

Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing restrictions on perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related substances

ECHA/RAC/ RES-O-0000006739-59-01/F

ECHA/SEAC/RES-O-0000006786-60-01/F

EC Number CAS Number

n/a

n/a

11 June 2020

TABLE OF CONTENTS

List of abbreviations.....	viii
Summary	1
Report.....	9
1. The problem identified.....	9
1.1. Hazard, exposure/emissions and risk.....	9
1.1.1. Identity of the substance(s), and physical and chemical properties	9
1.1.2. Justification for grouping	13
1.1.3. Classification and labelling.....	17
1.1.4. Hazard assessment	18
1.1.5. Emissions.....	18
1.1.6. Environmental exposure and trends.....	23
1.1.7. Human exposure and trends	24
1.1.8. Risk characterisation.....	26
1.2. Justification for an EU wide restriction measure	27
1.3. Baseline.....	28
2. Impact assessment	33
2.1. Introduction	33
2.2. Risk management options	33
2.3. Restriction scenario(s).....	35
2.4. Assessment of the restriction option	36
2.4.1. Economic impacts.....	36
2.4.2. Human health and environmental impacts	39
2.4.3. Other impacts, practicability and monitorability.....	42
2.4.4. Proportionality	44
3. Assumptions, uncertainties and sensitivities	45
4. Conclusion	46
Annexes	48
Annex A: Manufacture and uses	48
A.1. Manufacture, import and export.....	48

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS
AND PFHxS-RELATED SUBSTANCES

A.1.1	Manufacture of PFHxS	48
A.1.2.	REACH Registrations and CLP Notifications	50
A.2.	Uses.....	52
A.2.1	Introduction	52
A.2.2	Metal plating	55
A.2.3	Hydraulic fluids for the aviation industry	56
A.2.4	Polishing agents and cleaning/washing agents.....	57
A.2.5	Impregnation/proofing	57
A.2.6	Manufacture of semiconductors	57
A.2.7	Flame retardant.....	58
A.2.8	Textiles, carpets, leather and upholstery.....	58
A.2.9	Fire-fighting foams.....	62
A.2.10	PFHxS in continuing uses of PFOS	71
A.2.11	Conclusions.....	72
A.3.	Uses advised against by the registrants	77
Annex B:	Information on hazard and risk.....	77
B.1.	Identity of the substance(s) and physical and chemical properties	77
B.1.1.	Name and other identifiers of the substance(s)	77
B.1.2.	Composition of the substance(s)	77
B.1.3.	Physicochemical properties.....	77
B.1.4.	Justification for grouping	77
B.2.	Manufacture and uses (summary)	77
B.3.	Classification and labelling	78
B.3.1.	Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)	78
B.4.	Environmental fate properties	79
B.4.1.	Degradation	79
B.4.2.	Environmental distribution.....	81
B.4.3	Monitoring and trends.....	84
B.4.4.	Bioaccumulation.....	95

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS
AND PFHxS-RELATED SUBSTANCES

B.4.5. Secondary poisoning.....	97
B.5. Human health hazard assessment	97
B.5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)	97
B.5.2. Acute toxicity.....	100
B.5.3. Irritation	100
B.5.4. Corrosivity	100
B.5.5. Sensitisation.....	100
B.5.6. Repeated dosed toxicity	100
B.5.7. Mutagenicity.....	100
B.5.8. Carcinogenicity	100
B.5.9. Toxicity for reproduction	100
B.5.10. Other effects.....	100
B.5.11. Derivation of DNEL(s)/DMEL(s)	100
B.6. Human health hazard assessment of physicochemical properties	100
B.7. Environmental hazard assessment	100
B.8. PBT and vPvB assessment.....	101
B.8.1. Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII	101
B.8.2. Emission Characterisation	101
B.9. Exposure assessment	102
B.9.1. General discussion on emissions and exposure	102
B.9.2. Manufacturing.....	103
B.9.3. Other sources (unintentional releases).....	103
B.9.4. Human exposure.....	108
B.9.5. Environmental exposure.....	117
B.9.6. Overall exposure assessment.....	117
B.10. Risk characterisation	117
Annex C: Justification for action on a Union-wide basis	119
Annex D: Baseline	121
Annex E: Impact Assessment.....	127
E.1. Risk Management Options.....	127

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS
AND PFHxS-RELATED SUBSTANCES

E.1.1. Proposed option for restriction	127
E.1.2. Discarded restriction options.....	129
E.1.3. Other Union-wide risk management options than restriction	130
E.2. Alternatives.....	131
E.2.1. Description of the use and function of the restricted substance(s)	131
E.2.2. Identification of potential alternative substances and techniques fulfilling the function.....	134
E.2.3. Risk reduction, technical and economic feasibility, and availability of alternatives	140
E.3. Socio-economic impacts.....	159
E.3.1 Introduction	159
E.3.2 Economic impacts	159
E.3.3. Human health and environmental impacts	162
E.3.4. Other impacts, practicality and monitorability	166
E.4. Proportionality (comparison of options).....	170
Annex F: Assumptions, uncertainties and sensitivities	172
F.1. Data collection and uses	172
F.2. Imports of PFOS	172
F.3.Substitution after the C8-PFOA restriction applies	172
F.4.Environmental and health effects	173
Annex G: Stakeholder consultation	174
G.1. Launch	174
G.2. Reminders and extensions	174
G.3. Call for Evidence.....	174
G.4. Responses	174
G.4.1. Stakeholder consultation.....	174
G.4.2. Follow-up consultation with selected stakeholders	175
Appendix 1 List of identified CAS numbers that fall within the scope of the proposal	178
Appendix 2 Human and environmental monitoring data	202
References	268

TABLE OF TABLES

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 1 Text of proposed restriction on PFHxS, its salts and PFHxS-related substances.....	1
<i>Table 2 Linear perfluorohexanesulfonic acid, substance identity</i>	10
<i>Table 3 Physicochemical data for PFHxS, collected from the Danish (Q)SAR Database, unless otherwise noted</i>	12
Table 4: Summary of estimated emissions under the Baseline (BAU)	30
Table 5: Summary of emissions under the Baseline (BAU) and under the Restriction.....	36
Table 6: Data on manufacture and import	48
Table 7: Overview of harmonised classifications, notifications and self-classifications (C&L Inventory 2 April 2019).....	51
Table 8: Historical data on PFHxS “use” from the consumption of PFOS in mixtures used for the treatment of different product categories in the UK	53
Table 9: Presence of PFAS and PFHxS in ten samples taken from seven articles of outdoor clothing articles for children (Greenpeace, 2013).....	60
Table 10: Summary of data on detection of PFHxS and PFOA in outdoor gear in Greenpeace (2016)	61
Table 11: Estimates of quantities and use of Firefighting foams in the UK (RPA, 2004).....	64
Table 12: Estimated current Germany and EU stockpile of Class B foams based on UK data	64
Table 13: Estimated EU stockpile of Class B foams based on German data provided by Mineralölwirtschaftsverband to the stakeholder consultation in 2017.....	66
Table 14: Total foam concentrates stockpiled in the US (FFFC, 2011).....	67
Table 15: Calculated split between F3 and PFAS based foams in stockpile.....	69
Table 16: Estimates of annual replacement of PFAS foam stockpiles	70
Table 17: Estimated total quantity of PFHxS in the EU stockpile of foams	71
Table 18: Summary of information on Manufacture, Import and Use.....	73
Table 19: Summary of the emissions of PFHxS in the EU expressed in kg/year.....	101
<i>Table 20: Overview of the concentrations of PFHxS in WWTP effluents</i>	105
Table 21: Summary of alternatives identified	135
Table 22: Alternatives available for semi-conductors (UNEP-POPS, 2017)	138
Table 23: Alternatives available for metal plating (UNEP-POPS, 2017).....	139
Table 24: Human related PBT properties for PFHxS and fluorine-free foams	142
Table 25: Ecotoxicity data for selected fluorine free foams.....	143
<i>Table 26: Human related PBT properties for PFHxS and 6:2 FTS</i>	147
<i>Table 27: Aquatic toxicity data of 6:2 FTS and its degradation products</i>	148
<i>Table 28: Fluorine free alternatives in textiles</i>	150
<i>Table 29: Human related PBT properties for fluorine free alternatives in textiles</i>	151
<i>Table 30: Aquatic toxicity data of fluorine free alternatives in textiles</i>	152
<i>Table 31: Ecotoxicity data for PFHxS and 6:2 FTOH</i>	154
<i>Table 32: Aquatic toxicity data of 6:2 FTOH, 8:2 FTOH and other metabolites</i>	156
Table 33: Fluorine free alternatives for other potential uses	158
Table 34: Data from Mineralölwirtschaftsverband on PFHxS content of fire-fighting foams	176
Table 35 PFHxS, salts and related substances (per 2018-08-24)	178
Table 36 Concentrations in humans of PFHxS, and when available in the same study also PFOS, PFOA, PFUnDA, PFDoDA, PFTrDA and PFTeDA (copy of human data in Table 18 in SVHC support document, (ECHA, 2017a))	202
Table 37 (copy of Table 1.1. from additional data to POPs draft risk profile for PFHxS) Measured levels of PFHxS in aquatic biota	224
Table 38 (copy of Table 1.2. from additional data to POPs draft risk profile for PFHxS) Measured levels of PFHxS in amphibians and birds.....	227

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS
AND PFHxS-RELATED SUBSTANCES

Table 39 (copy of Table 1.3. from additional data to POPs draft risk profile for PFHxS) Measured levels of PFHxS in marine- and terrestrial mammals	229
Table 40 (copy of Table 1.4. from additional data to POPs draft risk profile for PFHxS) Measured levels of PFHxS in abiota	233
Table 41 (copy of Table 1.5. from additional data to POPs draft risk profile for PFHxS) Detection in waste water treatment, sludge, impacted biota, AFFF impacted sites and from manufacture	239
Table 42 (copy of Table 1.6. from additional data to POPs draft risk profile for PFHxS) Detection in Drinking water	245
Table 43 (copy of table 1.7 from additional data to POPs draft risk profile for PFHxS) PFHxS levels in food items.....	247
Table 44 (Copy of table 1.8 from additional data to POPs draft risk profile for PFHxS) Detection in indoor and outdoor dust and indoor air.....	249
Table 45 (Copy of table 1.9 from additional data to POPs draft risk profile for PFHxS) Detection in products	252
Table 46 (Copy of table 1.10 from additional data to POPs draft risk profile for PFHxS) Concentrations of PFHxS in human serum (See also ECHA 2017a, Annex II Table 14)	255
Table 47 (Copy of table 1.11 from additional data to POPs draft risk profile for PFHxS) Levels in cord blood (See also ECHA 2017a, annex II, Table 14).....	261
Table 48 (Copy of table 1.12. from additional data to POPs draft risk profile for PFHxS) Levels in Breast milk (See also ECHA 2017a, annex II, Table 14)	262
Table 49 (Copy of Table 3 from additional data to POPs draft risk profile for PFHxS) Comparison of half-lives of PFAS in male and females in a variety of species including human	264
Table 50: Effluent concentrations of PFHxS in WWTP.....	266

TABLE OF FIGURES

Figure 1 Degradation of selected PFHxS-related substances	15
Figure 2 Oxidation processes from sulphides to PFHxS.	16
Figure 3 Oxidation of sulfones to PFHxS.	16
Figure 4 Illustration of the relationship between PHxSF and PFHxS	17
Figure 5: Environmental stock profile under the Baseline (BAU) (no degradation)	31
Figure 6: Environmental stock profile under the Baseline (BAU) (Half life 42 years)	32
Figure 7: Environmental stock profile under the Baseline (BAU) and Restriction scenarios (half life 42 years)	40
Figure 8: Environmental stock profile under the Baseline (BAU) and Restriction scenarios (no degradation)	41
Figure 9: PFHxS, its salts and PFHxS-related substances main uses and applications	54
Figure 10: Concentrations of PFHxS and PFOS in human plasma, serum and milk.....	114
Figure 11: Temporal trends of PFHxS serum concentrations in occupational workers from 2008 to 2012.	116

List of abbreviations

ADME	absorption, distribution, metabolism, and excretion
AFFF	aqueous film-forming foams
BAF	Bioaccumulation factor
BAU	Business as Usual
BCF	Bioconcentration factor
BMF	Biomagnification factor
CAS No.	Chemical Abstracts Service number (substance identifier)
CLP	Classification, labelling and packaging
C&L Inventory	Classification and Labelling Inventory
CMR	Carcinogenic, mutagenic and toxic for reproduction
DOC	Dissolved organic carbon
DWR	Durable water repellent (textiles)
ECHA	The European Chemicals Agency
EC No.	European Community number (Substance identifier)
F3	fluorine-free foams
IUPAC	International Union of Pure and Applied Chemistry
K _d	Adsorption-desorption distribution coefficient
LOD	Limit of detection
log K _{AW}	base-10 logarithm of air-water partition coefficient
log K _{OA}	base-10 logarithm of octanol-air partition coefficient
log K _{OC}	base-10 logarithm of octanol-carbon partition coefficient
log K _{OW}	base-10 logarithm of octanol-water partition coefficient
MCI	First order Molecular Connectivity Index
MSC	The Member State Committee
PBT	Persistent Bioaccumulative and Toxic Substances
PFAA	Perfluoroalkyl acids
PFBS	Perfluorobutane sulfonic acid
PFAS	Per- and polyfluoroalkyl substances
PFCA	Perfluoroalkyl carboxylic acids
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonic acid
PFSA	Perfluoroalkyl sulfonic acids
PFHxA	Perfluorohexanoic acid
PFHxS	Perfluorohexane sulfonic acid
PHxSF	Perfluorohexane sulfonyl fluoride
POP	Persistent organic pollutant
POPRC	The Persistent Organic Pollutants POPs Review Committee
POSF	Perfluorooctane sulfonyl fluoride
PFNA	Perfluorononanoic acid
(Q)SAR	(Quantitative) Structure-Activity Relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical Substances (EU)
SEA	Socio-Economic Analysis
SVHC	Substances of Very High Concern
STP	Sewage Treatment Plant
TPA	Tonnes per annum
US EPA	US Environmental Protection Agency
vPvB	Very persistent, very bioaccumulative
WWTP	Waste water treatment plant

Summary

PFHxS pose a global threat. It takes nature many generations to reduce a certain amount of PFHxS by half. The human body needs more than seven years to eliminate only half of the amount of the PFHxS that it has taken up. PFHxS is found in human blood and in environmental samples from all around the world. A restriction on a Union-wide basis on PFHxS, its salts and related substances will reduce the release of these substances into the environment and prevent any future manufacturing, placing on the market and use. This EU-wide measure may be a first step for global action.

Based on the analysis of the effectiveness, practicability and monitorability of the Risk Management Options, the following restriction is proposed:

Table 1 Text of proposed restriction on PFHxS, its salts and PFHxS-related substances

<p>XX. Perfluorohexane sulfonic acid (PFHxS) (linear or branched), its salts and related substances¹:</p> <ul style="list-style-type: none"> a. Perfluorohexane sulfonic acids with the formula C₆F₁₃SO₃H, their salts and any combinations thereof; b. Any substance having a perfluoroalkyl group C₆F₁₃- directly attached to a sulfur atom. 	<ol style="list-style-type: none"> 1. Shall not be manufactured or placed on the market as substances on their own from <i>[date - 18 months after the entry into force of this Regulation]</i> 2. Shall not from <i>[date - 18 months after the entry into force of this Regulation]</i> be used in the production of or placed on the market in: <ul style="list-style-type: none"> (a) another substance, as a constituent, (b) a mixture, (c) an article or any parts thereof, in a concentration equal to or above 25 ppb for the sum of PFHxS and its salts or 1 000 ppb for the sum of PFHxS related substances. 3. The restriction in point 2 (c) on the placing on the market shall not apply to articles first placed on the market before <i>[date - 18 months after the entry into force of this Regulation]</i>. 4. Point 2 shall not apply to <ul style="list-style-type: none"> (a) substances or mixtures containing PFHxS as an impurity in PFOS² in applications of PFOS which are derogated from the prohibitions in Annex I Part A of Regulation (EU) No 2019/1021; (b) concentrated fire-fighting foam mixtures that were placed on the market before <i>[date - 18 months after the entry into force of this Regulation]</i> and are
--	--

¹ PFHxS related substances are substances that, based upon their structural formulae, are considered to have the potential to degrade or be transformed to perfluorohexane sulfonic acid (linear or branched). See section 2.2 of the report for more details.

² Perfluorooctane sulfonic acid and its derivatives (PFOS) C₈F₁₇SO₂X (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

	to be used, or are used in the production of other fire-fighting foam mixtures.
--	---

Explanatory notes

Column 1

Paragraph 1 – included substances

Both linear and branched substances containing the C₆F₁₃S element are included in the scope.

Polyfluorinated substances containing partially fluorinated structural elements (e.g. C₆HF₁₂S) are not included within the scope of the restriction because they will not form PFHxS in degradation.

Paragraph 1(a)

Any combination of linear and/or branched perfluorohexanesulfonic acids and/or their salts are covered by the proposed entry.

Example of a salt:

EC 269-511-6 CAS 68259-08-5	ammonium perfluorohexane-1-sulphonate; 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, ammonium salt (1:1)	PFHxS NH ₄ -salt
--------------------------------	---	---------------------------------

Paragraph 1(b)

These are the related substances which can degrade or be transformed to the perfluorohexane sulfonic acid (branched or linear). A definition of 'related substances' is provided as a footnote using wording based upon the definition in entry 68 to Annex XVII.

Examples of 1(b) substances include:

EC 217-581-3 CAS 1893-52-3	2-[ethyl[(tridecafluorohexyl)sulphonyl]amino]ethyl acrylate; 2-Propenoic acid, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulphonyl]amino]ethyl ester	
-------------------------------	--	--

Column 2

The revised entry follows the format of existing Annex XVII entries. [Paragraph 1](#)

"Placing on the market" includes also import, see REACH article 3 no. 12.

Paragraph 2(a)

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

The term "constituent" includes any constituent contributing to the composition of a substance, including therefore also impurities and additives. Any of these constituents can be either unintended or intended. See ECHA guidance for the identification and naming of substances under REACH and CLP:

https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d.

Paragraph 4(a)

The manufacture, placing on the market and use of PFOS and PFOS-related substances is prohibited by Regulation (EU) No 2019/1021. For the purposes of this proposal to restrict PFHxS, its salts and PFHxS-related substances, any specific exemptions for PFOS in Annex I Part A from the general prohibition of Regulation (EU) No 2019/1021 will apply. According to recent reporting from the European Commission to the POPs secretariat (UNEP, 2019a), the countries of the European Union do not use substances or mixtures containing PFOS in photo resist and anti-reflective coatings for semi-conductors, as etching agent for compound semi-conductors and ceramic filters, in photo-imaging or in aviation hydraulic fluids. However, the Commission reports that there is a continuous need within the EU for PFOS as mist suppressants for hard metal plating in closed-loop systems.

Paragraph 4(b)

The dilution of concentrated fire-fighting foam mixtures by an end-user is defined as formulation of a mixture in REACH. This particular use is exempted from the restriction in point 4 (b).

Summary of the justifications

This proposal aims at restricting perfluorohexane sulfonic acid (PFHxS) (linear or branched), its salts and PFHxS-related substances. PFHxS is a perfluoroalkane sulfonic acid (PFSA) with six perfluorinated carbons. PFHxS and its salts are included in the REACH Candidate list because of their very persistent and very bioaccumulating (vPvB) properties. In this document, 'PFHxS' is usually referred to while the conclusions are valid for PFHxS salts as well. Furthermore, PFHxS is the final degradation product to which the PFHxS salts and the PFHxS related compounds may degrade into.

The Persistent Organic Pollutants Review Committee (POPRC) decided at their meeting in September 2018 that PFHxS is likely to lead to significant adverse human health and/or environmental effects, such that global action is necessary (UNEP/POPS/POPRC.14/6, 2018). Furthermore, the committee decided to prepare a risk management evaluation that includes an analysis of possible control measures for PFHxS. The present proposal is coordinated with activities on PFHxS under the Stockholm Convention. An EU restriction will be an important step to reduce the risks from PFHxS, its salts and PFHxS-related substances within the EU internal market. It will also assist the global regulation in the POPs Convention by analysing the impact in the EU of an equivalent global regulation. At their meeting in October 2019, the POPRC recommended to the Conference of the Parties to the Stockholm Convention to consider listing perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds in Annex A to the Convention without specific exemptions (UNEP, 2019c).

The restriction is necessary to avoid the possibility that PFHxS, its salts and PFHxS-related substances are used as substitutes when the PFOA restriction becomes binding in 2020 and to reduce the environmental emissions of the substances present in imported articles and mixtures intentionally treated or manufactured with PFHxS, its salts and PFHxS-related substances.

PBT/vPvB properties

The ECHA Member States Committee (MSC) identified PFHxS and its salts as SVHCs in accordance with Article 57 (e) of Regulation (EC) 1907/2006 (REACH) due to their vPvB properties on 15 June 2017 (ECHA, 2017a).

Perfluorinated substances are among the most stable organic compounds known. No abiotic or biotic degradation of PFHxS is expected under relevant environmental conditions. Furthermore, the elimination half-lives observed for PFHxS in pigs, monkeys and humans, are among the longest (human blood of ca 7-8 years) reported for any perfluorinated substance (ECHA, 2017a).

According to REACH Annex I para 6.5, the risk to the environment cannot be adequately controlled for PBT/vPvB substances. No safe concentration, thus no threshold (PNEC), can be determined for PBT/vPvB substances (RAC/SEAC, 2015b). Due to these properties, PFHxS and its salts cause severe and irreversible adverse effects on the environment and on human health if their releases are not minimised.

PFHxS related substances can degrade to persistent PFHxS in the environment. If transformation/degradation products with PBT/vPvB properties are formed, the substances

themselves must be regarded as PBT/vPvB substances (ECHA, 2017c). Therefore, the hazard profile of PFHxS apply to these substances as well.

There are no harmonised classifications of PFHxS, its salts or PFHxS related substances. However, industry has submitted self-classifications on some of these substances.

Environmental distribution

PFHxS is expected to be more abundant in the water phase than PFOS. Conventional wastewater treatment plants and drinking water purification methods are not able to sufficiently remove PFHxS from contaminated water. Monitoring data show that PFHxS will leach from contaminated sites, such as airports and training areas for firefighters and can be a long-term source of contamination to underlying groundwater and drinking water.

Long-range transport potential and findings in remote areas

PFHxS, its salts and PFHxS-related substances are man-made substances that do not occur naturally. It is therefore of particular concern that PFHxS has been detected in remote areas, including, for example, in polar bears in the Arctic. This demonstrates that long-range transport of PFHxS and/or PFHxS-related substances occurs.

Environmental exposure

PFHxS is found everywhere in the environment – including, as mentioned above, in remote areas and in endangered species such as polar bears. The occurrence in the environment is a result of anthropogenic manufacture, use and disposal of substances, mixtures and articles containing PFHxS and related substances. Monitoring results from Europe and the rest of the world report elevated PFHxS levels in urban areas and near point sources. PFHxS is not removed from polluted water via wastewater treatment plants. Considering that PFHxS is expected to have an environmental half-life of much more than 42 years, at least 98% of emissions in one year persists into the next. This also implies that, PFHxS and PFHxS-related substances have the potential, over time, to be widespread in various environmental media and that the levels will build up over time. There is growing evidence that this is already happening.

Human exposure

Human exposure to PFHxS is complex and from multiple sources. Human exposure pathways for PFHxS includes indoor dust, diet, drinking water and indoor/outdoor air. PFHxS, along with PFOS and PFOA, is the most frequently detected PFAS in blood-based samples from the general population worldwide and is present in umbilical cord blood and breast milk. PFHxS is also found in all studied human organs and tissues. This is described in more detail in Annex B.9.4. Human exposure and Appendix 2.

Justification that action is required on a Union-wide basis

There is evidence that PFHxS, its salts and related substances has been (and is being) used as a substitute for PFOS and PFOA in a number of applications globally, including applications where the current use of PFHxS appears minimal today. This applies in particular to textiles and semiconductors, see Annex D for details. Regulatory action to reduce exposure to PFOA and PFOS may therefore result in increased use of PFHxS or PFHxS-related substances if no regulatory measures are taken.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

PFHxS, its salts and PFHxS-related substances enter the EU market via imported articles and are distributed to all parts of the EU environment via air and water transport. National regulatory action will therefore not adequately manage the risks of PFHxS and PFHxS-related substances. Risk management measures need to be taken on a Union-wide basis as a first step towards a global regulation of PFHxS.

An alternative to the restriction would be to list the substances in Annex XIV to REACH. However, since there are no registrations of PFHxS, its salts or PFHxS-related substances, the effects of such a measure would be marginal. Instead a REACH restriction is proposed that will regulate imported articles containing PFHxS, its salts and PFHxS-related substances.

Effectiveness

No current intentional uses of PFHxS, its salts or related substances within the EU were reported during the stakeholder consultation or call for evidence.

Historical (pre-2000) use of PFHxS included apparel and leather (20%), carpets (60%), fabric and upholstery (15%), coatings (0.4%) and fire-fighting foams (5%), see Annex A.2.1 for details. One stakeholder informed that old fire-fighting foams could contain PFHxS. Furthermore, PFHxS could be a contaminant in PFOS used for hard metal plating, see Annex A.2.2 for details. Any risk reducing measures on PFOS for hard metal plating will also reduce risks from PFHxS. However, the fact that there is no REACH registration, but some self-classifications of PFHxS, its salts and related substances indicate that the volumes are low, see Annex A.2 for details.

The use of old fire-fighting foams containing PFHxS (used for the testing of foam systems and/or equipment and for training exercises by industry) and the presence of PFHxS in old fire-fighting foam concentrates may result in emissions in the EEA of between 39 and 245 grams of PFHxS per year, see chapter 1.1.5.5 and Annex A.2.9.2. for details. The current total annual emission of PFHxS within the EEA is estimated to be between 0.22 and 0.44 tonnes, see Annex D for details. Hence the emissions from testing and training exercises using old fire-fighting foams is very small proportion compared to the total annual emissions. Regulating the testing and training of old fire-fighting foams containing PFHxS would therefore not affect the total yearly emissions of PFHxS within the EEA to a great extent. However, the current proposal implies that the manufacture or placing on the market of new fire-fighting foams containing PFHxS is restricted.

It is believed that PFHxS, its salts and related substances now enter the EU mainly via imported articles. As reported in Annex A, more recently there has been a shift away from the use of PFHxS and PFHxS-related substances as a waterproofing and protective agent in imported articles such as outdoor clothing. The same data, however, suggest significant use outside the EEA of PFOA across several article types for which PFHxS is known to have been used in the past. Thus, it is possible that, once the regulations on PFOA come into effect, a switch to alternatives such as PFHxS, its salts or related substances might increase the level of import of PFHxS via articles produced outside of the EEA in the future. The restriction would ensure that the emissions of PFHxS via imported textiles does not increase as a result of the changes brought about by the restriction on PFOA.

The use of PFHxS and PFHxS-related substances in textiles by producers in the EU was not confirmed during stakeholder consultation, with three associations indicating that these

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

substances are not used by their members. Import data also suggest no or negligible import of PFHxS in textiles at present. Fluorine-free alternatives are already used by parts of the industry both outside and within the EU. This could potentially change once the regulations on PFOA apply because PFHxS is a possible substitute for PFOA, see Annex A.2.8 for details. However, we consider it unlikely that producers, which have already changed to fluorine free alternatives, will go back to using fluorine-based alternatives such as PFHxS, when the ban on PFOA applies. As a result of this, the costs for industry that have already substituted to fluorine-free alternatives, and the effect on the prices of products produced by these producers, are expected to be negligible. This implies that costs to consumers arising from the restriction for these producers can be expected to be negligible.

This leaves the producers that use PFOA today. If PFHxS is not restricted some of these producers could choose to switch to PFHxS as a possible alternative when PFOA is restricted (Ma , et al., 2018) . It is difficult to assess the possible strategy of producers when they have to phase out PFOA. How likely is it that these producers will change to PFHxS if it is not restricted, given that they are likely to be aware that PFHxS might also be restricted at some point? On this basis, we expect that it is unlikely that a large part of the producers using PFOA today will change to PFHxS. In Annex D it is estimated that, if not restricted, imports of PFHxS in textiles would double to approximately 130 kg once the controls on PFOA comes into effect. The costs to producers and importers of articles if they are not allowed to substitute PFOA with PFHxS are expected to be small. This implies that the costs to consumers will also be small.

