likely that the derogation for certain PPE will result in very high continuing emissions: Just considering the proposed derogations without a time-limit, it might be possible that PPE will be responsible for more than 50 percent of continuing emissions.

E.2.12 Food contact materials (paper)

E.2.12.1 Overview

For the use in food contact materials (FCM) PFHxA and related substances possess valuable properties. They are chemically stable, heat resistant as well as water- and oil-repelling. In addition they are cost-effective, because low amounts are sufficient to achieve the desired effect (Begley et al., 2005; UBA, 2018). It has been reported that PFAS in general also might be used for non-food applications (folding cartons, containers, glossy papers, carbonless forms and masking papers) (Federal Office for the Environment, 2009). No further information is available from manufacturers, users or scientific literature.

Proposed restriction elements for PFHxA and related substances in mixtures for FCMs

Shall not be manufactured, used or placed on the market as substances on their own;
Shall not be used in the production of or placed on the market in or used in:
    (a) another substance, as a constituent,
    (b) a mixture,
    (c) an article
    in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1 000 ppb for the sum of PFHxA- related substances.
Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.
Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

E.2.12.2 Use and functions

For the use in FCMs PFHxA-related substances possess valuable properties. They are chemically stable, heat resistant as well as water- and oil-repelling. In addition they are cost-effective because low amounts are sufficient to achieve the desired effect (Begley et al., 2005; UBA, 2018).

For this restriction proposal the openly available literature was evaluated for reported data on PFHxA levels in or PFHxA release from FCM. The evaluation also included PFHxA-related substances. The search was performed in February of 2019 with the terms "PFHxA" OR "Perfluorohexanoic" AND "food contact material" in Pubmed, Scopus, SciFinder, Web of Science and Science Direct. Moreover, the CAS numbers of known fluorotelomers were used for research purposes in the above-mentioned search engines. Furthermore, the databases of ECHA and EFSA were browsed for helpful data.

Applied substances

The German Federal Institute for Risk Assessment (BfR) received no application for inclusion of PFHxA in the "BfR-Recommendations on food contact materials" (https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp?filter=clear), but for the respective related substances. The most important related substances are 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanole (6:2 FTOH, CAS 647-42-7), 3,3,4,4,5,5,6,6,7,7,8,8,8-

tridecafluorooctylacrylate (6:2 FTAC, CAS 17527-29-6) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoroctylmethacrylate (6:2 FTMA, CAS 2144-53-8). Starting with these, a large variety of polymers can be synthesised using acrylates, alkenes, divinylbenzene or other compounds as comonomers (Jensen et al., 2008; Liu et al., 2014a; UBA, 2018; Zhang et al., 2016a). However, a recent report by RIVM (National Institute for Public Health and Environment, Netherlands) shows, that FCM may contain PFHxA (Bokkers et al., 2019).

6:2 FTOH, 6:2 FTAC, 6:2 FTMA and several reaction products and (mixed) polymers are listed in the "BfR-Recommendations on food contact materials" (BfR), especially in the recommendation XXXVI "Paper and Board for Food Contact" (BfR, 2017a) and XXXVI/2 "Paper and Paperboard for Baking Purposes" (BfR, 2017b). Before listing, possible health risks arising from the migration of the substances from the paper into food and food simulants were assessed by the BfR on the basis of toxicological and analytical data according to the EFSA Note for Guidance (EFSA Panel on Food Contact Materials et al., 2008). If the migration is ≤ 50 µg/kg food, the EFSA accepts a reduced data set, consisting of two genotoxicity studies. Analytical studies demonstrated low migration of the respective fluorinated substances or migration below the detection limit. Accordingly, BfR´s risk assessment was based exclusively on genotoxicity studies indicating the absence of genotoxicity. Therein it was concluded that the resulting migration of very low amounts of these substances (and of PFHxA) is of no risk to human health. However, meanwhile there are additional data suggesting reprotoxic actions of PFHxA in rats.

Typical articles and applications

The most important application field is the production of paper and board for the packaging and preparation of food. The PFHxA-related substances are used in the paper pulp as well as for surface refining. They are applied to create water- and grease- /oil-repellent paper products, which can be used at higher temperatures without burning and adherence to food or other materials. Typical articles are baking paper, packaging for pet food, packing of take away food, tablecloths, microwave popcorn bags, cupcake forms and sandwich papers (Blom and Hanssen, 2015; Borg and Ivarsson, 2017; Jensen et al., 2008; UBA, 2018).

In addition, perfluorinated substances are used as emulsifiers during the production of temperature resistant polymer coating systems (e.g. polytetrafluoroethylene) for frying, cooking and baking utensils. For this application mainly PFOA was used. In course of the regulatory measures for PFOA a change to perfluorinated compounds with shorter C-chains is expected and already occurs – not only in the field of temperature resistant polymer coating systems but also for FCM from paper and board (Liu et al., 2014a; Ritter, 2010; Sinclair et al., 2007; UNEP, 2012a; Wang et al., 2013). As a consequence, the incidence of PFHxA and its related substances in FCM might increase in future times.

Content and release of PFHxA and related substances in /from food contact materials

Overall, there are only few data available on the content and release of PFHxA and its related substances molecules in /from food contact materials. Among the latter, only 6:2 FTOH was reported in the available sources. In the BfR recommendations XXXVI "Paper and Board for Food Contact" (BfR, 2017a) and XXXVI/2 "Paper and Paperboard for Baking Purposes" (BfR, 2017b) mixed polymers containing C_6-perfluorinated PFHxA-related substances are listed, which are typically used for surface refining and coating of FCM from paper and board. The recommended maximum content of these polymers in the final FCM varies between 0.16 % and 1.2 % (based on the dry fibres weight). Thereby, the recommended maximum fluorine content of the polymers applied varies between 35 % and 54 % (weight/weight).

In a report from 2019, the Dutch National Institute for Public Health and the Environment (RIVM) published a summary of existing literature and data on PFAS in food contact materials (Bokkers et al., 2019). It is reported, that PFHxA and related substances are detectable in various product types of FCM sampled in different countries. Thereby, food contact papers seem to form the category of products that is affected most frequently.

In a study of 2015, the extractable amount of different PFAS, including PFHxA, was analysed in consumer products (Kotthoff et al., 2015b). In 27 % of the paper-based food contact materials tested, PFHxA was detected and quantified with a median of 1.4 µg/kg FCM and a maximum of 182.8 µg/kg FCM. On request of the BfR, the BVL provided data from migration tests for PFHxA to the BfR (BVL). From 2010 to 2017, articles that are intended to come into contact with food (packaging paper /boards and kitchen aids) were analysed for the release of PFHxA. In 6.4 % of the samples (eight out of 126), release of PFHxA was detected and quantified. The median migration was 6.6 µg/kg FCM and the maximum was 250 µg/kg FCM.

Consumer products (food contact papers and baking forms) sampled in Norway and Sweden were analysed for the release of per- and polyfluorinated substances (Blom and Hanssen, 2015; Borg and Ivarsson, 2017). Taken the respective studies together, a release of PFHxA was detected in five samples out of 17 (29.4 %), whereas 6:2 FTOH was released from twelve samples (70.6 %). PFHxA migration was only detected in FCM from paper. The median content of all detects was 0.43 µg/m^2 article surface and the maximum content of all detects was 38.9 µg/m^2 article surface. 6:2 FTOH was detected in food contact papers as well as baking forms. The median content of all detects was 5.85 µg/m^2 article surface and the maximum detect was 76.4 µg/m^2 article surface, which would result in a median content of 0.35 µg 6:2 FTOH/kg food and a maximum content of 4.6 µg 6:2 FTOH/kg food.

In a study from 2014, PFHxA was found in ice-cream cups, fast food wrappers and microwave popcorn bags at contents ranging from 19 to 341 µg/kg FCM (Zafeiraki et al., 2014). 42 samples were analysed and even if values are not assigned to individual samples, data indicate that in the majority of samples (> 80 %) PFHxA was not detectable (LOD = 0.94 µg/kg). In a further study, data on PFHxA amounts in microwave popcorn bags from different countries were published by (Zabaleta et al.). The median PFHxA content, excluding samples with non-detectable PFHxA amounts, was 3 µg/kg FCM. The maximum level was 811 µg/kg FCM. Another publication on the presence of PFAS in FCM reports detectable amounts of PFHxA in wrapping papers. In six out of twelve samples, PFHxA was quantifiable at contents up to 1.1 ng/m^2 article surface (Surma et al., 2015).

Regarding migration of PFHxA from FCM into food and food simulants, scientific literature is scarce. A summary is given by the report of RIVM (Bokkers et al., 2019), thereby indicating that PFHxA as well as 6:2 FTOH can migrate into food simulants, particularly when containing alcohol.

Yuan et al. (2016) published data on the occurrence and migration of PFAS and FTOHs with regard to FCM. Various commercial paper-made food contact products from China and USA were analysed. Both PFHxA and 6:2 FTOH were detectable and were shown to migrate into food simulants within short durations (15 min) and high temperatures (cooling down from 100 °C). Thereby, migration efficiency increases with rising alcohol content of the food simulant. Paper bowls containing 3.9 µg/m^2 PFHxA were analysed for PFHxA migration efficiency. Depending on the type of food simulant, migration efficiency is reported to be approximately 5 % for water increasing to about 30 % for 50 % ethanol (EtOH). Migration of PFHxA into oil was not detectable. Using a conversion factor of 6 dm^2/kg food, as applied for plastic FCM according to (EU) No 10/2011, the resulting PFHxA content in food ranges between 11.7 ng/kg food (migration efficiency$_{\text{water}}$ = 5 %) and 70.2 ng/kg food (migration efficiency$_{\text{50 \% EtOH}}$ = 30 %). However, it should be noted that the experimental design of the respective study is not consistent with DIN standards for migration tests of paper/board FCMs as for example required for inclusion on BfR-Recommendation XXXVI. Consequently, the derived migration values are only a rough estimate and only applicable for the specified test conditions. The content of 6:2 FTOH in the paper bowls was 71 µg/m^2. Migration efficiency ranged from 0.24 % (water) to 13 % (50 % EtOH) and was 1.07 % for oil. According to the requirements of (EU) No 10/2011, the calculated amount of 6:2 FTOH in 1 kg food ranges between 10.2 ng/kg food (migration efficiency$_{\text{water}}$ = 0.24 %) and 553.8 ng/kg food (migration efficiency$_{\text{50 \% EtOH}}$ = 13 %).

Another study (Xu et al., 2013) investigated PFAS in commercial food contact papers that were treated with polyfluoroalkyl phosphate (PAP) or di-perfluoro-alkyloxy-amino-acid (PAA) surfactants. Beside other PFAS, PFHxA was determined in papers treated with both fluorochemicals at mean contents of 717 µg/kg (PAA) and 870 µg/kg (PAP). PFHxA migration into food simulants was shown to depend on contact duration, temperature and type of simulant. PFHxA migration efficiency values into oil ranged between 5 % to 10 %. The addition of an emulsifier to oil resulted in increased migration efficiencies up to about 20 %. PFHxA migration into EtOH was determined with efficiency up to 100 %. Compared to reported values from Yuan et al. (2016), data presented by Xu et al. (2013) suggest that the method of fluorochemical addition /incorporation into the FCM significantly affects the content of PFAS in the FCM as well as their release into food simulants. Thereby, the release of PFAS from fluorochemicals that are applied as coating can reach 100 % in the presence of EtOH. Due to deviations from standard test conditions and procedures, the comparability to existing data is not given. Hence, a conversion of the PFHxA content into a PFHxA exposure by migration into food is not useful. Noteworthy, there are no per- or polyfluorinated substances listed as surfactants in current BfR recommendations.

E.2.12.3 Baseline

(OECD, 2020) estimates that 13.8 million tonnes of paper and board are produced annually for food contact from three main sectors: folding box board, corrugated boxes and paper sacks. The Dossier Submitter estimates that up to 70% of grease-proof papers is treated with PFAS. According to industries, the content of side-chain fluorinated polymers is about 0.3 – 1.5 % by weight of the paper, depending on the specific purpose of the treated material (stakeholder consultation, (OECD, 2020) states a similar range of 0.2-1.5 % by weight of the paper). The Dossier Submitter found a broad range of 0.8 – 10 000 µg/kg for the use of PFHxA-related substances and for PFHxA-impurities of 1.4 – 180 µg/kg in food contact materials. The Dossier Submitter estimates that 27 600 – 207 000 t SFPs and 18 – 220 800 t PFHxA-related substances are used in the EU per year. 26 – 3 400 t PFHxA from impurities, 4 700 - 35 200 t C6 related SFPs and fluoropolymers and 15 – 188 900 t of low molecular PFHxA-related substances will be emitted over 20 years without the proposed restriction.

E.2.12.4 Alternatives for uses in food contact materials

The production of water- and oil- /grease-repellent paper and board products is predominantly based on fluorine technology (UBA, 2018). Apart from that, water repelling properties can be achieved (amongst others) by applying the following techniques (BfR, 2017a; BfR, 2017b; UNEP, 2012a):

- Plastics (films, melts, solutions, lacquers, dispersions), e.g. polyacrylates or polyvinyl alcohols with fatty alcohol sidechains, polyamides, modified polyethylenterephthalates and others,
- silicon oils /resins or silicon elastomers,
- paraffins, microcrystalline waxes, low-molecular polyolefins and polyterpenes,
- chromium-, aluminium-, calcium-, sodium- or potassium-salts of saturated straight fatty acids.
- paper refinement by micro- or nano fibrillated cellulose,
- paper refinement by intensive pulp treatment resulting in the formation of naturally greaseproof paper (NGP),
- natural materials with dense surfaces such as bamboo, elephant gras and palm leaves.

According to information from industry alternatives for PFHxA and related substances that provide similar oil- /grease-repelling properties (for FCM from paper and board as well as other materials) are scarce or less effective (UBA, 2018). This is even truer when stability at higher temperatures is needed – e.g. as packaging material in contact with hot foods or during baking or frying. Quite contradictory to that, a recent report of (OECD, 2020) on paper FCM concludes, that efficient PFAS-free alternatives are available for all applications, though higher costs for the paper production of approximately 10 – 30 % might result.

Application of perfluorinated substances with shorter carbon chains (e.g. C4-compounds such as PFBA, PFBS or FTOH 4:2) is possible as well as application of structurally different perfluorinated substances such as linear or cyclic perfluoropolyethers (PFPEs) and their salts and phosphoric acid esters as well as polyethersulfones (Sheng et al., 2018; UNEP, 2012a; Wang et al., 2013; Zhang et al., 2016a). Application of perfluorinated silanes is also described (Paxson et al., 2014), even if less stable polymer films may be formed. Recent data (Bokkers et al., 2019) indicate, that in course of the substitution of the C6-perfluorinated substances with C4-perfluorinated substances it might be necessary to apply higher amounts of the respective substance in order to achieve the desired properties of the FCM. Hence the overall amount of perfluorinated substances used during production of FCM might increase in course of the substitution of the C6-technology, which would not be desirable from an environmental point of view.

Some articles for baking and frying, such as cupcake forms or baking “papers”, can be made from silicone rather than coated paper board. Potential risk might arise from the migration of cyclic oligomers into food and ambient air (Fromme et al., 2019; Zhang et al., 2012), since some of the substances are suspected reprotoxicants (Greve et al., 2014) and identified as substances of very high concern due to PBT and vPvB properties.

For food packaging, specially adapted micro- or nano fibrillated cellulose-fibres could be added to the pulp during paper production or used as surface refining agents to achieve water- and oil-repelling properties ((Li et al., 2015); (OECD, 2020). But until now, concepts for the assessment of the risks of the possible migration of the nanomaterials into food are still discussed controversially in the EU. Alternatively, intensive pulp refinement can be performed in order to get NGP, which has a very dense surface with very few and small pores. Furthermore, certain natural alternatives like bamboo, palm leaves or elephant gras can be used as alternatives for PFAS equipped paper (OECD, 2020), but are expected to rather remain a niche application.

Alternatively, plastics or products containing a plastic layer in contact with the food could be used as packaging materials instead of paper and board. In course of the strategy of the EU to reduce plastics, this might not be desirable.

E.2.12.5 Economic and other impacts

Information on the use of fluorinated substances is very scarce. Several requests to discuss the issue of a potential restriction were not answered by paper producers. The following information are based on information from two substance importers /manufacturers.

Typical features relevant for paper applications are (food contact material):

- Oil and grease resistance and durability.
- Packaging materials for durable products: Oil repellence i.e. of pet food.
- Reduced potential for burns from hot oil migration.
- Maintains integrity and aesthetics of packaging material.

The two respondents claim that potential alternatives for paper applications do not reach an equivalent performance.

As discussed in E.2.12.2 Use and functions few data is available on the content and release of PFHxA and related substances in/from FCM. Studies report that varying percentages of fluorinated products have been detected for different categories of fast-food packaging. According to a summary of existing literature and data on PFAS in FCM PFHxA and related substances are detectable in various product types of FCM sampled in different countries. Food contact papers seem to form the category of products that is affected most frequently (Bokkers et al., 2019).

In general, the literature suggests use of PFAS in FCM but on the other hand it also suggests that FCM from the same product categories are available with and without PFAS. Therefore, it seems reasonable to assume that alternatives are available.

Denmark banned the use of all PFAS in paper and cardboard used in FCM by July 2020.[24] The ministry stated that alternatives with similar greaseproof and water-repellent properties are available. It is unknown to the Dossier Submitter whether the Danish authorities have

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[24] Miljø- og Fødevareministeriet, 2019: Fødevareministeren er klar til at forbyde fluorstoffer (https://mfvm.dk/nyheder/nyhed/nyhed/foedevareministeren-er-klar-til-at-forbyde-fluorstoffer/ (last access: 13.12.2019)).

gathered any additional information on impacts of this ban or whether they relied on available information.

In a recent report on PFAS in paper and board for food contact (Trier, 2017) the authors claim that non-fluorinated alternatives "are available and functional for all uses of paper and board" and that market research demonstrates that "these are cost neutral for retailers and hence most likely for manufacturers".

The authors argue that Danish retailer COOP successfully substituted PFAS-containing FCM with non-fluorinated alternatives in their own brands in a cost-effective way: "COOP estimates that substitution to non-fluorinated alternatives is not more expensive than the fluorinated coatings, and is aiming to expand the phase-out of non-fluorinated alternatives to all of COOP Nordic" (Trier, 2017).

Recently the argument on the availability of alternatives has been strengthened by (OECD, 2020). The level of grease resistance of paper or paperboard is measured by industry accepted methods in 'Kit value or rating'. Low grease resistance is indicated by a Kit value of 1, high resistance has a value of 12. OECD lists applications requiring low grease and water performance (with paper requiring low Kit values of 3, e.g. bread, nuts) to requiring paper with high Kit values (Kit value 12, e.g. pet food). For all applications alternatives are commercially available. For all applications alternatives based on short-chain PFAS, physical alternatives and chemical alternatives can be used.

However, Trier (2017) and (OECD, 2020) suggest that there might be some additional costs in the production process of alternatives. Trier (2017) reports on one alternative where machine speed will be slower because its content of dry solids is low compared to paper containing PFAS. In order to be able to estimate whether this leads to a substantial need for new machinery in the industry it would be necessary to obtain information that is not available to the Dossier Submitter, for example information on the number of machines available in the EU and their utilized capacity. No additional information was submitted during the public consultation.

OECD claims that efficient PFAS-free alternatives for paper FCM are available for all applications, though higher costs for the paper production might result (Hollins, 2020; OECD, 2020). The author states that the costs for the production of C6-PFAS equipped paper are approximately 1400 €/tonne (depending on the use of the paper). When physical or chemical alternatives are used for paper production, cost is approximately 1850 €/tonne or 1550 €/tonne, respectively. The authors argue that on a percentage scale the differences might be significant (approximately 10 – 30%), but due to the low share of costs for FCM in total costs, these higher costs for paper production are not relevant for the final (food) product. As an example, costs for a single muffin cup are estimated to rise by less than 0.5 cents (Hollins, 2020; OECD, 2020).

Using the information provided by (OECD, 2020) costs of a restriction on PFHxA, its salts and related substances can be derived. The Dossier Submitter estimates a use of 13.8 million t/a paper in the EU with 70% of greaseproof paper treated with PFHxA-related substances. This usage results in emissions of 235 – 1 760 t/a of C6 side-chain fluorinated polymers, 1 - 9 445 t/a PFHxA-related substances and 1 – 170 t/a of PFHxA as impurities. Central estimates are 1 000 t/a side-chain fluorinated polymers, 4 720 t/a PFHxA-related substances and 7 t/a PFHxA.

E.2.12.6 Cost-effectiveness, affordability and proportionality to risk

Accordingly, the costs for avoiding emissions will be as follows:

Table 41: Costs for avoiding emissions.

Paper/Board	Costs €/t (central estimate)	Costs million €/a	Additional costs million €/a	Emissions PFHxA-related substances t/a (central estimate)	CEA €/kg (central estimate)
PFHxA	1 400	13 520		236 – 11 374 (5 726)	
physical alternative	1 850	17 870	4 350		380 – 18 370 (760)
chemical alternative	1 550	14 970	1 450		127 – 6 120 (250)
C4 alternative (10-30 % higher use quantities)	1 540 – 1 820 (1 680)	14 880 – 17 580 (16 230)	1 350 – 4 060 (2 700)		118 – 5 710 (470)

In case of a restriction the central estimate for substitution costs is 1.45 billion €/a for the cheapest alternative, i.e. chemical alternatives. Emissions reduction would amount to approximately 5 726 t/a (central estimate), resulting in an average cost of 250 €/kg (central estimate) for every kg avoided emission. This cost-effectiveness estimate confirms OECD’s argument (with the cupcake example) that the additional costs lead to affordable price increases for the individual articles affected.

With regard to the affordability of the restriction, average costs of <4 €/a (chemical alternative) to <10 €/a (physical alternative) per EU citizen are very likely to be affordable.

Considering all the studies discussed in E.2.12.2 Use and functions the assumption that 70% of the 13.8 million t/a are treated might be an overestimation as for several product categories smaller percentages are reported. The Dossier Submitter notes that regarding cost-effectiveness such an overestimation makes no difference: additional costs and emissions are both linearly dependent on the use quantities.

E.2.12.7 Impact of different transitional periods

The Dossier Submitter has not identified uses that require longer transitional periods. According to the Danish authorities, substitution is possible within less than a year. However, the Danish ban affects only a comparatively small market. Therefore, the proposed transitional period of 18 months is reasonable to implement the restriction on the larger EU-market.

E.2.12.8 Uncertainties and sensitivity analysis

No information is available on the share of the quantities that are re-imported as part of finished products. Further, it is unknown whether the demand from non-EU buyers will change when greaseproof papers are coated with alternative materials. Therefore, exports represent

an uncertainty for the assumption that the restriction will have small impacts on paper manufacturing in the EU.
A minor uncertainty with regard to the restriction of PFHxA-related substances in FCM is the potential for functional losses. In case the alternatives are less greaseproof products could be less durable with reduced shelf-life. The potential for burns from hot oil migration and the potential for soiling could be increased. OECD (2020) and Trier et al. argue that for non-fluorinated chemical alternatives, the cost differential, rather than performance is the critical factor in determining competitiveness. Contrary to that, one stakeholder from the public consultation argued, that standards for high KIT-values cannot be met by alternatives. No further proof was given. The Dossier Submitter notes that the stakeholder is no paper manufacturer or user. Directly concerned stakeholders did not comment on performance issues in the public consultation.

Danish retailer Coop uses non-fluorinated alternatives for its food packaging since 2014. The Dossier Submitter is not aware of any performance-related issues. Denmark banned the use of PFAS in FCM in July 2020. The Dossier Submitter is not aware of any performance-related issues. In sum, no empirical evidence is available that suggests significant functional losses. However, considering that most substitution processes are still ongoing or have only been completed recently minor medium-term or long-term performance issues cannot be ruled out.

According to information available no additional machinery or other equipment is needed when chemical alternatives are applied to the paper. However, no information is available if the producers of the alternatives can meet increased demand. Some Manufacturers and importers claim that alternatives are not available for all uses.

Emissions might be severely underestimated because potentially large direct emissions to the environment are possible from pulp and paper mill sludge that is produced during the treatment of wastewater derived from a paper mill. Use quantities and therefore costs and emissions might be overestimated. No robust estimates are available regarding the percentage of paper and board that is treated with PFHxA-related substances. In the Dossier Submitters view conclusions on the proportionality and affordability of the restriction are not affected by the actual use quantities.

There are some indications that a part of the market is moving away from using PFAS in FCM. If this is true, emissions are overestimated. Additionally, there are indications that other short-chain PFAS are used in FCM products (Kotthoff et al., 2015b). However, even if the use of PFHxA-related substances is overestimated the conclusions regarding the affordability of a restriction do not change, because emissions and cost of substitution will change in parallel to each other.

Some potential alternatives have or might have undesirable impacts. Substitution with siloxanes, plastics or C4-perfluorinated substances could be regrettable substitutions as for food contact materials these potential alternative substances should be avoided. No information is available which substitution strategies would be pursued by the impacted industries in case of a restriction.

Although uncertainties remain, the Dossier Submitter assumes that both economic impacts of a restriction as well as avoided emissions of PFHxA and related substances are very high. Socio-economic consequences will be small for individual citizens and companies. The costs in relation to the avoided emissions are therefore likely to be proportionate and affordable.

E.2.13 Additional uses

E.2.13.1 PTFE (Polytetrafluoroethylene) micro-powders

Polytetrafluorethylene is a fine, inert, white micro-powder with desired mechanical, thermic, electrical and chemical characteristics. Even though PTFE is not produced with a C6 medium, it is still related to PFHxA because impurities of PFHxA are components of the PTFE micro-powder. These impurities are unintentionally created while producing PTFE. Therefore, it is linked to the restriction proposal of PFHxA and its related substances. PTFE micro-powders are used in the medical sector, in electronics, in the field of tribology, mechatronics and serve as an additive to different substances and liquids to enhance their attributes. Hence, it has a broad scope of applications.

Typical applications used in the medical sector are implantable devices (e.g. material for prostheses, predominantly for operations of synthetic bypasses) (Neufang, 2015) and non-implantable devices, such as the production of catheters, filter membranes or tubes (Domininghaus, 2013). More information regarding the medical sector can be found in the section E.2.13.6 Medical Devices. With regard to the field of tribology, an example could be the usage of PTFE in bearings and pistons, as well as implementing PFTE to reduce friction and therefore minimizing abrasion of the material. Other frequently used applications can be found in gaskets, expansion components, armatures, isolation of cables and coatings with repellent surfaces (Domininghaus, 2013).

In the following, the scope of application will be limited to the usage of PTFE micro-powders brought to the DSs attention during the public consultation.

These applications are:

- printing inks,
- paint, coatings,
- lubricants, greases,
- thermoplastic applications,
- ETFE industrial film laminating,
- cable insulation.