To give an indication of possible substitution costs of moving to fluorine-free DWR (durable water repellent), an example of the costs related to moving from a C6 chemistry based DWR to fluorine-free DWR is provided in chapter E.2.3.3.4.

According to REACH Annex I para 6.5, the risk to the environment cannot be adequately controlled for PBT/vPvB substances. There is no safe concentration for these substances, thus a threshold (PNEC) cannot be determined for PBT/vPvB substances (RAC/SEAC, 2015b). For such substances a REACH restriction would be based upon minimising the emissions of the substances to humans and the environment.

Practicality

The requirements of this restriction proposal are similar to those proposed for C9-C14 PFCAs. The EU regulatory approach put in place with respect to the PFCAs, PFOA and PFOS will also be relevant to the implementation of this restriction.

There are several analytical methods that can be used to measure PFHxS and PFAS in almost any media. Although no standardised analytical methods exist today, it should be possible to use the existing CEN-standard for the detection of PFOS to determine the levels of ionic forms of PFHxS, its salts and PFHxS related substances. For volatile neutral PFHxS-related chemicals, detection of PFHxS and PFHxS-related compounds using GC/PCI-MS is possible. The level of quantification in both methods is 0.06 ppb, which is far below the proposed limit values. See Annex E.4.4.3.2 for more details on this.

Implementability

No intentional use, manufacture or placing on the market of PFHxS or PFHxS-related substances has been identified in the EU except for old fire-fighting foams, textile articles

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

and mist suppressants for hard chromium plating containing PFHxS as an unintentional impurity in PFOS, see Annex A for details. The unintentional uses of PFHxS, its salts and related substances in old fire-fighting foams or concentrates and in mist suppressants for hard chromium plating containing PFHxS as an unintentional impurity in PFOS are not within the scope of the proposal. Therefore, the proposed transition time of 18 months should be feasible for all actors. In addition, the stakeholder consultation indicates that relevant EU actors have already foreseen the need to move away from PFASs more generally and are therefore already using fluorine-free alternatives or alternative technologies.

Manageability

Enforcement activities involving inspections and testing can be arranged so as to target the occurrence of PFOS, PFOA, C9-C14 PFCA and PFHxS (its salts and related substances) at the same time in articles. This would improve the cost effectiveness of such activities (as for any environmental monitoring). Hence, the enforcement costs specific to PFHxS should be moderate in magnitude.

Monitorability

For imported articles, compliance control can be accomplished by border authorities and notifications of any violation of the restriction can be reported in the RAPEX system (Rapid Exchange of Information System). Time trend monitoring can be performed with samples from the environment, biota or from humans. Methods and instruments available in (environmental) specimen banks could be used for such monitoring.

Report

1. The problem identified

1.1. Hazard, exposure/emissions and risk

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

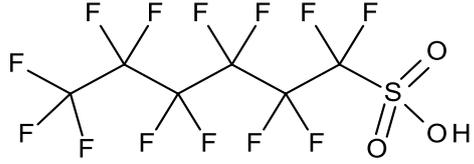
The main substance in the present restriction dossier is perfluorohexanesulfonic acid (PFHxS), including both linear and branched isomers. Chemical analysis of substances, articles or mixtures reports the amount of PFHxS that is present. This restriction proposal follows the 'arrow head' approach where the arrow head represents a final degradation product (i.e. PFHxS), which a group of PFHxS-related substances may degrade into. The rationale behind the arrow head approach is that if the arrow head substance has properties of concern, measures should address the arrow head substance itself, as well as the related substances, as they all contribute to the total amount of the arrow head substance in the environment. Hence, our proposal is to restrict linear or branched PFHxS, their salts and related substances as a risk management instrument addressing the concerns associated with PFHxS. A similar approach is used in the restriction of PFOA and related substances (see [Commission Regulation \(EU\) 2017/1000](#)).

The linear and branched isomers of PFHxS will have the same molecular formulas and identical molecular weights. They will differ only in the branching of the perfluorohexyl chain. Although they are in principle different, individual substances, with e.g. different melting points, their technical function will often be similar. In many cases, PFHxS will consist of the linear and branched isomers. The concerns for human health and the environment will be the same. Therefore, it is not necessary to distinguish between them when considering their impact. Identifiers for linear PFHxS are listed in [Table 2](#).

PFHxS-related substances are any substances containing, as a structural element, a linear or branched perfluorohexyl group directly attached to sulfur atom: C₆F₁₃S.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 2 Linear perfluorohexanesulfonic acid, substance identity

EC number:	206-587-1
EC name:	Perfluorohexane-1-sulfonic acid
CAS number (in the EC inventory):	355-46-4
CAS name:	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-
IUPAC name:	1,1,2,2,3,3,4,4,5,5,6,6,6- tridecafluorohexane-1-sulfonic acid
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	C ₆ F ₁₃ SO ₃ H
Molecular weight:	400.11 g/mol
Synonyms:	PFHxS;
Chemical structure:	

Physical and chemical properties

PFHxS belongs to the group of per- and polyfluoroalkyl substances (PFAS). It consists of a C₆ perfluoroalkyl chain attached to a sulfonic acid group. PFHxS is the shortest of the long-chain perfluoroalkyl sulfonic acids. It is similar to the more familiar perfluorooctane sulfonic acid (PFOS), but PFOS has a C₈ perfluoroalkyl chain.

As a sulfonic acid, PFHxS is a strong acid (pK_a = -5.8) that readily forms sulfonate salts with bases, e.g. sodium, potassium and ammonium salts. In aqueous solution the salt forms will exist in equilibrium with PFHxS itself. It is usually not differentiated between PFHxS and its salt forms in analyses and quantifications of PFHxS. In the literature, the concentrations reported in environmental and human monitoring studies will always include both the acid PFHxS and its conjugate base.

For simplicity, in the discussions and conclusions in this document, PFHxS is usually referred to. Based on the reasoning above, the conclusions are, however, considered valid for PFHxS salts as well.

As a member of the PFAS family of substances, PFHxS is very resistant to chemical, thermal and biological degradation. The resistance is explained by the strong carbon-fluorine bonds. These properties also make PFHxS persistent in the environment (see Annex B.4.1. Degradation for more details).

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

PFHxS has been reported to be a liquid with density 1.84 g/mL (ChemIndex, 2018), while a melting point of 41.3 °C has been calculated (Danish_(Q)SAR_Database, 2018). The salt forms of PFHxS are usually solid materials. For example, the PFHxS potassium salt is a pale brown, crystalline solid with melting point 272-274 °C (Synquest_Laboratories, 2018).

Not much physicochemical data has been published for PFHxS. The data included in this report has to a large extent been collected from the Danish (Q)SAR Database. Many of the values have been calculated from models. The (Q)SAR Database includes estimates from more than 200 (Q)SARs from free and commercial platforms and related to physicochemical properties, ecotoxicity, environmental fate, ADME and toxicity. (Q)SAR predictions for more than 600,000 chemical substances can be searched in the database (Danish_(Q)SAR_Database, 2018).

PFHxS is a strong acid, and in the environment PFHxS will be predominantly in its anionic form. However, model calculations are usually performed on the neutral acid compound. This may be a source of uncertainties in the calculations.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 3 Physicochemical data for PFHxS, collected from the Danish (Q)SAR Database³, unless otherwise noted

Property	Value
Appearance	Liquid*
Density	1.84 g/mL*
Boiling point, Bp	238.5 °C (exp) 221.9 °C (calc)
Acid dissociation constant, pKa	-5.8
Solubility in water	6.17 mg/L (calc from K _{ow}) 21.7 mg/L (calc from Fragments)
Vapour pressure	0.00458 mmHg (exp) = 0.61 Pa
Octanol-water partition coefficient, log K _{ow}	3.16
Air-water partition coefficient, log K _{aw}	-1.79
Octanol-air partition coefficient, log K _{oa}	4.95
Soil adsorption coefficient of organic compounds, log K _{oc}	3.55 (calc from MCI) 2.67 (calc from K _{ow})

*) Information collected from ChemIndex (ChemIndex, 2018).

³ Danish (Q)SAR Database, Division of Diet, Disease Prevention and Toxicology, National Food Institute, Technical University of Denmark, <http://qsar.food.dtu.dk>.

1.1.2. Justification for grouping

PFHxS-related substances can degrade to PFHxS under environmental conditions. According to ECHA guidance R.11 (ECHA, 2017c), if transformation/degradation products with PBT/vPvB properties are generated, the substances themselves must be regarded as PBT/vPvB substances and should be treated like PBT/vPvB substances with regard to emission estimation and exposure control. Hence, PFHxS-related substances also need to be covered by risk management measures in order to effectively limit environmental concentrations of PFHxS, see REACH Annex I no. 04 and ECHA (2017c). Therefore, in this restriction dossier, substances that may be converted to the arrow head substance PFHxS and contribute to its concentrations in the environment are grouped and covered by the scope of the restriction. This includes PFHxS salts and PFHxS related substances.

In a literature study carried out by the University of Oslo (Nielsen, 2017), the formation of PFHxS through abiotic degradation of precursors was investigated. PFHxS-related substances were found to include PFHxS sulfonic acid halides, sulfonic esters (alkyl, olefinic and aryl) and sulfonamides, side-chain fluorinated polymers containing the PFHxS moiety, as well as subclasses of PFHxS-related substances like sulfones and sulfinic acid. Biotic degradation of PFHxS-related substances is expected to form PFHxS via the same degradation pathways as has been demonstrated for PFOS-related substances (Tomy, et al., 2004; Zhao, et al., 2018; Letcher, et al., 2014; Eriksson, et al., 2017; Rhoads, et al., 2008). Information on this is presented in Annex B.4.1 of this proposal. Furthermore, the observed net increase of PFHxS in waste water treatment plants is linked to degradation of precursor compounds that are not yet analysed for (Eriksson, et al., 2017). Further information on this is presented in Annex B.4.3.3 of this proposal.

Abiotic degradation of the identified PFHxS-related substances to PFHxS may proceed either via reaction with water or via oxidative radical processes in the atmosphere. However, in the radical processes the sulfonyl group may also be cleaved off in a different degradation pathway with formation of perfluoroalkyl radicals that may suffer sequential CF₂-loss and formation of shorter chain-length PFCAs (Martin, et al., 2006; D'Eon, et al., 2006), see Figure 1. To what extent the PFHxS-related substances will end up as PFHxS or PFCAs may vary with the environmental conditions and is difficult to predict. Nevertheless, on the basis of the hydrolysis approach, PFHxS will be formed, and grouping as PFHxS-related substances is warranted.

The rate of degradation of PFHxS-related substances will vary from subclass to subclass and is further dependent upon the exact environmental conditions where they are present. Factors like pH, temperature, presence of water, oxygen, bacteria etc. will all influence the degradation rate. The full process may take years, decades or longer, while transformation of less stable precursor groups may be much faster. Little information about the rate of degradation of PFHxS-related substances has been published.

A study by Rhoads et al. (2008) shows that N-ethyl perfluorooctane sulfonamidoethanol (N-EtFOSE) aerobic biotransformation forms N-ethyl perfluorooctane sulfonamido acetic acid (NEtFOSAA) with an observed first-order rate of 0.99 ± 0.08 day⁻¹. The degradation product, N-EtFOSAA underwent further transformation to N-ethylperfluorooctane sulfonamide (N-EtFOSA) at a slower rate (0.093 ± 0.012 day⁻¹). N-EtFOSA then transformed via perfluorooctane sulfonamide (FOSA) and perfluorooctane sulfinic acid (PFOSI), to perfluorooctane sulfonate (PFOS) (Rhoads, et al., 2008).

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND
PFHxS-RELATED SUBSTANCES

A scheme showing the degradation of some relevant subclasses of PFHxS-related substances is presented in Figure 1.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

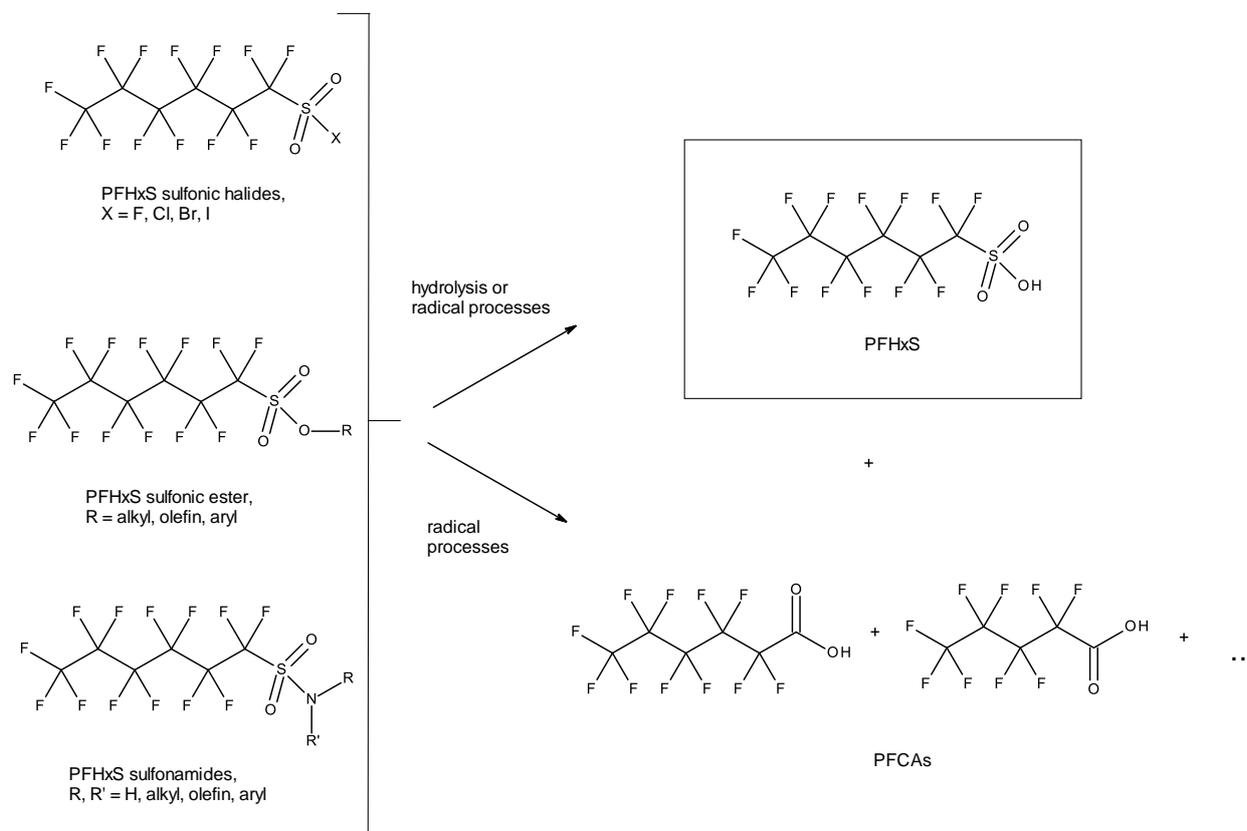


Figure 1 Degradation of selected PFHxS-related substances

Importantly, side-chain fluorinated polymers in many cases contain the same chemical groups and may degrade in the same way as the corresponding small-molecule precursors. This is important as the side-chain fluorinated polymers represent a large fraction of the volume of PFHxS-related substances that are manufactured and used. Specifically, many side-chain fluorinated polymers contain perfluoroalkane sulfonamide-based side-chains.

Almost 150 substances that belong to the different subclasses of PFHxS-related substances have been identified in the present work. The identified PFHxS-related substances are listed in Appendix 1. The list includes salt forms of PFHxS, and sulfonyl halides that may degrade to PFHxS in reaction with water in the environment, as well as sulfonyl esters and PFHxS-related sulfones. A major subgroup of PFHxS-related substances is the PFHxS sulfonamides. This subclass contains substances that are well known to be in used in various applications. Six polymers, all being PFHxS sulfonamides, have been identified. These are expected to represent a considerable part of the volume of PFHxS-related substances that may degrade to PFHxS in the environment.

A review article on the atmospheric oxidation of organic sulfur-containing substances shows that dimethyl sulphide is oxidized in radical initiated oxidation processes in the atmosphere via dimethylsulfoxide and methane sulfinic acid to methane sulfonic acid as the end product (Barnes, et al., 2006). Oxidation of the relevant sulfinic acid to PFHxS is also described in a study of potential precursors to PFBS and PFHxS (Nielsen, 2017). The findings suggest sulphides, thiols and intermediate oxidation products as PFHxS-related substances, as shown in Figure 2.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

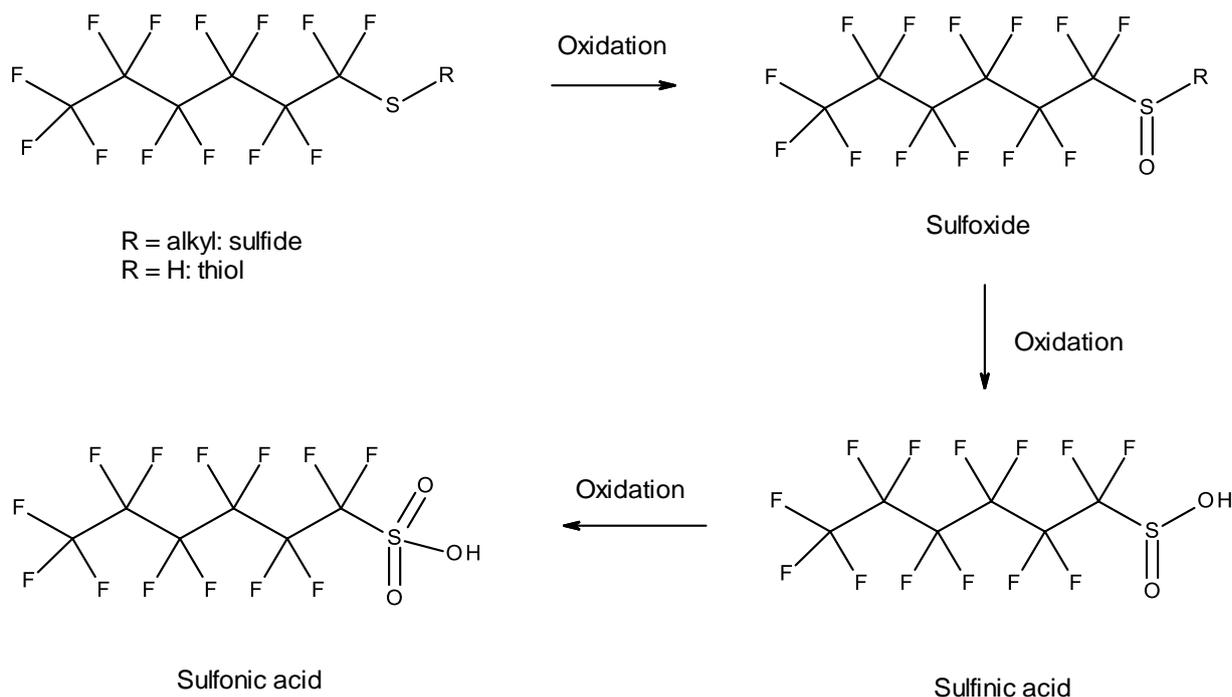


Figure 2 Oxidation processes from sulphides to PFHxS.

Nielsen concludes in his study of potential PFBS and PFHxS related substances that PFHxS-type sulfones may undergo photo-oxidation resulting in the release of PFHxS (Nielsen, 2017), see Figure 3.

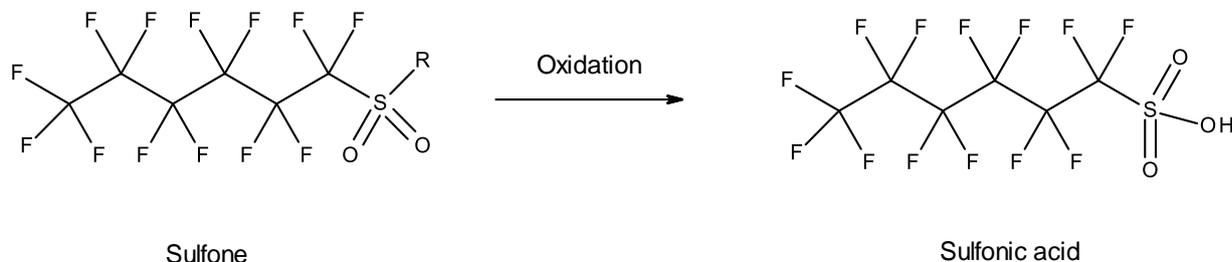


Figure 3 Oxidation of sulfones to PFHxS.

Out of the total almost 150 identified PFHxS-related substances, none have been registered under REACH (checked 6-8 April 2019). There are CLP notifications for eight of the substances. See Table 7 for details.

Perfluorohexane sulfonyl fluoride (PHxSF) is considered a key intermediate as most or all of the PFHxS-related substances may be prepared from PHxSF. PHxSF is a reactive substance used in manufacture. Since there are no registrations of PHxSF in REACH, any manufacture or placing on the market of this substance should be less than one tonne per year per producer or importer. When PHxSF is treated with alcohols or amines in a production process, sulfonic esters and sulfonamides are formed, respectively. PHxSF reacts with water in a hydrolytic process with the formation of PFHxS, see Figure 4.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

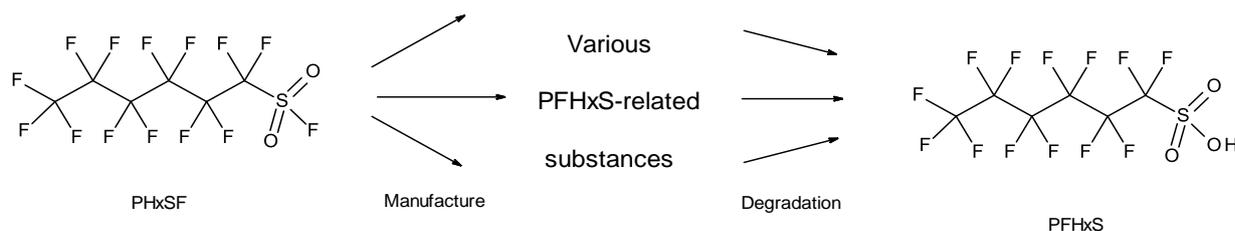


Figure 4 Illustration of the relationship between PHxSF and PFHxS

The amount of PFHxS that may be formed from PFHxS-related substances in the environment may be difficult to estimate, partly because PFHxS is an arrow head substance with a limited manufacture and use in itself. The volumes manufactured and used of PHxSF could be an indicator on how much PFHxS that may be formed from degradation of PFHxS-related substances in the environment. However, scarce information on the use and production of PHxSF was obtained during the preparation of this proposal. PHxSF is listed in the C&L inventory, indicating that use less than one tonne per year takes place within the EU.

Summary: There are several substances that may degrade to PFHxS in the environment. The rate of degradation of PFHxS precursors to PFHxS varies for the different subclasses of related substances and is dependent upon the environmental conditions where the substances are present. Almost 150 such related substances have been identified in the present work. When degrading, these substances will contribute to the environmental concentrations of PFHxS. It is considered that the restriction proposal should cover PFHxS-related substances, as well as the parent compound PFHxS, together with their salt forms. Among the PFHxS-related substances we find e.g. various PFHxS sulfonylamides, including side-chain fluorinated polymers, which are particularly relevant as they are frequently used. The stakeholder consultation did not confirm that intentional manufacture, placing on the market or use of these substances is still ongoing within the EU. However, one stakeholder informed that fire-fighting foams could contain PFHxS. Furthermore, these substances may enter the EU in imported articles.

1.1.3. Classification and labelling

PFHxS does not have a harmonised classification (Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)). Furthermore, to our knowledge, no PFHxS related substances have harmonised classifications. PFHxS itself, the potassium and ammonium salts of PFHxS, the sulfonyl fluoride (PHxSF), three sulfonylamide substances and the zinc salt of perfluorohexane *sulfinic* acid have notifications of self-classifications in the C&L-inventory. There are 23 and 17 CLP notifications respectively for the PFHxS potassium and ammonium salts, 23 notifications for the sulfinic acid zinc salt, while for the remaining substances there are one notification for each substance. Eight PFHxS-related substances are self-classified by industry as, among others, eye, respiratory and skin irritating. Five of these self-classifications were notified to ECHA within the last four years. See Table 7 for details.

1.1.4. Hazard assessment

PFHxS and its salts were added to the REACH Candidate List as Substances of Very High Concern (SVHC) due to their intrinsic properties as very persistent and very bioaccumulative (vPvB) according to article 57 e of REACH (ECHA, 2017a).

Detailed information on the vPvB assessment is presented in Annex B.8. Although human health effects are not the main argument for this restriction proposal, available scientific literature suggests that there is a risk for adverse effects, see Annex B.5 for more information. Furthermore, since these substances persist and accumulate in humans and wildlife, they may be impossible to remove if serious concerns should be documented in the future.

As described above, PFHxS-related substances can degrade to PFHxS under environmental conditions. If transformation/degradation products with PBT/vPvB properties are formed, the substances themselves must be regarded as PBT substances (ECHA, 2012). Therefore, the hazard profiles of PFHxS apply to these substances as well.

1.1.5. Emissions

1.1.5.1. Emissions of PFHxS from manufacturing and use

According to (Boucher, et al., 2019), the majority of the emissions of PFHxS and PFHxS-related substances are expected to come from historic production in United States, Western Europe, and Japan that occurred in the period before the phase-out of POSF-based products. However, the lack of quantitative data makes these assumptions uncertain. It is therefore still unclear to what extent current manufacturing and use of PFHxS, its salts and PFHxS-related substances will contribute to current and future releases of PFHxS to the environment. Furthermore, the modelling results by Boucher et al (2019) suggest that elevated environmental concentrations of, amongst others, PFHxS, its salts and PFHxS-related substances may continue for decades and may reach remote areas to a greater extent than what is observed today. The highest estimated current and future emission sources of PFHxS is predicted to come from product use and disposal (Boucher, et al., 2019).

A study by BIPRO (2018) , shows that the worldwide production of PFHxS in 2012 was about 700-750 kg and decreased to less than 700 kg in 2016. A further slight decrease in production of PFHxS is expected (BiPRO, 2018).

The draft POPs risk profile for PFHxS has this description of the releases of PFHxS, its salts and PFHxS-related substances from manufacturing and use (UNEP/POPS/POPRC.14/2, 2018):

"41. (...) The occurrence of PFHxS and its related compounds in the environment is a result of anthropogenic production, use and disposal, since they are not naturally occurring substances. (...)

44. The contributions of individual stages to overall releases throughout the life cycle, and receiving environmental media, may vary across compounds and applications. In general, manufacturing processes constitute a major source of PFHxS, its salts and PFHxS-related

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

compounds to the local environment, e.g., in elevated levels of PFHxS in water and the population close to a production plant in Minnesota, the United States. In addition, some uses of PFHxS, its salts and PFHxS-related compounds may result in direct environmental releases. For example, the use of relevant AFFFs in fire-fighting training and real incidences, as well as accidental releases, contribute a substantial amount of PFHxS, its salts and PFHxS-related compounds in the environment (e.g., Backe et al., 2013; Houtz et al., 2013; Ahrens et al., 2015; Baduel et al., 2017; Barzen-Hanson et al., 2017; Bräunig et al., 2017; Lanza et al., 2017) (UNEP/POPS/POPRC.14/2, 2018)."

As described in Annex A, PFHxS including its salts and PFHxS-related substances are not registered under REACH meaning they should not be manufactured or placed on the market in quantities above one tonne per year in the EU. This was confirmed during the stakeholder consultation and call for evidence, in which no one reported the intentional manufacture or placing on the market of PFHxS including its salts and PFHxS-related substances. However, one stakeholder informed that fire-fighting foams could contain PFHxS. The Italian company (Miteni, which was the major manufacturer of fluorinated substances in the EU including PFHxS) declared bankruptcy on 26 October 2018 and declared to suspend production activities by the end of the year. According to the company's management, the financial costs investigation of pollution of groundwater from perfluoroalkyl substances (PFAS) deriving from the investigations had an important impact on the budget and made it difficult the access to credit from local banks "worried about the company's reputation" (EMCC, 2018).