PTFE is used in printing inks as an additive in toner, powder for laser or fax and in liquids. PTFE has to be added to 1-5 % in weight to the product to reach desired aspects, for instance scuff-resistance, improved image protection and higher efficiency. Printing inks are commonly used for wrappings and similar products with a short functional life. With present data it cannot be determined in which quantities PFHxA is currently present in products and therefore released into the environment.

Similar characteristics (e.g. scratch resistance, slipping, matting effects and rubbing) are aspired for paints and coatings where 5-15 w% needs to be added. The PTFE lubricant powder can be used for a wide scope of industrial coating formulations like powder coating, wood coating, as well as can and coil coating. DS received information from one stakeholder stating amounts of products sold last year (2019). A statement of the purchased quantity of PTFE and its content of PFHxA was not given.

In lubricant and greases PTFE micro-powder is added up to 15 % in oils and 25-40 % in greases to adjust the viscosity and to obtain lubricity during a wide temperature range (-190 °C to +260 °C). It also reduces the static and dynamic coefficient of friction, does not absorb water and improves the thermal and corrosion resistance. In consequence, a good non-stick and sliding property is achieved. PTFE micro-powder is an additive which is used instead of graphite and molybdenum disulphide because of higher chemical resistance and the higher temperature range needed for specific applications.

PTFE can be used in a wide variety of materials like thermosets and thermoplastic (e.g. polyesters, polyacetals, polyamides, polycarbonates, polysulfides, melamine resin, polysulfones/epoxy, phenol-formaldehyde), as well as elastomers (e.g. silicones, nitriles, neoprenes and fluoroelastomers). Regarding thermoplastics, PTFE is added to 10-15 w% to improve tribological properties, such as reducing friction and abrasion. PTFE is added to elastomers with 15-25 w% to improve the abrasion resistance and tear strength. The micro-powder can be used to minimize drip and propagation of flame while fibrillating in the melt and blending process. Additionally, it is claimed to improve anti-fingerprint, anti-dust and has a flame-retardant effect. Similarly, it can be used in food and beverage cans. The necessary quantities of PTFE for the mentioned improvements are unclear, as well as the contained amount of PFHxA.

In the production of PTFE industrial film laminating for the automotive sector and other sectors, PTFE micro-powder can be also applied. The PTFE glide layer is combined with different materials to improve durability. The data from the public consultation neither shows how much PTFE is needed nor the amount of PFHxA that is contained.

Furthermore, PTFE can be used to insulate cables. These cables, as the manufacture claims, are used in aerospace application under therefore very harsh environmental conditions (e.g. wide temperature range, chemical forces). The materials for the cable have to be inert to their environment and guarantee functionality at different temperatures. The manufacturer also states that 100% of the wiring installed in an aircraft is based on fluoropolymers (e.g. PTFE, FEP, PFA, ETFE and PVDF). There is no information about the quantity of PTFE used to insulate cables or PFHxA impurities. One stakeholder provided information on their total amounts of fluoropolymers acquired per year but no specific information for amounts used for cable insulation was provided. The stakeholder requests a derogation based on major standards of cables used in aerospace and the need to sustain a high level of performance to guarantee the safety of passengers and aircraft.

Generally, there are alternative substances or alternative manufacturing processes for PTFE that create impurities of PFHxA lower than 25 ppb. As there is no openly available knowledge concerning the efficiency, availability for companies or potential risks with regard to regrettable substitution a derogation for use and manufacture of PTFE might be necessary. DS is of the opinion that this will be covered by the derogation for fluoropolymers (E.2.1 Fluoropolymers and side-chain fluorinated polymers). Even though more companies are looking for alternative production processes to reduce the amount of PFHxA produced, there is no clear timetable for completion. As a result, it remains unclear how many companies could replace their PTFE quantity or adjust their production in time for the sun set date. It should also be noted that an exemption for PTFE micro-powders used in industrial and commercial applications is already included in the draft delegated act implementing the POP Regulation on PFOA. This entered into force on July 4, 2020 and grants an exemption for two years until July 2022. Furthermore, the use of PTFE is accompanied by economic and societal advantages, such as improved properties of medical devices, cost savings and emission reductions due to reduced friction and improved tribological properties.

The Dossier Submitter assumes that the continued manufacture and use of PTFE micro-powder will be covered under a general derogation for fluoroelastomers with a concentration limit of 2000 ppb for the sum of PFHxA and its salts.

E.2.13.4 Filtration

Shall not be manufactured, used or placed on the market as substances on their own;

Shall not be used in the production of or placed on the market in or used in:
(a) another substance, as a constituent,
(b) a mixture,
(c) an article

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances.

Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.

Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

Paragraphs 1 and 2 shall not apply to any of the following:
filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency;

Filtration and separation media treated with C6 fluorinated polymers consist primarily of non-woven or paper composed of manmade fibres, natural fibres (or a combination of both), with resins that contribute to the structural or physical properties of the media. Filtration and separation media manufactured with C6 fluorinated polymers play a critical role in the following applications, among others: medical devices, PPE, HVAC (including EPA/HEPA/ULPA), Air Pollution Controls (APC), dust collectors, hydraulic systems, coalescers, gas turbines, and fuel systems.

Several stakeholders submitted information on the wide range of applications and requested derogations from the restriction.

The applications touch nearly every market sector in the global economy. The Dossier Submitter agrees that several applications fulfil important functions and propose a derogation.

Several stakeholders submitted information demonstrating very small release from production. They argue that emissions from the use phase are small as filters and membranes are enclosed in devices. However, very limited information on the waste phase is available.
The Dossier Submitter also notes that EU-wide use quantities and therefore potential for releases from end of life are unknown.
Some confidential information on individual use quantities has been submitted suggesting the possibility that significant quantities, possibly several hundred tonnes per year of PFHxA related substances are used in the European Union. Therefore, significant emissions, especially from the waste phase cannot be excluded.

Some stakeholders state that for some uses substitution could be possible within 10 – 15 years. Some stakeholders claim that longer transition periods are needed. Comment 3070 argues: "The absence of a derogation for these applications will put at risk manufacturing facilities located in the EU. It would furthermore result in a supply interruption of filtration and separation media within the current technical specifications until adequate alternative candidates are identified and completion of subsequent requalification. It must be noted that more than 80% of applications that require requalification have a link to other industrial activities – e.g. medical, pharmaceutical, food and nutrition, protective equipment electronics, energy, chemistry."

Consequently, derogations are requested for the following: (a) non-woven textiles which are critical to health of workers in the medical field, patients and general public, including but not limited to surgical gowns, medical drapes, packs, protective masks (face masks, FFP2 masks, FFP3 masks), sterilization wipes, (b) filtration for industrial application, including but not limited to, medical device filters, energy efficient HVAC filters, coalescer, automotive fuel and oil filters, swimming pool filters, air-conditioning filters, (c) automotive applications which are critical to functionality and safe operation of automobiles, including but not limited to, molded bonnet liners, battery separators and headliner backers.

Other stakeholders requested derogations for 'all industrial uses' or 'high-performance applications. The Dossier Submitter does not fully understand the consequences regarding implementability and enforceability of the different scope definitions.

Some cost estimates from manufacturers are available. In the Dossier Submitters view substantial costs of not using PFAS are demonstrated, however some cost estimates are likely to be overestimated. However, if technical claims from manufacturers are valid no alternatives are available at the moment. A restriction would lead to a large loss of effectiveness and potentially large societal costs.

Several stakeholders discuss possible alternatives and stress the functional advantages of PFHxA-related substances. However, no robust comparative analysis has been submitted on the consequences of using alternatives instead of PFHxA-related substances. Therefore, the magnitude of negative impacts remains unclear.

The Dossier Submitter notes that more detailed information on the different applications and a more detailed discussion on substitution possibilities for individual applications is missing. Information on estimated substitution costs and planned activities would be helpful to better understand the difficulties of the substitution process.

Considering information from the public consultation the Dossier Submitter proposes a derogation for filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency.

The Dossier Submitter notes high uncertainties with regard to the broad scope of the derogation. It might be possible that alternatives are already available for some applications (e.g. when mainly water-repellent properties are needed) or that substitution is available in the near future for applications.

E.2.13.5 Watches

Shall not be manufactured, used or placed on the market as substances on their own;

Shall not be used in the production of or placed on the market in or used in:

(d) another substance, as a constituent,
(e) a mixture,
(f) an article

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances.

Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.

Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

Paragraphs 1 and 2 shall not apply to any of the following: epilames used in watches

PFHxA-related substances are used by the watchmaking industry as epilames. Epilames are applied as coating on mechanical watch-parts that need lubrication due to their movement (e.g. wheels, pivots, escapements, stones). The epilame coating is required to obtain a low surface tension in order for the lubricant (oil) to stay in place and not spread through the movement of the mechanical watch-parts. Furthermore, the epilame coating must be chemically compatible with the substrate on which it is deposited and must also not react with the components of the lubricant. Historically, products based on stearic acid diluted in toluene were used as epilames in watchmaking until the 1970s (Ducommun, 1956, Osowiecki, 1962 cited by Tosatti and Zurchner, 2007)), but with the development of fluoropolymers the watchmaking process changed. Today's production processes rely on epilames having a structure on the basis of C6 fluorinated polymers. Alternatives are not available (information received from stakeholder). The overall mass of C6 fluorinated polymers used in watchmaking lies within the lower, one-digit kg/a area. As epilame coating takes place through immersion of the to-be-coated parts in a bath of the epilame mixture, a large proportion of the epilame mixtures goes to waste. According to stakeholder information the waste is collected as industrial chemical waste and is properly disposed of (i.e. high temperature incineration). So, emission of PFHxA related substances from watchmaking processes can be considered as low. The watches themselves only contain a small amount of C6 fluorinated polymers (< 1 kg/a on a global scale) and the coated parts are inside the hermetic watch case. Furthermore, mechanical watches usually are expensive products with a long service life. They are not likely to be disposed through household waste, but rather are resold or dismantled for their parts.

But still, emissions to the enviroment will eventually occur at the end of the products life. Following the information of the stakeholder, emissions of epilames from end of life products can be considered as low as they contain only a small amount of epilames. Exposure of consumers through the use of watches is neglible as the epilame-coated parts are inside the watch case which is usally not accessible to the consumer. During the public consultation DS was informed, that historically stearic acid was used for epilamisation. When asking stakeholders about this as a possible alternative, DS received information, that stearic acid does not fulfill current industry standards due to its poor oil repellency and wash resistance. Considering the low amounts of PFHxA related substances used in the production of epilame mixtures for watchmaking processes, the low emissions to the enviroment and neglible exposure of consumers, a derogation for this use could be considered. It could, however, also be questioned whether the production of mechanical watches should be considered as a crucial use that needs a derogation, as there are other watches available. DS is of the opinion, that a derogation for this use should be proposed only if all available risk reduction measures (in this case reduction of emissions) were taken by the manufacturer and downstream users. So far the relevant stakeholders demonstrated that the amounts of PFHxA related substances produced and used are already very small but no information on possibilities to further reduce the used amounts or substitution plans were provided.

From a socio-economic perspective a derogation is justified when just considering the low emissions and the potential impact for companies of no longer being able to produce mechanical watches according to international standards. Exports might be affected when standards can no longer be fulfilled.

However, with a view to information that alternatives do not fulfil industry standards the Dossier Submitter does not know what these standards are. If the only effect of using PFHxA-related substances is more precise functioning of watches the proportionality of a derogation could be questioned. If more precision means less maintenance and longer service life than it is highly likely that a derogation is justified. The Dossier Submitter deems information provided by stakeholders as sufficient to propose a derogation but notes that stakeholders did not provide detailed information on future substitution plans.

E.2.13.6 Medical Devices

Proposed restriction elements for PFHxA and related substances for medical devices

Shall not be manufactured, used or placed on the market as substances on their own;

Shall not be used in the production of or placed on the market in or used in:
(a) another substance, as a constituent,
(b) a mixture,
(c) an article

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances.

Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.

Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

Paragraphs 1 and 2 shall not apply to medical devices as specified in Regulation 2017/745 of the European Parliament and of the Council;

In the medical sector there are different applications for PFHxA and its related substances. Uses of PFHxA and PFHxA related substances, that were brought to the DSs attention during the public consultation, are:

- the production of detergent proof, one-use, washbowls,
- in non-active medical devices in ophthalmic applications,
- in specialty compounds blended with polymers for implantable and non-implantable medical devices.
- As coating for hearing aid devices.
- Medical textiles

The Dossier Submitter proposes a general derogation for medical devices as specified in Regulation 2017/745 of the European Parliament and of the Council. Some information on costs and benefits have been provided by stakeholders for the uses mentioned above. The Dossier Submitter considered analysing socio-economic information from the public consultation. However, he argues that this information is not relevant when he proposes a general derogation for medical devices. Only when no general derogation is proposed detailed information for individual uses needs to be assessed.

The Dossier Submitter argues that there are most probably current (and future) uses not identified in the public consultation. In two different personal meetings with stakeholders who submitted information he was informed that

a) the stakeholders became aware of the restriction proposal more or less by chance and

b) that it is very unlikely that there are no additional uses for medical devices.

Whether cost information submitted in the public consultation is representative for all uses is unknown. E.g. if there are several additional uses it is highly unlikely that the sample from the PC represents reliable information in regard to all uses for medical devices.

That said, the Dossier Submitter proposes a very broad derogation that might not be justified. However, considering possible negative impacts from limited use-specific derogations this seems to be a proportionate approach under uncertainty.

Production of detergent proof, one-use, washbowls

In the production of detergent proof washbowls, a fluorinated polymer is added to a pulp of molded paper to provide detergent proofing. These single-use and disposable washbowls are used in the medical sector to prevent cross infections and hospital acquired infections (e.g. Methicillin-resistant Staphylococcus aureus (MRSA)). For example, the introduction of disposable washbowls is reported to be part of the reason *Clostridium difficile* infections decreased at an NHS hospital. Not applying the fluorinated polymer in the production process results in failure of the washbowls as soon as they come into contact with detergents. With regard to the use of fluorine-free alternatives, to achieve detergent-proofing, stakeholders claim that they are not an option due to the method of manufacture and handling. Fluorine free film coatings do not allow the washbowl to be broken down inside a specific disposal unit and alternative detergent proofing agents cannot contain binding agent properties, because the washbowl needs to macerate after use. Binding agents will allow larger pieces of molded fibre to enter the drainage and sewer systems resulting in possible blockages. Furthermore, multi-use plastic washbowls have been identified as being contaminated with multi drug resistant human pathogens even after they have been washed and sterilized in specialized equipment. So there seems to be a health benefit in the use of detergent proof, one-use washbowls. However, it remains unclear to the DS, why the washbowls have to be disposed via a specific disposal unit and not via the regular medical waste of the hospital. There seem to be fluorine-free alternatives which allow the production of detergent-proof washbowls. So, if at all, only a time limited derogation for this use should be considered, to allow for the manufacturers to change their production processes.

Non-active medical devices in ophthalmic applications

In ophthalmic applications PFAS serve as non-active medical device in the application of eye drops for the treatment of dry eyes symptoms or after surgical treatment of severe retinal detachments. Products containing a semifluorinated alkane are applied topical to the outer eyes as water-free eye drops containing a pharmaceutically active ingredient. The eye drops penetrate into the cornea of the eye, where the pharmaceutically active ingredient unfolds its effect. As the outer membrane of the eye is lipophilic, water-based alternatives have a significantly shorter residual time on the eye and result in a lower bioavailability of the active ingredient. The manufacturer of this product claims that this is the first treatment for tear-lipid dysfunctional dry eyes and that they address a significant unmet medical need as traditional medical devices and pharmaceutical therapies often lack tolerability and efficacy (information received during meeting with stakeholder). Furthermore, it was stated that the semifluorinated alkane is chemically, biologically and physically inert due to a full saturation of the carbon-backbone and a complete lack of functional groups. The stakeholder provided data supporting this claim with regard to the biodegradability (OECD 301B: not readily biodegradable) and decomposition (decomposition temperature > 350 °C). After entering the human body, the substance is eliminated unchanged and unmetabolized via facies and urine as shown by different metabolism, distribution and mass balance and tissue distribution studies, provided by the stakeholder. Overall, there seems to be a health benefit through the application of this product but with the result of emissions of PFHxA related substances to the environment. As it is secreted unchanged, emissions would occur in the same amount the substance is used in the EU. The amounts used in the EU were submitted during the public consultation and taken into account by DS while assessing this use. The amounts are expected to increase in the future. To this moment it remains unclear to the DS (and the manufacturer of this product) whether a derogation for this use is needed as the claim is made, that the semifluorinated alkane is inert and doesn’t undergo degradation unless exposed to high temperatures (i.e. incinerated). Still the substance is listed as PFHxA related substance in Table 5 of appendix B of the restriction dossier.

Specialty compounds blended with polymers for implantable and non-implantable medical devices

For the use in implantable (e.g. catheters, shunts, drainage, stents, surgical meshes, pacemaker leads, or vascular grafts) and non-implantable medical devices (e.g. vascular/delivery catheters, delivery catheters, extracorporeal components, or wound closures) PFHxA related substances are used in specialty compounds blended with polymers. These specialty compounds are added to base polymers prior to forming into the device component by various manufacturing processes with no additional energy consumption or generation of waste requiring disposal. Therefore, the environmental impact of implementing the surface modification is low. Concentrations of these specialty compounds in the device component range from 1 to 10 wt% relative to the base polymer. The combined usage of PFHxA related substance in current catheter products is estimated at < 1 t/a. The potential usage of PFHxA related substance in hemodialyzer applications is estimated at double-digit t/a. A Future rise in tonnage can be expected (information received during stakeholder meeting). Reported benefits from the use of PFHxA related substances in the production of implantable and non-implantable medical devices are:

- Reduction in blood thrombosis resulting in improved function and reduced complications,
- reduction in bacterial adhesion resulting in reduced biofilm formation, infection and encrustation.

The manufacturer claims that these medical devices reduce medical complications, save patient lives, and reduce healthcare costs. The medical devices are collected as medical waste and disposed via medicinal waste incineration. A release of PFHxA related substances to the environment from the production, use or disposal of these medical devices is not expected. DS asked the stakeholder to provide more detailed information on benefits (e.g. thrombosis and infections reduction compared to competitor products) relative to emissions and a more detailed explanation why an open-ended derogation should be considered. Furthermore, the stakeholder was advised to elaborate a long-term substitution plan for the use of PFHxA related substances. As a first impression a derogation for this use should be considered as there are clear health benefits and emissions can be considered as low.

Coating for hearing aid devices

In the production of hearing aids PFHxA related substances are used as coating to provide hydrophobic and oleophobic properties. These properties are important, so that water, sweat and ear wax will not enter the interior of the device. When the hydrophobic coating is absent, water/sweat ingression may enter in the interior of the device, causing corrosion. Hearing aids cannot be fully sealed as components like battery, microphones and receivers need regular air exchange. For the hearing aids to work properly through the intended lifetime of 5-6 years, the industry is coating the components that are susceptible to moisture damage with a PFHxA related substance. The coating is applied to the hearing devices via a plasma coating process for which currently no alternatives are available (according to stakeholder information). Furthermore, the amounts used per device are very small. Stakeholder estimations of the use of PFHxA related substances for this application are in the one-digit kg/a area. The compounds for the coating process are manufactured under Medical Device Regulations such as EEC93/42 MDD, EU2017/745 MDR controls and only sold under contractual supply agreements with hearing aid manufactures. DS was informed that finding a suitable alternative and replacing the production processes will take approx. ten years. So at least a time limited derogation for this use should be considered.

Non-woven medical textiles

Non-woven are used in hospitals to avoid cross-contamination from re-using of woven gowns, masks or similar articles. Non-woven articles are considered as cost-effective and disposable alternative. They are considered to have good barrier properties, good performance characteristics (comfort, thickness and weight, water vapor transmission, air permeability etc.) and provide increased protection (tensile, tear resistance, abrasion resistance etc.).

Non-woven medical textiles are used in the following applications:[25]

- Personal health care/hygienic products: Bedding, clothing, surgical gowns, cloths, wipes surgical curves, surgical hosiery, diapers, etc.
- Non-implantable material or medical dressings and auxiliaries: Wound dressing, bandage, plasters, gauge, lint wadding, etc.
- Implantable materials: Sutures, vascular grafts, artificial ligaments, and artificial joints.
- Extra corporal devices: Artificial kidneys, liver & lungs, etc.

The nonwovens are used for the given applications in different forms and are used in ambulances, consultation couches, ICUs, laboratory, operating rooms, wards etc.

Woven medical textiles

Woven medical textiles are used similarly in the following applications:

- Protective and healthcare textiles,
- external devices,
- implantable materials,
- hygiene products,
- extracorporeal devices.

In the public consultation stakeholders submitted information that there is rising demand for reusable woven medical textiles which are considered as sustainable alternative to some disposable non-woven articles. Stakeholders claim that in order to avoid contamination issues the use of PFHxA-related substances is necessary.

Uncertainty remains regarding the necessity of the proposed exemptions. The Dossier Submitter has no information on actual risk reduction from using C6-treated textiles. Considering that the risks of equipment failure, need of early replacement, and other unwanted consequences could be potentially high, precautionary use of textiles treated with PFHxA-related substances might be justified. But the Dossier Submitter notes that emissions from this use are potentially large: The study from EC DG Environment (2020) assumes an annual EU wide use of industrial technical fabrics up to 520 t. It is assumed that two third of industrial fabrics are manufactured in the EU. It is further assumed that more than 20% of industrial fabrics are used for medical applications. This might result in emissions from medical textiles of up to 100 t PFHxA-related substances over 20 years. This is a very uncertain estimate.

The Dossier Submitter notes that most probably the derogation covers articles where the continued use of PFHxA-related substances is not justified. However, without further

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[25] The Indian Textile Journal, 2008: Application of nonwovens in medical field, http://indiantextilejournal.com/articles/FAdetails.asp?id=1452 (last access: 13.12.2019).

information the large variety of articles and uses makes it impossible to identify use categories for exclusion.

E.2.13.7 Optical fibres

The Dossier Submitter was informed about uses of PFHxA related substances for optical fibres during the public consultation.
In the telecommunications sector, ETFE is used for special optical cable applications called "buffer tubes", these tubes hold and carry the actual fibre optics. Protecting them from the adjacent environment (Comment 3000).
Mainly, the optical fibres are used for transmission media for in-vehicle data communication. Especially, to achieve safe driving or auto-pilot system (Advanced Driver Assistance Systems, ADAS, and self-driving cars), higher data rate transmission media will be mandatory in the near future. If optical fibres using fluorinated cladding were prohibited by a REACH restriction, there would be no suitable transmission medium which could the technical requirements for the noise resistance, mechanical properties and costs (Comment 3002).The Dossier Submitter does not fully understand what is meant by fluorinated polymers in the content. However, if SFPs are used a derogation is not justified by the information provided. More information on comparison between other materials and C6 fluorinated polymers regarding the refractive index properties would be needed. In order to evaluate the request for a derogation it also would have been helpful to receive more specific information on the claim that higher data rate transmission media will be mandatory in the near future, e.g., how many years from now this can be expected? What data rate would be required and what can alternatives achieve in that regard?

E.2.13.8 Other special uses of PFHxA related substances

A number of applications of PFHxA related substances has been reported in the information collection or is mentioned in the literature that does not completely fit in one of the areas described in more detail:

- Products made by PFHxA, its salts and related substances have properties that are crucial for handling of fragrance and odour compounds in products and articles, such as they are surface-active and inert to different chemicals. However, the use of PFHxA, its salts and related substances in this field of use is not clear so far.

- One company uses perfluoropolyethers in an aerosol application during their in-house quality control of other fluoropolymer products. They recognised that such laboratory applications might be sources of potential emissions (untreated off air) and they will reduce these emissions in the future.

- One company uses C6 fluorosurfactants in the production of polyester films as anti-fog coatings for face shields for surgeons. Probably this use would be covered under the exemption for personal protective equipment (**Error! Reference source not found.**).

- One company uses fluorinated substances in special glass for:
    - Construction (external glazing and interior decorative glass),

- automotive (original and replacement glass),
- solar sector.

For some applications they see a potential for substitution by fluorine-free alternatives if only water repellence is needed. In other sectors they do not consider this option.

For all this uses no further socioeconomic information has been submitted. No additional information has been submitted during the public consultation.

E.3 Other impacts, practicability and monitorability

Social and wider economic impacts:
The proposed restriction is not expected to have major effects on employment because for the vast majority of uses alternatives are available that are implementable at a reasonable cost. For most of the articles concerned the use of PFHxA, its salts and related products is only one step in the production process. Alternatives have been identified for most uses. Some of the alternatives do not provide all the functions that are resulting from the application of fluorinated substances. However, for consumer articles oil and stain repellency is just one additional function of the product. Consumers still have incentives to buy them for their remaining properties. For most of the identified uses alternatives are available and affordable. It is expected that production processes will not be interrupted. For some uses derogations have been proposed because alternatives are not available at the moment. For these industries (e.g. chrome metal plating, filtration and semiconductors) major employment effects could be expected when no derogation is granted.

For other uses imported articles and mixtures will also be covered by the restriction. Relocation of production facilities to countries outside the EU are not a likely response by the industries concerned.

In sum, closing down of business, relocation of business activities and employment effects are not expected. One uncertainty in this regard is the manufacturing of fluoropolymers and SFPs. Production facilities affected will need restructuring for alternative production purposes. Several stakeholders claimed in the public consultation that the restriction would endanger the production facilities in the European Union for fluoropolymers and substances covered by the restriction. It might be possible that due to the limited derogations and resulting limited uses production in the EU might no longer be economically viable. Stakeholders claim that this might be a strategic disadvantage in situations of crisis.

Manufacturers have not provided sufficient information to substantiate the claim that a shutdown of some manufacturing plants is the most probable outcome of a restriction. Therefore, this scenario is only considered an uncertainty for the sensitivity analysis.

The Dossier Submitter notes concerns that PFAS in general are increasingly seen as a concern worldwide. Early research and development activities and manufacturing of alternatives might be an advantage if other countries decide to regulate C6 substances in the future.

Also, considering the concerns with regard to persistence and transboundary mobility of the substances the restriction will encourage other countries to further regulate PFHxA, its salts and related substances.

Distributional impacts:
Distributional impacts are difficult to predict. It might be possible that in some sectors first movers that are already developing and marketing fluorine-free alternatives take over market shares from other market actors. However, stakeholder consultation and market review suggest that most companies affected are actively pursuing research on alternatives.

Any cost of the proposed restriction to EU and non-EU businesses are likely to be passed on along the supply chain. Most of the costs will consist of functional losses. As has been demonstrated monetary cost effects will be negligible or affordable considering the fact that non-fluorinated products are similarly priced as fluorinated products. Some properties of the products will be lost or reduced. Consumers could value these functional losses as decreased convenience or functionality.

However, in general no information on distributional effects of the proposed restriction could be identified.