In terms of uses of PFHxS, its salts and PFHxS-related substances, as described in more detail in Annex A, in spite of repeated and exhaustive stakeholder consultation as part of this study and also the previous BiPRO (2018) study, no current uses of PFHxS (including its salts and PFHxS-related substances) have been identified in the EU other than the following:

- Fire-fighting foams: older fire-fighting foams (AFFF) containing PFAS produced using the electrochemical fluorination (ECF) manufacturing process. PFHxS is not used for the production of new AFFF in the EU. It is unlikely that AFFF containing PFHxS will be imported to the EU during the transitional period. The stakeholder consultation has confirmed that PFAS based AFFF may contain PFHxS. Annex A estimates that the current EU stockpile of foams currently maintained at refineries, tank farms, chemical works and other installations contains around 0.5-3 kg PFHxS of which an estimated 39-245 gram is consumed or replaced annually;
- Textiles, carpet, leather and upholstery: imported finished textile articles such as overcoats, capes, cloaks, anoraks, windcheaters, outdoor gear and, potentially, other articles for which PFOS was previously used as a waterproofing/stain resistant textile treatment (which might include leather and carpets) - Estimated 66 kg per annum imported on waterproof jackets from China, Vietnam and Bangladesh and an unknown quantity in other applications such as outdoor gear in 2013. More recent data on PFHxS in imported outdoor gear suggests negligible use of PFHxS today but continuing PFOA use at present. Furthermore, as described in Annex D the ban on PFOA might lead to increasing use of PFHxS, its salts and related substances in textiles

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

- Import of PFOS in continuing (exempted) uses, namely, hard chromium (VI) plating. At present there is high uncertainty regarding the quantity this represents. See Annex A.2.2 and A.2.10 for more details on this. According to a recent reporting from the European Commission to the POPs secretariat (UNEP, 2019a), the countries of the European Union do not use substances or mixtures containing PFOS in photo resist and anti-reflective coatings for semi-conductors, as etching agent for compound semi-conductors and ceramic filters, in photo-imaging or in aviation hydraulic fluids. However, the Commission reports that there is a continuous need within the EU for PFOS in hard metal plating in closed-loop systems.

Estimating the PFHxS-emissions per use area is not relevant since – in line with the information summarised above and presented in more detail in Annex A - there seems to be no current intended use in the EU and except for the fire-fighting foams no information on the content of PFHxS including its salts and PFHxS-related substances in substances, mixtures and articles in the EU. In order to still estimate the emissions of PFHxS including its salts and PFHxS-related substances emissions from wastewater treatment plants were analysed, see chapter 1.1.5.2 below.

1.1.5.2. Emissions of PFHxS from wastewater treatment plants in the EU

After the use or disposal of PFHxS-containing products, these compounds may enter WWTP via industrial and/ or urban waste release. Conventional wastewater treatment has a limited efficiency in removing PFCs such as PFHxS from aqueous waste streams (Boulanger, et al., 2005) , however PFHxS has been detected in sewage sludge all around the world in concentrations up to 200 ng/g (Arvaniti & Stasinakis, 2015). The majority of sludge in Europe is disposed to landfills followed by land spreading, also for agricultural purposes. Furthermore, the highest levels of PFHxS in urban biota from Oslo, Norway, was seen in livers from rat living in the sewage system (Konieczny, et al., 2016).

PFHxS in wastewater treatment plants has been measured and reported in several literature sources. Concentrations of PFHxS in wastewater treatment plants have been investigated to estimate emissions to the environment from new or unknown intentional uses (as such, in articles or formulations) or due to PFHxS including its salts and PFHxS-related substances being present as an impurity together with other PFASs.

PFHxS does not adsorb very well onto sludge and most of it would pass through the wastewater treatment plant unmodified. Sludge is therefore not considered a major pathway for emissions of PFHxS to the environment. Therefore, the focus has been put on the effluent of wastewater treatment plants.

Concentration of PFHxS in wastewater treatment plants have been collected from several publications (Huset, et al., 2008; Ahrens, et al., 2009b; JRC, 2012; Stasinakis et al, 2013; Filipovic & Berger, 2015; Kärrman, et al., 2019; Eriksson, et al., 2017). The average concentration of PFHxS in wastewater treatment plants is 37.1 ng/L. Applying a similar strategy as used for the C9-C14 PFCAs restriction report (ECHA, 2017), the analysis provided in Annex B.9.3 suggests that a default wastewater treatment plant with an effluent concentration of 37.1 ng/L would emit 74.2 mg PFHxS per day and all wastewater treatment plants in the EU would together emit 5.75 kg PFHxS per day or 2.1 tonnes PFHxS per year.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Further analysis of the sample data revealed that the average value of 37.1 ng/L is driven by some high values compared to the majority of the data points. Splitting the data (n=124) on effluent concentrations of PFHxS demonstrated that the 10% highest concentrations were responsible for 1.79 tonnes PFHxS per year, i.e. around 90% of the emissions. This suggests that the emissions are not as evenly distributed as might first appear and that point sources are a major contribution.

Several literature sources have estimated an emission factor for PFHxS per inhabitant (Banjac et al., 2015; Huset et al., 2008; Eriksson et al., 2017). These range from 0.53 to 15 µg/day/inhabitant. The associated emissions on EU level taking into account circa 500 million inhabitants will subsequently range from 0.1 – 2.7 tonnes PFHxS per year.

The estimated total emission of 2.1 tonnes PFHxS by using the effluent concentrations of wastewater treatment plants falls within this range which strengthens the assessment. See Annex B.9.3 for details.

1.1.5.3. Emissions of PFHxS from landfills in the EU

Several authors have reported emissions of PFHxS from landfills (Eggen et al, 2010; Fuertes et al, 2017; Hamid et al, 2018). This means that even after its service life PFHxS can still enter the environment. Concentration of PFHxS in landfill leachates in the EU range from < LOD to 8900 ng/L (Fuertes et al., 2017). Since leachate volume is highly dependent on climate (in particular, rainfall and subsequent infiltration into landfill), and may vary substantially from month to month, and from year to year (Gallen et al, 2017) it is difficult to estimate the load of PFHxS being emitted via landfill leachates in the EU.

1.1.5.4. Releases of PFHxS its salts and related substances from point sources

Several local point sources for PFHxS contamination in Europe and Asia have been identified. In Italy PFHxS contamination have been detected in ground water, surface water and some fresh water wells for human use over an area of 200 km². An average PFHxS concentration of 32.5 ng/L in drinking water was measured. As point source a chemical plant producing e.g. PFHxS related compounds, has been identified (Polsetto & Valsecchi, 2013).

Photolithographic and semiconductor factories may be important sources of emissions of PFHxS to the environment. Final waste effluent of a semiconductor production plant in Taiwan contained high concentration of PFHxS (0.13 mg/L). The amount of final waste effluents from semiconductor manufacture was estimated to a corresponding mass of PFHxS >0.68 kg/ day (Lin, et al., 2009). Levels up to 0.15 mg/L for PFHxS in river water were reported downstream a photographic film production plant in China (Cui, et al., 2018). A riverine flux of PFHxS to lake Baiyangdian of 37.35 kg/y was estimated.

In Norway monitoring data of surface water, soil and biota in the vicinity of a company formulating and testing fire-fighting foam products showed elevated PFHxS concentrations (4.3 µg/L, 580 ng/kg wwt) in water and sea snails, respectively (COWI AS, 2017).

1.1.5.5. Emissions of PFHxS from the use of fire-fighting foams (AFFF) in the EU

PFHxS from current and former use of fire-fighting foams pollutes the surroundings of fire training sites. An American study shows that the number of (military) fire training areas in a

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

water system significantly increased the levels of PFHxS in drinking water ($p = 0.045$) and that each military fire training site was associated with a 20% increase in PFHxS ($p = 0.002$) (Hu, et al., 2016).

Studies from Europe (Dauchy, et al., 2019; Li, et al., 2017; Filipovic, et al., 2014; Weiß, et al., 2012) and the rest of the world (Bräunig, et al., 2017) demonstrate that PFHxS leaks to the ground water and may pollute the drinking water. The spreading of PFHxS from fire-fighting training areas to drinking water can pose problems to human health. A recent Swedish study by (Li, et al., 2018) found that fire-fighting foam used for training at an airfield since the mid-1980s had contaminated the drinking water to such an extent that PFHxS levels up to 1700 ng/L were detected in the municipal drinking water. This drinking water had been distributed to one-third of households in Ronneby, Sweden. The human blood serum levels of PFHxS from people drinking this water were the highest ever reported in Sweden, (277 ng/mL, range 12–1790 ng/mL) (Li, et al., 2018). Similar results were seen in Cologne, Germany (Weiß, et al., 2012).

The total amount of PFHxS including its salts and PFHxS-related substances used in AFFF depends on the number and type of fires occurring, training and testing of fire-fighting systems.

The amount of stocks and their renewal are discussed in Annex A.2.9. Renewal of the stocks can happen for two reasons; either the foam has passed its expiry date, or the foam has been used (to extinguish a fire, training and/ or for testing purposes). In the first case the expired foam should be collected and treated appropriately. It is, however unclear to what extent this has happened (IPEN, 2018).

In case the foam has been used to extinguish a fire, several possibilities arise:

- Either the foam was used in an area without firewater collection (e.g. road fire, offshore locations),
- used in a domestic area where the firewater would flow into the sewer system or
- at industrial sites where containment options are potentially available.

In the first case 100% of the PFHxS including its salts and PFHxS-related substances would enter the environment. Either into the ground which would lead to leaching to groundwater or via run-off into a nearby water stream. If the foam is used at an offshore location it would directly go to the marine compartment.

In the second case the firewater would go into the sewer system and pass in a municipal wastewater treatment plant. Unfortunately, except if special measures are taken, which is often not the case, PFHxS would just go through the system and completely released with the effluent. It could even be that the PFHxS concentrations would further increase due to the degradation of PFHxS-related substances during the biological treatment.

In the third case, a fire at an industrial facility, the firewater can be contained and collected although this depends on the country and obligations for the installations. Furthermore, the firewater should not be treated in standard wastewater treatment plants as they will not remove the PFHxS and discharge it with the effluent.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Although technically speaking there might be options to contain and treat firewater contaminated with PFHxS including its salts and PFHxS-related substances it seems that economically it's often not the case and also legally not mandatory to do so. In the end the substance is most likely going to end up in the environment.

One could assume that fluorine foams should not be used anymore in the first and second case and should only be used in the third case if really necessary.

Based on all the arguments above, trying to quantitatively estimate the current and future emissions to the environment is highly uncertain as no one can predict:

- When and where a fire might occur,
- If the recommendations are put into practise and
- What type of fluorine foams is used (including or excluding PFHxS its salts and PFHxS-related substances).

As a worst-case assumption one could assume that the emissions of PFHxS are equal to the replenishment rate calculated in Annex A.2.9.2. meaning between 39 g and 245 g of PFHxS are emitted across the whole of the EU per year via the use of AFFF. Compared to the amount of PFHxS emitted via wastewater treatment plants this is almost negligible.

It is expected that emissions from AFFF are decreasing as more and more companies like the Norwegian offshore industry, Heathrow airport or states like Queensland in Australia are switching to fluorine free foams for fire-fighting. Consultation with a major F3 (fluorine-free foam) producer (see Annex G) suggests that, while the F3 market may be around 60-70% of the market in Australia owing to increasing regulation and phasing out of PFAS, it is only around 20% in New Zealand where this strong regulation is not in force. Information was requested on the EU market as part of consultation for preparation of this dossier, but this has not been forthcoming.

1.1.6. Environmental exposure and trends

PFHxS is ubiquitously present in the environment. Numerous studies have reported detection of PFHxS in compartments such as surface water, deep-sea water, drinking water, wastewater treatment plant effluent, sediment, groundwater, soil, atmosphere, dust, biota, and humans globally (UNEP/POPS/POPRC.14/2, 2018). The highest environmental levels of PFHxS measured are found in urban and/or industrial areas both in terms of biotic- and abiotic matrices. (UNEP/POPS/POPRC.14/2, 2018).

PFHxS has mainly been detected in the lower ng/L range in European surface waters and in ground water, but higher values, up to 217 ng/l, have also been recorded for surface water, which can be attributed to human activity, industrial point sources, or previous use of the area (e.g. former fire-training area). In sediments PFHxS were measured in the ng/g (dw)-range in urban and industrial areas in Europe (Munoz, et al., 2015).

Detection of PFHxS in Arctic air and snow, shows that long-range transport of PFHxS and/or PFHxS-related compounds through the atmosphere may occur (Stock, et al., 2007; Genualdi, et al., 2010; Butt, et al., 2010; Wong, et al., 2018; Bohlin-Nizzetto, et al., 2017; Theobald, et al., 2007). A recent study reports a significant increase in concentrations of

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

PFHxS ($p < 0.006$) during the period 2009 - 2015 in Arctic air both in Canada and Norway. This indicates that an increase in long-range transport has occurred (Rauert, et al., 2018a).

Environmental monitoring results from China and France indicate increasing trends of PFHxS in the surface waters due to increased application of products containing PFHxS as a substitute for PFOA and PFOS (Ma et al., 2018). Further PFHxS has been detected in wildlife including seabird eggs and in marine mammals representing top predators in the lower ng/g range (Galatius, et al., 2013). However, the highest levels of PFHxS ever reported in bird eggs were in great tits (range of 37-355 ng/g ww) in the vicinity of a perfluorochemical plant in Antwerp, Belgium (Groffen, et al., 2017).

1.1.7. A recent study by Schultes et al (2019) on temporal trends of PFAS in liver tissue from Baltic Cod (*Gadus morhua*) shows that for the period 1981-2013, PFHxS increased at a rate of 3.0 ± 1.3 % per year. Human exposure and trends

Human exposure to PFHxS is complex and from multiple sources. Exposure pathways for PFHxS includes indoor dust, diet, drinking water and indoor/outdoor air (See Appendix 2, tables 46, 47 and 49). PFHxS, along with PFOS and PFOA, is the most frequently detected PFAS in blood-based samples from the general population worldwide (See Appendix 2, Tables 39, 49 and 52) and is present in umbilical cord blood and breast milk (Kärman, et al., 2007; Gützkow, et al., 2012). PFHxS is also found in all studied human organs and tissues (Perez, et al., 2013).

Occupational and consumer exposure

Several studies of occupationally exposed workers in manufacturing plants, investigated levels of PFHxS in dust, blood, serum and urine. The concentrations of PFHxS in serum (mean/geometric mean/median) were in the range of 5-863 ng/mL (Wang, et al., 2010; Ehresman, et al., 2007; Olsen, et al., 2003; Fu, et al., 2016; Gao, et al., 2015; Fu, et al., 2015; Rotander, et al., 2015).

Exposure to PFHxS in the home environment can lead to concentrations of PFHxS in blood (plasma/serum/whole blood) similar to or above those observed in occupational settings (ECHA, 2017a). Studies investigating PFHxS levels in dust in homes, offices, furniture stores and hotels, found median levels of PFHxS in the range of 0.1-2100 ng/g. (Huber, et al., 2011; D'Hollander, et al., 2010; Kubwabo, et al., 2005; Strynar & Lindstrom, 2008).

Exposure from food and drinking water

Contamination of tapwater with PFHxS at low levels (mean values in the range of n.d.- 2 ng/L) has been observed world wide (Mak, et al., 2009; Kaboré, et al., 2018; Zafeiraki, et al., 2015; Boiteux, et al., 2012; Ericson, et al., 2009) (see Appendix 2, Table 46 for details). The mean level of PFHxS in contaminated drinking water was in the range of 4.6-1770 ng/L (Council of Chemists of the Province of Treviso, 2017; Li, et al., 2018; Konieczny, et al., 2016). In or near contaminated areas drinking water consumption is considered to be one of the most important exposure pathways of PFASs. Several human biomonitoring studies have concluded that exposure to PFHxS via drinking water can lead to much higher blood serum levels compared to control groups, as observed in USA, Germany, Sweden and Italy (Wilhelm, et al., 2009; Li, et al., 2018; Hu, et al., 2016; Ingelido, et al., 2018).

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Several studies have analysed PFHxS in a large variety of food items. The results show that the presence of PFHxS in food varies greatly and ranges from the pg/kg to µg/kg level. The highest levels of PFHxS in food items are found in animal products (2.5-39 ng/kg), but although levels of PFHxS in cereals and fruits are relatively low, the contribution of these food items to the total dietary intake can be substantial (Vestergren, et al., 2012). Based on the available data, the European Food Safety Authority (EFSA) has calculated that the median chronic dietary exposure to PFHxS in average consumers (adults) ranged from 0.05 (lower-bound) to 1.22 (upper-bound) ng/kg b.w. per day. It should be noted that the results just indicate a range within which the real exposure potentially lies (EFSA, 2012).

Findings of PFHxS in blood, cord blood and breast milk

A large number of studies have investigated PFHxS in blood. It is clear that PFHxS is detected in human blood globally. The median concentrations of PFHxS in the general population measured in whole blood were in the range of 0.2-2.92 µg/L (Kannan, et al., 2004; Kärrman, et al., 2006; Ericson, et al., 2007), whereas in serum mean/median concentrations were in the range of 0.6-4.3 µg/L (Hansen, et al., 2001; Kannan, et al., 2004; Lin, et al., 2009; Jönsson, et al., 2010; Nelson, et al., 2010; Ji, et al., 2012; Maisonet, et al., 2012; Toft, et al., 2012; Bjeremo, et al., 2013; Zhang, et al., 2013) (Jönsson, et al., 2014; ATSDR, 2018).

Populations exposed to higher levels of PFHxS due to contamination had median serum values in the range of 2.98-277 µg/L (Stein & Savitz, 2011; Jakobsson, et al., 2014; Li, et al., 2018; Ingelido, et al., 2018).

PFHxS is detected in more than 98% of pregnant women in studies from Shanghai, Northern Norway, Greenland and Denmark (Bjerregaard-Olesen, et al., 2017). In a study from Arctic Russia, PFHxS was detected in all samples of maternal and umbilical cord whole blood and plasma from women and their newborn children (Hanssen, et al., 2013).

Breast milk is an important exposure pathway to PFHxS for infants. As shown in studies comparing serum concentrations of women who did or did not breastfeed their infants, breastfeeding significantly decreases maternal serum concentrations of PFHxS, PFOS, and PFOA (Bjeremo, et al., 2013; Brantsæter, et al., 2013; Papadopoulou, et al., 2015).

Temporal trends on human exposure

In a systematic review excluding data from occupational exposure and or populations exposed to point sources such as contaminated drinking water, the concentrations of PFOS, PFDS, and PFOA in humans are generally declining, and increasing concentrations of PFHxS have started to level off in recent years (Land, et al., 2018). However, in a study reconstructing past human exposure by using serum biomonitoring data from USA and Australia using a population based pharmacokinetic model, significant declines were observed for PFOS and PFOA, but no trend was observed for PFHxS (Gomis, et al., 2017).

Furthermore, the concentrations of PFHxS in serum followed a different age pattern than PFOS indicating that global exposure to PFHxS is still ongoing and has not significantly declined since the early 2000s when the voluntary phasing out of PFOS started.

PFHxS, along with PFOS and PFOA, is the most frequently detected PFAS in blood-based samples from the general population worldwide. The substance is also found in other human

organs and samples. More details on human exposure to PFHxS is presented in Annex B.9.4.

1.1.8. Risk characterisation

PFHxS and its salts were added to the REACH Candidate List as Substances of Very High Concern due to their vPvB-properties. Furthermore, PFHxS-related substances can degrade to PFHxS and must therefore be considered as vPvB substances as well (Regulation No 1907/2006 Annex XIII). PFOS and PFOA-related substances have previously been treated in the same manner under REACH (Regulation No 1907/2006 Annex XVII). The EU POPs regulation (Regulation (EU) No 2019/1021) has also had this approach to PFOS-related substances, and PFOA-related substances are assessed similarly under the Stockholm convention.

We have demonstrated in section 1.1.5-1.1.7 of the report that the environment, including human population, is exposed to PFHxS, its salts and PFHxS-related substances via various exposure pathways. Due to the vPvB-properties of PFHxS, its salts and PFHxS-related substances, no safe concentration, thus no threshold (PNEC), can be determined for PBT/vPvB substances (RAC/SEAC, 2015b). Derivation of PNECs is therefore not applicable (REACH Annex I, para 6.5). Furthermore, according to recital 70 of Regulation 1907/2006 exposure of the environment and humans from these substances should be reduced as much as possible.

Although human health effects are not the main argument for this restriction proposal, available scientific literature suggests that there is a risk for adverse effects on the general population, in particular for children and population groups that are exposed to elevated levels of PFHxS. This is briefly summarised in the concluding statement in the draft POPs risk profile referred to in Annex B (see sections B.5 and B.10).

PFHxS related substances can degrade to persistent PFHxS in the environment. If transformation/degradation products with PBT/vPvB properties are formed, the substances themselves must be regarded as PBT/vPvB substances (ECHA, 2017c). Therefore, the hazard profile of PFHxS apply to these substances as well.

1.2. Justification for an EU wide restriction measure

PFHxS is very persistent and very bioaccumulating. The substance has the potential for long-range transport.

There are currently no REACH registrations of PFHxS or PFHxS-related substances. CLP notifications exist for PFHxS, its salts and some PFHxS-related substances. This indicates that the use of these substances within the EU is limited. The stakeholder consultation and call for evidence (see Annex A and G) did not reveal any manufacture of PFHxS, its salts or PFHxS-related substances within EU, even though CLP notifications according to Regulation 1272/2008 of PFHxS, its salts and related substances have been submitted to ECHA, see Table 7 for details. One stakeholder informed that PFHxS could be used in old fire-fighting foams, see Annex G for details.

Even though regulatory measures for PFOS and PFOA have reduced the global emissions of PFHxS, its salts and PFHxS-related substances as an impurity in these substances, increasing levels of PFHxS in Arctic air (Rauert, et al., 2018a) and polar bear (Routti, et al., 2017) are reported. Furthermore, PFHxS is amongst the most frequently detected PFAS in human blood samples in Europe (see tables in Appendix 2) and has been detected in umbilical blood, human breast milk and in all studied human organs and tissues. Recent research by Boucher et al. (2019) predicts that elevated environmental concentrations of PFHxS will remain for decades and that PFHxS will reach remote areas to a greater extent than what is observed today.

POPRC decided at their meeting in September 2018 that PFHxS is likely to lead to significant adverse human health and/or environmental effects, such that global action is necessary (UNEP/POPS/POPRC.14/6, 2018). Furthermore, the committee decided to prepare a risk management evaluation that includes an analysis of possible control measures for PFHxS. An EU restriction will be an important step to reduce the risks from PFHxS, its salts and PFHxS-related substances within the EU internal market. It will also assist the global regulation by the POPs Convention by analysing the impact in the EU of an equivalent global regulation.

National regulatory actions will not adequately manage the risks of PFHxS and PFHxS-related substances. An EU-wide restriction on PFHxS and PFHxS-related substances is the most appropriate way to limit the risks (due to further releases into the environment) for human health and the environment on an EU level.

1.3. Baseline

The Baseline sets out a scenario for what is likely to occur should no additional actions be taken on the use of PFHxS (and related substances). As with other PFAS substances that have come under scrutiny (in particular C9-C14 PFCAs), a number of regulatory actions to reduce PFAS in general and some specific compounds (notably PFOA and PFOS) are of relevance because PFHxS (and related substances) can be (and are) used as technical substitutes for these substances in a number of applications. There is, then, the potential for use of PFHxS (and related substances) to increase once such measures take effect.

Amongst the binding measures of most importance and influence in the EU in this regard are:

- The Restriction on PFOA, PFOA salts and PFOA-related substances under REACH. The restriction was submitted by Germany and Norway in 2014 and will become binding in the EU for non-derogated uses in 2020;
- The outcome of considerations to add PFOA to the Annexes of the Stockholm Convention;
- Restrictions on PFOS (and related substances) under the POPs Regulation (EU) No 2019/1021 and under the Stockholm Convention.

From the analysis of uses in Annex A.2, no current uses or sources of PFHxS (including its salts and PFHxS-related substances) have been identified in the EU other than the following:

- Fire-fighting foams: older fire-fighting foams (AFFF) containing PFAS produced using the electrochemical fluorination (ECF) manufacturing process. The stakeholder consultation has confirmed that PFAS based AFFF are now based on C6 telomer technologies which do not contain PFHxS or PFHxS related substances as an impurity;
- Textiles, carpet, leather and upholstery: imported finished textile articles such as overcoats, capes, cloaks, anoraks, windcheaters, outdoor gear and, potentially, other articles for which PFOS was previously used as a waterproofing/stain resistant textile treatment (which might include leather and carpets); and
- Import of PFOS and continuing (exempted) uses, as, mist suppressants for non-decorative hard chromium (VI) plating.

The dominant potential source of PFHxS, its salts and PFHxS-related substances in the above in terms of quantity is the import of PFOS and continuing (exempted) uses, see Annex A.2 for details.

As described in section 1.1.5 and Annex B.9, there are no data on the specific uses that allow estimation of use-specific emissions today.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

The average concentration of PFHxS in effluent water from wastewater treatment plants is 37.1 ng/L based on measurements from the period 2008 – 2019, see chapter 1.1.5.2 for details. A default wastewater treatment plant with an effluent water concentration of 37.1 ng/L would emit 74.2 mg PFHxS per day. All wastewater treatment plants in the EU would together emit 5.75 kg PFHxS per day or 2.10 tonnes PFHxS per year. Please note that the measurements do not cover PFHxS-related substances.

The average effluent wastewater concentration (37.1 ng/L) is driven by some high values compared to the majority of the data points, as the median value is 2.6 ng/L. A closer look at the higher values reveals that they might be related to chemical plants and/or tank cleaning operations. Splitting the data (n=124) on effluent concentrations of PFHxS demonstrated that the 10% highest concentrations were responsible for approximately 90% of the emissions. This implies that 1.79 tonnes of the total can be associated with WWTP handling industrial waste water with high concentrations of PFHxS. The remaining 0.22 tonnes are emissions from the WWTP with lower levels (with these comprising both industrial and public waste water sources). See Table 50 for details. (The fact that these figures do not add up to 2.1 tonnes is due to rounding in the calculations.)

The higher emission values are dated 2010/2011 and they are expected to be related to historic industrial activities. European industries are no longer using PFHxS. As a result of this, the current emission of PFHxS via waste water is estimated to be 0.22 tonnes per year. In terms of future emissions, under the baseline BAU scenario we expect the emissions to increase above the estimated current level of 0.22 tonnes per annum once restrictions on PFOA apply in the EU (in 2020), internationally via the Stockholm Convention, and also in other states (See Box D.1-1 for example).

There is evidence that PFHxS has been (and is being) used as a substitute for PFOS and PFOA in a number of applications around the World. PFHxS (and related substances) are known to be technically feasible substitutes for PFOA (and PFOS) in a number of applications (Kemi, 2017), including several where current uses of PFHxS appears minimal. Examples include:

- **Textiles:** It is reported that water-proofing textile finishes based on PFHxS-based compounds have recently been developed by at least Hubei Hengxin Chemical Co., Ltd. (CAS numbers. 68259-15-4 (tridecafluoro-N-methylhexanesulphonamide), 68555-75-9 (tridecafluoro-N-(2-hydroxyethyl)-N-methylhexanesulphonamide), and 67584-57-0 (2-[methyl[(tridecafluorohexyl)sulphonyl]amino]ethyl acrylate)) and Wuhan Fengfan Surface Engineering Co., Ltd. from China (Huang et al., 2015; Hengxin, 2018), as alternatives to PFOS-based compounds (Huang et al., 2015). The industrial activities with C-6 waterproofing agent for textiles in the Taihu Lake region in China might be a potential source of PFHxS where recent production and use of PFHxS as an alternative to PFOS and PFOA has been reported (Ma et al., 2017). In 2010, it was estimated that the production of surface treatment products containing PFHxS- or perfluorobutane sulfonic acid (PFBS)-related compounds in China would reach 1000 tonnes per year in the next 5–10 years (Huang et al., 2010); no recent update of this estimate is currently available.
- **Semiconductors:** The POPs secretariat (2018) report that during the POPRC-13 meeting on the Stockholm Convention in 2017, an industry representative noted that

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

PFHxS, its salts and PFHxS-related compounds are currently being used as replacements to PFOS, PFOA and their related compounds in the semiconductor industry. This information is further strengthened by published information that indicates that PFHxS is used in the semiconductor industry in Taiwan province of China (Lin et al., 2010). PFHxS (133,330 ng/L), together with PFOS (128,670 ng/L), was one of the primary contaminants at a semiconductor fabrication plant waste water effluent site. Both PFASs are present in the effluent in similar amounts showing that PFHxS is a primary substance in this process and are not unintentionally present at this site.