E.4 Practicality and monitorability

Implementability: The proposed restriction is considered to represent an implementable option for the actors involved within the timeframe of 18 months for most uses. As described in Annex E.2 the necessary technology, techniques and alternatives are available and economically feasible. However, for some uses alternatives are not available. For other uses alternatives are available but a longer timeframe than 18 months is needed for the adjustment to new technology, techniques and alternatives.

Enforceability: Enforcement authorities can set up efficient supervision mechanisms to monitor industry`s compliance with the proposed restriction. Methods can be easily adapted from the methods to analyse of PFOA and longer-chain PFASs. Given that methods exist, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.

Manageability/Monitorability: There are numerous analytical methods reported in the scientific literature to determine easy extractable perfluorinated carboxylic and sulfonic acids of different chain length, including PFHxA. The methods are applicable as well to linear as to branched isomers. The majority of these methods focusses on water analysis (ground water, surface water, drinking water and sewage). However, it is possible to detect the perfluorinated acids in almost all environmental compartments besides water, e.g. sediment, soil, air, biota and humans by conveying the perfluorinated substances into a watery solution. The following steps are in general the same: the perfluorinated substances are enriched by solid phase extraction at a weak polymeric anion exchanger. The exchanger is rinsed with water and /or other solvents. Finally, the adsorbed substances are eluted from the solid phase with ammonised methanol. The substances are analysed with gas or liquid chromatography methods coupled with mass spectrometry. By comparing the resulting signals with the signals from internal standards are running together with the samples, the perfluorinated carboxylic and sulfonic acids could be characterised and quantified.
There are already exist standardised and international accepted methods like the ISO method ISO 25101:2009E or the German DIN norm DIN 38407-42 for analysing PFCAs and PFSAs. The detection limits already reach concentrations in water down to 0.001 ppb.

However, a vast variety of PFHxA-related substances is used in different applications instead of direct use of PFHxA. Many of these substances are unknown. The substance properties are as variable as the amount of substances. So, it is very difficult to extract and to characterise or even quantify every single PFHxA-related substance. Very often perfluorinated side chains are linked via an ester-bond to another molecule e.g. to acrylates or alcohols. A possibility to measure PFHxA-related substances without knowing every single substance, is the conversion of these substances to the corresponding perfluorinated acid or alcohol and a subsequent analysis of the substance derivatives.

Houtz and Sedlak 2012 proposed an oxidation of the related substances with hydroxyl radicals to gain corresponding PFCAs (Houtz and Sedlak, 2012). These can be produced in a water sample by thermolysis of persulfate under basic pH conditions (TOP-assay). The TOP-assay was further developed e.g. by Dauchy et al. (Dauchy et al., 2017). DAIKIN presented a method of degrading fluorotelomer monomers and polymers to the respective alcohol by severing the ester-bond by heating the sample (DAIKIN, 2019). However, it is important to know, the results gained with the methods mentioned above, are summarising many PFHxA-related substances at once. These methods are not feasible for characterisation of a single definite substance related to PFHxA. Furthermore, it should be considered that these methods may lead to an overestimation of PFHxA released into the environment. The ester-bond is fairly inert, especially to biological degradation. So, the amount of PFHxA released into the environment arising by natural degradation processes, e.g. from polymers with perfluorinated side chains, may be much lower than the analysis results are indicating.

This uncertainty is important to keep in mind in investigating the content of PFHxA-related substances in products and articles. Mainly polymers with perfluorinated side chains are used for treatment of products and articles. Although, there are already several methods provided by industries, the examining of products and articles is still a challenge. However, Sweden has already initiated the development of a new CEN (European Committee for Standardization) standard within the technical committee TC248/WG26, "EC restricted substances in textiles" that specifies a test method for detection and quantification of extractable perfluorinated and polyfluorinated substances in textile articles that includes PFHxA, its salts and related substances.

An overview of some methods for extracting and analysing of PFHxA, its salts and related substances is shown in Table 80 "Overview of methods for extracting and analysing PFHxA, its salts and related substances as well in environmental compartments as in products and articles" in the appendix E.1.

Besides the availability of analytical methods, a sampling strategy is needed to monitor the restriction. There are different possibilities:

- Time trend monitoring,
- monitoring of releases.

For both strategies it has to be kept in mind that PFHxA is persistent, which will remain in the environment for ages even if release to the environment is stopped immediately. In addition, there will be continuing releases from articles in use and from long-range transport from non-EU-countries. A time trend monitoring can be performed with samples from the environment, from animals or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring. Reductions of releases of PFHxA and related substances in the environment should result in decreasing PFHxA concentration in such a trend monitoring. It might be sufficient to measure PFHxA in such a trend monitoring, because the related substance will be degraded to the corresponding persistent acid in the environment. Decreasing trends in releases will then not be directly measurable in environmental samples, because time is needed for degradation.

A joint approach for different enforcement activities such as inspections and testing for the occurrence of several regulated PFASs as PFOS, PFOA, C9-C14 PFCAs and PFHxA, its salts and related substances at the same time would lower costs. Thereby, enhancing cost effectiveness and reducing enforcement costs for PFHxA, its salts and related substances.

SEAC box

SEAC notes that the RAPEX (Rapid Exchange of Information) system has been replaced by Safety Gate.

Regarding imported articles, border authorities can control compliance using the RAPEX system (Rapid Exchange of Information System) to report any violation of the restriction. A time trend monitoring can be performed with samples from the environment, from animals or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring.

This restriction proposal also includes recycled material and articles made from recycled materials. In the dossier the Dossier Submitter has demonstrated a concern resulting from the exposure to PFHxA, its salts and related substances. Subsequently, there is a concern if recycled materials contain these substances. An exemption for recycled materials would potentially lead to higher releases to the environment in comparison with an appropriate waste management. Recycling of contaminated wastes contributes to environmental releases and the contaminants may again circulate through use, disposal and recycling phase of articles.

No stakeholder information is available, especially from the related recycling industries, whether the proposed restriction on PFHxA would induce any cost on them. The Dossier Submitter for PFOA proposed a restriction for recycled materials. He argued that a derogation is justified, because enforcement would be difficult and that recycling would be a sustainable management of resources. SEAC agreed with this reasoning. The European Commission disagreed in its detailed explanation accompanying the draft commission regulation:

"RAC and SEAC proposed an exemption for the placing on the market of articles made from recycled materials, considering that this does not lead to additional emissions. The Commission considers that such an exemption potentially leads to higher emissions to the environment in comparison with an appropriate waste management. As indicated in the Annex XV dossier, it is assumed that recycling of contaminated wastes contributes to environmental releases and that the contaminants may again circulate through use, disposal and recycling phase of products. Furthermore, substances having the properties of a Persistent Organic Pollutant (POP) like PFOA, its salts and PFOA-related substances, in line with the objectives of Regulation (EC) No 850/2004, should not be recycled."

Subsequent PFAS-related restriction proposals on C9-C14 PFCAs and PFHxS have adapted this view. Reflecting on whether this is a reasonable approach for PFHxA, too, some issues have to be considered:

1. PFHxA is not a Persistent Organic Pollutant. Accordingly, the reasoning can be applied to PFHxA only partially;
2. Use quantities are much larger than for C9-C14 PFCAs and PFHxS (and most probably larger than for PFOA);
3. Recycling might be an issue with regard to paper, textiles, semiconductors and building material;
4. The Dossier Submitter is not aware of any impacts resulting from the PFOA-restriction on recycling.

Trier et al. (2017) shortly discuss four Danish studies on background levels of PFAS in paper and board and recycling as a possible source. They conclude that '(t)o get better values for the background levels of PFAS in paper and board, further samples of particularly non PFAS treated paper and board samples must be analysed using the total organic fluorine method'.

The Dossier Submitter notes that no information was submitted by the recycling sector during the public consultation and therefore assumes that conclusions by the Dossier Submitter and SEAC with regard to the restriction proposal for C9-C14 PFAS substances also apply to this restriction:

'As the timeframe for recycling paper and food packages is quite fast, the Dossier Submitter suggests that, due to economic and technical reasons, any stock would only last for a short period of time and in practice, it would not be a problem after 18 months transition period when the restriction would apply. Recycling of textiles might have a longer timeframe, but the market for recycling of textiles in Europe is still immature. Only recycling of treated work clothes might be a problem, but the Dossier Submitter is of the opinion that such articles should not be recycled but they should be incinerated since they can be dangerous due to the potential presence of other dangerous substances as well. Therefore, no derogation is needed for recycling of textiles.'

No information on recycling is available for other applications.

The Dossier Submitter agrees with the Commission view that recycling potentially leads to additional emissions and notes that no robust information is available that this restriction might impact European recycling-related industries. Therefore, as long as no additional information on impacts becomes available, it is assumed that recycling will not be affected by a restriction.

With regard to paper recycling it might be argued that the vast majority of releases is emitted during the waste stage. Consequently, repeated service-life through recycling would not be a major source of additional emissions. The Dossier Submitter notes that he is not aware of information with regard to emissions of PFHxA, its salts and related substances from the process of wastepaper recycling (e.g. deinking, effluent, air emissions). However, emissions might be significant. Considering this risk, the Dossier Submitter proposes no derogation for recycling.

The proposed restriction does not cover the "second-hand" market (e.g. used textiles and textiles in the supply chain). One reason for this is that the second-hand market is difficult to control, in most cases one consumer donates/sells single articles to another consumer (directly or via a second-hand store). It would not be practical to remove single articles from the market. Furthermore, to use e.g. a jacket as long as possible before it turns into waste is a sustainable management of resources.

E.5 Proportionality

SEAC box

SEAC reached different conclusions than the Dossier Submitter concerning the proportionality of the restriction proposal for some sectors or sub-sectors. Moreover, SEAC considered that it is not possible to conclude whether the overall restriction is proportionate, although there are arguments in favour of proportionality, i.e. irreversibility of the accumulating stocks of PFHxA in the environment and the extreme persistence of PFHxA.

Details of the SEAC assessment are reported in the SEAC opinion, together with the justification for conclusions on proportionality.

Proportionality has been discussed in 2.5.5. In order to assess proportionality, the Dossier Submitter assumed that PFHxA has different but equivalent concerns in comparison to previously restricted PFAS (e.g. PFOA). This assessment is based on new arguments and better scientific understanding:

Considering new arguments and an emerging more complete scientific understanding of the intrinsic hazards of extremely persistent substances the Dossier Submitter argues that PFHxA (extremely persistent and mobile in the environment) compared to PFOA (confirmed PBT) has different concerns. But the Dossier Submitter argues that these concerns are equivalent. Though a discussion on the SVHC status is not part of a restriction but rather whether risks are adequately controlled, it is worth noting that PFHxA was suggested as a substance with equivalent level of concern to article 57 a-d in 2018. Though the status was not unanimously confirmed the majority of member states did support the suggestion.

Meanwhile HFPO-DA (GenX) as well as PFBS have been identified as SVHC due to their persistent and mobile properties showing that conceptually substances having the properties of P and M are of equivalent level of concern. The identification as an SVHC is not considered necessary for the preparation of the restriction proposal.

Since the restriction proposal for PFOA which was elaborated in 2015, the recognition of further concerns other than PBT/vPvB has evolved. This is reflected in several scientific papers. This applies especially for the first paper listed here. These new scientific developments were considered when assessing PFHxA for this restriction, see for example:

Mind the Gap: Persistent and Mobile Organic Compounds-Water Contaminants That Slip Through: (Reemtsma et al., 2016) noted that PMT/vPvM substances may circulate in the anthropogenic water cycle and a contamination may be irreparable and thus a concern so far not recognized in regulation. That chemicals may pose a threat to drinking water was linked to the evolution of chemical analysis now allowing to better detect chemicals in drinking water. Thus, the PMT concern is linked to technical progress in chemical analysis and new scientific knowledge.

Though repeatedly brought up whether persistency alone is a matter of concern, the following papers specifically addressed PFAS when discussing this issue:

Zürich statement on future actions on per-and polyfluoroalkyl substances (PFASs): (Ritscher A et al., 2016) call for further development of current regulatory schemes to especially account for high (or very high) persistence in the environment “extraordinary persistence, human and environmental exposure to PFASs will be a long-term source of concern”

Why is high persistence alone a major cause of concern?: (Cousins et al., 2019) analyse the possibility of a **P**-sufficient approach „if a chemical is highly persistent, its continuous release will lead to continuously increasing contamination irrespective of the chemical's physical–chemical properties”

This restriction proposal assumes that PFAS of different but equivalent concern will be replaced by non-fluorinated alternatives where it is assumed that hazard and risk will be reduced to a larger degree. In the Dossier Submitter’s view, the risk reduction capacity of this restriction proposal is larger, resulting in the assumption that society’s willingness to pay should be expected to be larger than for previous regulatory measures on fluorinated substances.

Annex F: Assumptions, uncertainties and sensitivities of the measured data on PFHxA in consumer products, house dust and food

The presented measured data on concentrations of PFHxA and some of its related substances have been compiled in order to demonstrate the presence of PFHxA in potential sources of consumer exposure and to give rough indications on the level of contamination that has been reported in recent years. They have not been further validated and analyzed in order to deduce model parameters or distributions for quantitative assessments of external consumer exposure to PFHxA. Nevertheless, some limitations of the presented data shall be discussed here.

The presented data were compiled from samples taken in the recent years. They give some indications regarding present concentrations, although there is some uncertainty on their representativeness for the present time, due to the continuous changes in PFAS uses. However, they do not allow extrapolations to PFHxA concentrations in the coming years, which would be important in the context of the proposed restriction:

PFHxA is not intentionally added to the sources discussed here, but it is an impurity or degradation product of other substances. The technological and unintentional processes by which PFHxA reaches the sources differ, and they are submitted to changes. Historically, PFHxA could appear as technological by-product of C8-chemistry from electrochemical fluorination. As C8-chemistry and electrochemical fluorination is still used in Asia, and the restriction of PFOA in articles is not binding before 4 July 2020, they still may be relevant for the measured data presented here. This is especially true for the food data, which may reflect environmental contaminations from the past, and for the house dust data, which may reflect contaminations from articles that were bought in former years and/ or imported from Asia.

While the importance of electrochemical fluorination as a source of PFHxA contamination is expected to diminish in the future, the importance of PFHxA-related substances from C6-chemistry is expected to rise. These related substances differ according to their technical functions in different products and articles, and their market share in these functions is subject to changes depending on technological progress, worldwide regulatory risk management and availability of alternatives. This future development is highly uncertain, and so are the future PFHxA concentrations in consumer products and articles, house dust and food. They cannot be extrapolated from the presented data.

In case that the transition from C8 to C6 chemistry in consumer products and articles was ongoing at present, the PFHxA concentrations could rise in consumer products due to increased use of PFHxA-related substances. PFHxA-concentrations could also rise, if a higher quantity of C6-related substances would be needed for a certain function. The PFHxA concentrations in consumer products may be limited by the nature of the technical production processes, but the level of these limits is unknown.

Concentrations in food (and in drinking water and also, possibly and to a lesser degree, in house dust), may reflect long-term accumulation of PFHxA in environmental media. Due to the persistence of the substance, they may rise over a (long) time, and, in contrast to consumer products, an upper limit for the resulting concentrations cannot be foreseen. In addition, concentrations in food (and in drinking water) could be affected by local contaminations of water and /or soil. The probability for such "hot spots" would increase with the prevalence of PFHxA-related substances in technological processes in the EU.

All other limitations of the presented data are less relevant than the uncertainty regarding the future development of the concentrations:

The overall number of analyzed samples is limited compared to the number of product types and food items in the different regions of the EU. With few exceptions, the studies are limited to products and food items in a single country and far away from representativeness for the European countries and markets.

Moreover, the samples within the studies differ regarding influencing factors like product type (i.e. composition, function), food items and location (i.e. potential contamination /accumulation). It should be noted that if the number of analyses for a certain product type is low, the observed maximum value may still underestimate the concentration in a realistic worst case.

In addition, the reported studies differ in their sampling strategies and analytical methods, and also in the level of documentation of this information. The analytic procedures for detection of PFHxA are complex, and for most materials there is no harmonized method, neither for sampling nor for analysis. This makes it difficult to compare the results.

Taken together the differences within the samples, the low number of samples with comparable conditions and methods, and the lack of data for many product or food types and countries, the database seems to be explorative, giving indications on some orders of magnitude rather than the present distributions of PFHxA concentrations in European consumer products, food and house dust.

Many studies report a high number of non-detects for PFHxA, and the detected concentrations within a study often show considerable variation over several orders of magnitude. This may be the result of analytical difficulties in combination with the diversity of the samples. Analytical difficulties will produce underestimations as well as overestimations. The diversity of the samples should be compared to the expected diversity of the real products in order to decide, whether the observed upper range covers the realistic worst cases.

Assumptions relevant for the socio-economic analysis of the individual sectors in the scope of the restriction proposal are detailed in their respective sector-specific assessment presented in Annex E. The main uncertainties in the analysis are due to knowledge gaps regarding the tonnages of PFHxA, its salts and related substances affected by the proposed restriction and where relevant, the availability and or functionality of alternatives.

The information on amounts of PFHxA, its salts and related substances used in the EU and imported in articles is limited. Therefore, only rough estimates are possible. Limited data is available on amounts used and on environmental emissions, especially from downstream user sites. Therefore, only rough emission estimates are presented in this restriction proposal. The risk assessment of PFHxA is complicated by several uncertainties in relation to toxicity, potential for accumulation in organisms, fate and exposure. These uncertainties are described in the respective sections of this report. Not much is known about fate and especially about what areas function as sinks for PFHxA. The non-threshold-based approach to risk assessment (and the minimisation approach to risk management) was adopted in response to these uncertainties.

Furthermore, there are major uncertainties on whether all related substances with relevant uses have been identified.

Annex G: Stakeholder information

Several consultations have been realised for gathering information on e.g. uses and alternatives.

RAC and SEAC box

RAC and SEAC note that, in addition to the stakeholder consultations reported in Table 42, a consultation on the Annex XV restriction report was carried out between 25 March and 25 September 2020. During the consultation on the Annex XV restriction report, 202 comments were received from the following stakeholders: companies (124), trade/industry associations (22), Member States/national competent authorities (7), NGOs (4), individuals (3), fire brigades (2), alternative provider (1) and ECHA (1).

See: https://echa.europa.eu/fi/restrictions-under-consideration/-/substance-rev/25419/term

Table 42: Stakeholder consultations on PFHxA, its salts and related substances.

Consultation	**Date**	**Remark**
RMOA-consultation	March - May 2016	mail to importers, manufactures and downstream users of PFHxA, its salts, and related substances as well as concerned industry associations for circulation among their members. Link to consultation was available on DE-CA website and ECHA weekly.
Stakeholder consultation by Ökopol (in cooperation with RISE Research Institute of Sweden) on behalf of German Environment Agency	February - April 2018 (IT survey)	IT survey followed by targeted interviews; see below
public consultation within the context of SVHC-identification	September - October 2018	
Meeting with registrants of either PFHxA, its salts or related substances	9 April 2019 and 27 August 2019	
Meeting /telephone calls with AFFF stakeholders	May - June 2019	e.g. information gathering on alternatives; experience with fires in large tanks
Communication with experts of German Federal Ministry of Defence regarding defence application of AFFF	May – August 2019	
ECHA-Workshop on Per- and Polyfluoroalkyl substances (PFAS) in fire-fighting foams and their	24 September 2019	

alternatives		

Stakeholder consultation (survey and targeted interview)
The objective of the survey was to increase the information basis on:
1) Manufactured and imported amounts of PFHxA, its salts and related substances;
2) manufactured and imported amounts of their potential alternatives;
3) the type of uses the substances are applied to;
4) the economic effects that are linked to the use of the substances.

The invitation to the survey was sent (Europe-wide) to substance manufactures; formulators of mixtures; end users of substances or mixtures; importers of substances, mixtures or articles as well as article assemblers in the EU; and associations, NGOs or other interested third parties. Furthermore, the survey was promoted on UBA-REACH-website and ECHA Weekly (28 March 2018) with link to the consultation website.

The submitted information was considered for the preparation of the restriction proposal and is included in the relevant chapters. Further information on the survey itself as well as summaries of the submitted information divided in corresponding role and branches are available in the final report of the UBA-project (Wirth et al., 2019).

The survey was planned and set up in the open source survey tool "Lime Survey" hosted by an external service provider. The tool was assessable via a web interface. The survey was conducted from 15 February 2018 until 15 April 2018 (original plan was to run the survey only for one month but due to several reactions from stakeholders it was extended by another month).

More than 600 stakeholders were invited to participate in and to share information about the online survey with other stakeholders.

Overall, 98 organisations (companies, environmental and consumer NGOs associations) have participated in the online survey. Sometimes associations submitted information on behalf of a sector or a number of companies. Some organisations registered to the survey but in the end did not provide information via the tool or at all. Some organisations preferred to provide information via direct submission of documents (e.g. via e-mail, mail or via download from secured internet spaces). 59 organisations permitted the use of their submitted information.

Main sectors that contributed were:

- Chemical manufacturers / importers,
- formulators of chemical mixtures (textile, paper processing, printer inks and colours, surface treatment, fire-fighting foams),
- end users (mainly textile applications, fire-fighting foams, semiconductor industry).

The roles of the organisations can be broadly categorized as follows:

- Industry association: 16,
- NGO: 3,
- scientific research institution: 1,
- end users: 12,

- formulators: 14,
- importers: 7,
- manufacturers/chemical companies: 6.

The participants shared information on the following sectors:

- Analytical methods (PFHxA broad): 1,
- automotive: 2,
- chemicals (broad): 12,
- firefighting foam: 6,
- medical: 1,
- mixtures for consumer use: 2,
- NGO (PFHxA broad): 3,
- optical fibres and lenses: 1,
- paints and varnishes: 1,
- paper: 1,
- photo imaging: 2,
- printing: 4,
- semiconductors: 4,
- textiles:20.

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Appendix A.1: Additional information on read-across approach

Table 43: Basic substance information and physical chemical properties relevant to justify grouping.

abbreviation	C_4-PFCA	C_6-PFCA	C_8-PFCA	C_9-PFCA	C_{10}-PFCA	C_{11}-PFCA	C_{12}-PFCA	C_{13}-PFCA	C_{14}-PFCA
acronym	PFBA	PFHxA	PFOA	PFNA	PFDA	PFUnDA	PFDoDA	PFTrDA	PFTeDA
IUPAC name	butanoic acid, heptafluoro-	hexanoic acid, undecafluoro-	octanoic acid, pentadeca-fluoro-	nonanoic acid, heptadeca-fluoro-	decanoic acid, nonadeca-fluoro-	undecanoic acid, henicosa-fluoro-	dodecanoic acid, tricosafluoro-	tridecanoic acid, pentacosa-fluoro-	tetradecanoic acid, heptacosa-fluoro-
chemical structure	$CF_3(CF_2)_2$-COOH	$CF_3(CF_2)_4$-COOH	$CF_3(CF_2)_6$-COOH	$CF_3(CF_2)_7$-COOH	$CF_3(CF_2)_8$-COOH	$CF_3(CF_2)_9$-COOH	$CF_3(CF_2)_{10}$-COOH	$CF_3(CF_2)_{11}$-COOH	$CF_3(CF_2)_{12}$-COOH
CAS number	375-22-4	307-24-4	335-67-1	375-95-1	335-76-2	2058-94-8	307-55-1	72629-94-8	376-06-7
	physico-chemical data								
molecular weight g/mol	214.04	314.05	414.07	464.08	514.08	564.09	614.10	664.11	714.11
partitioning coefficient log K_{OW}	3.39 ± 0.60 (calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02)	4.06 (calc., COSMOtherm (temp. not specified) (Wang et al., 2011b)	5.30 (calc., COSMOtherm (temp. not specified) (Wang et al., 2011b)	5.9 (calc., COSMOtherm, (Wang et al., 2011b))	6.5 (calc., COSMOtherm, (Wang et al., 2011b))	7.2 (calc., COSMOtherm, (Wang et al., 2011b))	7.8 (calc., COSMOtherm, (Wang et al., 2011b))	8.25 (calc., COSMOtherm, (Wang et al., 2011b))	8.90 (calc., COSMOtherm, (Wang et al., 2011b))
log K_{OA}		6.63 (calc., COSMOtherm (Wang et al., 2011b)	7.23 (calc., COSMOtherm, (Wang et al., 2011b))	7.50 (calc., COSMOtherm, (Wang et al., 2011b))	7.77 (calc., COSMOtherm, (Wang et al., 2011b))	8.08 (calc., COSMOtherm, (Wang et al., 2011b))	8.36 (calc., COSMOtherm, (Wang et al., 2011b))	8.63 (calc., COSMOtherm, (Wang et al., 2011b))	8.87 (calc., COSMOtherm, (Wang et al., 2011b))

abbreviation	C_4-PFCA	C_6-PFCA	C_8-PFCA	C_9-PFCA	C_{10}-PFCA	C_{11}-PFCA	C_{12}-PFCA	C_{13}-PFCA	C_{14}-PFCA
acronym	PFBA	PFHxA	PFOA	PFNA	PFDA	PFUnDA	PFDoDA	PFTrDA	PFTeDA
log K_{AW}		-2.66 (calc., (European Chemicals Agency, 2016a))	-1.93 (calc., COSMOtherm, (Wang et al., 2011b))	-1.58 (calc., COSMOtherm, (Wang et al., 2011b))	-1.27 (calc., COSMOtherm, (Wang et al., 2011b))	-0.92 (calc., COSMOtherm, (Wang et al., 2011b))	-0.58 (calc., COSMOtherm, (Wang et al., 2011b))	-0.38 (calc., COSMOtherm, (Wang et al., 2011b))	0.03 (calc., COSMOtherm, (Wang et al., 2011b))
dissociation constant		-0.16 (Zhao et al., 2014)	0.5 (calculated from exp. values, (Vierke, 2014)) 1.3 (López-Fontán et al., 2005)	< 1.6 (calculated from exp. values, (Vierke, 2014)) 0.82 (calc., COSMOtherm, (Wang et al., 2011b))	< 1.6 (calculated from exp. values, (Vierke, 2014)) 2.58 (Moroi et al., 2001)	< 1.6 (calculated from exp. values, (Vierke, 2014))			
partition coefficients log K_d (sediment and overlapping dissolved phase)		1.4 – 3.1 (Li et al., 2011)	0.04 (Ahrens et al., 2010a)*	0.6 (Ahrens et al., 2010a)*	1.8 (Ahrens et al., 2010a)*	3.0 (Ahrens et al., 2010a)*			
log K_{OC} (sediment organic carbon-normalised distribution coefficient)		1.63 – 2.35 (Sepulvado et al., 2011)	2.06 (Higgins and Luthy, 2006) 1.09 (Ahrens et al., 2010a)*	2.39 (Higgins and Luthy, 2006) 2.4 (Ahrens et al., 2010a)*	2.76 (Higgins and Luthy, 2006) 3.6 (Ahrens et al., 2010a)*	3.3 (Higgins and Luthy, 2006) 4.8 (Ahrens et al., 2010a)*			