The potential for increased use of PFHxS is also confirmed by a Chinese manufacturer that currently advertises PHxSF as '*one of the most essential raw materials for preparing fluorine containing surfactants. The fluorine containing surfactant can be widely used in textile, leather, papermaking, pesticide, electroplating, oilfield, fire control, photosensitive material, synthetic material and other fields*' (Made in China.com). A recent article by Pan et al (2018) indicate remarkable increases in PFHxS use and emission in China in recent years.

Few data are available to predict the extent of the increase. As reported in Annex A, an estimated 66 kg per annum of PFHxS was imported on waterproof jackets from China, Vietnam and Bangladesh (and an unknown quantity in other applications such as outdoor gear) in 2013. As reported in Table 9 in Annex A, measurements in outdoor gear for 2016 suggest negligible use of PFHxS at present compared with other PFAS such as PFOA (where the latter was found in 67-100% of articles tested).

Based on a comparison of the average quantity of PFHxS measured in all articles sampled in 2013 (i.e. those with and those without PFHxS, its salts and PFHxS-related substances) the analysis in Annex D concludes that a shift to the use of PFHxS on such articles once controls on PFOA come into effect would have the effect of increasing annual import to 131.2 kg per year – a doubling of imports (and emissions) relative to 2013.

Conservatively taking the lesser of these factor increases (x2) as indicative of the potential shift to PFHxS as a result of controls on PFOA, it is assumed in that, under the baseline, the estimated 0.22 tonnes per annum of estimated current emissions of PFHxS increase to 0.44 tonnes per annum from 2020 onwards under the BAU. Table 4 summarises these annual emissions.

Table 4: Summary of estimated emissions under the Baseline (BAU)

Time period	Estimated annual emission of PFHxS (tonnes)
1990-2010	2.1
2011-2019	0.22
2020 onwards	0.44

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

There is considerable uncertainty about the half life of PFHxS. The Annex XV report identifying PFHxS as an SVHC (ECHA, 2017a)) concludes that PFHxS is stable under environmental conditions and abiotic degradation is expected to be at least as low as for the chemically similar substance PFOS, which has a half-life of >42 years. No degradation has been observed under environmental conditions for PFHxS, see Annex B.4.1 for details.

Error! Reference source not found. shows the change in environmental stock after 1990 in a situation with no degradation. Possible stock from releases prior to 1990 is not included in this figure. This stock (prior to 1990) has not been estimated and will not be affected by this restriction.

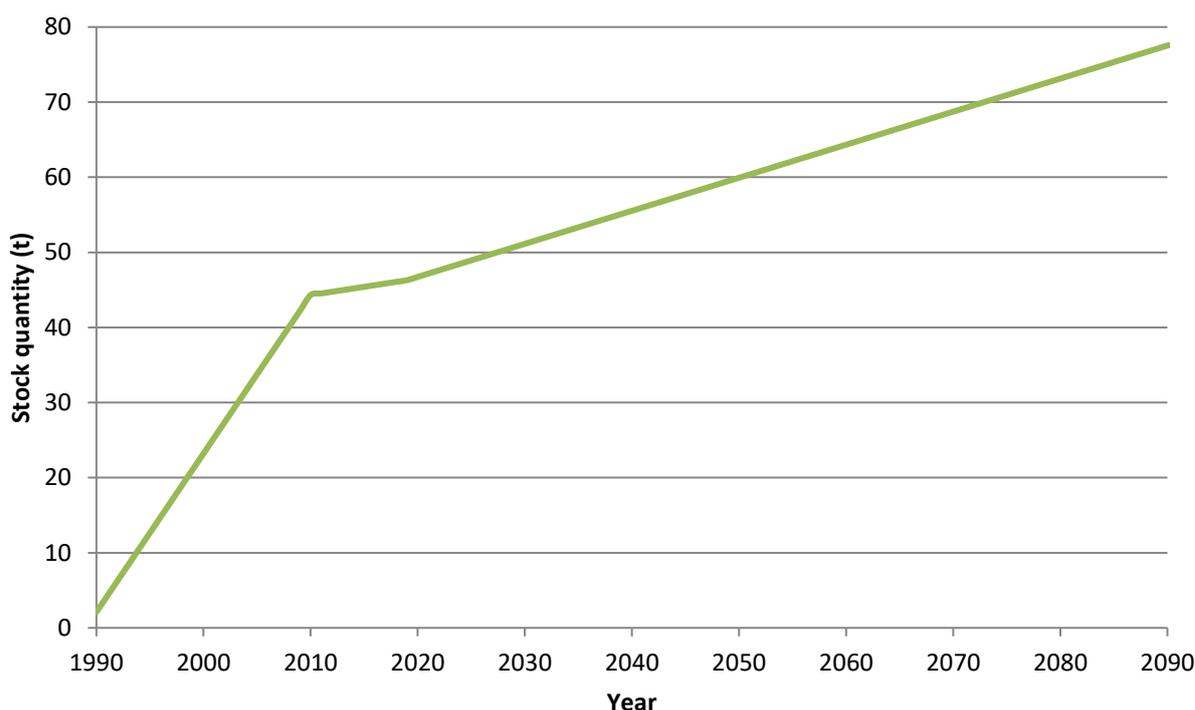


Figure 5: Environmental stock profile under the Baseline (BAU) (no degradation)

Applying a half-life of 42 years to the annual emissions set out in Table 4 provides a means to model a projected contribution to environmental loading or environmental stock at an EU level since 1990. Figure 6 provides the stock profile for PFHxS under the baseline (BAU) in a situation with degradation. At such levels of persistency, around 98% of an emission of PFHxS in year n persists into year n+1. This provides for a current (2019) environmental stock quantity of 34 tonnes for the purposes of the baseline and the impact assessment. Possible stock from releases prior to 1990 is not included in this figure. This stock (prior to 1990) has not been estimated and will not be affected by this restriction.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

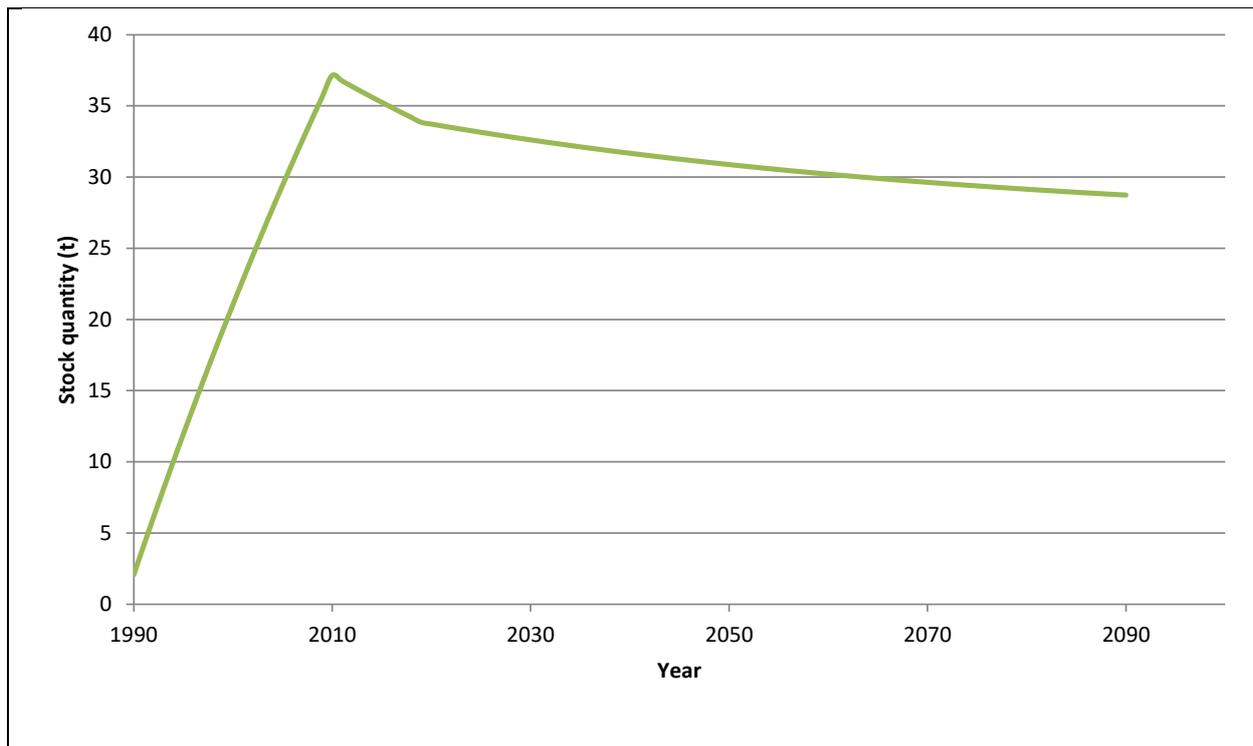


Figure 6: Environmental stock profile under the Baseline (BAU) (Half life 42 years)

2. Impact assessment

2.1. Introduction

When assessing the human health and the environmental impacts of the proposed restriction the status of PFHxS as PBT/vPvB substances must be taken into account. PFHxS, its salts and PFHxS-related substances have the potential to persist in the environment for many decades and, as such, even if emissions cease this will not result in an immediate reduction of environmental concentrations. In addition to their extreme persistence, PFHxS, its salts and PFHxS-related substances are highly mobile in the environment and have the potential to be distributed over long distances. This implies that continuous emissions will lead to rising concentrations in the environment and, consequently, greater exposure of humans and the environment with the potential of causing adverse effects. Owing again to the persistence of the substances, these impacts will be very difficult to reverse, once they have occurred.

Owing to lack of knowledge and data (in particular of long-term effects), the risks of PBT/vPvB substances cannot be predicted and quantified by standard risk assessment methods and quantification and valuation of benefits via the assessment of the impacts on environment and human health is not possible (see for example the SEAC Guide (ECHA, 2016)). Instead, a cost-effectiveness analysis based on emissions reduction and the total costs of implementing the proposed restriction is more appropriate. In this respect, total costs should include compliance costs, enforcement costs, and other additional social costs.

Within this type of analysis, emissions reductions normally act as a proxy for benefits in terms of a reduced risk. The total costs of the measure are divided by the reduction in emissions to derive a cost per unit of reduction. In this respect, the level of emissions reduction acts as a proxy for the unquantified environmental and human health benefits (in terms of reduced risk). The stakeholder consultation has shown that there is no intended use of PFHxS in the EU. As a result of this there is no calculated costs related to the proposed restriction. If it had been possible to estimate a cost per unit of reduction, this could have been compared to other past decisions (i.e. to suitable benchmarks) to confirm whether or not it is likely to reflect a net benefit to society. This has not been possible in this case.

The restriction is necessary to avoid the possibility that PFHxS, its salts and PFHxS-related substances are used as substitutes when the PFOA restriction becomes binding in 2020 and to reduce the environmental release of the substances present in imported articles and mixtures intentionally treated/manufactured with PFHxS, its salts and related substances.

2.2. Risk management options

Since PFHxS, its salts and PFHxS-related substances are not used within the EU and various imported articles and mixtures are a possible source of emissions of PFHxS, its salts and PFHxS-related substances, a restriction on only single uses would not result in sufficient exposure reduction.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

In terms of risk reduction capacity, a total phase out of manufacturing, use and contents in articles and mixtures (including imports) is needed. The proposed restriction comprises a ban on the use of PFHxS, its salts and its related substances with some derogations. The specific text of the proposed restriction is provided as Table 1

(Copy of Table 1 Text of proposed restriction on PFHxS, its salts and PFHxS-related substances)

<p>XX. Perfluorohexane sulfonic acid (PFHxS) (linear or branched), its salts and related substances⁴:</p> <ul style="list-style-type: none"> a. Perfluorohexane sulfonic acids with the formula C₆F₁₃SO₃H, their salts and any combinations thereof; b. Any substance having a perfluoroalkyl group C₆F₁₃- directly attached to a sulfur atom. 	<ol style="list-style-type: none"> 1. Shall not be manufactured or placed on the market as substances on their own from [<i>date - 18 months after the entry into force of this Regulation</i>] 2. Shall not from [<i>date - 18 months after the entry into force of this Regulation</i>] be used in the production of or placed on the market in: <ul style="list-style-type: none"> (a) another substance, as a constituent, (b) a mixture, (c) an article or any parts thereof, in a concentration equal to or above 25 ppb for the sum of PFHxS and its salts or 1000 ppb for the sum of PFHxS related substances. 3. The restriction in point 2 (c) on the placing on the market shall not apply to articles first placed on the market before [<i>date - 18 months after the entry into force of this Regulation</i>]. 4. Point 2 shall not apply to <ul style="list-style-type: none"> (a) substances or mixtures containing PFHxS as an impurity in PFOS⁵ in applications of PFOS which are derogated from the prohibitions in Annex I Part A of Regulation (EU) No 2019/1021; (b) concentrated fire-fighting foam mixtures that were placed on the market before [<i>date - 18 months after the entry into force of this Regulation</i>] and are to be used, or are used in the in the production of other fire-fighting foam mixtures.
--	--

The proposal is for a restriction on both manufacturing, placing on the market and use of PFHxS, its salts and its related substances in the EU. This includes the import of PFHxS, its

⁴ PFHxS related substances are substances that, based upon their structural formulae, are considered to have the potential to degrade or be transformed to perfluorohexane sulfonic acid (linear or branched). See section 2.2 of the report for more details.

⁵ Perfluorooctane sulfonic acid and its derivatives (PFOS) C₈F₁₇SO₂X (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

salts and its related substances in mixtures and articles above the proposed threshold of 25 ppb for the sum of PFHxS and its salts or 1000 ppb for the sum of PFHxS related substances.

The proposed limit values do not refer to surface area as this is in general difficult to check since the surface might be difficult to estimate depending on the structure and irregularities. See also ECHA Forum guide on Enforcement for Dossier Submitters (ECHA, 2016d).

These restrictions will apply 18 months after entry into force, except for new fire-fighting foams and fire-fighting foam concentrates where the regulation will apply after three months. The restriction will complement the decreasing trend in the use of PFHxS, its salts and its related substances in, for example, textile based outdoor gear while at the same time blocking a switch towards increased use of PFHxS. As noted above, such an increase may otherwise occur when controls on PFOA under REACH (and potentially under the Stockholm Convention) apply from 2020. This is because PFHxS is known to be a potential substitute for PFOA in a number of applications.

The restriction proposal also includes recycled material and articles made from recycled materials. This is in line with the Commission's regulation (EU) 2017/1000 on PFOA. 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. In addition, substances with POP properties like PFHxS, its salts and its related substances should not be recycled. This is also consistent with proposals made for restrictions on the C9-C14 PFCAs and in line with the objectives of Regulation (EU) No 2019/1021.

Also consistent with proposed EU-restrictions on the C9-C14 PFCAs, articles placed on the market before the proposed restriction entries into force (i.e. second-hand articles) are excluded from the scope. This is for two main reasons:

1. The second-hand market is difficult to control. In many cases this involves one single article donated or sold by one consumer to another, for example by a non-profit organisation. It would not be proportionate to revoke single articles, such as jackets, from the market.
2. To use, for example, a jacket as long as possible before it turns into waste is a sustainable management of resources.

As with the C9-C14 PFCAs, there is a potential need for managing the stock of PFHxS in for example landfills and other parts of the technosphere. This is, however, outside the scope of this restriction (and REACH), but if such EU-wide regulatory measures were considered, it would be a complement to this restriction and not represent double regulation.

2.3. Restriction scenario(s)

As shown in Annex A and G, repeated and exhaustive stakeholder consultation as part of the preparation of this dossier (and also the previous BiPRO - 2018 study) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in the manufacture of articles or mixtures in the EU but scope for an increase particularly outside the EU once controls on PFOA come into effect in 2020.

As noted in section 1.3, the baseline description predicts that the uses of PFHxS may increase from 2020 onwards when the restrictions on PFOA come into force in the EU. PFHxS (and related substances) are known to be technically feasible substitutes for PFOA (and PFOS) in a number of applications (Kemi, 2017), including applications where the current use of PFHxS appears to be negligible (see Annex D). Based on an expected increase of PFHxS use in outdoor clothing and semiconductors, the baseline estimates a doubling in emissions per annum from 0.22 to 0.44 tonnes after 2020. See Annex D for details. Based upon the scarce information that is available, reducing the limit value from 25 ppb to 2 ppb might reduce the total current yearly European emissions of PFHxS from textiles by approximately 5 kg (a worst case estimate when assuming that all PFHxS will enter the environment and that the concentration of PFHxS in all textiles is either 25 or 2 ppb which is in practise unlikely):

Concentration limit for PFHxS in textiles	Resulting total amount of PFHxS emissions from textiles
2 ppb	(2 ppb * 252 042 tonnes=) 0,5 kg
25 ppb	(25 ppb * 252 042 tonnes=) 6,3 kg

The threshold for PFHxS in the restriction proposal is 25 ppb (i.e. 25 µg/kg). Applying the same estimation method (see Annex E.3.3.2. Environmental impacts), when compared with the 260.4 µg/kg in textiles under the baseline, this suggests emissions after 2020 at 9.6% (taken as 10%) of those for 2019 (0.22 tonnes per annum), i.e. an annual emission of 0.02 tonnes per annum PFHxS after 2020. This estimate is based on the assumption that actors continue to use PFHxS, but stay under the threshold. We expect that many of the manufacturers will switch to alternatives. The emissions can be expected to be lower, but we don't know how much lower. As a result of this the estimate of 0.02 tonnes used in the baseline calculations must be considered a maximum estimate. Emissions under the Baseline (BAU) and under the Restriction are summarised in Table 5.

Table 5: Summary of emissions under the Baseline (BAU) and under the Restriction

Time period	Annual emission of PFHxS (BAU) (tonnes/year)	Annual emission of PFHxS (Restriction) (tonnes/year)
1990-2010	2.1	2.1
2011-2019	0.22	0.22
2020 onwards	0.44	0.02

2.4. Assessment of the restriction option

2.4.1. Economic impacts

2.4.1.1. Costs of alternatives and substitution

Based the evidence of exhaustive consultation and thorough data searches on PFHxS its salts or related substances in the EU it is concluded that the restriction proposal will have:

- No impacts on EU production of PFHxS, its salts or related substances because no such production exists (i.e. there are no economic impacts);

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

- No impact on the production of PFAS. Since PFAS production methods have now shifted to C6 fluorotelomer production, there is no longer any production of PFAS containing impurities of PFHxS, its salts or related substances above 25ppb and, as such, there are no economic impacts on manufacturers;
- No impact on the market for PFAS based fire-fighting foams. There is no longer any production of PFAS fire-fighting foams containing impurities of PFHxS, its salts or related substances above 25 ppb and, as such, there are no economic impacts;
- No impact on private companies and public bodies maintaining a stockpile of fire-fighting foams. The restriction does not extend retrospectively to fire-fighting foams already purchased and stockpiled for the purpose of fighting fires; and
- Small negative impact on importers of finished articles containing PFHxS, its salts or related substances above 25 ppb into the EU.

Our information suggests significant use of PFOA across a number of article types for which PFHxS is known to have been used in the past. Thus, it is possible that, once the restriction on PFOA comes into effect, a switch to alternatives such as PFHxS might act to increase the level of import of PFHxS in articles in the future. The restriction proposal for PFHxS, its salts and related substances would re-inforce this shift and ensure that use of the substances in imported textiles does not increase (again) as a result of the changes brought about by the restriction on PFOA.

The use of PFHxS and PFHxS-related substances in textiles by producers in the EU has not been confirmed during stakeholder consultation, with three associations indicating that these substances are not used by their members. Fluorine free alternatives are already used by EU industry. As a result of this, the costs for the EU industry are expected to be negligible.

As stated above import data suggest no or negligible import of PFHxS in textiles at present. The costs for importers are - as a result of this - expected to be negligible in today's market. This could change once the restriction on PFOA comes into effect. If producers in countries outside the EU choose to switch to alternatives such as PFHxS this might act to increase the level of import of PFHxS in articles in the future if this substance is not restricted. Fluorine free alternatives may be more expensive, but the cost is expected to decrease over time. The industry in the EU has already changed to fluorine free alternatives. As a result of this, and the fact that there are no or negligible import of PFHxS in textiles at present, we have concluded that these costs must be small. These costs are difficult to calculate, and an estimate would be very uncertain. As a result of this we have chosen not to try to calculate them.

This leads to the conclusion that the costs associated of this restriction proposal to EU producers and importers of articles was considered to be negligible.

In relation to the latter (imports of PFHxS in articles such as outdoor gear), as reported in Annex A, more recently there has recently been a shift away from the use of PFHxS as a waterproofing and protective agent in articles such as outdoor clothing imported from countries such as China, Vietnam and Bangladesh. The restriction would re-inforce this shift and ensure that use of PFHxS does not increase (again) as a result of the changes brought about by the restriction on PFOA.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

This action could provide a benefit to brands and retailers of articles such as outdoor gear that are environmentally friendly. As discussed in Annex E.3.2, there is consumer demand for more environmental friendly products, in for example the outdoor industry, which is driving a phasing out of PFAS in general. The proposed restriction on PFHxS should assist manufacturers and retailers who are pursuing such objectives by reinforcing their own requirements regarding the presence of PFAS in articles.

PFHxS could be used as an alternative to PFOS in applications such as semiconductors and metal plating. Stakeholders in these areas have repeatedly been contacted and have provided no information that would confirm such use within the EEA. The indication, then, is that the restriction will have no impact on these uses.

2.4.1.2. Administrative costs

In the consultation for the C9-C14 PFCAs (BAuA, 2017) some companies in the outdoor textile industry indicated that they intended to send some of their products to independent laboratories for testing once a restriction was implemented. The same is likely to be the case for PFHxS. As reported in Annex E.3.4.3, testing costs would be shared with the testing needed to comply with the PFOA restriction (and also any that may be required in relation to C9-C14 PFCAs). As a result of this these costs are expected to be small.

2.4.1.3. Comparison with other similar PBT and vPvB, PFAS cases

In cases with other similar PBT and vPvB substances, where concentrations have reached the recommended guidance level, for example PFAS in drinking water in Sweden (from fire-fighting foam), it has been proven (Swedish Chemicals Agency, 2016), to be a cost-effective measure to regulate these substances beforehand rather than paying for the abatement and substitution cost afterwards.

Avoidance of future emissions of PFHxS into the environment is important to reducing impacts on the environment and human health. There are numerous examples in the literature of the costs of remediating sites where contamination of groundwater and soil has occurred due to the past use of PFASs at industrial sites, at airports, as part of training activities in the use of fire-fighting foams, and due to the need to put out fires (see Annex E.4.2). Although these examples are not specific to PFHxS, they provide an indication of the potential for significant costs should there be a need to undertake such remediation activities specific to PFHxS, its salts and PFHxS-related substances in the future. Accordingly, it is more cost-effective to regulate the use of PFHxS, its salts and PFHxS-related substances to ensure that recommended guidance levels are not exceeded.

2.4.1.4. Enforcement Cost

Average enforcement costs have been identified in connection to the restriction on lead compounds in PVC (ECHA, 2016) for EU28 member state agencies to ensure compliance with EU regulation. ECHA assessed the administrative cost of member states to comply with restrictions to be approximately €55 600 per year. This number could be seen as an indication of the magnitude of the enforcement costs associated with the PFHxS restriction. However, enforcement costs are likely to be lower than this because analysis of PFHxS may be performed together with the analysis of other regulated PFASs, like PFOS, PFOS and C9-C14 PFCAs. PFHxS is one amongst several PFASs (ca. 20-30 depending on the lab) that are

usually analysed for in one standard PFAS analysis package. The sampling and sample preparation will be performed together for PFHxS and other PFASs in the same sample, without additional costs. Some minor additional costs may be added due to the need to report one extra substance from the analysis, but these extra costs are likely to be less than the difference in costs between different laboratories for the chemical analysis itself. One stakeholder informs that the costs for the analysis of all PFASs (including PFHxS) is ca. €300 per sample, and for PFHxS alone is €110. Competition

It is not anticipated that the restriction will have any negative competition effects as the restriction applies to all actors. In any case, there is no manufacture and use of PFHxS, its salts or related substances in the EU to produce such an effect. As the restriction includes thresholds for imported articles, EU manufacturers of products will not be at a disadvantage on the internal market.

2.4.2. Human health and environmental impacts

2.4.2.1. Human health impacts

The potential harm to humans from PFHxS, its salts and PFHxS-related substances follows from the PBT or vPvB properties of these substances. The main potential exposure pathways are intake via food and drinking water and through exposure to house dust. Monitoring data demonstrate the presence of PFHxS in human blood and serum. Some of these detected PFHxS levels in human blood and serum have also been seen to increase or level off despite decreasing uses in manufacture and production over time. PFHxS has also been observed in human breast milk (see Annex B.5 for a full description of the data and studies).

Due to their vPvB properties, minimizing the use of PFHxSs is an urgent priority. Although human health effects are not the main argument for this restriction proposal, available scientific literature suggests that there is a risk for adverse effects (see Annex B.5). Furthermore, since these substances persist and accumulate in humans and wildlife they may be impossible to remove if serious health concerns should be documented in the future.

No monetary valuation of human health impacts is possible because a quantitative cause and effect relationship between PFHxS levels and different health endpoints has not yet been defined.

2.4.2.2. Environmental impacts

Emissions under the Baseline (BAU) and under the Restriction were summarised in Table 5 and is shown in Figure 7 and Figure 8. As is described in Annex E.3.3.2, applying a half-life of 42 years to these emissions allows projection of environmental stocks of PFHxS under each scenario and, for reference purposes, under a zero emissions from 2020 scenario. This is provided in Figure 7. Figure 7 and Figure 8 show the change in environmental stock after 1990 in a situation with degradation and without degradation. Possible stock from releases prior to 1990 is not included in the figures. This stock (prior to 1990) has not been estimated and will not be affected by this restriction.

As can be seen from the figures, owing to the persistence of PFHxS (half-life >42 years) even relatively small annual emissions can quickly produce a large stock in the

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

environment. It is this attribute (together with the bioaccumulation and toxicity) that sets such substances apart from other, less persistent, substances for which half-lives are short enough for there to be no (or negligible) residue from one year to the next. Thus, for a non-persistent substance (i.e. the 'normal' case) the environmental stock is taken as broadly equalling the annual emissions (because no or negligible emissions from one year persist into the next). Acknowledging that no degradation has been observed under environmental conditions for PFHxS, see Annex B.4.1 for details, the baseline scenario probably underestimates the environmental stock quantities.

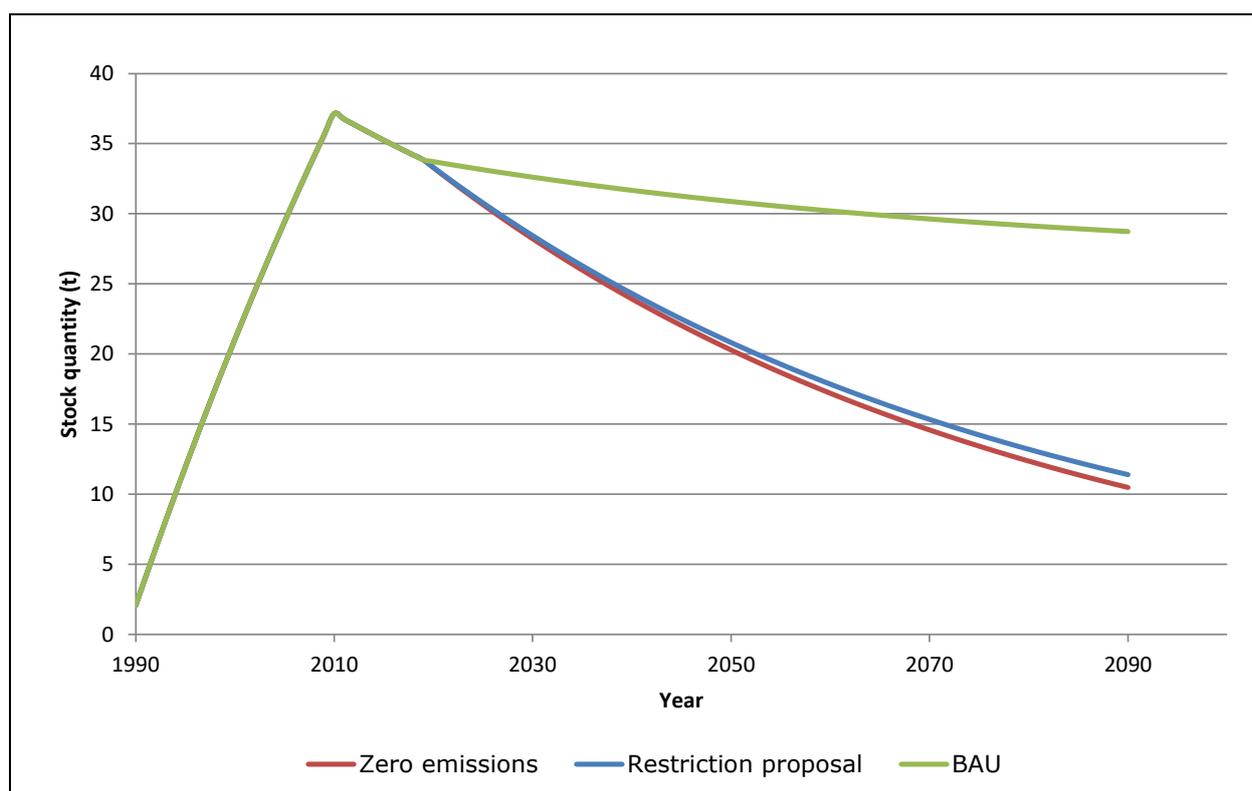


Figure 7: Environmental stock profile under the Baseline (BAU) and Restriction scenarios (half life 42 years)

In the case of emissions of PFHxS provided in Figure 7, it is estimated that 2.1 tonnes of annual emissions from 1990-2010 produced a total environmental stock quantity peaking at around 37.1 tonnes in 2010 when action to restrict PFOS and the resulting changes in manufacture and use of associated PFASs (such as PFHxS) took effect. The actions under the restriction on PFOS resulted in annual estimated emissions of 0.22 tonnes per annum and a new trajectory towards reduced environmental stocks of PFHxS. The stock is estimated to have been reduced to 33.8 tonnes at present (2019).

It is argued in this dossier that the restrictions on PFOA that apply from 2020 represent a split in the trajectory for environmental stocks of PFHxS. The evidence presented in Annex D on the baseline BAU scenario suggests that there might be increased use of PFHxS once the PFOA restriction applies and that this will have the effect of increasing the annual emissions from 0.22 to 0.44 tpa. Whilst maintaining the downward trajectory in

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

environmental stock instigated by action of PFOS, the rate of reduction is slowed such that, under the BAU, from an environmental stock of 33.8 tonnes at present stocks are reduced to only 32.6 tonnes by 2030 and 31.7 tonnes in 2040.

In contrast, by preventing a switch from PFOA to PFHxS and by setting thresholds to reduce the quantity of PFHxS in imported articles (and mixtures), the restriction proposal accelerates the rate of the downward trajectory. Here it is estimated that from an environmental stock of 33.8 tonnes at present stocks are reduced to 28 tonnes by 2030 and 24 tonnes in 2040.

The very persistent nature of PFHxS and the fact that no degradation of PFHxS has been observed under environmental condition, imply that the predictions in Figure 7 probably underestimate the real situation. Because of that, we have included Figure 8 that shows the baseline, a zero emission situation and the restriction proposal from 2020 in a situation with no degradation.

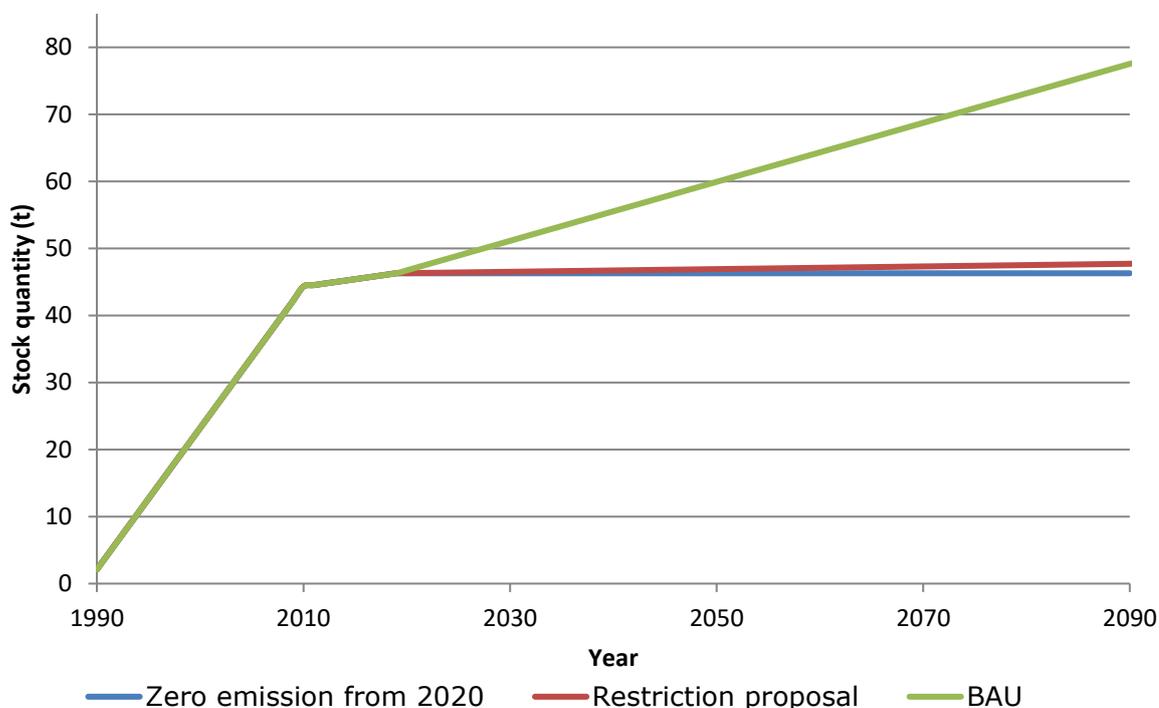


Figure 8: Environmental stock profile under the Baseline (BAU) and Restriction scenarios (no degradation)

In the case with no degradation as shown in Figure 7: Environmental stock profile under the Baseline (BAU) and Restriction scenarios (half life 42 years)⁸, it is estimated that 2.1 tonnes of annual emissions from 1990-2010 produced a total environmental stock quantity of around 44.3 tonnes in 2010 when action to restrict PFOS and the resulting changes in manufacture and use of associated PFASs (such as PFHxS) took effect. The actions under the restriction on PFOS resulted in annual estimated emissions of 0.22 tonnes per annum and a new trajectory towards reduced growth in environmental stocks of PFHxS. The stock from emissions between 2010 and 2019 is estimated to be 46.3 tonnes at present (2019).

It is argued in this dossier that the restrictions on PFOA that apply from 2020 represent a split in the trajectory for environmental stocks of PFHxS. The evidence presented in Annex D on the baseline BAU scenario suggest that there might be increased use of PFHxS once the PFOA restriction applies and that this will have the effect of increasing the annual emissions from 0.22 to 0.44 tpa. Whilst maintaining the trajectory in environmental stock instigated by action of PFOS, the rate of emission is increased such that, under the BAU, from an environmental stock of 46.3 tonnes at present stocks are increased to 51.1 tonnes by 2030 and 55.5 tonnes by 2040.

In contrast, by preventing a switch from PFOA to PFHxS and by setting thresholds to reduce the quantity of PFHxS in imported articles (and mixtures), the restriction proposal stops the emissions. As a result of that the environmental stock is expected to level out at 46.3 tonnes from 2020. By preventing a switch from PFOA to PFHxS and by setting thresholds to reduce the quantity of PFHxS in imported articles (and mixtures), the restriction proposal is expected to reduce the emissions to 0.02 tonnes per year. If the proposed restriction is implemented the stock will only be slightly larger than in the situation with zero emissions.

2.4.3. Other impacts, practicability and monitorability

2.4.3.1. Social and wider economic impacts

The social and wider economic impacts of the restriction are considered to be negligible. This is due to the fact that there is no identified manufacture or use of PFHxS in the EU at present. The impacts on the presence of PFHxS as an impurity in mixtures and articles should also give rise to only negligible impacts. With respect to initial concerns regarding fire-fighting foams, alternative methods of producing PFAS such that PFHxS impurities are avoidable are already in place. Furthermore, the stakeholder consultation indicates that the market is already moving to alternative fluorine-free fire-fighting foams. Similarly, use of PFHxS in DWR textiles is, currently, very limited (see Annex A) and the restriction merely reinforces this.

2.4.3.2. Distributional impacts

The distributional impacts of the proposed restriction are considered to be negligible, given that no manufacture or intentional use has been identified in the EU, and the restriction does not require the destruction of existing stocks of fire-fighting foams that may contain PFHxS as an impurity. In principle the most impacted set of actors could have been manufacturers and retailers of DWR clothing and outdoor gear. As noted in Annex E.2.1.2.1, however, there is consumer demand for more environmentally friendly products, in for example the outdoor industry, which is driving a phasing out of PFAS in general and evidence that manufacturers and retailers are trying to meet this demand with targets for PFAS free DWR. The proposed restriction on PFHxS should assist manufacturers and retailers who are pursuing such objectives by reinforcing their own requirements.

2.4.3.3. Practicality and monitorability

This restriction proposal meets requirements regarding practicality and monitorability, as its requirements are similar to those proposed for the other PFCAs and PFASs. The frameworks

put in place with respect to the C9-C14 PFCAs, PFOA and PFOS will also be relevant to implementation of this restriction.

Given that no intentional use has been identified in the EU and that alternative technologies or substances are available, see Annex E.2 for details, the proposed transition time of 18 months should also be feasible for all actors. Indeed, as indicated in Annex E.2, consultation indicates that relevant EU actors have already foreseen the need to move away from PFASs more generally and are therefore using fluorine free alternatives or alternative technologies.

Analytical methods for the detection of PFHxS are reported in the literature which can be used to measure PFHxS and PFASs in general in almost all environmental media. See Annex E.3.4.3 for details. Although no standardised analytical methods exist today, it is possible to use the method specified by CEN⁶ for PFOS to determine the levels of ionic forms of PFHxS, its salts and PFHxS related substances. For volatile neutral PFHxS related chemicals, Herzke et al. (2012) have reported detection of PFHxS and related compounds using a different analytical instrumentation (GC/PCI-MS) (Herzke, et al., 2012). The level of quantification in both mentioned methods is 0.06 ppb. This allows quantification of PFHxS and related compounds in levels below the proposed limit values. However, the detection level is dependent on the sample material measured, and for some matrices (like fire-fighting foams) a higher detection level must be expected.

More generally, as identified by the proposed restriction for C9-C14 PFCAs, a monitoring strategy is also required to monitor the implementation and success of the restriction. It is proposed here that this be developed to be consistent with and complementary to the strategy put forward for other regulated perfluorinated substances, for cost-effectiveness reasons. This includes a strategy finally agreed with respect to time trend monitoring and monitoring of emissions suited to very persistent substances, for example with respect to emissions from waste water treatment facilities.

As proposed for C9-C14 PFCAs, time trend monitoring should include sampling from the environment, from animals and from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring. However, it should be recognised that it may take a very long time period in order to detect downward trends in concentrations, due to the persistence of PFHxS, its salts and PFHxS-related substances and the potential for on-going releases from environmental sinks such as sediment and soil.

2.4.3.4. Enforceability

The costs of enforcing this restriction may be able to be shared with the costs of enforcing other restrictions on perfluorinated substances. Enforcement activities involving inspections and testing can be arranged to target the occurrence of PFOS, PFOA, C9-C14 PFCA and PFHxS, its salts and PFHxS-related substances in articles at the same time, with this

⁶ Technical Specification (CEN/TS) for "Determination of extractable perfluorooctanesulphonate (PFOS) in coated and impregnated solid articles, liquids and fire fighting foams - Method for sampling, extraction and analysis by LCqMS or LC-tandem/MS"

improving the cost effectiveness of such activities (as for any environmental monitoring). Thus, the enforcement costs specific to PFHxS should be small in magnitude.

2.4.4. Proportionality

PFHxS, its salts and PFHxS-related substances are substances of very high concern owing to their PBT/vPvB properties. Annex B concludes that:

- PFHxS accumulates in humans
- PFHxS is present in human blood of the general population
- Time trend studies indicate that the human bioaccumulation potential of PFHxS may even be larger than that of PFOS.
- The human elimination half-life for PFHxS is > 7 years which is the longest of all perfluoroalkyl and polyfluoroalkyl substances (PFAS) for which data are available. It is also comparable to the longest human elimination half-lives recorded for known PBT/vPvB- and POP-substances such as some PCBs.
- There is evidence that PFHxS preferentially bioaccumulates in air-breathing mammals, including endangered species and humans
- PFHxS accumulates in the air-breathing food chains at least as much as PFOS and more than the long-chained PFCAs which have already been identified as vB on the Candidate List.
- Elevated levels of PFHxS have been measured in both humans (up to 1790 µg/L in blood serum) and wildlife (>500 µg/kg in polar bear liver) showing that exposure to PFHxS has the potential to result in high levels in biota.

Due to the extreme persistency of the substances, every emission contributes to the environmental stock of the substances. REACH promotes the reduction of impacts of such substances by requiring the minimisation of releases and environmental and relevant human exposure (Annex I para 6.5 of REACH).

Given the lack of identified intentional uses of PFHxS, its salts and PFHxS-related substances within the EU, the costs are expected to be minimal to EU actors. Authorities will incur costs from undertaking monitoring and enforcement activities, but there should be the potential for these to be organised in a cost-effective manner by undertaking activities in a joint manner across PFOA, C9-C14 PFCA and PFHxS substances. This restriction proposal is therefore considered to be proportionate.

SEAC's guide *Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC* (SEAC, 2016) discusses use of cost-effectiveness analysis approach based on compliance cost per unit (e.g. kg) reduction. In terms of proportionality, the SEAC guidance describes efforts to define benchmarks for the proportionality/disproportionality of actions to reduce uses/emissions of PBTs/vPvBs.

The VU (Vrije Universiteit Amsterdam) project for the development of a benchmark for regulatory decision making under REACH for PBTs/vPvBs (ECHA, 2014b) reported a very wide 'grey zone' (with margins in the order of magnitude somewhere between €1000 and €50,000 per kg PBT substituted, remediated or reduced emission) within which measures may be either proportionate or disproportionate, SEAC concluded that it was not (yet) able to set (what would be a formal) benchmark. However, based on the evidence collected so

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

far on the costs of the proposed restriction, see chapter 2.4.1 Economic impacts for details, the costs are expected to be well below the €1000 per kg lower margin of the identified 'grey zone'. This supports the conclusion that the restriction proposal is proportionate.

3. Assumptions, uncertainties and sensitivities

There are uncertainties and assumptions which could affect the results of this socio-economic analysis. However, these are not anticipated to be sufficient to alter the direction of the conclusions and, where this potential existed in principle, this has been mitigated in the analysis by a conservative treatment of data and emissions.

The data collection exercises have identified no current manufacture or use of PFHxS, its salts or related substances in the EU except for old fire-fighting foams, mist suppressants and textiles. It is, however, possible that other uses exist but that this has been missed in the data collection process. The potential for this has been mitigated by repeated attempts to engage potential users and user groups as well as reviews of the international literature and data (including on PFOS) to identify potential uses. There have been several other studies undertaken to identify and consult with potential users (including the BiPRO, 2018 study) before the extensive consultation and ECHA call for evidence (see Annex G) was launched specifically for evidence presented in this (current) dossier. Through these efforts every possible opportunity to provide a response has been provided to potential users but all of these have either identified no use or no interest (also implying no use).

The predicted emissions and environmental stocks of PFHxS in the baseline scenario are based on emissions via WWTP. Concerning the estimate of 1.79 tonnes PFHxS via WWTP per year from industrial sources, all water samples were taken in 2010/2011. This time period coincides with action on PFOS under Directive 76/769/EEC which applied from 2008 onwards. The regulation of PFOS may have acted to reduce the industrial component (1.79 tonnes per annum) of the total (2.1 tonnes per annum) emissions. Furthermore, the baseline scenario does not take into account the lack of evidence that PFHxS degrades under environmental conditions. This might suggest that the baseline underestimates the real situation.

The dominant potential source of PFHxS, its salts and PFHxS-related substances in the above in terms of quantity is the import of PFOS and continuing (exempted) uses, see Annex A.2 for details.

The case for the restriction rests partially on the likelihood that the restrictions on PFOA will trigger substitution with PFHxS for some uses (particularly in textiles). Annex D provides the evidence for this which, we argue, is good evidence. The case for the restriction presented in this SEA, however, does not depend entirely on this potential increase in use because the thresholds to be implemented on articles (and mixtures) would still provide a reduction in imports of PFHxS, its salts and PFHxS-related substances in imported articles.

There are some uncertainties regarding the toxic effects on the environment and human health. One such uncertainty is the cause and effect relationship between PFHxS and different health impacts and outcomes. But as described in Annex E.3.3 these uncertainties together with the very persistent nature of PFHxS also provide a strong motivation for a restriction on PFHxS, its salts and PFHxS-related substances.

4. Conclusion

PFHxS and its salts are included in the REACH Candidate List as Substances of Very High Concern (SVHC) due to their intrinsic properties as very persistent and very bioaccumulative (vPvB). According to REACH Annex I para 6.5, the risk to the environment cannot be adequately controlled for PBT/vPvB substances. There is no safe concentration for these substances, thus a threshold (PNEC) cannot be determined for PBT/vPvB substances (RAC/SEAC, 2015b). For such substances a REACH restriction would be based upon minimising the emissions of the substances to humans and the environment.

Due to the high persistency, every emission of PFHxS will contribute to the increasing environmental stock of the substances. With a half-life in the environment of >42 years at least 98% of an emission in one year will persist into the next.

There is evidence that PFHxS bioaccumulates in air-breathing mammals, including endangered species and humans. PFHxS has the longest human elimination half-life (more than seven years) of all perfluoroalkyl and polyfluoroalkyl substances (PFAS) for which data are available.

Although human health effects are not the main argument for this restriction proposal, available scientific literature suggests that there is a risk for adverse effects on the general population that is exposed to elevated levels of PFHxS.

PFHxS is found ubiquitously in the environment; in wildlife and remote areas including in Arctic species such as polar cod, glaucous gull, herring gull, ringed seal, and polar bears. Increasing trends of PFHxS in liver samples of Baltic cod are reported. Some of the detected PFHxS levels in human blood and serum have also been seen to increase or level off despite decreasing uses in manufacture and production over time.

There is no evidence of manufacture of PFHxS, its salts and PFHxS-related substances in EU today. In the past 3M was the biggest global manufacturer of PFHxS and related compounds but production was ceased by the end of 2002 (3M, 2000). During consultation carried out for this dossier the Italian company Miteni identified that it stopped manufacturing PFHxS in 2013. Miteni have since declared bankruptcy (on 26 October 2018) and suspension of production activities by the end of the 2018 (EMCC, 2018). Thus there is no identified production of PFHxS, its salts and PFHxS-related substances in the EU.

The identified remaining uses of PFHxS, its salts and PFHxS-related substances in the EU are limited to:

- Old fire-fighting foams (AFFF) containing it as an impurity (where these foams are no longer produced)
- Potentially, as an impurity in PFOS used in mist suppressants for hard chromium plating in closed loop systems (use area is exempted under the POPs Regulation (EU) No 2019/1021); and
- Imported articles such as textiles.

PFHxS has been (and is being) used as a substitute for PFOS and PFOA in a number of applications outside the EU. This proposal addresses the concern that the restriction on PFOA, PFOA-related substances and its salts that applies from 4 July 2020 (with certain derogations) could trigger substitution of PFOA with PFHxS for some uses. Such a

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

substitution would undermine the more recent shift away from the use of PFHxS and result in an increase in the number of uses, quantities of use and levels imported to the EU in finished articles.

National regulatory actions will not adequately manage the risks of PFHxS, its salts and PFHxS-related substances. A restriction on PFHxS, its salts and PFHxS-related substances is the most appropriate way to limit the risks for human health and the environment at an EU level. An EU wide restriction would create a more level playing field amongst companies operating on the EU market, indeed it would assist manufacturers and retailers of outdoor gear who are known to be pursuing objectives for PFAS free articles.

The costs for industry and enforcement agencies have been assessed and found to be negligible. A transitional period of even less than 18 months seems to be manageable.

POPRC decided at their meeting in September 2018 that PFHxS is likely to lead to significant adverse human health and/or environmental effects, such that global action is necessary (UNEP/POPS/POPRC.14/6, 2018). Furthermore, the committee decided to prepare a risk management evaluation that includes an analysis of possible control measures for PFHxS. The present proposal is coordinated with activities on PFHxS under the Stockholm Convention. A European restriction will be an important step to reduce the risks from PFHxS and PFHxS-related substances within the EU internal market. It will also assist the global regulation by the POPs Convention by analysing the impact in the EU of an equivalent global regulation.

Annexes

Annex A: Manufacture and uses

A.1. Manufacture, import and export

A.1.1 Manufacture of PFHxS

A report on the sources of PFHxS in the environment was commissioned by the Norwegian Environment Agency in 2018 and prepared by the Brancheninstitut für Prozessoptimierung (BiPRO) GmbH with assistance from ETH Zürich (BiPRO, 2018). This report was mainly intended to provide background information for regulatory work under the Stockholm Convention and has a global scope.

The BiPRO study (2018) could not find complete information on global production and use but concludes that PFHxS itself has had limited production and use. According to available data, the worldwide production of PFHxS in 2012 was about 700-750 kg and decreased to less than 700 kg in 2016. A further slight decrease in production of PFHxS is expected for 2017. However, the BiPRO report estimates a steady increase in the global consumption of PHxSF, which is considered a key intermediate as most or all of the PFHxS-related substances (see section 1.1.2 of the report). The authors expects a maximum value of the global consumption of PHxSF in a range of 700 - 900 Million US\$ (in 2020), followed by a slight decline. The BiPRO study also indicates that 3M was previously likely to be the biggest global manufacturer of PFHxS and related compounds, with an annual global production of 227 tonnes of PHxSF in 1997.

Data provided by 3M to RPA during the preparation of the EU Risk Reduction Strategy (RRS) for PFOS by the UK Rapporteur (RPA, 2004) suggest total imports to the UK alone of some 47 tonnes per annum (tpa) of PFHxS and PFHxS related substances in 1999. Assuming that 3M's UK market was 20% of the total EU 28 market, this implies that some 235 tonnes per annum of PFHxS was imported into the EU prior to 2000. This suggests a much larger quantity for PFHxS than estimated by BiPRO. 3M had ceased production of PFHxS and related compounds by the end of 2002 (3M, 2000).

As shown in Table 6, perhaps owing to the action taken at the Community level (and globally) on other PFAS (in particular PFOS and PFOA) the data suggest a significant reduction of global production of PFHxS since 2000.

Table 6: Data on manufacture and import

Time	Region and quantity	Source
Pre 2000	World = 227 000 kg	(BiPRO, 2018)
	EU = 235 000 kg	3M data used in PFOS RRS (RPA, 2004)
2012	World = 700-750 kg	(BiPRO, 2018)

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

2017	World = <700 kg	
------	-----------------	--

Regarding manufacture in the EU, as noted above, 3M ceased manufacture by the end of 2002. In terms of more recent manufacture, the Annex XV report for the Identification of a Substance of Very High Concern for PFHxS (ECHA, 2017b) notes that one European company (in Italy) was known to be marketing the PFHxS potassium salt. During consultation carried out with the Italian company as part of preparing this dossier, the Italian company (Miteni, which was the major manufacturer of fluorinated substances in the EU) identified that it stopped manufacturing PFHxS in 2013 and that production of PFC decreased in the period 2011 – 2013 from 778 tonnes to 383 tonnes (Regione del Veneto, 2014). However, the company's website offered PFHxS as a product in 2018. On 26 October 2018, Miteni's management decided to declare bankruptcy and to suspend production activities by the end of the year. This was announced on 31 October 2018. According to the company's management, the financial costs investigation of pollution of groundwater from perfluoroalkyl substances (Pfas) deriving from the investigations had an important impact on the budget and made it difficult the access to credit from local banks "worried about the company's reputation" (EMCC, 2018).

In addition to PFHxS itself, efforts have been made to identify the level of production of the key intermediate for its production, PHxSF in the same manner as POSF for the corresponding PFOS-analogue. As part of BiPRO's work for the Norwegian Environment Agency, a market research report was commissioned. The BiPRO (2018) report estimates a world consumption of PHxSF in 2020 ranging between 80 tonnes to 400 tonnes. These quantities have been estimated based on a linear extrapolation of information from the market research reports on the value of global sales in the period 2010-2017, divided by the 2018 price of PHxSF of 2-10 USD per gram. According to the same calculations, between 10 and 60 tonnes are expected to be consumed in the US and Canada, between 60 to 300 tonnes in Asia and between 10 to 40 tonnes in Europe. Being based on an approximate distribution, these estimates should be treated with caution and are included here only for completeness. There is no information to corroborate the extrapolation.

Any production of PFHxS, its salts and PFHxS-related substances can be regarded as currently only taking place outside the EU. There is no evidence of manufacture of PFHxS in the EU.

A.1.2. REACH Registrations and CLP Notifications

Neither PFHxS nor any of the compounds considered to be PFHxS related substances are registered under REACH (either as an intermediate or full registration). As such, there is no (legal) manufacture or import of these substances or, more accurately, no legal entities manufacturing or importing the substances in quantities in excess of 1 tonnes per annum in or into the EU.⁷ This confirms the conclusions of the Swedish Chemicals Agency in 2017 as reported in the Annex XV report (ECHA, 2017b).

CLP notifications have been made for PFHxS and some PFHxS-related substances, including the potassium and ammonium salts of PFHxS with 23 and 17 notifications, respectively.⁸ As can be seen from Table 7, a number of these are very recent including one for PFHxS itself dated 19 January 2018. This suggests the substances may be available on the market albeit at the lower volumes of <1 tonne per annum per manufacturer or importer that do not require registration under REACH.

⁷ ECHA's database was checked in April 2019.

⁸ By way of comparison, the Dossier Submitter for PFCAs found that there were about two hundred C9-C14 PFCA related substances on the pre-registration list, as well as 132 of the 152 substances that may degrade into C9-PFCA. However, in practice only three substances were registered, with these registrations later deactivated (ECHA, 2017).

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 7: Overview of harmonised classifications, notifications and self-classifications (C&L Inventory 2 April 2019)

Substance	CAS no.	Harmonised classification	Notifications	Self-classification
Perfluorohexane-1-sulphonic acid	355-46-4	-	1 (19.01.2018)	Acute Tox. 4; H302 Acute Tox. 4; H312 Acute Tox. 4; H332 Skin Corr. 1B; H314
Potassium perfluorohexane-1-sulphonate	3871-99-6	-	23 (20.04.2016)	STOT SE 3; H335 Skin Irrit. 2; H315 Eye Irrit. 2; H319
Ammonium perfluorohexane-1-sulphonate	68259-08-5	-	17 (19.10.2010)	-
Tridecafluoro-N-methylhexane-sulphonamide	68259-15-4	-	1 (19.02.2018)	STOT SE 3; H335 Skin Irrit. 2; H315 Eye Irrit. 2; H319
N-ethyltridecafluoro-N-(2-hydroxy-ethyl)hexane-sulphonamide	34455-03-3	-	1 (19.02.2018)	STOT SE 3; H335 Skin Irrit. 2; H315 Eye Irrit. 2; H319
1-Hexanesulfinic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, zinc salt (2:1)	86525-30-6	-	23 (23.01.2014)	Skin Irrit. 2; H315 Eye Irrit. 2; H319
1-Hexane-sulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	41997-13-1	-	1 (16.10.2017)	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335 (Lungs) (Inhalation)
Perfluorohexane-sulphonyl fluoride (the raw material for PFHxS and PFHxS-related substances)	423-50-7	-	1 (27.02.2012)	Skin Corr. 1B; H314

A.2. Uses

A.2.1 Introduction

It is known that, in the past PFHxS was used in a number of applications in the EU and elsewhere.

Figure 9 overleaf provides an overview of the main historic uses and applications of PFHxS, its salts and PFHxS-related substances. The figure also highlights the fact that, in addition to the use of PFHxS and its salts and PFHxS-related substances as raw materials to produce PFAS based products, PFHxS is also unintentionally produced during industry processes and can be present as an impurity (POPs Review Committee, 2017). It is also a known impurity in the production of PFOS.

In terms of levels of historical (pre-2000) uses, 1999 3M data supplied to the PFOS RRS (RPA, 2004) have been screened for PFHxS related substances. The quantities used in different applications prior to 2000 are provided as Table 8. These suggest a total quantity of some 233 tonnes PFHxS for the EU imported divided between uses in apparel and leather (20%), carpets (60%), fabric and upholstery (15%), coatings (0.4%) and -fire-fighting foams (5%).