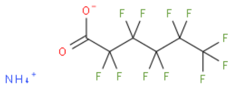
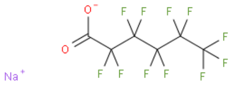
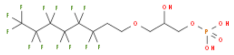
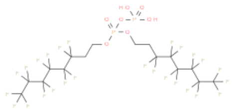
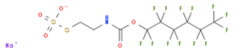
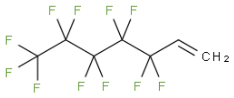
abbreviation	C_4-PFCA	C_6-PFCA	C_8-PFCA	C_9-PFCA	C_{10}-PFCA	C_{11}-PFCA	C_{12}-PFCA	C_{13}-PFCA	C_{14}-PFCA
acronym	PFBA	PFHxA	PFOA	PFNA	PFDA	PFUnDA	PFDoDA	PFTrDA	PFTeDA
water solubility		15.7 g/L (25 °C) (Zhao et al., 2014)	9.5 g/L (25° C) 4.14 g/L (22 °C) (European Chemicals Agency, 2013b)		5.14 g/L at 25 °C (European Chemicals Agency, 2016b)	$1.2 \cdot 10^{-4}$ g/L; pH 1 at 25 °C $9.0 \cdot 10^{-4}$ g/L; pH 2 at 25 °C $8.5 \cdot 10^{-3}$ g/L; pH 3 at 25 °C 0.056 g/L; pH 4 at 25 °C 0.14 g/L; pH 5 at 25 °C 0.16 g/L; pH 6-10 at 25 °C (calculated) (European Chemicals Agency, 2012a)	$2.9 \cdot 10^{-5}$ g/L pH 1 at 25 °C $2.2 \cdot 10^{-4}$ g/L pH 2 at 25 °C $2.0 \cdot 10^{-3}$ g/L pH 3 at 25 °C 0.014 g/L pH 4 at 25 °C 0.034 g/L pH 5 at 25 °C 0.039 g/L pH 6 at 25 °C 0.040 g/L pH 7 at 25 °C 0.041 g/L pH 8-10 at 25 °C (calculated) (European Chemicals Agency, 2012d)	$7.3 \cdot 10^{-6}$ g/L; pH 1 at 25 °C $5.5 \cdot 10^{-5}$ g/L; pH 2 at 25 °C $5.1 \cdot 10^{-4}$ g/L; pH 3 at 25 °C $3.5 \cdot 10^{-3}$ g/L; pH 4 at 25 °C $8.6 \cdot 10^{-3}$ g/L; pH 5 at 25 °C 0.0100 g/L; pH 6-10 at 25 °C (calculated) (European Chemicals Agency, 2012c)	$1.9 \cdot 10^{-6}$ g/L; pH 1 at 25 °C $1.4 \cdot 10^{-5}$ g/L; pH 2 at 25 °C $1.3 \cdot 10^{-4}$ g/L; pH 3 at 25 °C $9.3 \cdot 10^{-4}$ g/L; pH 4 at 25 °C $2.2 \cdot 10^{-3}$ g/L; pH 5 at 25 °C $2.6 \cdot 10^{-3}$ g/L; pH 6-10 at 25 °C (calculated) (European Chemicals Agency, 2012b)
vapour pressure		1.98 mm Hg at 25 °C; equals to 263.93 Pa	4.2 Pa (25 °C) extrapolated from		3.1 to 99.97 kPa	0.6 to 99.97 kPa (112 to	1.25 Pa at 25 °C (calculated)	0.48 Pa at 25 °C (calculated)	0.18 Pa at 25 °C (calculated)

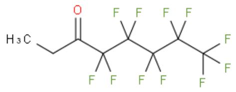
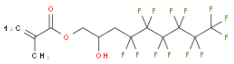
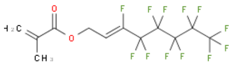
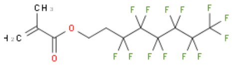
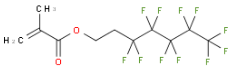
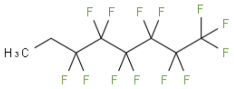
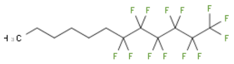
abbreviation	C_4-PFCA	C_6-PFCA	C_8-PFCA	C_9-PFCA	C_{10}-PFCA	C_{11}-PFCA	C_{12}-PFCA	C_{13}-PFCA	C_{14}-PFCA
acronym	PFBA	PFHxA	PFOA	PFNA	PFDA	PFUnDA	PFDoDA	PFTrDA	PFTeDA
		US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.11. Nov, 2012. Available from, as of Jan 11, 2015	measured data 2.3 Pa (20 ° C) extrapolated from measured data 128 Pa (59.3 °C) measured (European Chemicals Agency, 2013b)		(129.6 to 218.9 °C) (calculated) (European Chemicals Agency, 2016b)	237.7 °C) (calculated) (European Chemicals Agency, 2012a)	(European Chemicals Agency, 2012d)	(European Chemicals Agency, 2012c)	(European Chemicals Agency, 2012b)
boiling point		157 °C (Savu, 2000)		218 °C (European Chemicals Agency, 2015b)	218 °C measured (European Chemicals Agency, 2016b)	238.4 °C (calculated) (European Chemicals Agency, 2012a)	249 °C (European Chemicals Agency, 2012d)	260.7 °C (calculated) (European Chemicals Agency, 2012c)	270 °C (European Chemicals Agency, 2012b)

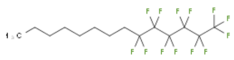
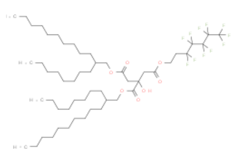
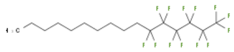
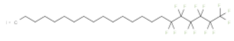
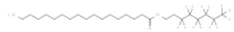
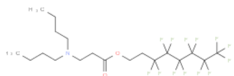
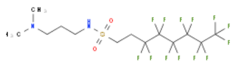
*pH of the water samples analysed 7.1 - 8.3 Temp.: 15.3 – 17.7 °C

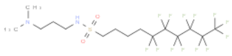
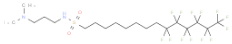
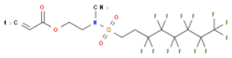
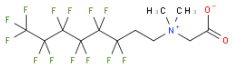
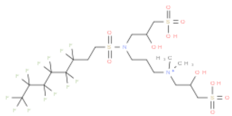
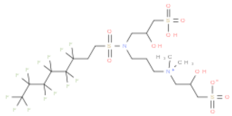
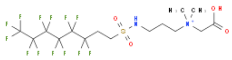
Appendix B.4.1: PFHxA-Related substances predicted via QSAR Toolbox v4.1 (European Chemicals Agency, 2018b)

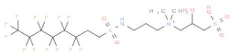
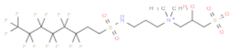
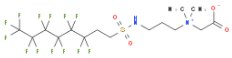
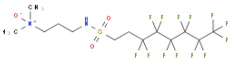
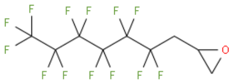
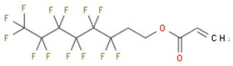
Table 44 PFHxA-related substances predicted via QSAR Toolbox v4.1 (European Chemicals Agency, 2018b).

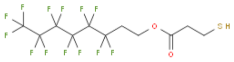
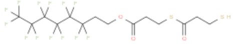
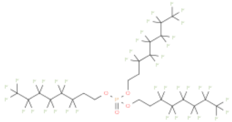
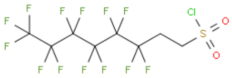
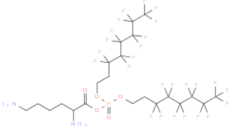
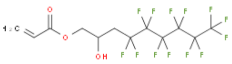
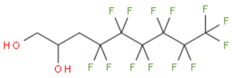
Structure depiction	Structural formula	Degradation pathway	CAS Number
	[NH4+].[O-]C(=O)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by dissociation|PFHxA by hydrolysis (acidic)|PFHxA by hydrolysis (basic)|PFHxA by hydrolysis (neutral)|PFHxA by microbial transformation	21615-47-4 (QSAR toolbox)
	[Na+].[O-]C(=O)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by dissociation|PFHxA by hydrolysis (acidic)|PFHxA by hydrolysis (basic)|PFHxA by hydrolysis (neutral)|PFHxA by microbial transformation	2923-26-4 (QSAR toolbox)
	OC(COCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)COP(O)(O)=O	PFHxA by microbial transformation	
	OP(O)(=O)OP(=O)(OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	[Na+].[O-]S(=O)(=O)SCCNC(=O)OC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C=C	PFHxA by microbial transformation	84100-13-0 (QSAR toolbox)

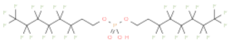
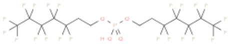
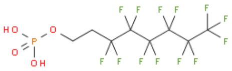
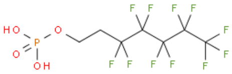
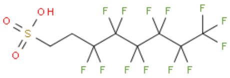
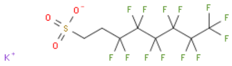
	CCC(=O)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	CC(=C)C(=O)OCC(O)CC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	CC(=C)C(=O)OCC=C(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	CC(=C)C(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	2144-53-8 (screening excersise and QSAR toolbox)
	CC(=C)C(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	65530-66-7 (QSAR toolbox)
	CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	80793-17-5 (screening excersise)
	CCCCCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	432-580-1 (EC-number screening exercise)

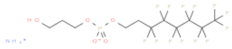
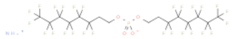
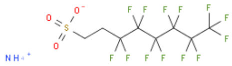
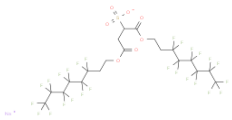
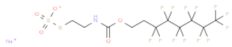
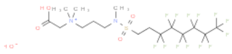
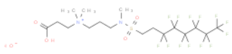
	CCCCCCCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	432-570-5 (EC-number screening exercise)
	CCCCCCCCCCC(CCCCCCCC)COC(=O)CC(O)(CC(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)C(=O)OCC(CCCCCCCC)CCCCCCCCCC	PFHxA by microbial transformation	214334-16-4 (QSAR Toolbox)
	CCCCCCCCCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	147492-59-9 (QSAR Toolbox)
	CCCCCCCCCCCCCCCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	CCCCCCCCCCCCCCCCCC(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	CCCCN(CCCC)CCC(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	402-910-7 (EC-Number screening exercise)
	CN(C)CCCNS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	34455-22-6 (screening excercise, QSAR Toolbox)

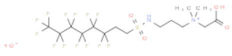
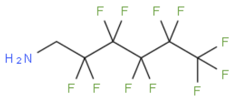
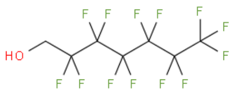
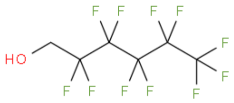
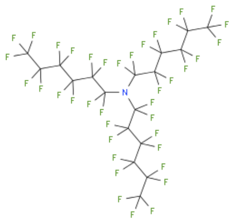
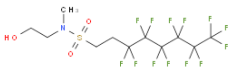
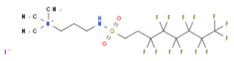
	CN(C)CCCNS(=O)(=O)CCCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	CN(C)CCCNS(=O)(=O)CCCCCCCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	CN(CCOC(=O)C=C)S(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	49859-70-3 (QSAR Toolbox)
	C[N+](C)(CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)CC([O-])=O	PFHxA by microbial transformation	145441-31-2 (QSAR Toolbox)
	C[N+](C)(CCCN(CC(O)CS(O)(=O)=O)S(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)CC(O)CS(O)(=O)=O	PFHxA by microbial transformation	
	C[N+](C)(CCCN(CC(O)CS(O)(=O)=O)S(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)CC(O)CS([O-])(=O)=O	PFHxA by microbial transformation	
	C[N+](C)(CCCNS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)CC(O)=O	PFHxA by microbial transformation	

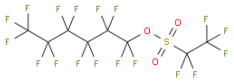
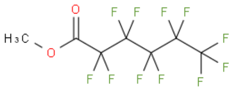
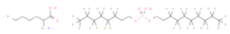
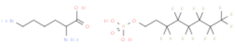
	C[N+](C)(CCCNS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)CC(O)CS(O)(=O)=O	PFHxA by microbial transformation	76201-56-4 (screening excercise)
	C[N+](C)(CCCNS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)CC(O)C[S-](=O)(=O)=O	PFHxA by microbial transformation	76201-56-4 (screening excercise)
	C[N+](C)(CCCNS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)CC([O-])=O	PFHxA by microbial transformation	34455-29-3 (QSAR Toolbox)
	C[N+](C)([O-])CCCNS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)CC1CO1	PFHxA by microbial transformation	38565-52-5 (QSAR Toolbox)
	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)CCOC(=O)C=C	PFHxA by microbial transformation	17527-29-6 (screening excercise, QSAR Toolbox)
	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)CCOC(=O)CCCCCCCCCCC(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	

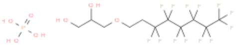
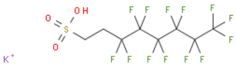
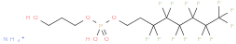
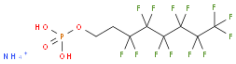
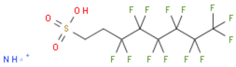
	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)CCOC(=O)CCS	PFHxA by microbial transformation	
	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)CCOC(=O)CCSC(=O)CCS	PFHxA by microbial transformation	
	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)CCOP(=O)(OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)CCS(Cl)(=O)=O	PFHxA by microbial transformation	27619-89-2 (screening excercise, QSAR Toolbox)
	NCCCCC(N)C(=O)OP(=O)(OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	OC(COC(=O)C=C)CC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	OCC(O)CC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	

	OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	647-42-7 (screening excercise, QSAR Toolbox); 68391-08-2 (screening excercise)
	OP(=O)(OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	OP(=O)(OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	65530-62-3 (QSAR Toolbox)
	OP(O)(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	OP(O)(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	65530-61-2 (QSAR Toolbox)
	OS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	27619-97-2 (QSAR Toolbox)
	[K+].[O-]S(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	59587-38-1 (QSAR Toolbox)

	[NH4+].OCCCOP([O-])(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	[NH4+].[O-]P(=O)(OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	1764-95-0 (QSAR Toolbox)
	[NH4+].[O-]S(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	[Na+].[O-]S(=O)(=O)C(CC(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)C(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	54950-05-9 (QSAR Toolbox)
	[Na+].[O-]S(=O)(=O)SCCNC(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	82199-07-3, (QSAR Toolbox)
	[OH-].CN(CCC[N+](C)(C)CC(O)=O)S(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	66008-71-7 (QSAR Toolbox)
	[OH-].CN(CCC[N+](C)(C)CCC(O)=O)S(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	66008-72-8 (QSAR Toolbox)

	[OH-].C[N+](C)(CCCNS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)CC(O)=O	PFHxA by microbial transformation	34455-29-3 (QSAR Toolbox)
	NCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	OCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	375-82-6 (QSAR Toolbox)
	OCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)N(C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	432-08-6 (QSAR Toolbox)
	CN(CCO)S(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	51619-73-9 (QSAR Toolbox)
	[I-].C[N+](C)(C)CCCNS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	94088-80-9 (QSAR Toolbox)

	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)OS(=O)(=O)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	COC(=O)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by hydrolysis (acidic)|PFHxA by hydrolysis (basic)|PFHxA by Hydrolysis (neutral)|PFHxA by microbial transformation	
	NCCCCC(N)C(O)=O.OP(=O)(OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	NCCCCC(N)C(O)=O.OP(=O)(OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	NCCCCC(N)C(O)=O.OP(=O)(OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	NCCCCC(N)C(O)=O.OP(O)(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	

	OP(O)(O)=O.OCC(O)COCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	[K+].OS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	[NH4+].OCCCOP(O)(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	[NH4+].OP(O)(=O)OCCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	
	[NH4+].OS(=O)(=O)CCC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F	PFHxA by microbial transformation	

Appendix B.4.2: Concentrations of PFHxA, its salts and related substances in environmental compartments

Table 45: PFHxA and related substances in wastewater treament plants and landfills (LOQ: Limit of quantification; LOD: Limit of Detection).

Sampling location	**PFHxA concentration [ng/L]**	**6:2 FTS concentration [ng/L]**	**6:2 FTCA concentration [ng/L]**	**6:2 FTUCA concentration [ng/L]**	**6:2 diPAP concentration [ng/L]**	**6:2/8:2 diPAP concentration [ng/L]**	**Sampling year**	**Reference**
wastewater treatment plant (WWTP)								
9 WWTP effluents along River Elbe, Germany	3.7 – 57.4	< 0.2 - 37.9					2007	(Ahrens et al., 2009b)
4 WWTP (1 industrial and 3 municipal) effluents, China	10.7 – 11.3						2009-2010	(Sun et al., 2011)
sewage sludge of 10 WWTPs (4 domestic, 5 industrial, 1 hospital), South West Nigeria	<0.0105 – 0.2458 ng/g						2012	(Sindiku et al., 2013)
90 European WWTP effluents	5.7 (media) 23800 (max) 72 % > LOQ						2010	(Loos et al., 2013)

Sampling location	**PFHxA concentration [ng/L]**	**6:2 FTS concentration [ng/L]**	**6:2 FTCA concentration [ng/L]**	**6:2 FTUCA concentration [ng/L]**	**6:2 diPAP concentration [ng/L]**	**6:2/8:2 diPAP concentration [ng/L]**	**Sampling year**	**Reference**
influent from 3 WWTP, Hong Kong	< 0.25				0.92-3.36	3.65 - 5.27	2012	(Loi et al., 2013)
effluent from 3 WWTP, Hong Kong	< 0.25				< 0.25 - 1.44	< 0.25 –-4.59		
sludge from 2 WWTP, Hong Kong	< 0.066 ng/g d.w.				10-13.5 ng/g dw	32.3 - 130 ng/g dw		
waster water, Austria	n.d. - 12 (n = 48, detection rate: 54.2 %, LOD = 0.5)						2014-2016	Provided by the Austrian Environment Agency in the Public Consultation
effluent Norway (urban)	2.2 – 6.6 100 % detection frequency						2017	(Norwegian Institute for Air Research (NILU), 2018b)
influent of two WWTP Australia	13-20 WWTP A 5-17 WWTP B significant positive trend forWWTP B	37 - 138 WWTP A 8.8 - 29 WWTP B samples analysed August 2016-October 2017					March 2014-October 2017	(Nguyen et al., 2019)

Sampling location	**PFHxA concentration [ng/L]**	**6:2 FTS concentration [ng/L]**	**6:2 FTCA concentration [ng/L]**	**6:2 FTUCA concentration [ng/L]**	**6:2 diPAP concentration [ng/L]**	**6:2/8:2 diPAP concentration [ng/L]**	**Sampling year**	**Reference**
landfill leachates								
one landfill leachate (Canada)	650 – 2500		40 - 280	7 - 64			2010	(Benskin et al., 2012a)
one landfill leachate, Finland	49 -200						2009-2010	(Perkola and Sainio, 2013)
landfill leachates (22 landfill sites in Germany)	<0.37 – 2509						-	(Busch et al., 2010)
effluent /landfill leachate (24 landfill sites in Germany)	< LOD—4256						2009	(Gellrich, 2014)
landfill leachates, (6 landfill sites in the USA)	270 - 790	56 - 280						(Perkola and Sainio, 2013)
landfill leachates laboratory bioreactor	< 2200	< 260					2010	(Perkola and Sainio, 2013)

Table 46: PFHxA in surface water and oceans (LOQ: Limit of quantification; LOD: Limit of Detection).

Sampling location	**PFHxA [ng/L]**	**Sampling year**	**Reference**
Atlantic and Canadian Arctic Oceans (cruises)	Atlantic: < 0.0046 – 0.51 Canadian Arctic: < 0.0024 – 0.0048	2005-2009	(Benskin et al., 2012b)
Northern Europe, Atlantic Ocean and Southern Ocean (cruise)	< 0.003 – 0.117	2008	(Ahrens et al., 2010b)
Greenland Sea, Atlantic and Southern Ocean (cruises)	Greenland Sea: < 0.0059 – 0.038 Atlantic: < 0.0059 – 0.120 Southern Ocean: < 0.0059	2009-2011	(Zhao et al., 2012)
seawater of the Western Merditerranean sea	0.096 (median) 0.02 – 0.189	2014	(Brumovský et al., 2016)
seawater of the German Baltic Sea	0.26 (median) 0.22 – 0.84	2017	(Joerss et al., 2019)
seawater of the German Bight (North Sea)	0.47 – 9.56	2007	(Ahrens et al., 2009a)
Hessian (Germany) surface water (32 samples)	11 (median) 81 % > LOQ	2009	(Gellrich et al., 2012)
10 lakes around Shenyang, China	< 0.63 – 25.0	2009	(Sun et al., 2011)
Guadalquivir and Ebro rivers (Spain)	9.6 – 31.4	2010	(Lorenzo et al., 2015)
40 river samples across the Hyogo prefecture, Japan	< 0.5 – 6.9 65 % > LOD	2010	(Takemine et al., 2014)
38 seawater samples across the Hyogo prefecture, Japan	1.5 – 510 100 % > LOD	2010	(Takemine et al., 2014)
22 surface water samples Ruhr area	< LOQ — 1248	2006	(Skutlarek et al., 2006)
38 surface water samples from River Rhine and selected tributaries	< LOQ — 77.0	2006	(Skutlarek et al., 2006)
12 surface water samples Moehne river and selected tributaries	< LOQ – 3040	2006	(Skutlarek et al., 2006)
River Alna River Drammenselva River Glomma	1.49 - 2.6 0.2 - 0.5 (concentration > LOD reported) 0.2 - 0.5 (concentration > LOD reported)	2016	(Norwegian Institute for Water Research (NIVA), 2017c)
input from storm water. Storm water samples were collected at one occasion at	5.42	2016	(Norwegian Institute for Water Research (NIVA), 2017c)

Sampling location	**PFHxA [ng/L]**	**Sampling year**	**Reference**
four specific sampling points (Bryning, Breivoll/Alnabru terminal, Breivoll downstream terminal and Hasle snow			
input from storm water	3.52	2015	(Norwegian Institute for Water Research (NIVA), 2016b)
Finnish rivers (128 samples from 20 different sites)	< 0.1 – 7.97 (88 % > LOD)	2014-2017	unpublished data, available in database https://wwwp2.ymparisto.fi/scripts/kirjaudu.asp
Finnish lakes (6 samples from different sites)	0.22 - 2.33	2014-2017	unpublished data, available in database https://wwwp2.ymparisto.fi/scripts/kirjaudu.asp (2018)
Deep sea (300 m and 1000 m depth) - Cap de Creus Canyon (north-western Mediterranean Sea)	sedimentary particle analyses: 0.89 to 4.47 ng/g (depth of 300 m) 4.57 to 10.66 ng/g (depth of 1000 m) (88 % > LOD) no PFASs were detected in the supernatant phases	2011/2012	(Sanchez-Vidal et al., 2015)
Ai River around a fluoropolymer plant in Osaka, collected within a 5 km radius of the plant	26.2 – 1 130 ng/L with 35 700 ng/L in 2009 in Ai River; Levels of PFOA decreased greatly over the last few decades, whereas those of PFHxA increased	Surface water 2003-2015	(Shiwaku et al., 2016)

Table 47: PFHxA in groundwater (LOQ: Limit of quantification).

Sampling location	**PFHxA [ng/L]**	**Sampling year**	**Reference**
Hessian (Germany) groundwater (150 samples)	4 (median) 14 % > LOQ	2008	(Gellrich et al., 2012)
groundwater recharge area (several perfluoroalkyl acids (PFAA) sources are present – a former landfill, a military base and a small commercial /industrial area) (Netherlands) Observation wells (OW, n = 2) Pumping wells (PW, n = 5)) – travel distance > 25 years	OW: (downstream of the potential PFAA sources): 0.7 – 570 PW: 0.22 – 0.8	2011	(Eschauzier et al., 2013)
164 individual groundwater samples from 23 European countries	< 0.5 0 % > LOD	2008	(Loos et al., 2010)
groundwater (n = 26) from an unlined firefighter training area at Ellsworth U.S. Air Force Base (AFFF used between 1970 and 1990)	< 100 – 320 000 96 % > LOD	2011	(Houtz et al., 2013)
Ground water (n = 2057) in Germany	< LOQ — 95.0	Not given	(von der Trenck et al., 2018) and Hessian Agency for Nature Conservation (2017) Environment and geology. Wiesbaden, Germany (unpublished data)
2 wells 5 km around a fluoropolymer plant in Osaka, Japan	well water (n = 44) 64.3 - 220 and 110 - 970) continuosly investigated; Levels of PFOA decreased greatly over the last few decades, whereas those of PFHxA increased	2006-2015	(Shiwaku et al., 2016)

Table 48: PFHxA in raw water and drinking water (LOQ: Limit of quantification).

Sampling location	**PFHxA [ng/L]**	**Sampling year**	**Reference**
findings in raw water samples			
raw water from public drinking water system (New Jersey, USA) (12 surface water and 18 groundwater)	<5 – 17 23 % > MRL (minimum reporting level)	2009-2010	(Post et al., 2013)
drinking water production chain, Amsterdam (Netherlands)	intake: 2.3 – 2.4 finished drinking water: 3.8 – 5.3	2010	(Eschauzier et al., 2012)
finding in tap water samples			
26 tap water samples from Germany	< 1 – 6.4 23 % > LOQ	not mentioned	(Gellrich et al., 2013)[26]
3 tap water samples from Norway (households receiving water from different water works)	< 0.11 0.31 0.78	2008-2009	(Haug et al., 2010)
84 tap water samples from Spain and 5 from Germany	Spain: 3.0 (median) 11 (max) 18 % > LOQ Germany: 0.7 (median) 1.8 (max) 80 % > LOQ	2010-2012	(Llorca et al., 2012a)
tap water samples in six European Countries (Sweden, Italy, Belgium, Netherlands, Norway, Germany) (n = 7)	< 0.38 – 5.15 86 % > LOQ	2010	(Ullah et al., 2011)
26 waterworks along the Ruhr River (Germany)	< 10 (median) 40 (max) 49 % > LOD	2008-2009	(Wilhelm et al., 2010)
21 tap water samples from Ruhr area	< LOQ – 56 66.6 % > LOQ	2006	(Skutlarek et al., 2006)
16 tap water samples from Germany (outside Ruhr area)	< LOQ – 9 6.3 % > LOQ	2006	(Skutlarek et al., 2006)
tap water 5 km around a fluoropolymer plant in Osaka	tap water Osaka 6.57-1.18 tap water Kyoto 3.35-4.4	2010-2015	(Shiwaku et al., 2016)

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[26] Concentrations of PFHxA were also investigated in 18 spring water samples (Switzerland, Czech Republic and Germany), 14 untreated raw water samples for preparation of mineral water (Germany, France and Italy) and 119 bottled or repackaged mineral water samples. No PFHxA was detected above the LOQ (1 ng/L).

Table 49: PFHxA and related substances in soil and sediment (LOQ: Limit of quantification).

Sampling location	**PFHxA concentration (soil [µg/kg], sediment [pg/kg])**	**6:2 diPAP concentration (soil [µg/kg], sediment [pg/kg])**	**6:2/8:2 diPAP concentration (soil [µg/kg], sediment [pg/kg])**	**Sampling year**	**Reference**
soil [µg/kg]					
soil (0.6 m below surface; n = 16) and aquifer solids (5 - 6 m below surface; n = 10) from an unlined firefighter training area at Ellsworth U.S. Air Force Base (AFFF used between 1970 and 1990)	Soil: < 0.8 – 2 000 88 % > LOQ aquifer solids: 16 – 210 100 % > LOQ			2011	(Houtz et al., 2013)
soil (n = 60) and aquifer solids (n = 16) from a former firefighter training area at Ellsworth Air Force Base (USA)	soil < 0.05 – 2 761 93 % > LOQ Aquifer Solids 0.445 – 297 100 % > LOQ			2011	(McGuire et al., 2014)
soil from a fire-fighting training ground at Flesland airport, Norway based on dryweight	0.18 – 18.5			2009	(Klima- og forurensningsdirektoratet (KLIF), 2010)
different sites (n = 10) at Rastatt contaminated with PFHxA	3.1 - 32.3			2015-2017	German Environmental Specimen Bank unpublished data
soil dw 5 stations in Oslo, based on dryweight	0.00043			2016	(Norwegian Institute for Air Research (NILU), 2017a)
sediment [pg/g]					
sediment from 16 locations in Hong Kong, based on dryweight	< 17 – 95	< 17 – 80	< 17	2009	(Loi et al., 2013)

Sampling location	**PFHxA concentration** **(soil [µg/kg], sediment [pg/kg])**	**6:2 diPAP concentration** **(soil [µg/kg], sediment [pg/kg])**	**6:2/8:2 diPAP concentration** **(soil [µg/kg], sediment [pg/kg])**	**Sampling year**	**Reference**
surface sediment samples from 26 stations and sediment core samples (n = 31) from 3 stations in Lake Ontario, Canada	surface: < 50 – 56 6 % > LOQ core: < 50 – 409 23 % > LOQ			2006 and 2008	(Yeung et al., 2013)
sediment from Langavatnet near Flesland airport., Norway, based on dryweight	< 600 – 1 600			2009	(Klima- og forurensningsdirektoratet (KLIF), 2010)
cores of sediments from Lake Erie, St Clair and Ontario including pore water	Ponar samples: 0.9 ng/g Ontario (n = 42) 0.3 ng/g St Clair (n = 16) 0.3 ng/g Erie (n = 49) Core samples 1.1 ng/g Ontario (n = 100) 0.4 ng/g St Clair (n = 21) 3.5 ng/g Erie (n = 49)[27]			Lake Ontario in 2013 and Lake Erie and Lake St. Clair in 2014	(Codling et al., 2018)

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[27] In sediment from Lake Erie with layers in the core corresponding to 1959 to 2013, concentrations of both PFOS and PFHxA increased from earlier to more recently deposited sediments.

Appendix B.4.3: Concentrations of PFHxA, its salts and related substances in remote areas

Table 50: Findings of PFHxA and related substances in remote areas (LOQ: Limit Of Quantification).

Environmental Media	Sampling location	PFHxA concentration	6:2FTS [pg/m³]	Sampling year	Reference
ocean	Atlantic and Canadian Arctic Oceans (cruises)	Atlantic: < 0.0046 ng/L – 0.51 ng/L Canadian Arctic: < 0.0024 ng/L – 0.0048 ng/L	-	2005-2009	(Benskin et al., 2012b)
snow	European Alps (Colle Gnifetti; 10 m shallow firn core; 1996 - 2008)	0.06 ng/L – 0.34 ng/L 100 % > LOQ	-	2008	(Kirchgeorg et al., 2013)
oceanic plankton seawater	tropical /subtropical Pacific, Atlantic, Indian Oceans	frequency detected: Plankton: 7 % Seawater: 10 %	-	2010	(Casal et al., 2017)
air	Zeppelin (Norwegian Polar research station) monthly mean concentrations	< 0.015 - 0.047 pg/m³ monthly mean concentrations. In 2016, most of the monitored PFASs were below the analytical detection limit in all samples at all sites.	0.154	2016	(Norwegian Institute for Air Research (NILU), 2017b)
		< 0.05 - 0.07 pg/m³. Frequency detected ~20 %	> 0.2	2015	(Norwegian Institute for Air Research (NILU), 2016)
		< 0.05 - < 0.24 pg/m³	< 0.14 - < 0.89	2014	(Norwegian Institute for Air Research (NILU), 2015)

Environmental Media	**Sampling location**	**PFHxA concentration**	**6:2FTS [pg/m³]**	**Sampling year**	**Reference**
		0.05 - 0.19 pg/m³ PFHxA was observed with high detection frequency	0.22 - 0.53	2013	(Norwegian Institute for Air Research (NILU), 2014; Norwegian Institute for Air Research (NILU), 2015)
		0.02 – 0.24 pg/m³ (above detection limit in 11 out of 12 samples)	> 0.2	2017	(Norwegian Institute for Air Research (NILU), 2018a)

Appendix B.4.4: Concentrations of PFHxA, its salts and related substances in cosmetics and in house dust

Table 51: Reported concentrations of PFHxA in cosmetic products.

Data source	**PFHxA**		**µg/kg**		
Brinch et al. (2018)[a]	samples (n)	positive samples	max.	min.	median
all products	18	15	3 340.0	n.d.	4.9
facial scrub	1	1	6.3	5.4	5.9
BB /CC creams	3	3	397.0	12.0	16.5
body lotions	2	2	24.0	4.5	14.2
cream /lotion	2	2	2.6	1.1	2.1
ryeliner	1	0	n.d.	n.d.	n.d.
foundations	4	3	3 340.0	n.d.	178.5
concealer	1	1	1 940.0	1 930.0	1 935.0
highlighter	1	1	18.0	17.0	17.5
hair spray	1	0	n.d.	n.d.	n.d.
powder	1	1	34.0	30.0	32.0
eye shadow	1	1	5.5	5.4	5.5

Schultes et al. (2018)					
all products	31	10	4 640	< 3.35	< 3.35
cremes	7	0			
foundations	9	4	4 640	< 3.35	< 3.35
pencil	1	0			
powders	12	6	447	< 3.35	3.62
shaving Creme	2	0			
Fujii et al. (2013)					
all products	23	18	6 500	< 1.9	350
foundations	9	8	2 100	< 1.9	410
manicure	3	3	140	4.7	24
lip rouge	2	0	< 5.7	< 3.8	
sunscreen (milk)[b]	6	5	6 500	< 4.6	2 800
sunscreen (foundations)	3	2	350	< 2.3	180

[a] two individual products were analyzed per sample

[b] four different lots of a specific sunscreen milk were analyzed

Table 52: Reported Concentrations of PFHxA in House Dust from European Samples.

Reference	**Sampling Year**	**Location**	**LOD**	**N**	**>LOD**	**Min.** [ng/g]	**Median** [ng/g]	**Mean** [ng/g]	**Max.** [ng/g]	**Remarks on Sampling and Sieving**
Huber et al. (2011)	2007-2008	Norway	0.18-7.89 (MDL)	7	6	<2.2	10.1	11.3	26.7	Living rooms, industrial vacuum cleaner, forensic nozzle, surfaces above floor
				1	1		27.5			Sleeping room, industrial vacuum cleaner, forensic nozzle, surfaces above floor
D'Hollander et al. (2010)	2008	Belgium	0.1 (LOQ)	45			0.3		5.8 (95P)	Nylon socks, only floor, 500 µm
Haug et al. (2011)	2008	Norway	2.1-13 (LOQ)	41	31	4.3	28	33	96	Forensic nozzle, surfaces above floor
Ericson Jogsten et al. (2012)	2009	Catalonia	0,019	10	10	0,40	1.01		2.9	Vaccum cleaner, 150 µm

Eriksson and Karrman (2015)	2013-2014	Greece	1.4 – 7.9	7		<3.21	3.85	6.24	26.2	Vaccum cleaner, 150 µm
	2009	Spain		10		<3.21	3.39	3.16	5.45	
	2013-2014	Sweden		10		<3.21	7.05	9.65	39.6	
Lankova et al. (2015)	2013	Czech Rep.	0.25-1 (LOQ)	18	2	<1			9.73	From 6 households, vacuum cleaner
Karaskova et al. (2016)	2013	Czech Rep.	0.01 ng/ml (LOQ)	16	16	1.4	3.8	12.8	69.1	Polyester sampling sock, 500 µm
Winkens et al. (2018)	2014-2015	Finland	0.82 (MDL)	65	33	<0.82	2.33	5.17	54.5	Childrens bedrooms, Polyester sampling sock, floor after 1 week, 0,5 mm
Bohlin-Nizzetto et al. (2015)	2015	Norway	0.05	36	32	<0.05	9.29		40.2	From 6 households, industrial vacuum cleaner, forensic nozzle, all surfaces
Padilla-Sánchez and Haug (2016)	2015	Norway	Not given	7	3	<LOD	<LOD		10	Vacuum cleaner, 500 µm

N: number of samples; LOD: limit of detection; LOQ: limit of quantification; MDL: method detection limit

Several of the studies gave additional information on PFHxA-related substances in house dust: According to Eriksson and Karrman (2015), polyfluoroalkyl phosphate esters (PAPs) can be degraded by microbial hydrolysis to fluorotelomer alcohols (FTOH) which can be oxidized to saturated and unsaturated carboxylic acids (FTCA and FTUCA) and form polyfluorinated carboxylic acids (PFCA).

Huber et al. (2011) analyzed indoor air in six of the living rooms where the house dust samples were taken. They found 6:2 FTOH concentrations between 16.0 and 332 pg/m³ and a strong positive correlation between 6:2 FTOH concentrations in indoor air and PFHxA concentrations in dust.

In the house dust samples taken by Eriksson and Karrman (2015), mono-and diPAPs accounted for a vast majority of the analyzed perfluorinated compounds. 6:2 diPAP contributed 27 % to the total amount of diPAP homologues in the whole study, 6:2/8:2 diPAP 17 % and 6:2/10:2 diPAP 13 %. The median values for 6:2 diPAP were 5.26 ng/g in Greece, 2.08 ng/g in Spain and 15.4 ng/g in Sweden.

Also in the study by Winkens et al. (2018), the house dust samples were dominated by PAPs and FTOHs. Medians were 16.6 ng/g for monoPAP, 53.9 ng/g for 6:2 diPAP and 27.6 ng/g for 6:2 FTOH.

Appendix B.4.5: Concentrations of PFHxA, its salts and related substances in biota and humans

Table 53: Concentration of PFHxA in different organisms (LOQ Limit of quantification; MDL method detection limit; MQL method quantification limits; MLOD method limits of detection; n.d. not detected).

Organisms	PFHxA concentration [ng/g] ww	Sampling location	Reference /Sampling year
zooplankton herring sprat guillemot egg	< 0.04 (MQL), < 0.2 (MQL) < 0.5 (MQL) 0.0026	Baltic Sea	(Gebbink et al., 2016) 2013-2014
albatross liver albatross muscle albatross adipose	0.09 n. d. – 0.06 n. d. – 0.05	Midway Atoll (North Pacific Ocean	(Chu et al., 2015) 2011
fish muscle fish liver prawn	68 % recovery 44 % recovery 38 % recovery All samples < LOQ	Australia, contaminated estuaries	(Taylor and Johnson, 2016) 2015
crucian carp blood crucian carp liver mandarin fish blood mandarin fish liver	n. d. – 0.36 n. d. n. d. n. d.	Korea	(Lam et al., 2016) 2010 - 2012
amphipod damselfly shrimp sunfish bullhead turtle plasma	2.22 < MDL (0.25) < MDL (0.25) < MDL (0.25) < MDL (0.25) < MDL (0.1)	Hamilton, Canada; downstream of an airport	(de Solla et al., 2012) 2007 - 2010
wild boar (liver)	0.49	Ingolstadt, Germany	(Klein et al., 2016) 2011 - 2012
fish skin fish liver fish muscle roe fish algae guano algae penguin dung penguin tissue	< MLOD – 12.3 207 – 232 < MLOD - 72 1.44 – 2.31 3.4 – 240 < MLOD – 1190 < MLOQ 17.3 – 237 0.26 – 0.61	Tierra del Fuego Tierra del Fuego Tierra del Fuego Tierra del Fuego Tierra del Fuego Tierra del Fuego Antarctica Antarctica Antarctica	(Llorca et al., 2012b)
beaver, liver cod, blood velvet scoter eider duck long-tailed duck long-tailed duck red-throated diver razorbill	0.08 0.17 pg/mL < 0.05 < 0.05 < 0.05 < 0.05 < 0.05 < 0.05	Poland	(Falandysz et al., 2007) 2003
roe deer	Recovery 5.5 % < 0.02 (LOQ) – 0.7	Germany	(Falk et al., 2012) (2010)

Organisms	PFHxA concentration [ng/g] ww	Sampling location	Reference /Sampling year
zooplankton Arctic cod ringed seal bearded seal	n.d. (LOD 0.3) n.d. (LOD 0.3) n.d. (LOD 0.3) n.d. (LOD 0.3)	Canadian Western Arctic	(Powley et al., 2008) 2004
PFHxA detected in 3 of 16 monitored organisms: white shrimp whitebait gobies	2.11 0.815 3.29	Taihu Lake China	(Fang et al., 2014) 2012
fish homogenates	4.67	Ohio, Missouri, and Upper Mississippi Rivers	(Ye et al., 2008)
fish plasma (European chub)	0.2 (not found in Liver, Gills, Gonads, Muscle)	Orge River (nearby Paris)	(Labadie and Chevreuil, 2011) 2010
soft tissue of seafood samples, PFHxA detected in 1 of 16 monitored organisms: swimming crab	0.29	fish market China	(Gulkowska et al., 2006) 2004
common eider European shag kittiwake glaucous gull polar bear mink	0.0 – 0.06 100 % detection frequency < 0.10 – 0.03 40 % detection frequency < 0.10 – 0.09 40 % detection frequency < 0.10 – 0.03 40 % detection frequency 0.06 – 0.05 40 % detection frequency < 0.10 0 % detection frequency	Norwegian Arctic	(Norwegian Institute for Air Research (NILU), 2018b)
common gull	< 0.10 – 0.04 20 %	Norway (urban)	(Norwegian Institute for Air Research (NILU), 2018b)

Organisms	**PFHxA concentration [ng/g] ww**	**Sampling location**	**Reference /Sampling year**
Cod liver	< LOD	Coastal waters Norway	(Guelfo et al., 2018; Norwegian Institute for Water Research (NIVA), 2013; Norwegian Institute for Water Research (NIVA), 2014; Norwegian Institute for Water Research (NIVA), 2015; Norwegian Institute for Water Research (NIVA), 2016a; Norwegian Institute for Water Research (NIVA), 2017a)
ice amphipod polar cod black guillemot glaucous gull	n.d. (LOD 0.41) 6:2 FTS: n.d. – 1.68 (LOD) 0.64 – 5.38 n.d. – 0.39 (LOD 0.22) n.d. – 1.55 (LOD 0.22)	Barants Sea	(Haukas et al., 2007) 2004
polychaeta blue mussel krill prawns herring cod gull blood gull egg	All < LOD	Urban Fjord, Norway	(Norwegian Institute for Water Research (NIVA), 2017b)

Organisms	**PFHxA concentration [ng/g] ww**	**Sampling location**	**Reference /Sampling year**
earthworm eggs of fieldfare eggs of tawny owl red fox liver sparrowhawk egg brown rat liver	3.28 < LOD 0.01 < LOD < LOD < LOD	Oslo	(Norwegian Institute for Air Research (NILU), 2017a)

Appendix B.5: Human health hazard assessment

B.5.1 Toxicokinetics (absorption, distribution, metabolism and elimination)

Regarding the evaluation of the bioaccumulation potential, elimination half-lives have been proven to be of importance for long-chain PFASs. Elevated levels of PFOA in human blood and a half-life in humans of 2-4 years lead to the conclusion that PFOA is bioaccumulative (ECHA, 2013b).

The free undecafluorohexanoic acid (PFHxA) is in equilibrium with undecafluorohexanoate (PFHx), the conjugate base; however, due to its low pK_a (< 1), PFHxA primarily exists in the environment as an anion. However, some laboratories report results for the acidic form of PFHxA and the standards used by some laboratories to perform toxicity testing include various PFHxA salts, such as ammonium perfluorohexanoate (CAS-No 21615-47-4) and sodium perfluorohexanoate (CAS-No 2923-26-4). This is important, as the acid has been shown to be more irritating than associated salts. However, regardless of the administered compound, once absorbed into the bloodstream, the PFHx-anion will form. Additionally, when the salt or acid exists in liquids, it will dissociate and the salt or acid will break off, resulting in the anion (Luz et al., 2019).

Absorption

Oral absorption.

PFHxA and APFHx were rapidly absorbed after oral (gavage) administration. In rats of both sexes maximum levels of PFHxA in serum were reached one hour after repeated oral administration (Chengelis et al., 2009a). Following repeated oral dosing, approximately 90 % of the administered daily dose of PFHxA was recovered in the urine of male rats during 24 h post dosing. Urinary elimination in female rats was variable, with about 70 – 100 % of the administered daily dose of PFHxA recovered in the urine 24 h post-dosing (Chengelis et al., 2009a).

From the study performed by (Iwai, 2011) it can be concluded that up to 90 % of the administered dose is systemically absorbed and excreted within 24 h after single and repeated (14d) oral administration of 50 mg/kg APFHx to male and female rats and mice.

The rapid absorption can also be demonstrated by the rapid achievement of the maximum serum concentration after oral administration of radiolabelled ^{14}C-PFHx in male and female CD-1 mice and Sprague Dawley rats. Within 15 - 30 minutes after administration of 2 or 100 mg/kg of the substance, maximum serum concentrations were achieved (Gannon et al., 2011b). Based on the fact that PFHxA is mainly excreted via urine at the longest 24 h after dosing, it can be assumed that the uptake of the substance via the gastrointestinal tract of rat and mice is rapid and complete.

No data are available for oral absorption in humans. The fact that PFHxA can be detected in human blood, serum, plasma or urine samples is a proof that the systematic absorption occurs. The detection of the substance in human biomaterial does not allow any statement about the route of administration. Although the oral route (e.g. via drinking water or food) is more likely than the others.

Dermal absorption.

No data are available for dermal absorption in experimental animals or humans. According to the physicochemical properties of PFHxA and the rule of achieved (Gannon et al., 2011b), the dermal absorption was assumed as 100 %.

De Heer et al. defined criteria to discriminate between chemicals with high and low dermal absorption assuming that there is an optimum in log P_{OW} and a maximum in molecular weight for facilitating percutaneous absorption. If the molecular weight is higher than 500 Da and the log P_{OW} is smaller than -1 or higher than 4, the dermal absorption would be estimated with 10 %. If the molecular weight and the log P_{OW} are different, 100 % dermal absorption would be assumed (de Heer et al., 1999). The assumption of 100 % dermal absorption is a conservative approach, because PFHxA contains an acid group which might counteract the dermal absorption.

Inhalation absorption.

No data are available for inhalation absorption in experimental animals or humans. However, the study of (Nilsson et al., 2010b) suggests a significant inhalation exposure of ski waxers. Nilsson et al. (2013b) measured concentrations from 27 to 14 900 ng/m³ of PFHxA in the air of the breathing zone of some ski wax technicians. PFHxA exposure via inhalation was supposed to contribute to the increased blood level measured during the World Cup season. The lower blood concentrations of PFHxA in pre- and postseason are accompanied by no or decreased inhalation exposure. Further information on inhalation exposure, especially on further source, are given in chapter E.2.9.

Distribution

After oral administration, PFHxA was mainly detected in plasma, kidney, liver and bladder of rats and mice (Gannon et al., 2016).

In another study, 50 mg/kg bw/d APFHx were orally administered to male and female Sprague Dawley-rats and CD-1 mice for 14 days. 7 days after the final dose, the substance remained quantifiable in blood and liver of both species and sexes. In all other examined organs the contents of PFHxA were very low or below the limit of detection (Iwai, 2011).

Numata et al. (2014) and co-workers report that accumulation of PFHxA in fattening pigs mainly occurs in plasma, muscle tissue (i.e. meat), fat, liver and kidney in descending body burden order.

Guruge et al. (2016) showed that PFHxA was rapidly absorbed by micromini pigs after administration of a single capsulated dose of 3 mg/kg and the maximum blood levels were achieved 12 h after administration.

PFHxA has been shown to occur in several human tissues (Pérez et al., 2013). PFHxA was found in lung, brain, liver, kidney and bone. PFHxA represented the highest median PFAS-concentrations in brain and liver (brain: mean 180 ng/g and median 141 ng/g; liver: mean 115 ng/g and median 68.3 ng/g wet weight). The concentrations of 21 PFASs were analysed from 99 samples of autopsy tissues (brain, liver, lung, bone, and kidney) from 20 subjects which have been living in Catalonia, Spain. PFHxA showed the highest concentrations in the brain and liver. In brain, mean concentration of PFHxA was higher than all other PFAS and was detected in all the samples at concentrations ranging from 10.1 to 486 ng/g. In liver, PFHxA was detected in the samples at concentrations up to 353 ng/g. In general terms, the highest concentrations of PFAS were found in lung tissues (PFHxA mean: 50.1 ng/g and median 207 ng/g, ranging up to 559 ng/g). Mean concentrations of PFHxA in the bone and kidney were 36 and 6 ng/g. Results from this study support the conclusion that the substance is distributed to multiple organs.

PFHxA strongly binds to serum albumin. (Bischel et al., 2011) investigated with equilibrium dialysis the binding of PFCAs to bovine serum albumin (BSA). More than 99 % of PFHxA was bound to BSA and the protein water distribution coefficient (log K_{PW}) was 4.05 (Bischel et al., 2011)). An increase in K_{PW} with increasing carbon chain length was observed for PFCAs with four to six fluorinated carbons. For PFCAs with greater than six fluorinated carbons, K_{PW} values generally decreased. The authors suggest that increased rigidity associated with long-chain PFCAs may contribute to the observed nonlinear relationship of K_{PW} with the fluorocarbon tail length. The comparison with PFOA shows that the fraction bound to BSA is equally high with > 99 % and that the K_{PW} of PFHxA is higher than for PFOA (log K_{PW} was 4.14). However, there are huge differences in the elimination half-lives of PFOA (years) and PFHxA (days) in humans.

The general population is exposed to PFHxA and its related substances via different routes and different sources. Oral administration occurs via drinking water and food intake. Dermal and inhalation exposure also contribute to the general uptake of PFHxA. The exposure estimation via biomonitoring data reflects all sources of exposure. A summary of measured levels of PFHxA in human blood samples is given in Table 54-Table 56. It seems that the type of medium in which PFHxA is determined has an influence on the detectability of PFHxA. Poothong et al. (2017) showed that the best medium to determine the content of PFHxA is whole blood.

Table 54: Concentrations of PFHxA in human **whole blood** [ng/mL] (LOD: limit of detection; FOD: frequency of detection; n.r.: not reported).

Country / Study	**Sample Size**	**LOD**	**FOD**	**Max**	**Min**	**Mean**	**Median**	**95th per-centile**	**Reference**
Sweden/ Stockholm	66	< 0.1 – 0.5 ng/mL	8 %	1.6	< 0.1	n.r.	n.r.	n.r.	(Kärrman et al., 2006)
Norway / A-Team Study	**58**	**0.09**	**100 %**	**1.65**	**0.14**	**0.68**	**0.62**	**n.r.**	(Poothong et al., 2017)
Poland/ Gdansk or nearby	15 dockers	not given	20 %	0.02	< 0.002	0.004	< 0.002	n.r.	(Falandysz et al., 2006)
Poland/ Gdansk or nearby	15 farmers	not given	n.r.	0.06	0.005	0.03	0.02	n.r.	(Falandysz et al., 2006)
Poland/ Gdansk or nearby	15 fish-dish fanciers	not given	n.r.	0.24	0.01	0.06	0.03	n.r.	(Falandysz et al., 2006)
Poland/ Gdansk or nearby	15 reference group	not given	n.r.	0.07	0.004	0.03	0.03	n.r.	(Falandysz et al., 2006)

Table 55: Concentrations of PFHxA in human **serum** [ng/mL] (LOD: limit of detection; FOD: frequency of detection; n.r.: not reported).

Country / Study	Sample Size	LOD	FOD	Max	Min	Mean	Median	95th per-centile	Reference
U.S. / C8 Health Study	67 000	< 0.5	53 %	n.r.	n.r.	1.4	1.0	n.r.	(Frisbee et al., 2009)
New Zealand/ POP Study	747	< 0.5	0 %	< LOD	< LOD	< LOD	< LOD	< LOD	(New Zealand Ministry of Health, 2013)
U.S. / American Red Cross (year 2000-2001)	**645**	**< 0.02 – 0.1**	**3.4** %	**6**	**< LOQ**	**< LOQ**	**n.r.**	**0.05**	(Olsen et al., 2017)
South Korea	1 874	< 0.11	0 %	< LOD	< LOD	< LOD	< LOD	< LOD	(Lee et al., 2017)
Canada/ Health Measures Study	1 524	< 0.1	2 %	< LOD	< LOD	< LOD	< LOD	< LOD	(Environment Canada Health Canada, 2013)
Japan/ Exposure to Chemical Compounds	326	< 0.1	0 %	< LOD	< LOD	< LOD	< LOD	< LOD	(Ministry of the Environment Japan, 2016)
China/ General Population Study of Three Provinces	202	< 0.01	53 %	1.1	< LOD	0.07	0.01	n.r.	(Li et al., 2017b)
Norway/ A-Team Study	61	0.045	0 %	< LOD	< LOD	< LOD	< LOD	n.r.	(Poothong et al., 2017)
Germany/ HBM Studie Altötting	**906**	**< 0.25**	**1.98** %	**1.88**	**< LOD**	**n.r.**	**n.r.**	**< 0.25**	(LGL, 2018)
Italy/ Veneto Region	257 ex-posed	not given	20 %	0.68	< LOQ	n.r.	< LOQ	0.27	(Ingelido et al., 2018)
Italy/ Veneto Region	250 un-ex-posed	not given	18 %	0.26	< LOQ	n.r.	< LOQ	0.09	(Ingelido et al., 2018)
Troms arctic district of Norway	940 adolescents (age 15–19 years	<0.5	22%	n.r.	n.r.	0.08	n.r	n.r	(Averina M et al., 2018)
UK/Hull	Women (n=29) recruited from a UK fertility clinic	< 0.5	0%	< LOD	< LOD	< LOD	< LOD	< LOD	(Heffernan AL et al., 2018)
Cchec Republic/ Prague, Ostrava, Liberec andˇZd'ár nadSázavou	300	<0.013	0%	n.r.	n.r.	n.r.	n.r.	n.r.	(Sochorová L et al., 2017)

Table 56: Concentrations of PFHxA in human **plasma** [ng/mL] (LOD: limit of detection; FOD: frequency of detection; n.r.: not reported).