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 8: Historical data on PFHxS "use" from the consumption of PFOS in mixtures used for the treatment of different product categories in the UK

Mixture used for treatment of	Product name	CAS Number	PFHxS related substance in product content %	Total kgs of product imported to UK 1999	Kg PFHxS imported to UK 1999	Implied Kg PFHxS imported to EU 1999*
Apparel and leather	FC-248	68586-14-1	30.0%	840	252	1 260
	FC-251	68555-90-8	19.0%	1300	247	1 235
	FC-251	68608-14-0	9.0%	1300	117	585
	FC-270	68555-90-8	11.7%	4 300	503	2 516
	FC-270	68608-14-0	6.2%	4 300	267	,333
	FC-3530	68555-92-0	25.0%	3 718	930	4 648
	FC-824	68329-56-6	38.0%	18 330	6 965	34 827
Sub-Total				34 088	9 281	4 403
Carpet	FC-3615	91081-99-1	14.0%	7800	1 092	5 460
	FC-393	68586-14-1	1.5%	14 811	222	1 111
	FC-393	91081-99-1	12.9%	14 811	1 911	9 553
	FC-396	68555-90-8	4.7%	35 150	1 652	8 260
	FC-396	68586-14-1	1.3%	35 150	457	2 285
	FC-396	91081-99-1	8.9%	35 150	3 128	15 642
	FX-3606	68555-90-8	4.8%	7 859	377	1 886
	FX-3606	68586-14-1	2.1%	7 859	165	825
	FX-3606	91081-99-1	16.9%	7 859	1 328	6 641
	FC-3611	91081-99-1	12.0%	139 850	16 782	83 910
	FC-3611	68586-14-1	0.7%	139 850	979	4 895
Sub-Total				446 149	28 094	140 168
Fabric and upholstery	FC-3548	91081-99-1	12.6%	23 065	2 906	14 531
	FC-3862N	68555-92-0	2.1%	19 485	409	2 046
	FX-3568	68555-90-8	14.2%	2 420	344	1 718
	FX-3569	68555-90-8	4.8%	13 020	625	3 125
	FX-3569	68586-14-1	2.1%	13 020	273	1 367
	FX-3569	91081-99-1	16.9%	13 020	2 200	11 002
	FX-3860	68586-14-1	7.9%	1 320	104	521
Sub-Total				85 350	6 862	34 310
Coatings	FC-431	68867-62-9	50.0%	357	179	893
	FC-725	127133-66-8	30.0%	6	2	9
Sub-Total				363	180	902
Fire-fighting foams	FC-600	38850-58-7	2.0%	17 620	352	1 762
	FC-602	38850-58-7	2.0%	12 120	242	1 212
	FC-603EF	38850-58-7	2.6%	19 620	510	2 551
	FC-203	38850-58-7	2.7%	1 360	36	181
	FC-203A	38850-58-7	2.7%	1 600	43	213
	FC-206	38850-58-7	1.3%	79 204	1 053	5 267
	FC-3041G	38850-58-7	1.3%	800	11	53
Sub-Total				132 324	2 248	11 239
Grand Total				698 274	46 664	233 321
* Assuming UK = 20% of the EU						
Source: 1999 data supplied by 3M to the PFOS RRS (RPA, 2004)						

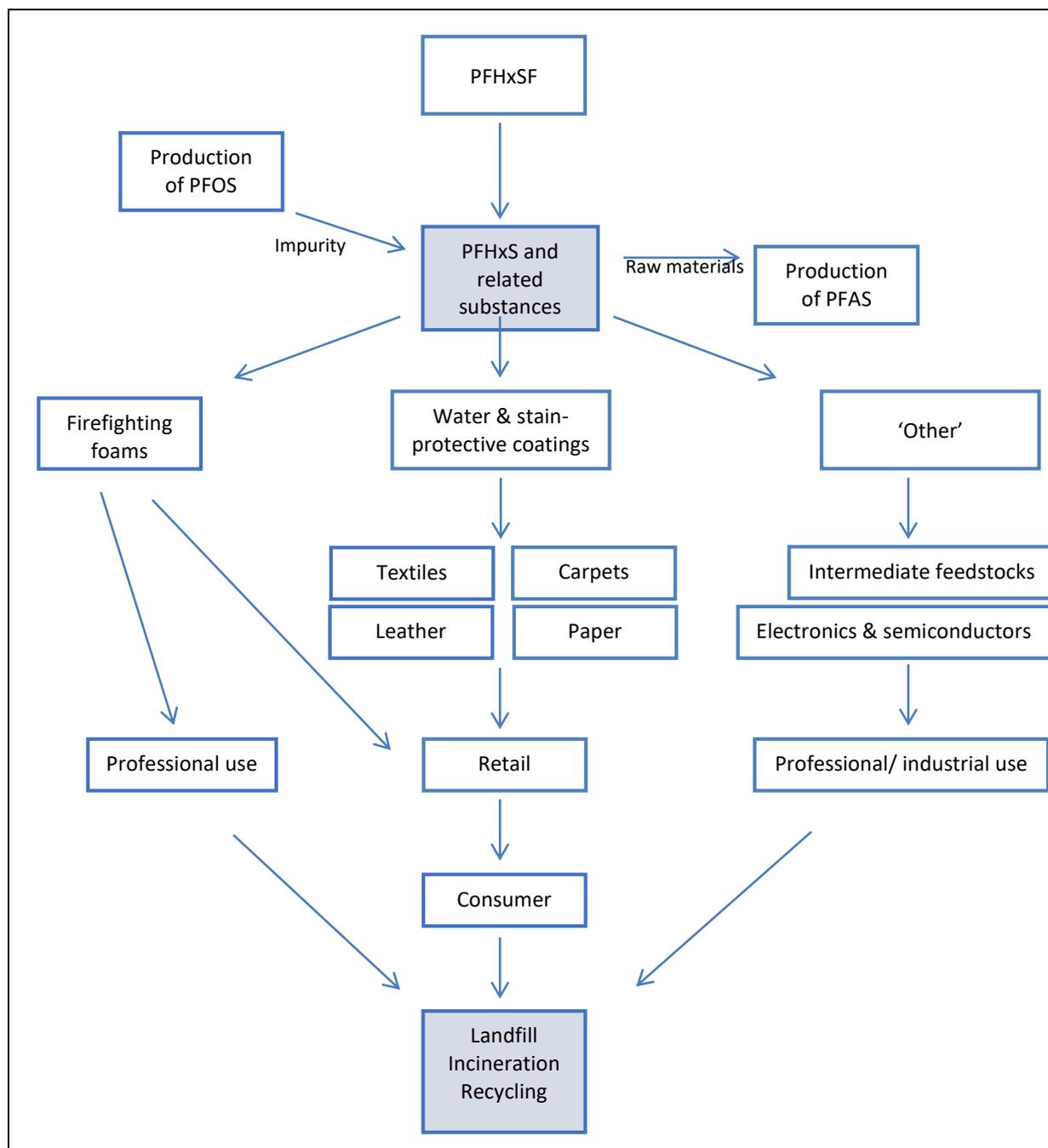


Figure 9: PFHxS, its salts and PFHxS-related substances main uses and applications

According to the BiPRO study (BiPRO, 2018), PHxSF may be used as intermediate feedstock and in different applications: textiles, surfactants and foams, packaging, electronics and semiconductors, industrial fluids, coatings and agrichemicals. The market research reports on which the BiPRO study is based did not define “intermediate feedstock”, but PFHxSF cannot be used directly in any application (BiPRO, 2018, p.19).

BiPRO (2018) also reports that two thirds of the total amount of PFHxS, its salts and PFHxS-related substances are used in fire-fighting foams, around 22% in textile finishing and the remaining 12% in other applications (BiPRO, 2018). Other applications include food contact

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

papers, cleaning and polishing products (as surfactants or surface protection agents), electronic equipment, semiconductors and metal plating (TÜV SÜD, 2017).

According to the updated Environment, Health and Safety Summary for the Massachusetts Toxics Use Reduction Act Science Advisory Board (Massachusetts Toxics Use Reduction Act Science Advisory Board, 2017) dated March 2017, the primary use of PFHxS is as a surfactant to make fluoropolymers and as water and stain protective coatings for carpets, paper and textiles.

Kotthoff et al. (2015) investigated the presence of different classes of PFAS in consumer products and found only traces of PFHxS in paper-based food contact material (found in only 6% of the samples in a maximum concentration of 0.6 µg/kg), in ski wax (found in 35% of the samples at a maximum concentration of 9.3 µg/kg) and leather (found in 96% of the samples with a maximum and median concentration of 10.1 µg/m²).

Similarly, ECHA (2017) outlines the uses of perfluoroalkyl sulfonic acids and perfluorooctanesulfonic acid (PFOS) substances, and notes that PFHxS substances are a known impurity of PFOS and can be used as a substitute chemical in a number of uses.

These and other potential uses of PFHxS have been thoroughly investigated for this Annex XV dossier. After repeated and exhaustive stakeholder consultation as part of the preparation of this dossier (and also the previous BiPRO - 2018 study), no current and intended uses of PFHxS (including its salts and PFHxS-related substances) have been identified in the EU. There is, however, some evidence of import/use of products and articles that may contain PFHxS as an impurity, albeit at relatively low levels. For completeness, the following sections set out evidence from the literature on uses of PFHxS in different applications and findings and conclusions made during preparation of this Annex XV dossier.

A.2.2 Metal plating

The draft POPs risk management evaluation on Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds (UNEP, 2019b) reports the following on the use of PFHxS in hard metal plating:

"82. Metal plating (hard metal plating) only in closed-loop systems is listed as an acceptable purpose for the production and use of PFOS, its salts and PFOSF in Annex B under the Stockholm Convention and some Parties are registered for this derogation. Hard metal plating is used to protect metal components from wear and corrosion. Industrial rollers, hydraulic cylinders and crankshafts are examples of industrial applications of hard chromium electroplating. Through the electroplating process, a thin layer of chromium is deposited on the base metal or metal alloy surface of a workpiece where resistance and hardness are important attributes. In these applications the workpiece is submerged in a chromic acid (hexavalent chromium) bath. Fume suppressants are chemical agents added to the chromium bath to reduce the amount of chromium lost at the surface. Chemical fume (mist) suppressants are surfactants that lower the surface tension of the plating solution and by controlling the surface tension, the process gas bubbles become smaller and rise more slowly than larger bubbles and mist is less likely to be emitted into the air and the droplets fall back into the plating bath.

83. *It is not clear from the publicly available information on PFHxS how extensively the substance is used in metal plating. However, some patents (Dainippon Ink and Chemicals, 1979; Dainippon Ink and Chemicals, 1988; 3M, 1981; Hengxin, 2015) were identified for the use of PFHxS, its salts and various PFHxS-related compounds in metal plating as mist suppressants, suggesting that such use may have occurred (reviewed in (BiPRO, 2018)). It is likely that at least Hubei Hengxin in China has marketed the potassium salt of PFHxS for metal plating and PHxSF as a raw material for electroplating (Hengxin, 2019). It should be noted that the manufacturing (including importing) or processing of one salt of PFHxS (tridecafluorohexanesulfonic acid, compound with 2,2'-iminodiethanol (1:1); CAS No: 70225-16-0) for use as a component of an etchant, including a surfactant or fume suppressant, used in the plating process to produce electronic devices shall not be considered a significant new use subject to reporting under the USEPA Significant New Use Rule on perfluoroalkyl sulfonates and long-chain perfluoroalkyl carboxylate chemical substances (US EPA, 2013). Furthermore, due to unintentional production of PFHxS during the ECF process (Wang, et al., 2017), it is likely that the PFOS-containing mist/fume suppressants used for metal plating contain unintentional amounts of PFHxS, its salts and/or PFHxS-related compounds." (UNEP, 2019b)*

The EU POPs regulation derogates PFOS used as mist suppressant for hard chromium plating in closed loop systems from the general prohibition on PFO. Furthermore, the European Commission recently reported to the POPs secretariat that some EU/EEA countries still uses PFOS in closed-loop systems for hard metal plating (UNEP, 2019a). PFHxS may be an impurity in the PFOS used as mist suppressants for hard chromium plating in closed loop systems.

Subsequent to the cessation in production of PFOS by the major manufacturer, the diethanolammonium salt of PFHxS was reported to be used as a component of etchants for electroplating according to UNEP. Limited data are available to evaluate the degree to which the remaining salts in this group are used for the above listed purposes. Nevertheless, it is noted that use of the three potassium salts in this group was reported in 2012 in Denmark (Australian Government, 2015).

POPRC identified a number of patents that suggested that PFHxS, its salts and various PFHxS-related compounds may have been used in metal plating as mist suppressants (POPs Review Committee, 2018). The report identified that it was likely that at least Hubei Hengxin from China had marketed the potassium salt of PFHxS for metal plating.

Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier (and also the previous BiPRO - 2018 study) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in metal plating in the EU. However, as PFHxS is a known potential impurity in PFOS formulations and use of PFOS *as mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems* is exempted under the POPs Regulation (EU) No 2019/1021 consideration has been given to the levels of PFHxS in continuing (exempted) uses of PFOS. All of these uses are considered together in Annex A.2.10.

A.2.3 Hydraulic fluids for the aviation industry

KEMI (2015) report that PFHxS, its salts and PFHxS-related substances may be used in the EU in quantities below one tonne per year for the manufacture of phosphate ester-based

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

hydraulic fluids for the aviation industry, to prevent fire, corrosion and evaporation. However, due to the low quantities involved, it is not clear which specific PFAS are used (KEMI, 2015).

Hydraulic fluids for aviation is an exempted use of PFOS under POPs Regulation (EU) No 2019/1021. However, the EU (and Norway) has notified the Stockholm Convention secretariat this exemption is no longer required. A suitable amendment to the POPs regulation has yet to be made.

Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier (and also the previous BiPRO - 2018 study) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in this use category in the EU.

A.2.4 Polishing agents and cleaning/washing agents

The POPRC Draft Risk Profile (2017) identifies that one PFHxS-related compound (CAS number 67584-53-6; [N-Ethyl-N-(tridecafluorohexyl) sulfonyl]glycine, potassium salt) was reportedly used in polishing agents and cleaning/washing agents at least between 2000 and 2015 in Denmark, Norway and Sweden with the use volumes claimed as confidential business information. Furthermore, the PFHxS-related compound (CAS No: 67584-61-6, 2-[Methyl[(Tridecafluorohexyl) Sulfonyl]Amino]Ethyl Methacrylate) was reportedly used in impregnation/proofing for protection from damp, fungus, etc. at least in four products between 2003 and 2009 in Denmark (SPIN, 2018). This PFHxS-related compound (CAS No: 67584-61-6, 2-Propenoic acid, 2-methyl-, 2 [methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl ester) was also found registered in the same use category in Norway in 2011.

Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier (and also the previous BiPRO - 2018 study) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in this use category in the EU.

A.2.5 Impregnation/proofing

The POPRC Draft Risk Profile (2017) identifies that one PFHxS-related compound (CAS number 67584-61-6; 2-[Methyl[(Tridecafluorohexyl) Sulphonyl]Amino]Ethyl Methacrylate) was reportedly used in impregnation/proofing for protection from damp, fungus, etc. at least in four products between 2003 and 2009 in Denmark.

Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier (and also the previous BiPRO - 2018 study) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in this use category.

A.2.6 Manufacture of semiconductors

The POPRC Draft Risk Profile (2017) identifies that during the POPRC 13 meeting in 2017, an industry representative noted that PFHxS, its salts and PFHxS-related compounds are currently being used as replacements to PFOS, PFOA and their related compounds in the semiconductor industry. The review committee note that this information is further strengthened by published information that indicates that PFHxS is used in the semiconductor industry in Taiwan (Lin, Panchangam, & Ciou, 2010). PFHxS (133-330 ng/L), together with PFOS (128-670 ng/L), was one of the primary contaminants at a

semiconductor fabrication plant waste water effluent site. Both PFOS and PFHxS were found present in the effluent in similar amounts showing that PFHxS is a primary substance in this process and not unintentionally present. Lin et al (2009) found that, while PFOS was the major constituent in semiconductor wastewaters (up to 0.13 mg/L) the amount of final waste effluents of PFHxS from semiconductor manufacturing process was estimated to be >0.68 kg. In a more recent article (Cui, et al., 2018) the riverine flux of PFHxS to lake Baiyangdian was estimated at 37.35 kg/y.

Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier (and also the previous BiPRO - 2018 study) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in this use category in the EU. It remains possible that small quantities of PFHxS may be imported in articles comprised of or made with semiconductors produced using preparations containing PFHxS.

As PFHxS is a known potential impurity in PFOS formulations and uses of PFOS for *photoresists or anti-reflective coatings for photolithography processes (used in semiconductor manufacturing) as well as photographic coatings applied to films, papers or printing plates* are exempted under the POPs Regulation (EU) No 2019/1021, consideration has been given to the levels of PFHxS in continuing (exempted) uses of PFOS. All of these uses are considered together in Annex A.2.10.

A.2.7 Flame retardant

The POPRC Draft Risk Profile (2017) identifies that the potassium salt of PFHxS and PFHxS-related compounds (CAS No. 68259-15-4; tridecafluoro-N-methylhexanesulphonamide) has been marketed for potential uses as a flame retardant and in pesticides by Hubei Hengxin (China).

Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier (and also the previous BiPRO - 2018 study) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) for these purposes in the EU. The only consultation response received was from Dainippon Ink and Chemicals Inc. (Japan) (See Annex G). This company claimed that they did not directly use any of the target substances, but PFHxS may be present as an unintentional impurity in some of their final products. The company also manufactures less than 7 tonnes of flame retardants for polycarbonate every year, with an average content of PFHxS of 0.1% or less. They have no emissions to water or air, and the solid waste that leaves the plant is subsequently incinerated. They claim that there are no alternatives, and their response to a restriction under the Stockholm Convention would be to cease production of the materials as there are no technically feasible alternatives that would not also have PFHxS present as an impurity.

A.2.8 Textiles, carpets, leather and upholstery

As is identified in Table 8, 3M produced a variety of products containing PFHxS for use as waterproofing and dirt/stain proofing treatments for carpets, upholstery, textile and leather applications. 3M ceased production of PFHxS and related compounds by the end of 2002 (3M, 2000).

In a report from SFT (Norwegian Pollution Control Authority, 2006) analysis of results from different textiles are presented. PFHxS was found in close to 30% of the tested items.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

In 2009 SFT and NILU (Norway) screened possible PFAS sources in Norway⁹ in 30 products with household uses and industrial manufacturing uses (Herzke, et al., 2012). None of the tested waterproofing agents contained PFHxS. PFHxS was detected in two of the analysed wet room sealing paints, four non-stick products, one carpet (probably due to Teflon treatment), a pair of leather shoes and an electronic toy.

Norin and Schulze (2007) investigated the PFAS content in impregnation products for textiles (weather clothing and shoes). There was limited information about content of fluorinated substances on the products or in the safety data sheets received from the distributors but 46% (6 of 13 tested products) contained PFHxS as well as PFOS.

Greenpeace Research Laboratories have conducted several studies analysing perfluorinated substances in different types of clothing articles and outdoor gear over a number of years. In 2013 the presence of PFASs were analysed in ten samples taken from seven articles of outdoor clothing articles for children (as well as shoes and swimwear articles) (Greenpeace, 2013). The results are summarised in Table 9.

PFCs were detected in nine of the ten waterproof clothing samples. In five of the samples PFHxS was detected at levels of 20-2260 µg/kg (an average 520.7 µg/kg across all samples containing PFHxS). Where country of manufacture was known (8 out of 10), all of the products containing PFHxS were manufactured in China. Averaged across all samples (including those without PFHxS) the PFHxS content was 260.4 µg/kg. The data also show that PFOA was present in three of the waterproof clothing samples, notably samples for which PFHxS was not present¹⁰.

⁹ Products from both Norway and Sweden were included in the study.

¹⁰ PFOA was, however, also present in three of the six swimwear article samples.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 9: Presence of PFAS and PFHxS in ten samples taken from seven articles of outdoor clothing articles for children (Greenpeace, 2013)

Type of product	Country of Manufacture	Total PFCs (micro g/kg)	PFHxS (micro g/kg)	PFHxS as % of total PFC %	PFCs present	PFOA as % of total PERF (%)
coat	China	2.18	0	0%	PFBA	
coat	China	10.2	0	0%	PFHxA, PFOA, PFNA, PFDA	64%
jacket	Unknown	7.40	0	0%	PFBA, PFHxA, PFOA	8%
coat	China	32.7	20.0	61%	PFHxS, PFBA, PFPA, PFHxA	
coat	China	314	300.0	96%	PFHxS, PFBS, PFHpS, PFOS, PFBA, PFPA, PFHxA	
trouser	China	2290	2260.0	99%	PFHxS, PFBS, PFBA, PFHxA	
trousers	China	26.4	21.3	81%	PFHxS, PFHxA	
coat	Bangladesh	29.7	0	0%	PFBA, PFOA, PFDA	25%
coat	Unknown	2.43	2.4	100%	PFHxS	
jacket	Vietnam	0	0	0%		

A more recent study from NORAP (Nordic Risk Assessment Group, 2014) analysed 29 different consumer products including impregnated textiles (and also articles such as kitchenware and dental floss) but did not detect any PFHxS.

Greenpeace Laboratories undertook a further study on Per- and poly-fluorinated chemicals in outdoor gear (including waterproof clothing) in 2016 (Greenpeace, 2016). The results are summarised in Table 10 and show that across the multiple articles and samples tested found PFHxS in only one item (a jacket manufactured in Vietnam). PFOA, however, was detected in most of the items (most of which were manufactured in China but also Vietnam and Bangladesh). This is of relevance because limit values on PFOA will soon apply to such articles and are likely to promote a switch to alternatives, of which PFHxS is, technically, one.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 10: Summary of data on detection of PFHxS and PFOA in outdoor gear in Greenpeace (2016)

		Total number in sample	PFHxS (ng/kg)	PFOA (ng/kg)	% PFOA	
Appendix 1. Concentrations of PFCs in all articles tested						
Jackets	Number of items identified	13	1	9	69%	items
	Average Conc. (ng/kg)	-	897	1 696	9%	of total PFC content
Trousers	Number of items identified	9	-	6	67%	items
	Average Conc. (ng/kg)	-	-	44 123	31%	of total PFC content
Footwear	Number of items identified	13	-	9	69%	items
	Average Conc. (ng/kg)	-	-	4 130	29%	of total PFC content
Backpacks	Number of items identified	14	-	11	79%	items
	Average Conc. (ng/kg)	-	-	3 474	75%	of total PFC content
sleeping bag	Number of items identified	3	-	2	67%	items
	Average Conc. (ng/kg)	-	-	82 335	51%	of total PFC content
Tent	Number of items identified	4	-	3	75%	items
	Average Conc. (ng/kg)	-	-	4 486	64%	of total PFC content
Appendix 3. Analysis of material from 3 articles in duplicate						
trouser	Number of items identified	2	-	2	100%	items
	Average Conc. (ng/kg)	-	-	132 000	34%	of total PFC content
backpack	Number of items identified	2	-	2	100%	items
	Average Conc. (ng/kg)	-	-	15 800	50%	of total PFC content
Sleeping bag	Number of items identified	2	-	2	100%	items
	Average Conc. (ng/kg)	-	-	157 000	59%	of total PFC content

Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier (and also the previous BiPRO - 2018 study) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in the manufacture of textiles and textile articles in the EU.

However, data from the various studies that have analysed PFCs in textile articles (particularly waterproof clothing and outdoor gear) suggest that PFHxS has been (and is) used in these applications and perhaps particularly in China (but also Vietnam and Bangladesh). As such, quantities of PFHxS will be imported on finished textile articles and, potentially, other articles for which PFOS was previously used as a waterproofing/stain resistant textile treatment (which might include leather and carpets)

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

and for which PFOA is also, at present used. For example, a Norwegian screening report found high amounts of PFHxS in dust at a storage for new furniture and in dust from a hotel (Norwegian Environment Agency, 2017).

It is reported that water-proofing textile finishes based on PFHxS-based compounds have recently been developed by at least Hubei Hengxin Chemical Co., Ltd. (CAS numbers. 68259-15-4 (tridecafluoro-N-methylhexanesulphonamide), 68555-75-9 (tridecafluoro-N-(2-hydroxyethyl)-N-methylhexanesulphonamide), and 67584-57-0 (2-[methyl[(tridecafluorohexyl)sulphonyl]amino]ethyl acrylate)) and Wuhan Fengfan Surface Engineering Co., Ltd. from China (Huang et al, 2015; Hengxin, 2018), as alternatives to PFOS-based compounds (Huang et al, 2015). The industrial activities with C-6 waterproofing agent for textiles in the Taihu Lake region in China might be a potential source of PFHxS where recent production and use of PFHxS-related substances as alternatives to PFOS and PFOA-related substances has been reported (Ma et al, 2018). In 2010, it was estimated that the production of surface treatment products containing PFHxS- or perfluorobutane sulfonic acid (PFBS)-related compounds in China would reach 1000 tonnes per year in the next 5–10 years (Huang et al, 2010) no recent update of this estimate is currently available.

These data suggest, then, that imports of textile articles (including waterproof clothing, outdoor gear and potentially also carpets and leather) to the EU may result in the import of quantities of PFHxS. According to the Greenpeace monitoring data, the most likely countries of origin for such imports are China, Vietnam and Bangladesh.

Import data specific to all the articles in question is difficult to obtain. However, UN COMTRADE data are available for the commodity of 'overcoats, car coats, capes, cloaks, anoraks, incl. ski jackets, windcheaters' (Commodity numbers 6201 and 6202) (UN COMTRADE). These data suggest that, in 2013 some 252,042t of articles were imported into the EU from China, Vietnam and Bangladesh. As identified above, the 2013 Greenpeace study (Greenpeace, 2013) suggests an average PFHxS content of 260.4 µg/kg across all samples (i.e. including those without PFHxS). Applying this to the total quantity imported suggests that around 66 kg of PFHxS may have been imported into the EU from these articles alone in 2013.

The more recent Greenpeace study (Greenpeace, 2016) identified only one jacket out of 13 containing PFHxS (at 0.897 µg/kg). These data would suggest no or negligible import of PFHxS at present. The same data, however, suggest significant use of PFOA across a number of article types for which PFHxS is known to have been used in the past. Thus, it is possible that, once the limit value on PFOA comes into effect, a switch to alternatives such as PFHxS might act to increase level of import of PFHxS in articles in the future.

A.2.9 Fire-fighting foams

Fluorinated surfactants are used in fire-fighting foams as they are very effective for extinguishing liquid fuel fires at airports, oil refineries etc. While water is vital and effective in extinguishing a majority of fires, when fighting fires involving flammable liquids (Class B) water tends to sink below the burning fuel and, thus, has little effect in extinguishing the fire and in some cases results in the flammable liquid spilling out of its contained area. With the properties of being extremely thermally stable and extremely repellent of both oil and water, Aqueous Film Forming foams (AFFF) based on per- and polyfluoroalkyl substances

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

(PFAS – which include PFOS, PFOA and PFHxS amongst others) were developed in the 1960s to address the issues for fighting Class B fires.

The use of PFOS in AFFF was first restricted under REACH and, once included in Annex B of the Stockholm Convention in 2009, the restriction was transferred to Regulation 757/2010 which is now replaced by Regulation (EU) No 2019/1021. Regulation 757/2010 sets out specific exemptions on the use of PFOS which, in the case of fire-fighting foams, meant that, in EU, fire-fighting foams that were placed on the EU market before 27 December 2006 could be used until 27 June 2011. The restriction resulted in a shift away from PFOS based AFFF towards alternatives that were also, largely, based on PFASs.

In terms of PFHxS itself, this has also been used as the active ingredient in AFFF. The 1999 3M data supplied to the PFOS RRS (RPA, 2004) (presented in Table 8.) suggests that, prior to the restriction on PFOS, some 132 324 tonnes of AFFF containing PFHxS (at 1-2.6%) were imported into the UK in 1999. This is equivalent to around 11.2t of PFHxS at an EU scale¹¹.

Information from the stakeholder consultation and literature review suggests whilst, in the past, there were foams for which PFHxS was the (main) active fluoro ingredient these foams are no longer manufactured (or imported) into the EU. In response to the stakeholder consultation (see Annex G), the German Mineralölwirtschaftsverband informed that PFHxS may be present in old fire-fighting foams. However, for AFFF produced currently (in the EU) the AFFF industry has indicated that PFHxS and PFHxS-related substances are not present as impurities in modern AFFF because the synthesis route is now by telomerisation rather than the electrochemical fluorination methods which may give rise to PFHxS and other substance impurities during the manufacturing process.