Country / Study	Sample Size	LOD	FOD	Max	Min	Mean	Median	95th per-centile	Reference
U.S. / American Red Cross (year 2006)	600	< 0.02 – 0.1	2.8 %	**1.5**	< LOQ	**< LOQ**	n.r.	< LOQ	(Olsen et al., 2017)
U.S. / American Red Cross (year 2010)	600	< 0.02 – 0.1	18 %	0.4	< LOQ	< LOQ	n.r.	0.13	(Olsen et al., 2017)
U.S. / American Red Cross (year 2015)	616	< 0.02 – 0.1	3.3 %	0.27	< LOQ	< LOQ	n.r.	< LOQ	(Olsen et al., 2017)
Canada/ Health Measures Study	1 524	< 0.1	2 %	n.r.	< LOD	< LOD	< LOD	< LOD	(Environment Canada Health Canada, 2013)
Norway/ A-Team Study	59	0.045	0 %	< LOD	< LOD	< LOD	< LOD	n.r.	(Poothong et al., 2017)
Canada/ onreserve and crown land population aged 20 years old and older,	473	< 100 ng/L	0 %	< LOD	< LOD	< LOD	< LOD	< LOD	(AFN, 2013)

PFHxA was also found in breast milk as shown in Table 57.

Table 57: Concentrations of PFHxA in human breast milk (LOD: limit of detection; FOD: frequency of detection).

Country / Study	Sample year	Sample Size	PFHxA concentration [ng/mL]	LOD [ng/ml]	FOD	Reference
South Korea/PFAS in human breast milk	2013	264	median: 0.047	n.r.	70.8 %	(Kang et al., 2016)
Spain/ PFAS in breast milk	2012	10	mean: 0.006 median: 0.06	0.0003	10 %	(Lorenzo et al., 2016)
France/ PFAS in human breast milk	2013	48	< LOD - 0.053	0.05	2 %	(Antignac et al., 2013)

Metabolism

No metabolism of APFHx was observed when incubating isolated primary hepatocytes from rats with a concentration of 50 µM for 120 minutes (Gannon et al., 2011b). The authors neither observed any changes in the concentration of APFHx nor found any metabolites in the cell culture medium. After oral administration of APFHx to CD-1 mice and Sprague Dawley rats, (Gannon et al., 2011b) did not detect any metabolites of the substance in the urine, faeces or plasma samples of the animals. Therefore, it can be concluded that APFHx is a highly stable substance that is not metabolised to a detectable extent.

Elimination

Several studies proved that renal excretion via urine is the main route of elimination of PFHxA or APFHx (Chengelis et al., 2009a; Fujii et al., 2015; Gannon et al., 2011b; Guruge et al., 2016).

Gannon et al. (2011b) reported that in mice >99 % of the oral dose of ^{14}C-PFHxA was eliminated within 24 hours and 48 hours by males and females, respectively. In rats, 100 % of an orally administered dose was excreted in the urine after 24 hours in both males and females. The excretion via faeces was negligible.

Chengelis et al. (2009c) reported that 80 % of the i.v. administered dose was excreted in urine within 24 hours in rats. Following repeated oral exposure, 70 - 100 or 90 % of PFHxA was excreted within 24 hours in males and females, respectively.

From the study performed by (Iwai, 2011) it can be concluded that up to 90 % of the administered dose is systemically absorbed and excreted within 24 hr after single and repeated (14d) oral administration of 50 mg/kg APFHx to male and female rats and mice whereas 9.6 to 12.9 % of the dose is excreted via faeces.

Fujii et al. (2015) reported for mice the recovery of 68.8 – 100 % of the administered dose (0.313 µmol/kg). The majority was found in the urine (47 – 100 %). Only 4.7 - 15.6 % were detected in the faeces.

The amount of PFHxA eliminated in the faeces in both mice and rats was negligible. After a single oral dose, 7 - 15.5 % of 14C-PFHx was eliminated in faeces by mice and rats, and 10 -13 % of APFHx was eliminated after repeated exposure (Gannon et al., 2011b; Iwai, 2011).

PFHxA was also detected in human urine. The summary of PFHxA concentrations found in human urine samples is given in Table 58.

Table 58: Concentrations of PFHxA in human urine (LOD: limit of detection; FOD: frequency of detection).

Country / Study	Sample year	Sample Size	PFHxA concentration [ng/mL]	LOD/ LOQ [ng/mL]	FOD	Reference
Austria/ human urine from male and female adults aged 25-46 years	2016	11	median: 0.0015 mean: 0.0016 creatinine-adjusted concentrations	0.0002/ 0.0005	100 %	(Hartmann et al., 2017)
South Korea/ children aged 5-13 years	2012	120	< LOD-2.34 (mean: 1.38) (LOD: 0.163)	n.r.	11 %	(Kim et al., 2014)
South Korea/ adults	2012	n.r.	< LOD-5.63 µg/L (mean: 1.38 µg/L) (LOD: 0.163 µg/L)	n.r.	5 %	(Kim et al., 2014)

Beside elimination via urine, the serum or plasma elimination kinetics in mammals were also analysed in different species. The serum elimination occurs in a biphasic pattern. High amounts of PFHxA were rapidly eliminated in the first or alpha phase.

For mammals, there are several studies available reporting on elimination half-lives of PFHxA. The summary of reported half-lives is given in Table 59.

Table 59: Serum or plasma elimination half-lives of PFHxA in humans and laboratory animals.

Organism	**Half-life PFHxA (M = male, F = female)**	**Comments**	**Reference**
Rat	M: 1.0 h, F: 0.42 h in serum	mean β-phase of two compartment model with first-order elimination, single IV dose of 10 mg/kg	Chengelis et al. (2009a)
	M: 2.2 h, F: 2.7 h in Serum	mean β-phase of two compartment model with first-order elimination, repeated oral dose of 50 mg/kg, day 25	Chengelis et al. (2009a)
	M: 2.7 h, F: 2.4 h in serum	mean β-phase of two compartment model with first-order elimination, repeated oral dose of 150 mg/kg, day 25	Chengelis et al. (2009a)
	M: 2.8 h, F: 2.3 h in serum	mean β-phase of two compartment model with first-order elimination, repeated oral dose of 300 mg/kg, day 25	Chengelis et al. (2009a)
	M: 1.7 h, F: 0.5 h in serum	mean β-phase of one compartment model with first-order elimination, single oral dose of 2 mg/kg	Gannon et al. (2011b)
	M: 1.5 h, F: 0.7 h in serum	mean β-phase of one compartment model with first-order elimination, single oral dose of 100 mg/kg	Gannon et al. (2011b)
Mice	0.89 - 1.24 h in serum	mean β-phase elimination	Russell et al. (2013)
Pig	M, F: 4.1 d in plasma	mean β-phase of two compartment model with first-order elimination, 21 d exposure to 48 µg/kg	Numata et al. (2014)

Organism	Half-life PFHxA (M = male, F = female)	Comments	Reference
		dw in diet	
Monkey	M: 5.3 h, F: 2.4 h (mean) in serum	mean β-phase of two compartment model with first-order elimination, single IV dose of 10 mg/kg	Chengelis et al. (2009a)
Human	Male: 7.2 d in blood	serum elimination half-life of one compartment model	Hethey et al., unpublished
	Male: 5.1 d in serum	serum elimination half-life for β phase elimination	Buck and Gannon (2017) cited by Luz et al. (2019)

Available studies suggest a gender specific difference in PFHxA serum clearance in rats, as female rats eliminated PFHxA about two to three times faster (0.42 h compared to 1.0 h). This would be in line with (Gannon et al., 2011b) observing also serum elimination half-lives of PFHxA in rats and mice in the range of hours, with two- to three-fold faster elimination half-lives in female rats compared to male rats. However, there was no appreciable gender-specific difference in the extent or rate of urinary elimination. The gender-specific difference in serum clearance in Sprague-Dawley rats remains to be established, especially in view of the conclusions drawn by (Russell et al., 2013) who stated that "the half-lives of PFHxA in mice, rats, monkeys and humans were proportional to body weight with no differences observed between genders, indicating similar volumes of distribution and similar elimination mechanisms among mammalian species."

Nilsson et al. (2010b) monitored blood samples of ski wax technicians using fluorinated ski wax containing PFHxA during ski season. Using these data, (Russell et al., 2013) estimated the mean serum elimination half-life at 32 d. However, a calculation of exact elimination half-lives from the monitoring data in this study is very uncertain. In the original study it is stated that "it is not possible to calculate an exact terminal half-life". The half-life of PFHxA in humans could therefore only be estimated as less than four weeks (32 days as geometric mean; (Russell et al., 2013).

In a recent re-evaluation of the data from the ski technicians, a serum elimination half-life of 5.1 d was proposed, Buck and Gannon (2017) cited by Luz et al. (2019).

Re-evaluation of the Nilsson-data by the German CA

Due to the discrepancy of half-lives calculated from data of the ski technicians the German CA re-evaluated the data published by Nilsson et al. (2010b) and Nilsson et al. (2013b).

A toxicokinetic model was developed, calibrated and validated to predict internal dose (= blood concentrations), given some external dose (= exposure) for PFHxA in humans.

Ultimately, this model allows to correlate external exposure (e.g. a dose equivalent to the derived no-effect level (DNEL)) with the corresponding internal dose.

The approach focused on reports documenting the occupational exposure of ski technicians to fluorinated ski wax (Nilsson et al., 2010a; Nilsson et al., 2013a; Nilsson et al., 2010b). A non-linear mixed effects modelling approach was used and accounted – in contrast to previous studies (Russell et al., 2015) – for the information about observations below the limit of quantification and /or limit of detection. As the reports extended to other substances beyond PFHxA, also including the kinetically much better characterized PFOA, the validity of the approach was checked against the results of additional external kinetic studies.

Preparation of data and definition of exposure function

Three types of data were integrated: (1) Inhalation exposure, (2) Ski World Cup dates and (3) Blood kinetics over five years. With respect to (1), reported air concentrations in the breathing zone of individual ski technicians (Nilsson et al., 2010b) informed the definition of a Bayesian prior on the amounts of substance per ski season (AMT) to which the technicians were exposed. Combination of (1) with publicly available data on (2), reported working time of the technicians and the alveolar inhalation rate for light work (Birnbaum et al., 1994) resulted in the definition of a time dependent *exposure function*. This exposure function had the form of a step function switching between constant exposure (during skiing seasons) and no exposure (rest of the year).

Development and calibration of the toxicokinetic models

Single compartment models were parameterized via first order elimination rate constant (k) and volume of distribution (V) for PFOA and PFHxA, respectively. Assuming total bioavailability for both substances, the exposure function directly dosed into the central compartment. Unknown parameters (AMT for each of 5 seasons, k and V) were estimated with the stochastic expectation maximisation algorithm implemented in Monolix (Lavielle, 2014).

The calibrated models for were positively assessed with respect to acceptable precision of the estimated parameters (relative standard errors < 150 %) and practical parameter identifiability indicated by low sensitivity of the parameter estimates on variation on the initial values for the optimisation problem.

Results for PFOA

Distinctive differences between reported 2007 and 2008 measurements of the air concentration of PFOA propagated to the corresponding AMT estimates. Consistently, the estimated AMT of the individual technicians to PFOA dropped over time (seasons 2006, 2007 and 2008 compared to 2009 and 2010 season at least one order of magnitude). The blood half-life based on the population estimate was 2.8 (2.2 – 3.6) years, with the 95 % confidence interval in brackets. This compares reasonably well to 3.5[28] (3.1 – 4.4) years reported in previous kinetic studies (Olsen et al., 2007). The population estimate for V was 818 L, which is in line with reports of PFOA mainly distributing in body compartments different from.

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[28] Geometric mean

Results for PFHxA

Compared to PFOA, no distinctive drop in AMT was estimated with on-going seasons. The half-life in blood was estimated to be 7.2 (4.2 – 27.5)[29] days, with a volume of distribution of 361 L. The inter-individual variability for the kinetic parameters V and k was low compared to observed variability in the exposure parameters AMT for 2008, 2009 and 2010 based on the measured air concentrations.

Prediction of internal dose

The model was used to calculate internal PFHxA exposure from external exposure values, e.g. for deriving an internal blood PFHxA concentration at derived external DNELs (see section B5.11). In order to do so, the following assumptions were made: body weight of 75 kg, light work alveolar ventilation rate of 20 L/min (Birnbaum et al., 1994) and total bioavailability of PFHxA.

Since related substances may be metabolized to PFOA and PFHxA during the course of the study, the corresponding half-life estimated based on decay in blood concentrations is an *apparent* half-life. This apparent half-life represents an overprediction of the underlying exposure-independent half-life. However, as inhalation exposure for the PFOA and PFHxA related substances were reportedly low (Nilsson et al., 2010a), the apparent half-life was expected to be a good approximation for realistic simulation scenarios.

Inference of the parameter correlation via stochastic approximation of the fisher information matrix revealed some negative correlation between k and V (correlation coefficient -0.52 for PFHxA). Accordingly, the individual estimates should be used with caution. Furthermore, and per definition of a concentration, AMT and V show strong positive correlations (up to correlation coefficient 0.72 for PFOA). Thus, for a more precise estimation of V, more precise information on the exposure would be needed.

Unfortunately, the authors did not report the exact sampling time-points, but rather the month. While the analysis under the assumption of sampling at the start of each month already gave meaningful results on the time-scale of this 5-year study, even more precise estimates will be expected with full information on sampling time-points. A query to the authors is still pending.

Summary of elimination

In general, the reported half-lives for PFHxA in mammals are considerably lower when compared to PFOA. For PFOA, half-lives in mice, rat, pig and monkey are up to one order of magnitude higher compared to PFHxA, ranging from 0.08 days in female rat, 236 days in pig and several years in humans.

On basis of the considerably lower half-life reported for PFHxA of 5.1 or 7.2 days in comparison to the half-lives of PFOA, it is concluded that PFHxA is less bioaccumulative.

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[29] PFHxA values were modeled as described in text. The values correspond roughly to the median and the 95 % confidence interval

B.5.2 Repeated dose toxicity

A **subacute toxicity study** was performed with rats (Harlan Sprague Dawley) using ten animals /sex /dose. Animals received PFHxA via gavage (0 /62.6 /125 /250 /500 and 1 000 mg/kg bw/d) over a study period of 28 days (NTP, 2018). The doses were split and administered twice per day. The mentioned doses are the total daily doses. The study was GLP compliant.

No mortality was observed. In the highest dose group, the mean body weight of males was significantly lower in comparison to the control group (13 %). In the females, the mean body weight was unaffected by PFHxA treatment.

Furthermore, a significant decrease of haematocrit, haemoglobin and red blood cell count was observed in all dose groups of males and from 250 mg/kg bw/d upwards in females. The decrease is below 10 % up to 250 mg/kg bw/d in males and females. In addition, the decrease of red blood cells was accompanied by an increase of reticulocytes from 500 mg/ kg bw/d in both sexes. The increase of reticulocytes in the 500 and 1 000 mg/kg bw/d groups were 152 % and 456 % in males and 189 % and 323 % in females, respectively. Additionally, the mean cell haemoglobin and the mean cell haemoglobin concentration were elevated in both sexes. At the highest dose group of both sexes, the increases of mean cell haemoglobin exceed the 10 % value. In the highest dose group of both sexes, the amount of platelets was increased. In males, the level of basophils was halved from 250 mg/kg bw/d upwards. In highest dose group of females, the amount of neutrophils was significantly higher in comparison to the control group.

Furthermore, there were elevations in the alanine aminotransferase (ALT) and aspartate aminotransferase (ASAT) in both sexes from 500 mg/kg bw/d upwards. In both sexes, the increase of ALT in the 500 and 1 000 mg/kg bw/d dose groups was 126 % and 164 % in males and 135 % and 144 % in females, respectively. In males, ASAT was increased by 116 % and 136 % at 500 and 1 000 mg/kg bw/d. In females, ASAT was increased by 111 % and 118 % in the mentioned dose groups. Alkaline phosphatase (ALP) was only elevated in the 500 and 1 000 mg/kg bw/d male group and exceeds 150 % in the highest dose group. A decrease was observed for the amount of globulin and total protein in males from 125 mg/kg bw/d upwards and in females at 1 000 mg/kg bw/d, respectively. Furthermore, in males from 250 mg/kg bw/d upwards and in females at 1 000 mg/kg bw/d, the albumin/ globulin ratio was significantly higher in comparison to the corresponding control groups. Beyond the mentioned treatment-related effects of PFHxA, the levels of some clinical biochemical parameters were decreased in the 1 000 mg/kg bw/d group of males (creatinine, albumin, sorbitol dehydrogenase). The levels of cholesterol were reduced in both sexes, in males from 62.6 mg/kg bw/d upwards and in females at 1 000 mg/kg bw/d, respectively. Additionally, the levels of total and indirect bilirubin were reduced in both sexes at 500 and 1 000 mg/kg bw/d in males and at 1 000 mg/kg bw/d in females. Furthermore, the mount of bile salt and acids was increased at the highest dose in both sexes.

A statistically elevated relative kidney weight was observed in males from 500 mg/kg bw/d upwards (11.8 and 18.8 %, respectively) and in the females of the highest dose group (11.5 %). Additionally, the relative liver weights were increased in males from 250 mg/kg bw/d upwards (14.3, 31.6, 63.6 %, respectively) and in females from 500 mg/kg bw/d upwards (15.2 and 47.5 %). The absolute liver weights were also elevated from 500 mg/kg bw/d upwards in both sexes. In males, there were increases of 27 and 42 % observed and in the females for 14.1 and 44.2 %, respectively. In the 1 000 mg/kg bw/d males, the weights of several organs were reduced (absolute heart weight and absolute thymus weight). Beyond that, the weights of several organs were increased in comparison to the control (relative lung weight, relative spleen weight, relative testis weight). In the highest dose group of females, the absolute kidney weights and the relative spleen weights were increased.

The aforementioned increase of liver weight was accompanied by histological changes. Cytoplasmic alterations and a hypertrophy of hepatocytes were observed in males of the 500 and 1 000 mg/kg bw/d dose group and in females of the 1 000 mg/kg bw/d dose group, respectively. As result of the mentioned effects on red blood cells, increased extramedullary haematopoiesis in the spleen was observed in both sexes from 500 mg/kg bw/d upwards. Besides, the olfactory epithelium was also affected by PFHxA treatment. In both sexes, degeneration (male rats 0/10, 0/10, 1/10, 6/10, 6/10 and 6/10; female rats 0/10, 1/10, 3/10, 9/10, 9/10 and 6/10) and hyperplasia of the olfactory epithelium (male rats 0/10, 0/10, 0/10, 6/10, 5/10 and 6/10; female rats 0/10, 0/10, 3/10, 4/10, 7/10 and 3/10) were observed. Furthermore, inflammation of the olfactory epithelium was observed (male rats 0/10, 0/10, 0/10, 0/10, 3/10 and 6/10; female rats 0/10, 0/10, 0/10, 1/10, 5/10 and 8/10).

Treatment-related changes associated with PFHxA treatment were also observed on the amount of thyroid hormones, namely T3 and T4, respectively. In males, total T3, total T4 and free T4 were significantly decreased in all dose groups. Even in the lowest dose group (62.6 mg/kg bw/d) the decrease of total T3, total T4 and free T4 was approximately 20 % lower in comparison to the control group. At the highest dose groups, free and total T4 were 73 % and 59 % lower than the control values. TSH levels were unaffected by PFHxA treatment. In accordance with the unaffected TSH level, the thyroid gland weight is unaffected. In females, the levels of thyroid hormones were unaffected by PFHxA treatment.

For comparison, PFOA is known to reduce the level of thyroid hormones, namely T3 and T4, in male monkeys and rats (Butenhoff et al., 2002; Martin et al., 2007). The mentioned substance also does not affect the TSH level. Therefore, it is assumed that the described influence on thyroid hormones is a common property of perfluorinated chemicals.

Significant reductions in T3 /T4 levels alone were considered as adverse effects even if no associated increase in TSH was observed (ECHA / EFSA, 2018; Ghassabian et al., 2014). The lack of increases in TSH expected as feedback response is considered as not contradictory as difficulties in the measurement in rats may occur (Kortenkamp et al., 2017). No further information is available on the underlying mode of action. T4 reduction of PFHxA was consistently observed in studies on PFOA.

Dose-related increased incidences of degenerated olfactory epithelium were observed in all dose groups. However, no information on the severity is available and the incidences at the low dose levels of 62.5 and 125 mg/kg bw/d were low (1/10). Thus, the effects at these dose levels were considered as not robust enough to derive a N/LOAEL. Treatment-related increased incidences were observed at doses from 250 mg/kg bw/d with incidences of 3/10 and 6/10 animals affected either for degeneration or hyperplasia (most likely of regenerative nature) of the olfactory epithelium.

Adverse effects were identified in the liver. Coincidentally, increased relative liver weights, increased incidence of cytoplasmic alterations and liver cell hypertrophy and increased activities of liver enzymes ASAT and ALP were observed with liver weight increase starting at 250 mg/kg bw/d as the most sensitive effect. At this dose, decreases in red blood cell parameters indicated adverse anaemic effects.

Based on the significantly decreased levels of thyroid hormones (total T3, total T4 and free T4), a LOAEL of 62.6 mg/kg bw/d was derived.

A **sub chronic toxicity study** was performed with male and female rats (Crl:CD(SD), at least 10 animals/sex/dose). Animals received PFHxA dissolved in deionised water via gavage (0, 10, 50, 200 mg PFHxA/kg bw/d) over a study period of three months (Chengelis et al., 2009c). The publication made no statement on guideline conformity.

No mortality was observed. There were no treatment-related clinical observations. Mean body weight of males was significantly lower in the 50 and 200 mg/kg bw/d group. Similar trends were obtained in 50 and 200 mg/kg bw/d group females, but these were not statistically significant. Slightly but significantly decreased red blood cell counts, haemoglobin and haematocrit (< 10 %) were noted in males and females of the 200 mg/kg bw/d group. These changes were reversible following the 28-day recovery period. Additionally, the mean reticulocytes in the 200 mg/kg bw/d group males were significantly increased. Furthermore, there were elevations in alanine transaminase (ALT), aspartate transaminase (AST) and alkaline phosphatase (ALP) in the 50 and 200 mg/kg bw/d male groups (although not statistically significant at 50 mg/kg bw/d) and statistically significant decreases in cholesterol in the 50 and 200 mg/kg bw/d males. Decreases also occurred in globulin in males and females in the 200 mg/kg bw/d group with lower total protein and higher albumin/globulin ratio in males only.

Statistically significantly increased relative kidney weights were observed in males at 10 ($p < 0.05$), 50 ($p < 0.05$) and 200 ($p < 0.01$) mg/kg bw/d and females in the 50 ($p < 0.01$) and 200 (without statistical significance) mg/kg bw/d group. Relative liver weight increased in males in the 200 mg/kg bw/d group. Liver samples of males of the 200 mg/kg bw/d group showed an increased peroxisomal beta oxidation activity using palmitoyl-CoA (coenzyme A) as substrate (only the 200 mg group was compared to controls).

Treatment-related histological changes associated with PFHxA administration were limited to the liver in high-dose males only. Minimal centrilobular hepatocellular hypertrophy was observed in seven of ten animals. One animal had moderate hepatocellular necrosis that was characterised by multifocal foci of coagulative necrosis with variable number of inflammatory cells within or around the necrosis.

Based on this sub chronic study a LOAEL of 50 mg/kg bw/d could be derived based on lower body weight throughout the dosing period gain in male rats (NOAEL 10 mg/kg bw/d).

In a **combined subacute /reproductive /sub chronic study** in rats (Crl:CD(SD)) the sub chronic part of the study was in conformity to OECD TG 408. Animals (at least 10/sex/dose) were treated orally (0, 20, 100, 500 mg/kg bw/d) via gavage with sodium perfluorohexanoate (NaPFHxA, CAS-No. 2923-26-4) as the sodium salt of PFHxA for 90 days (Loveless et al., 2009a).

No clinical signs of toxicity or mortality related to the NaPFHxA administration were observed in the rats during the course of the study. Statistically significant decreases in mean body weight were observed in male rats in the 500 mg/kg bw/d group. Liver weights were increased in male rats dosed with 100 and 500 mg/kg bw/d. Mild to minimal degeneration /atrophy of olfactory epithelium was present in male and female rats at 100 and 500 mg/kg bw/d. In males 4/10 animals at 100 mg/kg bw/d and 7/10 animals at 500 mg/kg bw/d showed lesions. In females this was the case for 5/10 animals at 100 mg/kg bw/d and for 4/10 animals at 500 mg/kg bw/d.

Other adverse changes observed included hepatic peroxisomal β-oxidation and hepatic changes, generally at lowest observed adverse effect levels (LOAELs) of 100 mg/kg bw/d in males and 500 mg/kg bw/d in females.

Minimal hypertrophy of thyroid follicular epithelium was present in male and female rats in the 500 mg/kg bw/d group. The effects were reversible after 90 days of recovery but not following 30 days of recovery.

Based on nasal lesions in this study, the NOAEL was derived with 20 mg/kg bw/d.

In a **combined chronic toxicity/carcinogenicity study** in rats (Crl:CD(SD), male/female rats (at least 60 animals/sex/dose) were orally exposed via gavage (0, 2.5, 15, and 100 mg PFHxA/kg bw/d (males) and 5, 30, and 200 mg PFHxA/kg bw/d (females)) over a study period of 104 weeks (Klaunig et al., 2015a). Purity of the substance was 98.1 %. At the scheduled necropsy after 104 weeks of treatment, no statistically significant difference was seen in survival rates in male rats in any of the three groups compared to controls. Only in high-dose female rats a significant dose-related decrease in survival rates was seen.

No effect of PFHxA treatment on body weights or food consumption was seen in male and female rats.

Histopathological investigations of kidneys of females of the 200 mg/kg bw/d treatment group showed papillary necrosis (17/70 - 24 %) (0/60 in controls – 0 %) and tubular degeneration (7/70 – 10 %) (1/60 in controls – 1.7 %). Liver effects such as hepatocellular necrosis were seen in females at 30 mg/kg bw/d (3/60 – 5 %) and at 200 mg/kg bw/d (12/70 – 17 %). In male rats the liver showed 25 % congestion in the control group (15/60 animals) and 33 % in the treated group at 100 mg/kg bw/d (23/70). Congestions in the lung were observed in males (control 5/60 - 8.3 %, low-dose 9/60, medium-dose 9/60 - 15 % and high-dose 19/70 - 27 %). In females of the 200 mg/kg bw/d group 21/70 (30 %) alveolar macrophages in the lung were shown compared to 3/60 (5.0 %) in the control group. In females of the high-dose group erosions in the glandular stomach (16/70 - 23 % compared to 5/60 - 8.3 % in controls) were observed (Klaunig et al., 2015a).