Whilst the AFFFs currently on the EU market do not contain PFHxS, the lifespan of fire-fighting foams has been variously reported as 10-20 years (British Fire Protection Association in the PFOS RRS (RPA, 2004)) and 10-25 years¹². As such, some of the older legacy foams that do contain PFHxS as an impurity are likely to still be in the AFFF stockpiles maintained at various types of installation (such as refineries, tank farms, chemical works, etc.) for the fighting of major fires.

Large stockpiles must be maintained in readiness at key sites such as refineries, petrochemical sites or fuel storage plants (tank farms), oil and gas facilities offshore to deal with the unlikely (but potentially catastrophic) possibility of a fire.

Owing to the stockpiling of foams for such emergency uses, the current market (or volume sold annually) of different types of foam very poorly describes the actual use or consumption of different types of foam that may contain PFHxS. Stockpiles will contain

¹¹ Assuming the UK market = 20% of the EU.

¹² [Comment no. 1225 to the PFOA restriction](#) proposal (ECHA, 2014) says "By far the largest part of the fire-fighting foams are stored for 10-25 years"

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

foams that are up to 15, 20 or even 25 years old and these will need to be replenished owing to:

- Consumption as a result of an actual fire-fighting operation, training, system testing, accidental discharge or leakage; or
- Disposal of (older) foams that have reached the end of their shelf-life.

Thus, foams that are actually 'used' or 'consumed' in any given year are more likely to be of an older variety than a newer one (and, in the case of disposal, all will be old). In other words, the new foams purchased to replenish a depleted stockpile in any given year are not necessarily the same foams that are 'used' or 'consumed' in that same (or following) year.

Fire-fighting foam stockpiles

In terms of the size of the stockpiles in the EU, since the risk reduction strategy (RRS) on PFOS was completed in 2004 for the UK competent authority (RPA, 2004), no assessment has been made on the size of the EU stockpiles of Class B fire-fighting foams or the markets (see for example the restriction dossiers on PFOA and the recent dossier on PFCAs).

As part of the 2004 PFOS study, an extensive survey of all Fire Authorities in the UK and other users was undertaken. This suggested that the total stock quantity of all Class B foam concentrates (i.e. PFOS and non-PFOS) in the UK was some 3945 tonnes with an estimated 2959 tonnes being stored at industrial complexes and 986 tonnes being stored by Fire Authorities (see Table 11). A crude aggregation to the EU was made at the time (RPA, 2004) but, since then, a number of Member States have acceded to the EU.

Table 11: Estimates of quantities and use of Firefighting foams in the UK (RPA, 2004)

	All foam concentrates (Litres)
Estimated quantities in Fire Authority inventories	986 350
Estimated emergency stores at industrial complexes	2 959 040
Total	3 945 390
Source RPA, 2004	

As it is unlikely that this total has changed significantly over time, the UK data has been used to generate a new estimate of the total EU stockpile of Class B foams. As the data suggest that the majority (~75%) of the stockpiles are stored at industrial sites, the aggregation has been made on the basis of the numbers of Seveso sites in the UK versus the EU. The results of this aggregation are provided in Table 12 and suggest an estimated 35 491 tonnes of total Class B fire-fighting foam concentrates being stored at Seveso sites across the EU.

Table 12: Estimated current Germany and EU stockpile of Class B foams based on UK data

	Number of Upper Tier Seveso Sites	Number of Lower Tier Seveso Sites	Estimated quantity of Class B fire-fighting foam concentrates (tonnes)
UK	353	532	3 945
Germany	1 194	2 389	15 973
EU	5 080	6 767	35 491

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

As can be seen from the table, the same aggregation approach has been applied to develop an estimate for Germany based on the UK data. This allows comparison of the estimate based on the UK data with a different estimate made possible by data on stockpiles at German refineries provided by Mineralölwirtschaftsverband which identified that in Germany:

- there are 12 oil refineries with 100 - 400 tonnes capacity of fire-fighting foam each;
- there are about 100 tank farms in Germany which store also fire-fighting foams. The amount of foam varies from 50-280 tonnes in each tank farm; and
- Chemical plants also use AFFF for large scale fires with 100 tonnes and more in each chemical plant.

Based on the data provided on tank farms and refineries by Mineralölwirtschaftsverband, these values suggest a total of between 16 200 and 47 800 tonnes of foam concentrate in Germany with 32 000 tonnes being the central value. This estimate based on the Mineralölwirtschaftsverband estimates of the quantity of foam concentrate at each type of site have also been applied to data on the numbers of relevant types of Upper and lower tier Seveso sites in Germany. The relevant sites in the Commission's eSPIRS database would appear to be 'fuel storage', 'general chemicals manufacture' and 'petrochemical/oil refineries'. However, the Commission's eSPIRS database does not appear to be complete at this point in time. For example, there is no data breaking down Seveso sites by type for the UK (hence why the earlier aggregation used the total number of sites and why a UK estimate from the figures has not been provided) and the database records no sites in Germany for 'general chemicals manufacture'.

Table 13 provides a series of estimates of the total stockpile of fire-fighting foam concentrates in Germany and the EU using the data provided to the consultation by Mineralölwirtschaftsverband. These differ by the method used to derive the estimate as follows:

- A: Multiplying number of relevant upper tier sites by higher capacity value and lower tier sites by lower capacity values given by Mineralölwirtschaftsverband
- B: Multiplying number of relevant upper tier sites by upper capacity values given by Mineralölwirtschaftsverband
- C: Multiplying number of relevant upper tier sites by average of capacity values

Estimates for the EU also differ by whether or not data on total numbers of sites identified as 'general chemicals manufacture' are or are not included in the estimate.

Both of the methods A and B produce estimates from Seveso data for Germany which, at 31 970t and 27 320t, are close to the middle value estimate of 32 000t derived directly from the information provided by Mineralölwirtschaftsverband. The matching estimates for the EU are 173 980t and 152 880t. However, none of these estimates (including those made on data supplied by Mineralölwirtschaftsverband) include stocks held at chemical sites. As noted above, Mineralölwirtschaftsverband identified that chemical plants maintain stocks of 100 tonnes and more in each chemical plant. Including Seveso sites that are identified as 'general chemicals manufacture' increases the EU estimates to 225 230t and 183 630t respectively for methods A and B.

The third method (C) produces much lower estimates for Germany of 16 385t, which is similar to the estimate of 15 973t generated by aggregating the UK data to Germany (see

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 12). However, the matching estimates for the EU (91 790t to 117 415t) are much higher than the estimate of 35 491t estimated by aggregating the UK data.

As can be seen from Table 13, all estimates produced by applying the German Mineralölwirtschaftsverband data on stock capacities at different types of site to Seveso data on numbers of sites for the EU (in Table 12) are significantly higher than the 35 491t estimated by aggregating the UK data from RPA (2004) to the EU. This suggests that either:

- the estimate of 35 491t of foam concentrate based on the UK aggregation from RPA (2004) underestimates the total stock for the EU; or
- the estimations (91 790t to 225 230t) based on Mineralölwirtschaftsverband data submitted to the stakeholder consultation overestimates the total stock for the EU; or
- a combination of both.

Table 13: Estimated EU stockpile of Class B foams based on German data provided by Mineralölwirtschaftsverband to the stakeholder consultation in 2017

Estimation and method	Tonnes of Foam Concentrate		
	Germany (Based on fuel storage sites and petrochemical/oil refineries)	EU (Based on fuel storage sites and petrochemical/oil refineries)	EU (Based on fuel storage sites, petrochemical/oil refineries and general chemicals manufacture)
A: Multiplying number of relevant upper tier sites by higher capacity value and lower tier sites by lower capacity values given by Mineralölwirtschaftsverband	31 970	173 980	225 230
B: Multiplying number of relevant upper tier sites by upper capacity values	27 320	152 880	183 630
C: Multiplying number of relevant upper tier sites by average of capacity values	16 385	91 790	117 415

In order to determine which of the above is most likely, US data submitted to the Stockholm Convention has been reviewed. The US appears to be the only signatory to have undertaken a thorough inventory of all Class B foams in 2004 and provided updated estimates of the amount that contains PFOS. The US submission (compiled by the US Fire-fighting Foam Coalition - FFFC by surveys and representative sampling of all types of installation stockpiling foams in the US including the Military (FFFC, 2011)) provides the estimates of total fire-fighting foam concentrates which, when converted from US gallons, provide the values given in Table 14. As can be seen from the table, the US documentation (FFFC, 2011) suggests a total of 37,661t foam concentrate at all facilities and for all uses. As it is unlikely that the EU has a stockpile of foam that is 2.5 to 5 times that of all of the US facilities (including the military) combined, it is concluded that the estimates produced

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

using the German Mineralölwirtschaftsverband data provided to the consultation are likely to overestimate the total EU stockpile.

Accordingly, for the rest of the calculations in this report, it is estimated that the EU's total stockpile of Class B fire-fighting foam is around 35,500t based on the aggregation of the UK data to the EU.

Table 14: Total foam concentrates stockpiled in the US (FFFC, 2011)

Type of facility	Class B foam concentrates (t)
US military	10 737
Other Federal	164
Aviation (AREF)	2 760
Aviation (hangars)	3 218
Fire depts (non-aviation)	5 148
Oil refineries	7 192
Other petrochemicals	7 571
Merchant ships/offshore rigs	303
Misc applications	568
Total	37 661t

A.2.9.1 Fluorine-containing versus fluorine-free stocks

Some of the foam concentrates in the EU's estimated 35 500t stockpile of AFFF will be PFAS- based foams (comprising those that have been produced in a way that leads to PFHxS being present as an impurity and those where PFHxS is not present) and some will be fluorine-free (F3) foams.

In terms of the split between F3 and PFAS based foams, available data suggest that, even in today's marketplace, fluorine free (F3) Class B fire-fighting foams have a relatively small share of the market. Consultation with a major F3 producer (see Annex G) suggests that, while the F3 market may be around 60-70% of the market in Australia owing to increasing regulation and phasing out of PFAS, it is only around 20% in New Zealand where this strong regulation is not in force (as previously noted). Information has been requested on the EU market as part of consultation for preparation of this dossier, but this has not been forthcoming. On the basis that the regulatory context in the EU is more similar to New Zealand than to Australia, the current EU market is likely to be around 20% F3 (and therefore 80% PFAS).

In contrast to this, when the PFOS work was undertaken in 2004 for the UK Competent Authorities (RPA, 2004), the market for F3 foams was known to be in its infancy. Thus, it is assumed that the market for F3 foams has grown from an estimated 1% of annual sales in 2004 to around 20% at present.

As noted earlier, sales for fire-fighting foam concentrates replenish stocks of foam that are depleted by:

- Consumption as a result of an actual fire-fighting operation, training, system testing, accidental discharge or leakage; or

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

- Disposal of (older) foams that have reached the end of their shelf-life.

In the updates of foam inventories submitted to Stockholm by the US (FFFC, 2011), the consumption rate in the US is estimated to range from 6 to 10% per year and the mid-point of that range, 8%, is used in calculations.

Applying this value implies that, every year, 8% of the total stock is replenished owing to use or to stocks reaching their shelf-life. 8% would imply an average 'life-time' of foam in the stockpile of 12.5 years, which is consistent with the fact that foam concentrates are known to have a 'shelf life' of 15 to 20 years and taking into account the fact that some of the 8% will have been used on actual fires, system testing or training (and so may not have reached the end of life).

8% also implies that the market (sales) of foam concentrates are equivalent to 8% of the total stock quantity. From the above, if the market for fluorine free foams was 1% in 2004 then 1% of the 8% (0.08%) of the stock replenished in 2004 was F3 foam. Moving on through time, if the market for F3 had grown to 2% by 2005 then 2% of the 8% for that year (0.16%) would be fluorine-free such that, by the end of 2005, total stocks of F3 foam would represent 0.24% of the total stockpile (0.08% + 0.16%). This process can be continued through every year since 2004 to develop the predicted split between F3 foams and PFAS based foams in the EU stockpile. This projection is provided as Table 15 where it should be noted that the cumulative total is adjusted from 2015 onwards to account for foams purchased 12 years earlier going out of date. It should also be noted that this will not account for the early disposal of any remaining PFOS based AFFF before the end of the function shelf-life in 2011 (when use of PFOS based foams was no longer permitted).

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 15: Calculated split between F3 and PFAS based foams in stockpile

Year	Market share of F3 foam (%)	Market share of F3 foam as a percentage of the 8% of stock foam replenished (%)	Cumulative total F3 foam in stockpile (%)	Total PFAS based foam in stockpile (%)
2004	1%	0.08%	0.08%	99.9%
2005	2%	0.16%	0.24%	99.8%
2006	3%	0.24%	0.48%	99.5%
2007	4%	0.32%	0.80%	99.2%
2008	5%	0.40%	1.20%	98.8%
2009	6%	0.48%	1.68%	98.3%
2010	8%	0.64%	2.32%	97.7%
2011	10%	0.80%	3.12%	96.9%
2012	12%	0.96%	4.08%	95.9%
2013	14%	1.12%	5.20%	94.8%
2014	16%	1.28%	6.48%	93.5%
2015	18%	1.44%	7.84%	92.2%
2016	20%	1.60%	9.28%	90.7%
2017	20%	1.60%	10.64%	89.4%
2018	20%	1.60%	11.92%	88.1%

These data suggest that the current stockpile of Class B fire-fighting foam concentrates is around 88% PFAS based and 12% F3 foam. Applying this to the 35,500t estimate of the size of the EU stockpile suggests that PFAS based foams make up some 31,240t of the total EU stockpile of foam concentrates.

Fluorinated compounds make up 1-6% of the concentrate but 3% is often reported (for example (FFFC, 2011), (RPA, 2004) and others). Applying this 3% content to the total amount of PFAS based foam concentrate (31 240t) suggests a total of 937.2t of PFAS in the EU stockpile of foams. As is described above, estimates have been based on 8% of the stock being use/replenished per year. As such this implies annual use/replenishment of 2 499t of PFAS based foam containing 75t of PFAS itself. The calculations are summarised in Table 15.

Although derived through a completely different method, the above estimate is consistent with the 50-100 tonnes per annum estimate of annual use of fluorinated surfactants applied in the PFOA Annex XV report.

Table 16: Estimates of annual replacement of PFAS foam stockpiles

Endpoint	Value	Unit
EU stockpile of Class B foam concentrates (t)	35 500	t
Percentage of the stockpile that is PFAS based (%)	88%	%
PFAS content of PFAS based foams (%)	3%	%
Annual use/consumption/depletion of stock (%)	8%	%
Total EU stockpile of PFAS based foam concentrates (t)	31 240	t
Annual use/consumption/depletion of PFAS based foam (t)	2 499	t
Total PFAS content of EE stockpile (t)	937.2	t
Total annual 'use'/disposal of PFAS in stockpile (t)	75.0	t

A.2.9.2 Estimated quantity of PFHxS present as an impurity in the stockpile of foams

From the above it is estimated that the EU AFFF stockpile consists of some 31 240t of PFAS based foams at present. Some of these PFAS based foams may contain PFHxS present as an impurity and some will have been produced using synthesis by telomerisation and will not (because synthesis via this route does not give rise to PFHxS or PFHxS related substances). There are no data on the percentage split between PFAS based foams that contain PFHxS as an impurity and those that do not. In order to derive estimates of the quantities involved, three scenarios have been applied to provide a spread of possibilities:

- Scenario 1: 50% of the PFAS based foams stockpiled contain PFHxS impurities;
- Scenario 2: 70% of the PFAS based foams stockpiled contain PFHxS impurities; and
- Scenario 3: 100% of the PFAS based foams stockpiled contain PFHxS impurities.

Applying these percentages to the total estimated 31 240t of PFAS based foams suggests the following amounts of AFFF containing PFHxS:

- Scenario 1: 15 620t of foam containing PFHxS in the EU stockpile of which 1250t is used/disposed of and replenished each year;
- Scenario 2: 21 868 of foam containing PFHxS in the EU stockpile of which 1749t is used/disposed of and replenished each year;
- Scenario 3: 31 240 of foam containing PFHxS in the EU stockpile of which 2499t is used/disposed of and replenished each year.

In terms of the quantities of PFHxS present as an impurity in these foams, in its response to the stakeholder consultation (Annex G) the German Mineralölwirtschaftsverband provided data on the measured content of substances including PFHxS in a selection of legacy fire-fighting foams that are part of the stockpiles of fire-fighting foams maintained at refineries and tank farms in Germany. These data suggest a range of between 31 and 98 µg/kg (ppb) of PFHxS and an average of 59 µg/kg (ppb) PFHxS in foam concentrates. See Annex G.1.4 for details.

A report providing the results of chemical analyses of fire-fighting foams on the Swedish market in 2014 published by (Kemi, 2015b) also provides data on concentration of PFHxS in older AFFF concentrates. Most of the tested foams were found to have PFHxS-concentrations of less than 1 µg/kg (ppb), but three foams had concentrations above this.

Two had concentrations ranging from 52 to 74, which is consistent with the above estimate based on the response from the German Mineralölwirtschaftsverband. The third had concentrations of 12 126 µg/kg (ppb) but also had high levels of PFOS, PFOSA and PFBuS. As this latter foam was PFOS based its use would have not been allowed after 27 June 2011 according to Regulation 757/2010, no such foams would (or should) be in any stockpiles in the EU.

Applying the measured values of between 31 and 98 µg/kg (ppb) of PFHxS and an average of 59 µg/kg (ppb) PFHxS in foam concentrates to the estimates of PFAS foam that may contain PFHxS impurities provides estimates of both the total quantity of PFHxS in the EU stockpile and the amount used/disposed and replenished per year. These are provided in Table 17. As can be seen from the table, owing to the very low levels of PFHxS present as an impurity (for example, 59 µg/kg or 59 parts per billion as an average), the estimated quantity of PFHxS 'used' is low, with estimates ranging between 39g and 245g across the whole of the EU per year.

Table 17: Estimated total quantity of PFHxS in the EU stockpile of foams

		Scenario 1: 50% of PFAS foams contain PFHxS as an impurity	Scenario 2: 70% of PFAS foams contain PFHxS as an impurity	Scenario 3: 100% of PFAS foams contain PFHxS as an impurity
% of PFAS foams containing PFHxS		50%	70%	100%
Total EU Stockpile of foams				
Total stock quantity of PFAS foam containing PFHxS (t)		15 620	21 868	31 240
Total PFHxS (g)	PFHxS content min	484	678	968
	PFHxS content max	1 531	2 143	3 062
	PFHxS content average	922	1 290	1 843
Annual 'use'/disposal from stockpile				
Annual use/consumption/depletion of foam containing PFHxS		1 250	1 749	2 499
PFHxS in foam used per year (g)	PFHxS content min	39	54	77
	PFHxS content max	122	171	245
	PFHxS content average	74	103	147

A.2.10 PFHxS in continuing uses of PFOS

ECHA (2017b) notes that PFHxS substances are a known impurity of PFOS. Whilst production and use of PFOS and PFOS-related substances was restricted by the inclusion of PFOS on Annex B of the Stockholm Convention in 2009, there are a number of acceptable purposes and specific exemptions of PFOS and related substances listed in the Annex. In the EU, Regulation (EU) No 2019/1021 (EU, 2019) sets out specific exemptions on the intermediate use of PFOS, together with other specifications. The Regulation identifies that PFOS can continue to be used at the thresholds set in the REACH Regulation (EC) 1907/2006) with these limiting use to a level corresponding to an unintentional trace contaminant. These thresholds correspond to 0,001% by weight in substances or preparations and 0,1% by weight for textiles and other coating materials if the amount of PFOS is lower than 1 microgram/m² of coated material. Uses exempted under Regulation (EU) 2019/1021 and which may still take place within the EU are defined as follows:

“3. Use of articles already in use in the Union before 25 August 2010 containing PFOS shall be allowed

4. If the quantity released into the environment is minimised, manufacturing and placing on the market is allowed for the following specific uses provided that Member States report to the Commission every four years on progress made to eliminate PFOS:

mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems. (...).”

The Stockholm Secretariat publishes information provided in the reports submitted by parties pursuant to Article 15 of the Stockholm Convention including information on quantities of PFOS used (UNEP, 2015). Data from that report indicates that only 50 kg of PFOS use is reported for the EU in 2014¹³.

A.2.11 Conclusions

In spite of repeated and exhaustive stakeholder consultation as part of this study and also the previous BiPRO (2018) study, no current uses of PFHxS (including its salts and PFHxS-related substances) have been identified in the EU other than the following:

- Fire-fighting foams: older fire-fighting foams (AFFF) containing PFAS produced using the electrochemical fluorination (ECF) manufacturing process. The stakeholder consultation has confirmed that PFAS based AFFF are now based on C6 telomer technologies which do not contain PFHxS as an impurity;
- Textiles, carpet, leather and upholstery: imported finished textile articles such as overcoats, capes, cloaks, anoraks, windcheaters, outdoor gear and, potentially, other articles for which PFOS was previously used as a waterproofing/stain resistant textile treatment (which might include leather and carpets); and
- Import of PFOS and continuing (exempted) uses as mist suppressants for non-decorative hard chromium (VI) plating.

Submissions from EU Member States to the Stockholm Convention suggest 50 kg of PFOS total use per year (equivalent to only 2 to 7 kg PFHxS, its salts and PFHxS-related substances, assuming that this PFOS contains such impurities

Uses and available data on these uses are summarised in Table 18 overleaf.

¹³ Note that not all parties provide quantitative data and instead report ‘minimal’ or similar wording.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 18: Summary of information on Manufacture, Import and Use

Category	Scale	Time	Quantity (PFHxS)	Notes
Manufacture and import of PFHxS	World	1999	227 000 kg pa	(BiPRO, 2018)
	EU	1999	235 000 kg pa	3M data used in PFOS RRS (RPA, 2004)
	EU	2014	None	Miteni, which was the major manufacturer of fluorinated substances in the EU) identified that it stopped manufacturing PFHxS in 2013 and that production of PFC decreased in the period 2011 – 2013 from 778 tonnes to 383 tonnes (Regione del Veneto, 2014).
	World	2012	700-750 kg pa	(BiPRO, 2018)
	World	2017	<700 kg pa	(BiPRO, 2018)
	EU	2018	Zero production	On 26 October 2018, Miteni’s management decided to declare bankruptcy and to suspend production activities by the end of the year. This was announced on 31 October 2018 (EMCC, 2018)
Net import in PFOS containing PFHxS impurities for uses exempted under Regulation (EU) 757/2010	EU	2014	50 kg (PFOS) (equivalent to 2 - 7 kg PFHxS, its salts and PFHxS-related substances)	Based on reports submitted by parties pursuant to Article 15 of the Stockholm Convention including information on quantities of PFOS used (UNEP, 2015).
Metal plating	World	Past and present	Evidence of use but no quantitative data	Various sources
	EU	Past	Evidence of use but no quantitative data	Various sources
	EU	2018	Zero*	Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier and also the BiPRO study (BiPRO, 2018) has identified no current uses of PFHxS

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Category	Scale	Time	Quantity (PFHxS)	Notes
				(including its salts and PFHxS-related substances) in the EU.
Hydraulic fluids for the aviation industry	EU	2018	Zero*	Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier and also the BiPRO study (BiPRO, 2018) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in the EU.
Polishing agents and cleaning/washing agents	EU	2000-2015	Evidence of use but no quantitative data	The POPRC Draft Risk Profile (2017) identifies one PFHxS-related compound at least between 2000 and 2015 in Denmark, Norway and Sweden with the use volumes claimed as confidential business information.
	EU	2018	Zero	Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier and also the BiPRO study (BiPRO, 2018) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in the EU.
Impregnation/proofing	EU	2003-2009	Evidence of use but no quantitative data	The POPRC Draft Risk Profile (2017) identifies that one PFHxS-related compound was reportedly used in impregnation/proofing for protection from damp, fungus, etc. at least in four products between 2003 and 2009 in Denmark.
	EU	2018	Zero	Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier and also the BiPRO study (BiPRO, 2018) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in the EU.
Manufacture of semiconductors	World	2017	Evidence of use but no quantitative data	The POPRC Draft Risk Profile (2017)

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Category	Scale	Time	Quantity (PFHxS)	Notes
	EU		Zero*	Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier and also the BiPRO study (BiPRO, 2018) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in the EU.
Flame retardant	World	Past	Evidence of use but no quantitative data	The POPRC Draft Risk Profile (2017)
	EU	2018	Zero	Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier and also the BiPRO study (BiPRO, 2018) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in the EU.
Textiles, carpet, leather and upholstery	EU	pre 2000	Apparel and leather = 46t Carpet = 140t Fabric and upholstery = 34t	1999 data supplied by 3M to the PFOS RRS (RPA, 2004)
	World	2018	Evidence of use but no quantitative data	The POPRC Draft Risk Profile (2017)
	EU	2018	Zero in article manufacture	Repeated and exhaustive stakeholder consultation as part of the preparation of this dossier and also the BiPRO study (BiPRO, 2018) has identified no current uses of PFHxS (including its salts and PFHxS-related substances) in the EU.
	EU	2013	Estimated 66 kg per annum imported on waterproof jackets from China, Vietnam and Bangladesh and an unknown	Analysis undertaken in this dossier

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Category	Scale	Time	Quantity (PFHxS)	Notes
			quantity in other applications (no data)	
Fire-fighting foams	EU	1999	11.2 tonnes	1999 data supplied by 3M to the PFOS RRS (RPA, 2004)
	World	2018	Evidence of use (manufacture of AFFF) but no quantitative data	The POPRC Draft Risk Profile (2017)
	EU	2018	0.5-3 kg PFHxS impurity in EU Stockpile of which an estimated 39-245 gram is consumed or replaced annually.	Analysis undertaken in this dossier
* PFHxS is a known impurity in PFOS formulations used in marked applications. Owing to data limitations, quantities of use are aggregated under the heading 'PFHxS in continuing uses of PFOS'.				

A.3. Uses advised against by the registrants

There are no registrations of PFHxS or PFHxS-related substances in ECHAs databases.

Annex B: Information on hazard and risk

B.1. Identity of the substance(s) and physical and chemical properties

B.1.1. Name and other identifiers of the substance(s)

This is described in the relevant sections of the main report.

B.1.2. Composition of the substance(s)

Not relevant.

B.1.3. Physicochemical properties

This is described in the relevant sections of the main report.

B.1.4. Justification for grouping

This is described in the relevant sections of the main report.

B.2. Manufacture and uses (summary)

This is described in Annex A.2.11.

B.3. Classification and labelling

See table below.

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

(Copy of Table 7: Overview of harmonised classifications, notifications and self-classifications (C&L Inventory 2 April 2019)

Substance	CAS no.	Harmonised classification	Notifications	Self-classification
Perfluorohexane-1-sulphonic acid	355-46-4	-	1 (19.01.2018)	Acute Tox. 4; H302 Acute Tox. 4; H312 Acute Tox. 4; H332 Skin Corr. 1B; H314
Potassium perfluorohexane-1-sulphonate	3871-99-6	-	23 (20.04.2016)	STOT SE 3; H335 Skin Irrit. 2; H315 Eye Irrit. 2; H319
Ammonium perfluorohexane-1-sulphonate	68259-08-5	-	17 (19.10.2010)	-
Tridecafluoro-N-methylhexanesulphonamide	68259-15-4	-	1 (19.02.2018)	STOT SE 3; H335 Skin Irrit. 2; H315 Eye Irrit. 2; H319
N-ethyltridecafluoro-N-(2-hydroxyethyl)hexanesulphonamide	34455-03-3	-	1 (19.02.2018)	STOT SE 3; H335 Skin Irrit. 2; H315 Eye Irrit. 2; H319
1-Hexanesulfinic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, zinc salt (2:1)	86525-30-6	-	23 (23.01.2014)	Skin Irrit. 2; H315 Eye Irrit. 2; H319
1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	41997-13-1	-	1 (16.10.2017)	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335 (Lungs) (Inhalation)
Perfluorohexanesulphonyl fluoride (the raw material for PFHxS and PFHxS-related substances)	423-50-7	-	1 (27.02.2012)	Skin Corr. 1B; H314

B.4. Environmental fate properties

B.4.1. Degradation

B.4.1.1. Degradation of PFHxS

The Member State Committee's (MSC) support document for the identification of perfluorohexane-1-sulphonic acid and its salts as substances of very high concern because of their vPvB (Article 57 e) properties, concludes that PFHxS is a very persistent (vP) compound (ECHA, 2017a).