In this 104-week study the NOAEL of 30 mg/kg bw/d was identified based on the papillary kidney necrosis in females at 200 mg/kg bw/d (LOAEL).

Summary and discussion of repeated dose toxicity

One oral subacute toxicity study, two oral sub chronic toxicity studies and one oral chronic toxicity study of PFHxA in rats are available. All studies show treatment-related effects. The subacute study showed an influence of PFHxA on clinical chemistry such as altered level of

AST, ASAT and ALP in both sexes. Additionally, altered organ weights were observed in males and females. The relative liver and kidney weights were decreased in both sexes. Furthermore, PFHxA had an effect on haematological parameters: haematocrit, reduced levels of red blood cells and haemoglobin exceeded the 10 % level at doses of at 250 mg/kg bw/d. Degeneration and hyperplasia of the olfactory epithelium was observed in both sexes in a dose-dependent manner, relevant increase in incidences were noted at 250 mg/kg bw/d and above. The most sensitive effect was a significant reduction of total T3, total T4 and free T4 at all dose groups of males justifying a LOAEL of 62.6 mg/kg bw/d.

The first sub chronic study with PFHxA showed significantly lower mean body weights of males at 50 and 200 mg/kg bw/d group and similar trends in female rats at 50 and 200 mg/kg bw/d. Slight effects (< 10 % ranges) on haematological parameters were seen in 200 mg/kg bw/d-rats of both sexes. Furthermore, the liver enzymes ALT, AST and ALP were increased in 200 mg/kg bw/d in male rats, this was accompanied with minimal centrilobular hepatocellular hypertrophy in seven of ten animals. Kidney effects such as increased relative kidney weight at 50 mg/kg bw/d were not accompanied by other histopathological findings. Based on this sub chronic study a LOAEL of 50 mg/kg bw/d could be derived based on lower body weight gain in male rats (NOAEL 10 mg/kg bw/d).

The second sub chronic study was performed with sodium PFHxA and showed lower body weights in high-dose males in comparison to control values. Furthermore, liver weights (without any other abnormality) were increased in male rats at 100 and 500 mg/kg bw/d. The relevant adverse effect is the mild to minimal degeneration/atrophy of the olfactory epithelium in male and female rats at 100 and 500 mg/kg bw/d. The NOAEL was derived with 20 mg/kg bw/d.

After chronic gavage administration of PFHxA to Sprague Dawley rats a dose-dependent decrease in survival rate was observed in female animals only. In histopathological investigations the kidney and liver of female rats of the 200 mg/kg bw/d group showed degenerative/necrotic lesions. Thus, kidneys and livers represented the main targets for non-neoplastic effects after chronic administration of PFHxA. Up to oral doses of 100 (males) and 200 (females) mg/kg bw/d over 104 weeks, no carcinogenic effects were observed. Thyroid hormone levels, shown to be sensitive effects in subacute studies, were not investigated in this chronic study. Histological examination of the thyroid was not performed. According the protocol cited by the authors (Fiette and Slaoui, 2011) the thyroid gland with the parathyroids should be weighed, but the results were not given in the publication.

B.5.3 Mutagenicity

A bacterial reverse mutation test was performed with NaPFHxA in either the presence or absence of S9 (Aroclor-induced rat liver S9) metabolic activation in the following tester strains: TA98, TA100, TA1535, TA1537 and WP2*uvr*A. A positive control and a vehicle control were investigated for each strain, the test was performed according to OECD TG 471. No toxicity, NaPFHxA precipitation or positive mutagenic responses were observed at any dose level or with any tester strain (Loveless et al., 2009a).

The ability of NaPFHxA to induce structural and numerical chromosome aberrations *in vitro* was evaluated using human peripheral blood lymphocytes from a healthy volunteer donor in the absence and presence of an exogenous metabolic activation system (arochlor-induced rat liver S9) according to OECD TG 473. Mitomycin C and cyclophosphamide were used as positive controls. Based on the results from preliminary experiments, the chromosome aberration assay was performed with cytogenetic evaluations conducted at 2 000, 3 000, and 3 860 µg/mL (10 mM) for the 4-h non-activated test condition and at 250, 500, and 1 000 µg/mL (2.59 mM) for the 4-h activated and 22-h non-activated test condition (Loveless et al., 2009a).

A reduction in the mitotic index of > 50 % in the NaPFHxA treated cells was observed. The percentage of cells with structural or numerical aberrations in the NaPFHxA-treated groups was not significantly increased above that of the vehicle control at any concentration. NaPFHxA was not found to induce structural or numerical chromosomal aberrations in human peripheral blood lymphocytes in either the non-activated or S9-activated test system (Loveless et al., 2009a).

DNA damage was measured using the comet assay in HepG2 cells. Positive and negative controls were investigated. Cells were exposed to concentrations of 100 or 400 µM PFHxA. PFHxA did not generate DNA damage (Eriksen et al., 2010).

A bacterial reverse mutation test was performed with PFHxA in either the presence or absence of S9 (phenobarbitone- and ß-naphtoflavone-induced rat liver S9) metabolic activation in the following tester strains: TA98, TA100, TA1535, TA1537 and TA1538. The test was performed according to OECD TG 471. PFHxA did not show any mutagenic responses (Buhrke et al., 2013).

The in vitro mammalian cell micronucleus test was performed with V79-cells according to OECD TG 487. Cells were incubated with PFHxA with and without metabolic activation (phenobarbitone- and ß-naphtoflavone-induced rat liver S9). Positive and negative controls were included. PFHxA did not show any clastogenic potential (Buhrke et al., 2013).

A bacterial reverse mutation test was performed with PFHxA in presence or absence of 10 % S9 metabolic activation in S. typhimurium TA98 and TA100 and E. coli WP2 uvrA pKM101. PFHxA did not show any mutagenic responses (NTP, 2018).

Furthermore, the mutagenic properties of PFHxA were analysed in an *in vivo* micronucleus assay in peripheral blood. The results were equivocal in male and negative in female rats (NTP, 2018).

Summary and discussion of mutagenicity

The Dossier Submitter concludes on PFHxA that the studies presented give no evidence for mutagenic properties of PFHxA.

B.5.4 Carcinogenicity

In a combined chronic toxicity /carcinogenicity study in rats (Crl:CD(SD), male /female at least 60 animals/sex/dose) were orally exposed via gavage to 0, 2.5, 15, and 100 mg PFHxA/kg bw/d (males) and 5, 30, and 200 mg PFHxA/kg bw/d (females) over a study period of 104 weeks (Klaunig et al., 2015a). The publication made no statement on guideline conformity.

At the scheduled necropsy after 104 weeks of treatment, no statistically significant difference was seen in survival rates in male rats in any of the three groups compared to controls. The survival rate of males, excluding the incidental deaths, at the end of week 104 in the control, 2.5, 15, and 100 mg/kg bw/d group was 31 %, 43 %, 43 % and 47 %. In contrast, in treated female rats, a significant dose-related decrease in survival rates was seen. In addition, there was a statistically significant decrease in pairwise comparisons between the control group and high-dose group. The survival rate of females, excluding the incidental deaths, at the end of week 104 in the control, 5, 30, and 200 mg/kg bw/d group was 36 %, 43 %, 33 % and 22 %.

No increase in neoplasms related to treatment of PFHxA at any of the three dosage levels examined after treatment for 104 weeks was seen in either male of female rats (Klaunig et al., 2015a).

Summary and discussion of carcinogenicity

Based on the information available there is no indication for carcinogenic properties of PFHxA. However, this conclusion is based on the publication of study results available in public literature. The original study report was not available for evaluation.

B.5.5 Toxicity for reproduction

Effects on fertility

A one-generation reproductive toxicity study was performed with NaPFHx (CAS-No. 2923-26-4) in Crl:CD(SD) rats (Loveless et al., 2009a). According to the authors, the study was in alignment with OECD TG 415. Nano pure water was used as vehicle and the substance was administered by oral gavage at dose levels of 0, 20, 100 and 500 mg/kg bw/d using a dose volume of 5.0 mL/kg. P1 female rats were dosed for about 70 days prior to cohabitation, through gestation and lactation for a total of about 126 days. P1 male rats were dosed for about 110 days. F1 rats were not dosed. Clinical observations, bodyweights, and food consumption were determined weekly throughout the study. Estrous cycle, sperm parameters, survival, and reproductive performance parameters were assessed. Litter examinations (number of live and dead, individual pup weights, clinical observations) were determined on day four pp, and weekly during lactation. F1 offspring were given a gross pathological examination at weaning. A subset of F1 generation rats was maintained for six weeks after weaning to assess developmental landmarks. The subset was given a gross pathological examination and selected reproductive organs were weighed.

No mortalities were observed in parental animals. Compared to controls, overall body weight gain was reduced by 12 and 29 % at 100 and 500 mg/kg bw/d, respectively. No substance-related effects were observed on mating, fertility, gestation length, number of implantation sites, estrous cyclicity, sperm parameters, litter size, sex ratio, pup clinical observations, pup survival, or F1 adult developmental landmarks at any dose tested. Substance-related effects on mean pup weights (17 - 18 % lower than control group) were observed during lactation at the highest dose tested. Overall bodyweight gain from test day 0 to 39 for F1 adults (postweaning) was comparable across dose levels for both sexes and no substance-related organ weight changes were observed at any dose in F1 adult males or females. No treatment-related gross pathology findings were observed at any dose in animals designated for the reproductive evaluation.

Developmental toxicity

An OECD TG 414 study investigated developmental toxicity of NaPFHx in Crl:CD(SD) rats (Loveless et al., 2009a). Nano pure water was used as vehicle and the substance was administered by oral gavage at dose levels of 0, 20, 100 and 500 mg/kg bw/d using a dose volume of 5.0 mL/kg. 22 animals per group were dosed once daily on days 6 – 20 of gestation. In-life observations were recorded and rats sacrificed on gestation day (GD) 21. All dams underwent a gross pathological examination and the foetuses were removed from the uteri by Caesarean section. Foetuses were weighed and sexed and examined for morphological alterations. All foetuses were examined for external and skeletal alterations, and approximately 50 % of the foetuses were examined for soft tissue and visceral head examinations.

There were no NaPFHxA-related deaths or gross post-mortem findings in dams at any dose. Maternal toxicity occurred at 500 mg/kg bw/d and consisted of reductions in bodyweight parameters of total weight gain from GD 6 to 21 and overall net gain (corrected body weight gain minus products of conception on day 21), which were 19 % and 26 % lower compared to the control group, respectively at a 5 % reduction in food consumption. Developmental toxicity was limited to an approximately 10 % lower foetal weight at 500 mg/kg bw/d in comparison to controls.

Based on reduced body weight in maternal and offspring animals, a maternal and developmental NOAEL of 100 mg/kg bw/d was derived.

In a study according to ICH Harmonised Tripartite Guideline S5(R2), stages C through F, Iwai and Hoberman (2014) investigated the developmental toxicity of ammonium perfluorohexanoic acid in female mice (Crl:CD I(ICR). The guideline stages C to F integrate the following sequences of one life cycle:

C. Implantation to closure of the hard palate (adult female reproductive functions, embryonic development, major organ formation).
D. Closure of the hard palate to the end of pregnancy (adult female reproductive functions, foetal development and growth, organ development and growth).
E. Birth to weaning (adult female reproductive functions, neonate adaptation to extrauterine life, preweaning development and growth).
F. Weaning to sexual maturity (postweaning development and growth, adaptation to independent life, attainment of full sexual function).

Post-weaning observations on female and male pups were finalised on PPD 20 and 26, respectively. Thus, duration of the testing took approximately 104 days. The test substance had a purity of 93.4 %. In phase I of the study doses of 0, 100, 350 and 500 mg/kg bw/d were applied; the full study report has been published in Hoberman (2011a). In phase II of the study the doses were 0, 7, 35 and 175 mg/kg bw/d; the full study report has been published in (Hoberman, 2011b). Twenty-time mated animals were used per group. The substance was dissolved in deionised water and applied orally via gavage (5 mL/kg bw). The animals were treated once daily from gestation day (GD) 6 to 18. Both parts of the study have been performed in compliance with GLP.

Parental animals were observed for viability and clinical findings and body weights were recorded throughout dosage and post-dosage periods. Animals were evaluated for adverse clinical signs observed during parturition, duration of gestation, litter sizes (all pups delivered) and pup viability at birth, fertility index, gestation index, number of offspring per litter (live and dead pups), number of implantation sites, general condition of dam and litter during the postpartum period, viability indices, and lactation index (percentage of pups born that survive 20 days). Maternal behaviour was evaluated on postnatal days (PND) 0, 4, 7, 14, and 20.

The pups in each litter were counted once daily; clinical observations, body weights, viability and eye opening were recorded during pre- and /or postweaning periods. Female mice were evaluated for vaginal patency (from PND 20) and male mice were evaluated preputial separation (from PND 26). On PND 20, all pups not selected for continued evaluation were killed by carbon dioxide asphyxiation and examined for gross lesions. Five pups per sex per group were killed on PND 41 for determination of body burden. In the following two tables results of both study phases are summarised.

Deaths of parental animals during lactation occurred in phase I only (3 controls, 6 at 100 mg/kg bw/d, one at 350 mg/kg bw/d and 500 mg/kg bw/d group (see Table 61).

At PND 0 there was no difference in body weights of control dams and any treatment group. Taken together with fact that the only clinical observations related to PFHxA were slight excess salivation in three of 20 mice at 350 mg/kg bw/d and slight to moderate excess salivation in six of 20 mice at 500 mg/kg bw/d, no maternal toxicity was observed during gestation and at PND 0 in any treatment group. Body weight gains from PNDs 0 – 20 were 97.7 %, 110.3 %, and 64.4 % of the control group values; however, these differences were not statistically significant (see Table 61).

Table 60: Developmental toxicity of PFHxA in mice according to (Hoberman, 2011b) (GD = day of gestation, PND = postnatal day).

	control	**7 mg/kg bw/d**	**35 mg/kg bw/d**	**175 mg/kg bw/d**
no of dams	20	20	20	20
pregnant dams	20	17	20	20
mortality	0	0	0	0
BW gain (GD 6-18) in g	25.1 ± 3.8	26.0 ± 4.6	23.7 ± 5.6	22.8 ± 4.8
BW gain (PND 0-20) in g	9.5 ± 3.3	9.4 ± 4.0	8.5 ± 2.8	10.9 ± 3.6
BW PND 0 in g	33.6 ± 2.2	34.3 ± 1.8	34.5 ± 2.1	33.2 ± 2.4
litters delivered	20	17	19	20
pups delivered	249	213	232	241
dams with stillborn pups	0	0	0	1
dams with no liveborn pups	0	0	0	0
dams with all	0	1	0	0

pups dying days 0-3				
stillborn N	0	0	0	**3 (1.2 %)****
stillborn in 23 control groups [a]	0 – 2.3 %			
no. of pups dead on day 0 N	0	0	0	**4 (1.7 %)****
pups dead on days 1-4 N	3 (1.2 %)	6 (2.8 %)	2 (0.9 %)	3 (1.3 %)
day 4 viability index	98.8 %	97.2 %	99.1 %	97.0 %
day 7 viability index	98.4 %	97.2 %	99.1 %	95.8 %
mortality in dams during lactation	0	0	0	0
pup weight day 0 in g [b]	1.6 ± 0.1	1.6 ± 0.1	1.6 ± 0.1	**1.4 ± 0.2 ***

Treatment occurred on days 6 through 18 of gestation

[a] Data from (Iwai et al., 2019)

[b] Data were statistically re-evaluated based on individual animal data. The influence of litter size was considered in the evaluation.

* Significantly different from the vehicle control group ($p \leq 0.05$)

** Significantly different from the vehicle control group ($p \leq 0.01$)

Table 61: Developmental toxicity of PFHxA in mice according to Hoberman (2011a) (GD = day of gestation, PND = postnatal day).

	control	**100 mg/kg bw/d**	**350 mg/kg bw/d**	**500 mg/kg bw/d**
no of dams	20	20	20	20
pregnant dams	19	19	20	18
mortality	0	0	1	1
BW gain (GD 6-18) in g	26.7 ± 7.8	29.6 ± 3.6	26.2 ± 6.5	26.6 ± 7.6
BW gain (PND 0-20) in g	8.7 ± 2.7	8.5 ± 1.9	9.6 ± 4.8	5.6 ± 4.2
BW PND 0 in g	34.0 ± 1.8	34.9 ± 2.1	34.5 ± 3.0	35.3 ± 3.0
litters delivered	19	19	19	17
pups delivered	221	250	245	177
dams with stillborn pups	2	0	5	**7****
dams with no liveborn pups	0	0	0	1
dams with all pups dying days 0-3	1	0	2	**5****
stillborn N	4 (1.8 %)	0	5 (2.0 %)	**16 (9.0 %)****
Stillborn in 23 control groups [a]	0 – 2.3 %			
pups dead on	0	0	3 (1.3 %)	**21 (14.0 %)****

day 0 N				
pups dead on days 1-4 N, (%)	2 (0.9 %)	3 (1.2 %)	**25 (10.9 %)****	**20 (15.5 %)****
day 4 viability index	99.1 %	98.8 %	87.9 %	**72.7 %****
day 7 viability index	98.6 %	98.4 %	**86.6 %***	**72.7 %****
mortality in dams during lactation N	3	6	0	2
pup weight day 0 in g[b]	1.6 ± 0.2	1.5 ± 0.1	**1.4 ± 0.2****	**1.4 ± 0.2****

Treatment occurred on days 6 through 18 of gestation

[a] Data from (Iwai et al., 2019)

[b] Data were statistically re-evaluated based on individual animal data by the Dossier Submitter. The influence of litter size was considered in the evaluation.

* Significantly different from the vehicle control group (p ≤ 0.05)

** Significantly different from the vehicle control group (p ≤ 0.01)

As shown in Table 61, pregnancy occurred in 19, 19, 20, and 18 of the 20 mated female mice in the 0 (vehicle), 100, 350, and 500 mg/kg bw/d dosage groups, respectively. The number of stillborn pups was significantly (p ≤ 0.01) increased at 500 mg/kg bw/d (16/177). The number of pups dying on the day of delivery (PND 0) was (non-significantly) increased at 350 mg/kg bw/d (3/232) and significantly increased (p ≤ 0.01) at 500 mg/kg bw/d (21/150). The number of pups dying on PNDs 1 to 4 in the two highest dose groups was significantly increased (p ≤ 0.01) compared to controls. Furthermore, viability indices were significantly reduced at the highest dose, PND 7 viability index also at 350 mg/kg bw/d. Statistically significantly reduced pup body weights were observed at doses ≥ 350 mg/kg bw/d tested (p ≤ 0.01) compared to the control group (see Table 61). Compared to controls, percentage of pups per litter with open eyes was significantly reduced at 350 and 500 mg/kg bw/d on PND 14.

In phase II body weights and body weight gains of dams during the gestation and lactation periods were unaffected by dosages of the test substance as high as 175 mg/kg/d. Pregnancy occurred in all the 20 mated female mice in all dose groups including vehicle. The number of stillborn pups (3/241) and pups dying on day 0 postpartum (4/238) were significantly increased (p ≤ 0.01). Furthermore, the average pup weight per litter was significantly reduced on day 0 postpartum at 175 mg/kg bw/d dosage group (1.4 ± 0.2) compared to controls (1.6 ± 0.1) (see Table 60). Comparing the results of both study phases for the pup weight at PND 0, a dose-related effect was observed (see Table 60 and Table 61).

The study authors considered 175 mg/kg bw/d as a maternally toxic dose without giving a justification to support this statement. In fact, the original publication does not indicate any sign of maternal toxicity at 175 mg/kg bw/d and so does not the study report of (Hoberman, 2011a).

Based on the outcome of this study a NOAEL of 100 mg/kg bw/d can be derived for developmental toxicity. The DS interpreted the outcome of the phase II study as to the significantly increased number of pups dying on PND 0 as a borderline effect. The incidence of 4/238 pups dying on PND 0 appears to just gain the significance level and was not robust enough to conclude on developmental toxicity. The observed decrease in pup survival at PND 0 was minimal (non-significant) at 350 mg/kg bw/d in the phase I study, but a clear and significant ($p \leq 0.01$) decrease in pup survival was seen at the 500 mg/kg bw/d dose. Comparing death rates in pups on PND 1-4 no significant increase was seen at 175 mg/kg bw/d (phase II), while the incidence was significantly elevated at 350 mg/kg bw/d (phase I).

Summary and discussion of reproductive toxicity

In an one generation reproductive toxicity study with NaPFHxA in rats no substance-related effects were observed on mating, fertility, gestation length, number of implantation sites, estrous cyclicity, sperm parameters, litter size, sex ratio, pup clinical observations, pup survival, or F1 adult developmental landmarks at any dose tested. Substance-related effects were observed during lactation at 500 mg/kg bw/d on mean pup weights (17-18 % decrease compared to controls).

In a guideline study on prenatal developmental toxicity of NaPFHxA in rats, there were no substance-related deaths or gross post-mortem findings in dams at any dose. Maternal and developmental toxicity occurred at 500 mg/kg bw/d and consisted of reductions in bodyweight.

In a non-guideline study on prenatal developmental toxicity of ammonium perfluorohexanoate in mice adverse effects on offspring occurred at 175 mg/kg bw/d and higher whereas no maternal toxicity was observed up to 500 mg/kg bw/d. The number of stillborn pups and pups dying on day 0 and from day 1-4 postpartum were significantly increased on day 0 postpartum at 500 mg/kg bw/d. The significant increase of stillborn pups furthermore indicated an effect from exposure of the foetuses during maternal treatment due to placental transfer of the compound. Additionally, the pup weight was reduced dose-dependently from 1.6 g to 1.4 g; the first effect was noted at 175 mg/kg bw/d.

A developmental NOAEL of 100 mg/kg bw/d was derived.

In comparison to the developmental LOAEL of PFHxA of 175 mg/kg bw/d, the restriction dossier of PFOA reported LOAEL values of 1.0 (maternal) and 3.0 (foetal) mg/kg bw/d (ECHA, 2015a) for developmental toxicity. In conclusion, there are indications that PFHxA has a considerably lower potency when compared to PFOA under the experimental conditions of the tests conducted so and thus presumably a lower potential to affect fertility and development.

B.5.6 Derivation of DNEL(s)/DMEL(s)

Uncertainties

The key study for the derivation of DNELs was the NTP study (NTP, 2018). This study was a subacute toxicity study. The relevant effects were decreased levels of free and total T4 and total T3. It was not possible to derive a NOAEL. Therefore, the LOAEL value was used for DNEL derivation. The uncertainties due to both aspects (short study duration and LOAEL as point of departure) were reflected using additional assessment factors of 6 and 3. It should be noted that the assessment factor of 6 for the extrapolation from subacute to chronic reflects not only the short period of exposure in the subacute study but also the smaller numbers of animals per group in a subacute toxicity study compared to the number of animals per group in a chronic toxicity study. The resulting additional assessment factor of 18 adequately addresses the uncertainty following the use of this subacute toxicity study.

The NOAEL of 10 mg/kg bw/d (Chengelis et al., 2009c) is the lowest value; however, it was not used as PoD (point of departure) for DNEL-derivation. The body weights at 50 and 200 mg/kg bw/d in males were significantly lower in comparison to the control group, but at the highest dose the difference between treated and control animals is below 10 %. Therefore, the observed effect is assessed as insufficient to be used as PoD for DNEL-derivation.

Instead, the LOAEL of 62.6 mg/kg bw/d was chosen as PoD for DNEL-derivation. The reduction of thyroid hormones, namely free and total T4 and total T3, is assessed to be the most sensitive endpoint regarding PFHxA treatment.

All relevant NOAEL and LOAEL values were summarised in Table 14.

Table 62: Assessment factors (AF) and DNEL-derivation (long-term, systemic, oral, general population) based on reduced level of thyroid hormones in rats (NTP, 2018).

		Assessment Factors	**Comments**
interspecies difference	rat	4	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
duration	subacute to chronic	6	*
dose response	LOAEL as starting point	3	*
overall AF for general population		**1 800**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, oral

LOAEL for reduced level of thyroid hormones: 62.6 mg/kg bw/d

$\mathrm{DNEL}_{\text{general population}}$: $\frac{62.6\,\frac{mg}{kg}\,bw/d}{1800}$ = **0.03 mg/kg bw/d**

In order to derive an inhalation DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into NOAEC is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated with 90 %. According to the physicochemical properties of PFHxA, absorption via inhalation was assumed to be 100 %. The standard respiratory volume (sRV) of rat is 0.2 L/min corresponding to 0.8 L/min/kg bw. For general population, the exposure is set to 24 h, therefore the sRV is estimated to be 1.15 m^3/kg bw.

NOAEC was calculated according to the following equations:

$$\text{NOAEC}=\text{NOAEL oral}\cdot\frac{1}{\text{SV rat}}\cdot*\frac{\text{Abs oral rat}}{\text{Abs inh human}}$$

$$\text{NOAEC}=\frac{62.6\frac{\text{mg}}{\text{kg}}\text{bw}}{\text{d}}\cdot\frac{1}{1.15}\cdot 0.9$$

NOAEC=49 mg/m³

Table 63: Assessment factors (AF) and DNEL-derivation (long-term, systemic, inhalation, general population) based on reduced level of thyroid hormones in rats(NTP, 2018).

		Assessement factors	**Comments**
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
duration	subacute to chronic	6	*
dose response	LOAEL as starting point	3	*
overall AF for general population		**450**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, inhalation

NOAEC for reduced level of thyroid hormones: 48.99 mg/m³

$\text{DNEL}_{\text{general population}}$: $\frac{49\ \text{mg/m}^3}{450}$ = **0.11 mg/m³**

In order to derive a dermal DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into a dermal NOAEL is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated as 90 %. According the physicochemical properties of PFHxA and the rule of de Heer, the dermal absorption was assumed as 100 %. De Heer et al. defined criteria to discriminate between chemicals with high and low dermal absorption assuming that there is an optimum in log P_{OW} and a maximum in molecular weight for facilitating percutaneous absorption. If the molecular weight is higher than 500 Da and the log P_{OW} is smaller than -1 or higher than 4, the dermal absorption would be estimated with 10 %. If the molecular weight and the log P_{OW} are different, 100 % dermal absorption would be assumed (de Heer, 1999). The assumption of 100 % dermal absorption is a conservative approach, because PFHxA contains an acid group which may counteract the dermal absorption.

$\text{NOAEL}_{\text{dermal}}$ was calculated according to the following equations:

$$\text{NOAEL}_{\text{dermal}} = \text{NOAEL oral} \cdot \frac{\text{Abs oral rat}}{\text{Abs dermal human}}$$

$$\text{NOAEL}_{\text{dermal}} = \frac{62.6 \frac{\text{mg}}{\text{kg}} \text{bw}}{\text{d}} \cdot 0.9$$

$\text{NOAEL}_{\text{dermal}}$ = 56.34 mg/kg bw/d

Table 64: Assessment factors (AF) and DNEL –derivation (long-term, systemic, dermal, general population) based on reduced level of thyroid hormones in rats(NTP, 2018).

		Assessment factors	**Comments**
interspecies difference	Rat	4	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
duration	subacute to chronic	6	*
dose response	LOAEL as starting point	3	*
overall AF for general population		**1 800**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, dermal

NOAEL for reduced level of thyroid hormones: 56.34 mg/kg bw/d

DNEL $_{\text{general population}}$: $\frac{56.34 \frac{\text{mg}}{\text{kg}} \text{bw/d}}{1800}$ = **0.031 mg/kg bw/d**

Table 65: Assessment factors (AF) and calculation of DNEL (long-term, systemic, oral, general population) based on lower body weight in comparison to the control group (Chengelis et al., 2009c).

		Assessment factors	**Comments**
interspecies difference	rat	4	*

remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
duration	subchronic to chronic	3	*
overall AF for general population		**300**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, oral

NOAEL for lower body weight in comparison to the control group: 10 mg/kg bw/d

DNEL$_{\text{general population}}$: $\frac{10\frac{mg}{kg}bw/d}{300}$ = **0.03 mg/kg bw/d**

In order to derive the inhalation DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into a NOAEC is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated to be 90 %. According to the physicochemical properties of PFHxA, the absorption via inhalation was assumed to be 100 %. The sRV of rat is 0.2 L/min corresponding to 0.8 L/min/kg bw. For general population, the exposure is set to 24 h, therefore the sRV is estimated to be 1.15 m^3/kg bw.

NOAEC was calculated according to the following equations:

$$\text{NOAEC} = \text{NOAEL oral} \cdot \frac{1}{\text{SV rat}} \cdot \frac{\text{Abs oral rat}}{\text{Abs inh human}}$$

$$\text{NOAEC} = \frac{10\frac{mg}{kg}bw}{d} \cdot \frac{1}{1.15\frac{m^3}{kg}bw} \cdot 0.9$$

NOAEC = 7.83 mg/m^3

Table 66: Assessment factors (AF) and DNEL-derivation (long-term, systemic, inhalation, general population) based on lower body weight in comparison to the control group (Chengelis et al., 2009c).

		Assessment Factors	Comments
remaining differences on toxicodynamics		2.5	*
intraspecies	general population	10	*

difference			
duration	subchronic to chronic	3	*
overall AF for general population		**75**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, inhalation

NOAEC for lower body weight in comparison to the control group: 7.83 mg/m³

$\text{DNEL}_{\text{general population}}: \frac{7.83\ \text{mg/m}^3}{75} = \mathbf{0.10\ mg/m^3}$

In order to derive a dermal DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into dermal NOAEL is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated with 90 %. According to the physicochemical properties of PFHxA and the rule of de Heer et al., the dermal absorption was 100 %.

$\text{NOAEL}_{\text{dermal}}$ was calculated according to the following equations:

$$\text{NOAEL}_{\text{dermal}} = \text{NOAEL oral} \cdot \frac{\text{Abs oral rat}}{\text{Abs inh human}}$$

$$\text{NOAEL}_{\text{dermal}} = \frac{10\frac{\text{mg}}{\text{kg}}\text{bw}}{\text{d}} \cdot 0.9$$

$$\text{NOAEL}_{\text{dermal}} = 9\frac{\text{mg}}{\text{kg}}\text{bw/d}$$

Table 67: Assessment factors (AF) and DNEL-derivation (long-term, systemic, dermal, general population) based on lower body weight in comparison to the control group (Chengelis et al., 2009c).

		Assessment Factors	**Comments**
interspecies difference	rat	4	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
duration	subchronic to chronic	3	*
overall AF for		**300**	

general population			

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, dermal

NOAEL$_{dermal}$ for lower body weight in comparison to the control group: 9 mg/kg bw/d

DNEL$_{general\ population}$: $\frac{9\frac{mg}{kg}bw/d}{300}$ = **0.03 mg/kg bw/d**

Table 68: Assessment factors (AF) and DNEL-derivation (long-term, systemic, oral, general population) based on nasal lesions (Loveless et al., 2009b).

		Assessment Factors	**Comments**
interspecies difference	rat	4	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
duration	subchronic to chronic	3	*
overall AF for general population		**300**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, oral

NOAEL for nasal lesions: 20 mg/kg bw/d

DNEL$_{general\ population}$: $\frac{20\frac{mg}{kg}bw/d}{300}$ = **0.067 mg/kg bw/d**

In order to derive the inhalation DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into a NOAEC is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated to be 90 %. According to the physicochemical properties of PFHxA, the inhalation absorption was 100 %. The sRV of rat is 0.2 L/min corresponding with 0.8 L/min/kg bw. For general population, the exposure is set to 24 h, therefore the sRV is estimated with 1.15 m^3/kg bw.

NOAEC was calculated according to the following equations:

$$\text{NOAEC} = \text{NOAEL oral} * \frac{1}{\text{SV rat}} \cdot \frac{\text{Abs oral rat}}{\text{Abs inh human}}$$

$$\text{NOAEC} = \frac{20 \frac{mg}{kg} bw}{d} \cdot \frac{1}{1.15 \frac{m^3}{kg} bw} \cdot 0.9$$

NOAEC=15.65 mg/m³

Table 69: Assessment factors (AF) and DNEL-derivation (long-term, systemic, inhalation, general population) based on nasal lesions (Loveless et al., 2009b).

		Assessment Factors	**Comments**
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
duration	sub chronic to chronic	3	*
overall AF for general population		**75**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, inhalation

NOAEC for nasal lesions: 15.65 mg/m³

DNEL$_{\text{general population}}$: $\frac{15.65 \frac{mg}{m^3}}{75}$ = **0.21 mg/m³**

In order to derive the dermal DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into dermal NOAEL is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated with 90 %. According to the physicochemical properties of PFHxA and the rule of de Heer et al., the dermal absorption was 100 %.

NOAEL$_{\text{dermal}}$ was calculated according to the following equations:

$$\text{NOAEL}_{\text{dermal}} = \text{NOAEL}_{\text{oral}} \cdot \frac{\text{Abs oral rat}}{\text{Abs dermal human}}$$

$$\text{NOAEL}_{\text{dermal}} = \frac{20 \frac{mg}{kg} bw}{d} \cdot 0.9$$

$$\text{NOAEL}_{\text{dermal}} = 18 \frac{mg}{kg} bw/d$$

Table 70: Assessment factors (AF) and DNEL-derivation (long-term, systemic, dermal, general population) based on nasal lesions (Loveless et al., 2009b).

		Assessment Factors	**Comments**
interspecies difference	rat	4	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
duration	sub chronic to chronic	3	*
overall AF for general population		**300**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, dermal

NOAEL for nasal lesions: 18 mg/kg bw/d

DNEL$_{\text{general population}}$: $\frac{18\frac{mg}{kg}bw/d}{300}$ = **0.06 mg/kg bw/d**

Table 71: Assessment factors (AF) and DNEL-derivation (long-term, systemic, oral, general population) based on kidney necrosis (Klaunig et al., 2015b).

		Assessment Factors	**Comments**
interspecies difference	rat	4	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
overall AF for general population		**100**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, oral

NOAEL for kidney necrosis: 30 mg/kg bw/d

$\mathrm{DNEL}_{\text{general population}}$: $\frac{30\frac{\mathrm{mg}}{\mathrm{kg}}\mathrm{bw/d}}{100}$ = **0.3 mg/kg bw/d**

In order to derive the DNEL or long-term systemic effects on general population after inhalation, the conversion of the oral NOAEL into NOAEC is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated with 90 %. According to the physicochemical properties of PFHxA, the inhalation absorption was 100 %. The sRV of rat is 0.2 L/min corresponding with 0.8 L/min/kg bw. For general population, the exposure is set to 24 h, therefore the sRV is estimated with 1.15 m³/kg bw.

NOAEC was calculated according to the following equations:

$$\mathrm{NOAEC} = \mathrm{NOAEL}_{\mathrm{oral}} \cdot \frac{1}{\mathrm{SV\ rat}} \cdot \frac{\mathrm{Abs\ oral\ rat}}{\mathrm{Abs\ inh\ human}}$$

$$\mathrm{NOAEC} = \frac{30\frac{\mathrm{mg}}{\mathrm{kg}}\mathrm{bw}}{\mathrm{d}} \cdot \frac{1}{1.15\frac{\mathrm{m}^3}{\mathrm{kg}}\mathrm{bw}} \cdot 0.9$$

NOAEC=23.48 mg/m³

Table 72: Assessment factors (AF) and DNEL-derivation (long-term, systemic, inhalation, general population) on kidney necrosis (Klaunig et al., 2015b).

		Assessment Factors	**Comments**
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
overall AF for general population		**25**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL –derivation for general population, long-term, systemic effects, inhalation

NOAEC for kidney necrosis: 23.48 mg/m³

DNEL$_{\text{general population}}$: $\frac{23.48\,\frac{mg}{m^3}}{25}$ = **0.94 mg/m³**

In order to derive the dermal DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into dermal NOAEL is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated with 90 %. According to the physicochemical properties of PFHxA and the rule of de Heer et al., the dermal absorption was 100 %.

NOAEL$_{\text{dermal}}$ was calculated according to the following equations:

$$\text{NOAEL}_{\text{dermal}} = \text{NOAEL}_{\text{oral}} \cdot \frac{\text{Abs oral rat}}{\text{Abs dermal human}}$$

$$\text{NOAEL}_{\text{dermal}} = \frac{30\frac{mg}{kg}\text{bw}}{d} \cdot 0.9$$

$$\text{NOAEL}_{\text{dermal}} = 27\frac{mg}{kg}\text{bw/d}$$

Table 73: Assessment factors (AF) and DNEL-derivation (long-term, systemic, dermal, general population) based on kidney necrosis (Klaunig et al., 2015b).

		Assessment Factors	**Comments**
interspecies difference	rat	4	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
overall AF for general population		**100**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL –derivation for general population, long-term, systemic effects, dermal

NOAEL$_{dermal}$ for kidney necrosis: 27 mg/kg bw/d

DNEL$_{general\ population}$: $\frac{27\ \frac{mg}{kg}bw/d}{100}$ = **0.27 mg/kg bw/d**

Table 74: Assessment factors (AF) and DNEL-derivation (long-term, systemic, oral, general population) based on lower foetal body weight gain in comparison to the control group (Loveless et al., 2009b).

		Assessment Factors	**Comments**
interspecies difference	rat	4	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
overall AF for general population		**100**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL –derivation for general population, long-term, systemic effects, oral

NOAEL for lower fetal body weight gain in comparison to the control group: 100 mg/kg bw/d

DNEL$_{general\ population}$: $\frac{100\frac{mg}{kg}bw/d}{100}$ = **1 mg/kg bw/d**

In order to derive the inhalation DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into NOAEC is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated with 90 %. According to the physicochemical properties of PFHxA, the inhalation absorption was 100 %. The sRV of rat is 0.2 L/min corresponding with 0.8 L/min/kg bw. For general population, the exposure is set to 24 h, therefore the sRV is estimated with 1.15 m³/kg bw.

NOAEC was calculated according to the following equations:

$$\mathrm{NOAEC}=\mathrm{NOAEL}_{oral}\cdot\frac{1}{\mathrm{SV\ rat}}\cdot\frac{\mathrm{Abs\ oral\ rat}}{\mathrm{Abs\ inh\ human}}$$

$$\mathrm{NOAEC}=\frac{100\frac{\mathrm{mg}}{\mathrm{kg}}\mathrm{bw}}{\mathrm{d}}\cdot\frac{1}{\frac{1.15\ \mathrm{m}^3}{\mathrm{kg}}\mathrm{bw}}\cdot 0.9$$

NOAEC=78.26 mg/m³

Table 75: Assessment factors (AF) and DNEL-derivation (long-term, systemic, inhalation, general population) based on lower foetal body weight gain in comparison to the control group (Loveless et al., 2009b).

		Assessment Factors	**Comments**
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
overall AF for general population		**25**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL-derivation for general population, long-term, systemic effects, inhalation

NOAEC for lower foetal body weight gain in comparison to the control group: 78.26 mg/m³

DNEL $_{\text{general population}}$: $\frac{78.26\ \frac{\mathrm{mg}}{\mathrm{m}^3}}{25}$ = **3.13 mg/m³**

In order to derive the dermal DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into dermal NOAEL is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated with 90 %. According to the physicochemical properties of PFHxA and the rule of de Heer et al., the dermal absorption was 100 %.

$\mathrm{NOAEL}_{\mathrm{dermal}}$ was calculated according to the following equations:

$$\mathrm{NOAEL}_{\mathrm{dermal}}=\mathrm{NOAEL}_{\mathrm{oral}}\cdot\frac{\text{Abs oral rat}}{\text{Abs dermal human}}$$

$$\mathrm{NOAEL}_{\mathrm{dermal}}=\frac{100\frac{\mathrm{mg}}{\mathrm{kg}}\mathrm{bw}}{\mathrm{d}}\cdot 0.9$$

$$\mathrm{NOAEL}_{\mathrm{dermal}}=90\frac{\mathrm{mg}}{\mathrm{kg}}\mathrm{bw/d}$$

Table 76: Assessment factors (AF) and DNEL-derivation (long-term, systemic, dermal, general population) on lower foetal body weight gain in comparison to the control group (Loveless et al., 2009b).

		Assessment Factors	**Comments**
interspecies difference	rat	4	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
overall AF for general population		**100**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL–derivation for general population, long-term, systemic effects, dermal

$\text{NOAEL}_{\text{dermal}}$ for lower foetal body weight gain in comparison to the control group: 90 mg/kg bw/d

$\text{DNEL}_{\text{general population}}$: $\frac{90\ \frac{mg}{kg}\text{bw/d}}{100}$ = **0.9 mg/kg bw/d**

Table 77: Assessment factors (AF) and calculation of DNEL (long-term, systemic, oral, general population) on lower absolute foetal body weight in comparison to the control group (Hoberman, 2011b).

		AF	**Comments**
interspecies difference	mouse	7	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
overall AF for general population		**175**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL –derivation for general population, long-term, systemic effects, oral

NOAEL for lower absolute foetal body weight in comparison to the control group:
100 mg/kg bw/d

DNEL$_{\text{general population}}$: $\frac{100\frac{mg}{kg}bw/d}{175}$ = **0.57 mg/kg bw/d**

In order to derive the inhalation DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into NOAEC is necessary. Based on toxicokinetic data, the oral absorption of mouse was estimated with 90 %. According to the physicochemical properties of PFHxA, the inhalation absorption was 100 %. The sRV of mouse is 0.02 L/min/mouse corresponding with 0.52 L/min/kg bw. For general population, the exposure is set to 24 h, therefore the sRV is estimated with 0.749 m³/kg bw (US EPA, 1988).

NOAEC was calculated according to the following equations:

$$\text{NOAEC}=\text{NOAEL}_{\text{oral}}\cdot\frac{1}{\text{SV mouse}}\cdot\frac{\text{Abs oral mouse}}{\text{Abs inh human}}$$

$$\text{NOAEC}=\frac{100\frac{mg}{kg}bw}{d}\cdot\frac{1}{0.749\frac{m^3}{kg}bw}\cdot 0.9$$

NOAEC=120 mg/m³

Table 78: Assessment factors (AF) and DNEL-derivation (long-term, systemic, inhalation, general population) on lower absolute foetal body weight in comparison to the control group (Hoberman, 2011b).

		Assessment Factors	**Comments**
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
overall AF for general population		**25**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL –derivation for general population, long-term, systemic effects, inhalation

NOAEC for lower absolute foetal body weight in comparison to the control group: 0.120 mg/m³

DNEL$_{\text{general population}}$: $\frac{120\frac{mg}{m^3}}{25}$ = 4**.80 mg/m³**

To be able to derive the dermal DNEL for long-term systemic effects in the general population, the conversion of the oral NOAEL into dermal NOAEL is necessary. Based on toxicokinetic data, the oral absorption of rats was estimated with 90 %. According to the physicochemical properties of PFHxA and the rule of de Heer et al., the dermal absorption was 100 %.

NOAEL$_{\text{dermal}}$ was calculated according to the following equations:

$$\text{NOAEL}_{\text{dermal}} = \text{NOAEL}_{\text{oral}} \cdot \frac{\text{Abs oral mouse}}{\text{Abs dermal human}}$$

$$\text{NOAEL}_{\text{dermal}} = \frac{100\frac{mg}{kg}\text{bw}}{d} \cdot 0.9$$

NOAEL$_{\text{dermal}}$ = 90 mg/kg bw/d

Table 79: Assessment factors (AF) and DNEL-derivation (long-term, systemic, dermal, general population) on lower absolute foetal body weight in comparison to the control group (Hoberman, 2011b).

		Assessment Factors	Comments
interspecies difference	mouse	7	*
remaining differences on toxicodynamics		2.5	*
intraspecies difference	general population	10	*
overall AF for general population		**175**	

* Default values for systemic effects obtained from ECHA guidance on chemical safety assessment, Chapter R.8, table R.8-3 and table R.8-6

DNEL –derivation for general population, long-term, systemic effects, dermal

$\text{NOAEL}_{\text{dermal}}$ for lower absolute foetal body weight in comparison to the control group: 90 mg/kg bw/d

$\text{DNEL}_{\text{general population}}$: $\frac{90\frac{\text{mg}}{\text{kg}}\text{bw/d}}{175}$ = **0.51 mg/kg bw/d**

All DNEL values for general population were summarised in Table 15.

The external total DNEL was calculated with 3.17 mg/d (based on effects on thyroid hormones T3 and T4).

The total DNEL was estimated as follows:

$$\mathrm{DNELtotal}=2\cdot 0.03\left[\frac{\frac{\mathrm{mg}}{\mathrm{kg}}\,\mathrm{bw}}{\mathrm{d}}\right]\cdot 1\mathrm{e}^{3}\left[\frac{\mathrm{ng}}{\mathrm{mg}}\right]\cdot 75\ [\mathrm{kg\ bw}]+0.11\left[\frac{\mathrm{mg}}{\mathrm{m}^{3}}\right]\cdot 1\mathrm{e}^{3}\left[\frac{\mathrm{ng}}{\mathrm{mg}}\right]\cdot 20\left[\frac{\mathrm{L}}{\mathrm{min}}\right]\cdot 1440\ [\frac{\mathrm{min}}{\mathrm{d}}]$$

The overall external DNEL of 3.17 mg/d DNEL corresponds to a blood level of 91.7 ng/mL.

The steady state blood concentration (C_{ss}) was calculated as followed:

$$C_{SS}=\frac{\mathrm{AMT}}{V\cdot k\cdot \tau}$$

$$C_{SS}=\frac{3172200\ [\mathrm{ng}]}{3.61\cdot \mathrm{e}^{0.5}[\mathrm{mL}]\cdot 0.0958\left[\frac{1}{\mathrm{d}}\right]\cdot 1\ [\mathrm{d}]}$$

The PK modell proposed a volume of distribution at 361 L.

Appendix E.1: Available methods for extracting and analysing PFHxA, its salts and related substances

Table 80: Overview of methods for extracting and analysing PFHxA, its salts and related substances as well in environmental comprtments as in products and articles.

Source	Substances to be determinated	Matrix to be investigated	LOD		LOQ		Scope	Method applicable to:	Extraction method	Extraction Solvents	Derivatisation (substance or method)	derivat actually is measured	Detection method	Remarks	uncertainties
			ppb	ng/L (kg)	ppb	ng/L (kg)									
**Water quality — Determination of perfluorooctanesulfonate (PFOS) and perfluorooctanoate (PFOA) — Method for unfiltered samples using solid phase extraction and liquid chromatography/ mass spectrometry, ISO 25101:2009E*	**linear isomer of PFOS-anion**	**drinking water, ground water, surface water**	0.002	2			determination of linear isomers of PFOS and PFOA	non-linear isomers of PFOS-and PFOA anions, other perfluorinated acids **including PFHxA** (linear- and nonlinear isomers)	solid-phase extraction followed by solvent elution	ammonia / methanol solution			liquid chromatography with tandem mass-spectrometric detection	focus on PFAs	only perfluorinated acids are captured, no primary detection of related substances with perfluorinated side chains
	linear isomers of PFOA-anion		0.01	10											
**German standard methods for the examination of water, wastewater and sludge - Jointly determinable substances (group F) - Part 42: Determination of selected polyfluorinated compounds (PFC) in water - Method using high performance liquid chromatography and mass spectrometric detection (HPLC/MS-MS) after solid-liquid extraction (F 42), DIN 38407-42:2011*	**perfluorinated carboxylic and sulfonic anions (linear and branched isomers)**	**drinking water, ground water, surface water**	0.001	1			determination of linear and branched isomers of perfluorinated alkylic and sulfonic acids in water		solid-phase extraction of sampled water without adding further chemicals followed by solvent elution	ammonia / methanol solution			liquid chromatography with tandem mass-spectrometric detection	amendmet of ISO 25101 to detect further perfluorinated substances and branched isomers	

**Determination of perfluoroalkyl compounds in water, sediment, and biota, ICES, Ahrens et al. 2010*	**anions from perfluorinated acids 3 - 18 C-atoms (including C6), anions from sulfonic acids anions from 4 - 10 C-atoms (including C6), several perfluorinated telomer substances (including C6)**	**water, sediment, and biota**			depending on the matrix and the analytical methods		monitoring of aquatic and marine environment		solid-phase extraction followed by solvent elution, several alternatives are provided for different compartments respectively	several alternatives provided			liquid chromatography coupled with a tandem mass spectrometer and interfaced with an electrospray ionization source in negative-ion mode (LC/(−)ESI-MS/MS	several methods provided, the most efficient method should be selected depending on the compartment to be investigated and the LOQ is sufficient	the suitable method has to be chosen for the results which are expected
SOP for Extraction of Residuals from Fluoropolymer Products, Chemours,	**residuals from fluoropolymer products**	**fluoropolymer cubes and granular, fine powder and micropowder fluoropolymers**					extraction and quantification of residual compounds in two polymer matrices	perfluorinated acids (linear- and nonlinear isomers), **including PFHxA** - see ISO 25101!	method described in ISO 25101	0.4 % potassium hydroxide / methanol solution, Vertrel XF®			method described in ISO 25101		which residues are meant? The perfluorinated acids itself or substances related to the acids of different chain length, like perfluorinated telomer substances?
Method for the Quantitative Determination of PFOA in Fluorotelomer- Based Intermediates and Products, Chemours,	**C8-fluorotelomer-based intermediates and products**	**perfluorinated intermediates in different production steps**			50	50 000	quantitative determination of potential low molecular PFOA-related substances substances in fluorotelomer-based intermediates and products	fluorotelomer-based intermediates and products with different chain length, **including perfluorinated C6-telomer substances**		acetonitrile, Vertrel XF®			gas chromatographic separation followed by detection via a dual mass spectrometer operating in the TRM mode (GC/MS/MS)		very high LOQ, reliable results in final products not proven, yet; extraction method is not further described

Method for the Quantitative Determination of PFOA in Fluorotelomer-Based Intermediates and Products, Chemours,	**PFOA-anion**	**finished products and intermediates**	0.5	500	12.5	12 500	determining concentration of residual PFOA in finished products and intermediates	Perfluorinated acids of different chain length, **including PFHxA**			methanolic sulfuric acid	methyl ester of the perfluorinated acids	gas chromatographic separation followed by detection via a dual mass spectrometer (GC/MS/MS)		method was developed to determine perfluorinated acids
Per- and polyfluoroalkyl substances in firefighting foam concentrates and water samples collected near sites impacted by the use of these foams, Dauchy et al. 2017	**anions from perfluorinated acids 3 - 18 C-atoms (including C6), anions from sulfonic acids anions from 4 - 10 C-atoms (including C6), several perfluorinated telomer substances (including C6)**	**fire-fighting foams**			0.004 - 0.025 (water samples)	4 - 25 (water samples)	quantitatively determining of specific PFAS substances in fire-fighting foams and in environmental compartments	potentially to all perfluorinated (side chain) substances	solid-phase extraction followed by subsequent solvent elution based on (Boiteux et al., 2017); oxidative conversion method according to (Houtz and Sedlak, 2012)	methanol, methanol-ammonium hydroxide, NH_4OH-isopropanol/ dichloromethane	derivatisation with hydroxyl radicals, generated by thermolysis of persulfate under alkaline pH conditions (oxidative conversion method)	related PFCAs of the perfluorinated chain length	high performance liquid chromatography coupled to a mass spectrometer interfaced with an electrospray ionization source in a negative-ion mode, liquid chromatograph coupled with a quadrupole ion trap mass spectrometer according (Boiteux et al., 2017)		artefacts like from polymer degradation by the oxidative conversion method are likely

Chemical Analysis of Selected Fire-fighting Foams on the Swedish Market 2014, Kemi 2015	**perfluorinated alkyl acids and sulfonates (PFCAs, PFSAs), fluorotelomersulfonates (FTS), sulfonamides including perfluorooctane sulfonamides (PFOSA, N-ethylFOSA, NmethylFOSA) and perfluorooctanesulfonamidoethanols (FOSEs), unsaturated and saturated telomer acids (FTUCAs and FTCAs)**	**fire-fighting foam concentrares**			0.002 (sediment samples)	2 (sediment samples)	detection of perfluorinated substances in fire-fighting foams	all liquid or soluble matrices	dilution in a polar solvent and filtration via GHP filters	methanol and MilliQ water	no derivatisation		liquid chromatography coupled with a mass spectrometer; gas chromatography coupled with a mass spectrometer		only capturing of easy extractable perfluorinated substances
Oxidative conversion as a mean of detecting precursors to perfluoroalkyl acids in urban runoff, Houtz, E. F., & Sedlak, D. L. 2012	**substances with C8 perfluorinated side chains, including sulfonamides**	**water**			0.025	25	quantification of low molecular PFCA-related substances in sum	other substances with perfluorinated side chains of different chain length, including C6	solid-phase extraction followed by solvent elution	0.1 % NH_4OH in methanol	thermolysis of persulfate ($S_2O_8^{2-}$) to generate OH-radikals, oxidation of related substances to respective perfluorinated acid with these OH-radikals	Perfluorinated carboxylic and sulfonic acid	analysis before and after oxidation step with liqud chromatography coupled with mass spectrometry	TOP-assay, detection of sumarised related substances related to respective perfluorinated carboxylic and sulfonic acids	special related substances are unknown
Further methods are available – see confidential annex															

** Methods accepted and recommended by international organisations*