The perfluorinated substances are among the most stable organic compounds due to the high electronegativity and low polarizability of fluorine, which results in a high bond energy of the C-F bond. The C-F bond is among the strongest covalent bonds known and is resistant to acids, bases, oxidation and reduction, even at elevated temperatures. The strength of the C-F bond increases with increasing fluorine substitution at the carbon atom (Kissa, 2001). The persistence of PFOS and the eight entries of PFCAs included into the Candidate List has already been confirmed.

The group of perfluoroalkane sulfonic acids consists of closely related substances with very similar properties. The PFSA's include a perfluoroalkyl group of varying carbon chain length, attached to a sulfonic acid group. Hence, they only differ in the number of CF₂-units whereas the other structural features are the same. The perfluoroalkyl chain is persistent due to the high stability of the C-F-bond. The sulfonic acid group is at its highest oxidation state and cannot be oxidized further under environmentally relevant conditions. It is not expected that the sulfonic acid group will make the attached perfluoroalkyl chain more susceptible to chemical transformations.

Parsons et al. (2008) reviewed the biodegradation of perfluorinated compounds. The authors pointed out that the most theoretically plausible degradation pathway for PFASs, such as PFHxS, is through reductive defluorination, which could occur under anaerobic conditions. For PFOS it was reported that no biodegradation was observed under aerobic conditions, while there were some observations of degradation of PFOS under anaerobic conditions (though no metabolites were measured in these studies). In principle, it cannot be ruled out that some degradation of PFHxS under anaerobic conditions can occur (e.g. in hypoxic groundwater, marine water or sediments), or will occur in the future if bacteria adapt to utilize the energy present in the PFAS substrates. Indications for such bacterial behaviour were found when a PFOA-degrading bacterial strain was isolated from soil near a PFAS production plant (Yi, et al., 2016). The PFOA-degradation has been demonstrated at lab conditions with a low degradation efficiency only. The rates of these processes under environmental conditions are unknown, and potentially very slow or negligible, and have yet to be observed in the environment.

B.4.1.2. Degradation of PFHxS-related substances

Section 1.1.2 (Justification for grouping) of the main report explains how molecules containing the PFHxS-moiety in principle can form PFHxS through abiotic degradation. The degradation schemes are to a large extent based on an assessment of abiotic degradation of PFHxS-precursors with formation of PFHxS (Nielsen, 2017).

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

The draft POPs risk profile for PFHxS has the following description of the degradation of PFHxS-related substances (UNEP/POPS/POP/RC.14/2, 2018):

"56. Applying the read-across approach (see Section 1) and results from studies on other PFASs, indicates that PFHxS-related compounds may have the potential to degrade to PFHxS in the environment. Biodegradation data available for the C₈N-ethylperfluorooctane-sulfonamidoethyl alcohol (CAS No: 1691-99-2) demonstrate conversion with the ultimate biodegradation product being PFOS (Hekster, et al., 2002; Martin, et al., 2010). Other chemicals containing the perfluorooctyl sulfonate group are expected to be susceptible to a similar biotransformation process (Martin, et al., 2010). Further, data available for the C₄N-methylperfluorobutanesulfonamidoethyl alcohol (CAS No: 34454-97-2) indicate potential for atmospheric degradation to PFBS through oxidation by hydroxyl radicals (Martin, et al., 2010; D'eon, et al., 2006). Moreover, PFBS is expected to be a highly stable transformation product in which several precursors ultimately degrade into (Quinete, et al., 2010; D'Agostino & Mabury, 2017; Wang, et al., 2013; Nielsen, 2017)."

A review of the microbial degradation of polyfluoroalkyl chemicals in the environment points out that perfluoroalkane sulfonamido derivatives may undergo aerobic biodegradation, via the relatively stable intermediate sulfonamides, to the sulfonic acids (e.g. PFHxS) as the final degradation products (Liu & Avendaño, 2013). Liu et al. (2019) investigated the biotransformation of perfluoroalkane sulfonamide compounds in aerobic soil and looked specifically at differences between the linear and branched isomers in the transformation of PFOS-related substances to PFOS. However, as there are several degradation pathways for the different precursors, there was no clear overall trend that differentiates between the linear and the branched isomers.

In biological systems it has been demonstrated that perfluoroalkane sulfonamides like N-EtFOSA are precursors of PFOS in fish (Tomy, et al., 2004). Furthermore, N-EtFOSA was biotransformed by earthworms to PFOS after in vivo and in vitro exposure (Zhao, et al., 2018). Further in vitro depletion of PFOS-related substances (N-EtFOSA and perfluorooctane sulfonamide (FOSA)) was confirmed in a liver microsomal assay approach in polar bear, ringed seal and laboratory rat (Letcher, et al., 2014). Perfluoroalkane sulfonamido alcohols like N-EtFOSE are degraded to PFOS in activated sludge (Rhoads, et al., 2008) and levels of PFSA-precursors in sludge from WWTP exceeded those of PFSA itself (Eriksson, et al., 2017). PFHxS showed a net mass increase in all WWTPs and the authors hypothesise that the substantial increase is linked to degradation of precursor compounds. Acknowledging the stability of the PFHxS-moiety, one should expect that N-EtFHxSA and N-EtFHxSE will ultimately degrade to PFHxS in the environment via the same degradation mechanism. Biotic degradation of PFHxS-related substances is expected to form PFHxS.

In summary, there is already agreement that PFHxS and its salts are very persistent substances. Furthermore, PFHxS-related substances degrade to PFHxS in biotic and abiotic systems. The rate of degradation of PFHxS precursors to PFHxS varies for the different subclasses of related substances and is dependent upon the environmental conditions where the substances are present, see chapter 1.1.2 for details.

B.4.2. Environmental distribution

Section 3.2 of the MSC support document for the SVHC-identification of PFHxS and its salts has the following description of the predicted environmental distribution of PFHxS:

"Using the described read-across approach, the environmental distribution of PFHxS is predicted to be similar to that of PFOS, with the difference that the two carbon longer alkyl chain of PFOS will result in a higher hydrophobicity of PFOS, as compared to that of PFHxS. The primary compartments for PFOS are expected to be water, sediment and soil (UNEP, 2006).

The water solubility, adsorption potential and environmental distribution express a regular pattern depending on the alkyl chain length of PFSAs and PFCAs, with an increased alkyl chain length resulting in increased hydrophobic behaviour with decreased water solubility, increased sorption potential, etc. Environmental behaviour and fate of the PFSAs can be assumed to be broadly similar to that of PFCAs. PFSAs are persistent, mostly distributed to surface waters (Armitage, et al., 2009), bind weakly to organic phases (Higgins & Luthy, 2006) compared to more hydrophobic substances.

Due to the different acidic groups of the PFSAs and PFCAs, the PFSAs with same perfluoroalkyl chain length as the PFCAs tend to sorb (Higgins & Luthy, 2006) and bioaccumulate (Conder, et al., 2008); (Martin, et al., 2003a) more strongly than their corresponding PFCAs. Both PFSAs and PFCAs are found in biota, with the highest concentrations detected in air-breathing organisms (...)." (ECHA, 2017a)

B.4.2.1 Adsorption/desorption

PFHxS is expected to be more abundant in the waterphase than PFOS but less than PFBS. Adsorption/desorption describes the extent to which adsorption takes place for example to soil and reflects a substance's mobility and transfer between various environmental media. When comparing experimental and estimated data, it can be assumed that for PFSAs the water solubility decreases and the sorption potential increases with increasing perfluorinated carbon chain length.

In general, for PFASs with chain lengths ~C5 - ~C15 the sorption of PFAS substances is dependent on chain length in a predictable way (Zhang, et al., 2013). (Higgins & Luthy, 2006) demonstrated this trend for sediments, and (Elmoznino, et al., 2018) also demonstrated that an increase in log K_{oc} correlates to the alkyl chain length. They also observed that PFSAs would partition more strongly to effluent-derived suspended particulate matter than PFCAs with the same number of perfluorinated carbons. (Houtz, et al., 2018) also noted that, PFOS would be more efficiently retained in sewage treatment plants than PFHxS and PFBS. The authors attribute this to differences in sorption, as log K_{oc} values are one and two units lower for PFHxS and PFBS, respectively, than for PFOS.

In soil, (Pereira, et al., 2018) demonstrated that the perfluorosulfonic acids' (PFSAs) sorption was stronger than that of perfluorocarboxylic acids (PFCAs) and the PFAS sorption increased with increasing perfluorocarbon chain length. An increase of 0.60 and 0.83 log KOC units per CF_2 moiety for PFCAs and PFSAs, respectively, was observed. Sorption to organic matter is also affected by pH and available multivalent cations in the medium.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

While longer chain PFAS like C9–C11 and C13 PFCAs, C8 PFSA and perfluorooctane sulfonamide (PFOSA) will have the greatest effect from pH, intermediate length PFAS (C5–C8) will be more affected by changes to the composition of cations, especially calcium and aluminium (Pereira, et al., 2018). This is also supported by the findings of (Nguyen, et al., 2017) in river water, where PFASs like PFHxS, PFHxA, PFBS and PFOA were shown to be co-transported with dissolved organic carbon (DOC). These PFCAs and PFSAs carry a negative charge in natural waters, and the correlation was observed only for the shorter chained and more hydrophilic substances; in this publication considered to be $\leq C_7$ for PFCAs and $\leq C_6$ for PFSAs. The authors suggest that one possible explanation for the observed phenomenon could be that these PFASs readily bind to positively charged ions that are complex bound to DOC (e.g. Ca^{2+}) with negatively charged head groups, while the longer chained PFASs ($\geq C_7$ for PFCAs and $\geq C_6$ for PFSAs) rather partition to even more hydrophobic phases in the water, such as the organic carbon fraction of suspended particulate matter.

Baduel et al. (2017) demonstrated a predictable pattern for the effect of alkyl-chain length on mobility in soil for PFSAs, where the vertical distribution is a function of the alkyl chain length, such that mobility is higher for shorter chain lengths. In sewage sludge, (Zhang, et al., 2013) also recorded an increased sorption with increasing chain length. An additional important factor influencing the adsorption to sewage sludge was the presence of protein for PFAS, leading to an increased adsorption to sludge. For PFSAs, unlike PFCAs, carbohydrates were found to lead to increased adsorption. A study by Wang et al. (2015), PFHxS showed an increased sorption with increasing Al^{3+} and Fe^{3+} concentration, and that this was due to stronger sorption and coagulation effects by formation of colloids or precipitation. The same study investigated sorption of PFAS to sludge after removal of the organic part (thermal treatment), and the results indicate that the sorption to minerals were lower than to organic matter.

In summary, adsorption of PFHxS to particles is expected to be lower than for PFOS but higher than for C4 substances, as shorter chain-lengths have been found to correlate with lower adsorption, as it is mainly determined by hydrophobic interactions. In other words, PFHxS will be more abundant in the waterphase than PFOS but less than PFBS. These are predictable from the carbon chain length, but distribution between various phases (K_d) has been demonstrated to be affected by factors such as pH, ions, protein and carbohydrate content.

B.4.2.2 Distribution modelling and long-range transport potential of PFHxS

The SVHC support document for identification of PFHxS and its salts as substances of very high concern because of their vPvB (article 57e) properties (ECHA, 2017a) notes that *"Perfluorohexanesulfonic acid (PFHxS) is a strong acid which has a fully fluorinated six carbons long chain, making it both oil- and water repellent (Kissa, 2001). Not much else is known about the specific physicochemical properties of PFHxS. However, there are some characteristics which are valid for the whole group of perfluoroalkylated substances (PFAS), and therefore also PFHxS. PFAS are very resistant to chemical, thermal and biological degradation due to their strong carbon-fluorine bonds (Kissa, 2001). It is this resistance to degradation that makes many of them persistent in the environment.*

Due to the scarcity of experimental values for PFHxS, estimated values are used instead. However, since PFHxS is a strong acid, which is fully dissociated in the environment, the predictions made for the neutral (non-ionised) species are uncertain. The relevance of the

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

log KOW and log D is questionable due to the surface active properties of the substance. A discussion on the reliability of the predictions is included in Annex I of the annex XV report for PFHxS." (ECHA, 2017a)

Distribution modelling on PFHxS in general, and especially on long-range is difficult due to the lack of reliable physicochemical data. Not much has been performed directly on PFHxS or on the atmospheric transport of PFASs in general. PFHxS is expected to be fully dissociated in the environment and is expected to have limited volatility, making the atmospheric transport less likely. Nevertheless, monitoring data has demonstrated that PFHxS may undergo long range transport by other means, and the substance is regularly detected in arctic snow and air.

For example, (Genualdi, et al., 2010) have detected PFHxS in arctic air (0,087 pg/m³, and a recent study by (Rauert, et al., 2018a) documents a statistically significant increase of PFHxS from 2009 – 2015 in several sites, including arctic air. Also, (Codling, et al., 2014) found PFHxS in a snowpack in a remote area of northern Sweden. (Kwok, et al., 2013) found PFHxS in river water samples from locations downstream of Longyearbreen glacier on Svalbard, but not in the ice cores from the glacier itself, unlike many other PFASs, suggesting the existence of local sources of PFHxS. However, in air monitoring studies from the Norwegian arctic, including Svalbard, PFASs are found infrequently and when detected, often at concentrations close to the detection limit. PFHxS was not detected in air samples at any of the sites (Norwegian mainland and in the Arctic) in 2017 indicating low presence of PFHxS in Norwegian background air (Bohlin-Nizzetto, et al., 2017). The discrepancy may be a result of different sampling strategies, with the Bohlin-Nizzetto study using active air sampling while the Genualdi and Rauert studies used passive air sampling. While the passive sampling is more representative of the gas phase, active sampling will more closely reflect the particulate phase. Different locations as well as different methods applied, hamper a direct comparison of the findings. However, all three studies point to low PFHxS presence in Arctic air.

Neutral PFHxS-related substances are more volatile than PFHxS, and most of the modelling efforts on long range transport seem to have been performed with these. Atmospheric long-range transport is more likely for these substances, which may subsequently be degraded to stable end products. The PFHxS-related substances thereby act as indirect sources of PFHxS in some cases. In a study from the Netherlands PFHxS (0.3 – 25 pg/L) has been detected in rainwater and the authors suggest that the presence in rainwater could be due to degradation of precursors (PFHxS-related substances) in the atmosphere (Eschauzier, et al., 2010).

According to (Ahrens, 2010) ocean currents may be more relevant than atmospheric transport for the direct long-range transport for PFASs, as opposed to the atmospheric transport of PFAS precursors. (Webster & Ellis, 2010; McMurdo, et al., 2008) suggest that for PFOA, sea spray may have the potential for contributing large amounts of PFOA to the atmosphere and may therefore contribute significantly to the concentrations observed in remote locations. The same may be relevant for PFHxS, as (Johansson, et al., 2018) describe a statistically significant ($p < 0.05$) positive correlation with sodium, which can be used as a proxy for sea spray aerosol in one of the 2 sites (Corvo and Råö) where PFHxS was determined in atmospheric deposition samples. Corvo is the smallest and the northernmost island of the Azores archipelago, and Råö is a rural island on the Swedish west coast and is used as a background station in the Swedish environmental monitoring

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

program. The positive correlation being made for Råö. Furthermore, in precipitation samples taken at the Swedish west coast (Råö), concentration in winter samples (November-February) were elevated in relation to summer samples (July-September) by on average a factor of 5 for PFHxS (Johansson, et al., 2018)

In studies of ice cores from inland Greenland, collected at the Devon Ice Cap near Nunavut, (MacInnis, et al., 2017; Pickard, et al., 2018), the authors were unable to detect PFHxS in the samples, which consisted of non-marine (i.e., freshwater) input, while the substance was measured in most ocean samples. Analyses of sodium in the ice cores indicated that there were limited oceanic sources depositing on the Devon Ice Cap. The composition of PFAS substances in the Ice Cap samples compared to the ocean samples cannot be explained by differences in surfactant strength, which is an important factor for water-to-air transport. The critical micelle concentration (CMC, mol/L), the maximum concentration at which surfactants remain freely dissolved in water (i.e. without forming micelles), is used as a physicochemical indicator of the hydrophobicity of surfactants and thus their tendency to partition out of the bulk phase to accumulate at the air-water interface (Reth, et al., 2011). This is used as an estimation of surfactant strength. The absence of PFHxS on the Devon Ice Cap therefore suggests that marine aerosols may not be a significant source for PFSA deposition to the Devon Ice Cap, which was at high elevation (1846 meters a.s.l) and 46 kilometers inland from nearest shore according to provided coordinates¹⁴. (Casal, et al., 2017) investigated the role of snow deposition as a source for PFAS in the Antarctic marine environment and found relatively high concentrations of PFCAs and low concentrations of PFSAs. This indicates a limited relevance of snow deposition for the levels PFSAs in maritime Antarctica compared to other sources; such as oceanic transport or atmospheric deposition of neutral precursors.

The occurrence of PFHxS in almost all investigated Arctic biota samples within the 2017 Arctic Screening (Schlabach, et al., 2018). Even being only present at low concentrations of < 0.5 ng/g ww in Arctic biota (except polar bear), the high detection rate points to a considerable exposure risk within the Arctic marine ecosystem, caused by a combination of local and LRT sources. See also Annex B.4.3.6 Arctic/ remote areas.

In summary, ocean currents are likely to be more relevant than atmospheric transport for long range transport for PFSAs. The potential for atmospheric long-range transport of PFHxS seems limited due to its chemical properties. Nevertheless, neutral PFHxS-related substances, that are likely to be transported via air, may lead to some indirect transport of PFHxS since they are degraded to PFHxS.

B.4.3 Monitoring and trends

Monitoring results from Europe and the rest of the world show that elevated PFHxS levels can be found in urban areas and near point sources, such as fluorine producing industry and fire-fighting training sites.

¹⁴ Sampling site provided by authors as DMS LatitudeN S 75 ° 20 ' 51.935 " LongitudeE W 82 ° 40 ' 54.089", nearest shore set by dossier submitter to DMS LatitudeN S 75 ° 44 ' 35.606 " LongitudeE W 83 ° 6 ' 38.923 "

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

PFHxS or PFHxS-related substances are not registered under REACH (see above), but some PFHxS-related substances are notified in ECHAs databases (see Table 7). This means that the tonnage of these appears to be low. As described in section 1.1.5 and Annex B.5, estimation based on WWTP suggests a total annual emission of 2.1 tonnes PFHxS in the EU with 1.79 tonnes of this being associated with WWTP handling industrial waste water. However, the fact that PFHxS, which is the ultimate degradation product of PFHxS-related substances, is very persistent means that the substance will have a very long residence time in the environment. This also implies that, PFHxS and PFHxS-related substances have the potential, over time, to be widespread in various environmental media, including the aquatic environment, and that the levels will build up over time. There is growing evidence that this has already occurred (Land, et al., 2018; Routti, et al., 2017; Rauert, et al., 2018a; UK Environment Agency, 2019b).

Land et al. (2018) performed a systematic review of the effects of phasing out long-chain PFASs. In general, this analysis indicates increasing or unchanging temporal trends of PFHxS in biota. Furthermore, no differences between geographical areas were demonstrated. Annex B.9.4.6 presents the human exposure data from this article.

The draft POPs risk profile for PFHxS has this description of the environmental monitoring results and time trends ((UNEP/POPS/POPRC.14/2, 2018)):

"75. Environmental monitoring shows that PFHxS is ubiquitous in the environment. Numerous studies have reported detection of PFHxS in compartments such as surface water, deep-sea water, drinking water, wastewater treatment plant effluent, sediment, groundwater, soil, atmosphere, dust, biota, and humans globally (ECHA 2017a, annex II, Table 13; Tables 1.1–1.12 in UNEP/POPS/POPRC.14/INF/4).

76. The highest environmental levels of PFHxS measured are found in urban and/or industrial areas both in terms of biotic- and abiotic matrices (Gewurtz, et al., 2013); (Ma , et al., 2018).

(...)

81. A number of studies have reported time-trends for PFHxS in various species and matrixes. However, there are some discrepancies in these data and trends are both increasing (Routti et al., 2017; Holmstrom et al., 2010), decreasing (Lam et al., 2016; Huber et al., 2012), and without any significant trend (Ullah et al., 2014; Roos et al., 2013). In a systematic review of trend studies most data on PFHxS showed no significant change, while an increasing or decreasing trends were observed in a few matrixes and regions (Land et al., 2018). However, as mentioned above the trend of PFHxS in polar bears in the European Arctic (Svalbard, Norway) is increasing (although non-significant within 95% of the confidence interval) in the time-period 2010 – 2014, while the trend in the Arctic fox from the same area is decreasing (Routti et al., 2017, and personal communication with the author). The increasing trend in polar bears (Routti et al., 2017) corresponds well with a recent study reporting increasing trends in Arctic air during the same time-period (Rauert et al., 2018). Hence, the temporal trend in each case is most likely dependent of emission sources, food choices (terrestrial, marine) and location (urban versus rural) among other factors."

The following sub sections presents some selected monitoring results in more detail.

B.4.3.1 Surface water monitoring

Several surface water monitoring studies of perfluorinated substances are available. In the following we present some selected studies from Europe and China.

In a study of 40 Swedish rivers and recipient seawater (Baltic Sea and Kattegat) by (Nguyen, et al., 2017), Perfluorobutanoic acid (PFBS) was the most predominant PFAS (21 % of the sumPFAS) followed by PFHxS (18 %). The PFHxS concentration in the 40 rivers ranged between 0.051-18 ng/L with an average PFHxS concentration of 9 ng/L and a detection frequency of 77 %. The levels of PFASs were remarkably higher in ten of the investigated rivers. A cluster analysis indicated that there were similar kinds of point sources for PFASs in the ten rivers, but the authors were not able to identify the main contamination source(s) due to the large number of potential sources such as STP effluents, landfills or fire-fighting training areas (Ahrens, et al., 2009b; Ahrens, et al., 2015; Becker, et al., 2008; Busch, et al., 2010b; Möller, et al., 2010). There was, however, a positive correlation between the PFHxS levels in the river waters and population density.

The presence of PFAS was analysed in water of the Jucar River basin in Spain (Campo, et al., 2016). PFHxS concentration were between 12.1-36.7 ng/L with a mean of 24.4 ng/L, but with a low detection frequency of 13 %. The occurrence of PFAS was related to urban and industrial discharges (car factory) upstream the Jucar River basin.

In a French nationwide survey, water and sediment samples were taken at 133 locations including rivers and lakes to investigate the spatial distribution of PFASs in surface water bodies (Munoz, et al., 2015). PFHxS concentration in surface water ranged between <0.02-217 ng/L with a detection frequency of 81 % and in sediment <0.02-0.6 ng/g dw with 7% detection frequency. PFASs have also been reported at relatively high levels in urban rivers, river Seine and river Orge nearby Paris. (Labadie & Chevreuil, 2011 a), (Labadie & M, 2011 b) identified PFHxS and PFOS as the dominant congeners in both rivers, with a mean PFHxS concentration of 13.6 ng/L and 7.1 ng/L for river Orge and river Seine respectively. Both rivers are impacted by urban runoff and sewage discharge and the authors concluded that industrial locations displayed markedly higher levels of PFHxA, PFHxS and PFOS in general.

In the Netherlands infiltrated river Rhine water and infiltrated rain water in coastal dunes is used for producing drinking water. PFHxS concentration were higher in infiltrated rainwater (0.3-25 ng/L) than in infiltrated river water (<0.8-4.0 ng/L) and the authors suggest as a possible contamination pathway atmospheric transport of precursors. Perfluoroheptanoic acid (PFHpA), PFBS, PFOS, and PFHxS in infiltrated river water showed an increasing trend with decreasing age of the water (Eschauzier, et al., 2010).

Concentration of PFAS in surface water along the river Rhine was investigated (Möller, et al., 2010). Stations upstream of the city Leverkusen had PFHxS concentrations in the range of <0.5-14.5 ng/L with a mean of 3.0 ng/L. The concentration increased significantly between two stations by a factor of 10. However, the source could not be verified and the authors suggested that the increase was likely caused by direct industrial emissions or indirectly via (WWTP) effluents.

Concentration of PFHxS was analysed in 21 rivers in Scotland, United Kingdom in 2018. PFHxS was detected in 14 of the 21 rivers. The PFHxS concentration ranged between <0.068 – 1.16 ng/L with an average PFHxS concentration of 0.43 ng/L and a detection frequency of 61%. The highest concentration was found in the river Almond which is close

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

to Edinburgh where concentrations were between 0.68-1.16 ng/L. The rivers where the PFHxS concentration was below LOD were the rivers Beaully, Lunan Burn, Annan, Tay, Nairn, Ness and Brora. Except for the river Tay, which is located in the vicinity of Perth (ca 45 000 inhabitants), and the river Ness, which is located in the vicinity of Inverness (ca 57 000 inhabitants), the other 4 rivers with PFHxS concentrations <LOD are in rural areas with smaller villages (less than 10 000 inhabitants).

In China PFHxS was found to be the predominant PFAS in water samples in a range of 45.9–182 ng/L) from Taihu Lake and its in-flow rivers. In Taihu Lake the PFHxS concentration was at low level (n.d.–6.9 ng/L) in 2009 and 2012, but displayed a distinct increase in 2014–2015 resulting from the increased application of products containing PFHxS, as a substitute for PFOA and PFOS, (Ma, et al., 2018).

B.4.3.2 Marine Environment

Perfluoroalkyl acids are ubiquitous contaminants of the marine environments and in northern Europe. (Nguyen, et al., 2017) studied the spatial distribution of PFAS at 18 sites in the receiving Baltic Sea and Kattegatt. The PFHxS concentrations in seawater were between 0.11-1.7 ng/L with 100 % detection frequency. However, the long chained PFASs (PFCAs>C7 and PFSAs>C6) were predominant in the Baltic Sea and Kattegatt with Perfluorononanoic acid (PFNA) contributing by 34 %, followed by PFOS (19 %) and PFOA (13 %).

Kwok et al. (2013) quantified 17 PFAS in ice cores, surface snow and surface water samples on the Arctic island Svalbard, Norway. PFHxS was not detected in the glacier, but in the downstream locations the levels in surface snow ranged between 20-30 pg/L and in surface water between 20-500 pg/L. The authors suggested that the contamination might be due to local sources rather than atmospheric transport.

Oil companies operating on the Norwegian continental shelf are required to carry out regular environmental monitoring for the water column and sediment compartment. PFHxS was measured at 43 and 14 µg/kg dw in two sediment samples at Njord oil field (DNV GL, 2016). Contamination may be attributed to discharges of fire-fighting foams or leakage from a disposal well nearby.

Results from a screening study on PFAS in six Nordic countries (Denmark, Faroe Islands, Finland, Iceland, Norway, Sweden) showed PFHxS concentrations between 0.08-4.4 ng/L in seawater (Kallenborn R, et al., 2004).

Benskin et al. (2012) determined PFAA concentrations in previously unstudied areas of the Atlantic and Arctic Oceans, North and Southwestern Atlantic and the Canadian Arctic Archipelago. PFOS and PFOA were typically the predominant PFAA in Atlantic water but PFHxS was also detected however at low concentrations (n.d.–51 pg/L). In the mid-northwest Atlantic/Gulf Stream PFAA concentrations increased rapidly crossing into U.S coastal waters (up to 5800 pg/L near Rhode Island). In the northeast Atlantic highest PFAA concentration were north of the Canary Islands (280–980 pg/L) decreasing with latitude, suggesting that human activities could be responsible for PFAA emissions.

In the Greenland Sea, PFHxS was one of the five most frequently detected PFAS compounds (Zhao, et al., 2012) with concentrations between < 6.5- 45 pg/L in 88 % of the water samples.

B.4.3.3 Urban Terrestrial Environment

The use of PFHxS and PFHxS-related substances in a modern urban environment can be a source of release of the substance. This is also confirmed by elevated levels of, amongst others, PFHxS in river water near urban areas, as described above.

The draft POPs risk management evaluation on Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds reports the following on sources to PFHxS in waste water:

"32. Annex F information submitted by the UK reported that a waste company responded to the request for information that the substance is used in textiles, carpet protectors, leather, papermaking, pesticides, electroplating, firefighting foams, photosensitive material and some synthetic materials. It has also been found in printing inks, sealants and in non-stick cookware. Although according to the UK Annex F information, no use or production of the chemical as a raw product takes place, it is assumed that there will be some embedded in everyday materials (UK Annex F information)." (UNEP, 2019b)

After use or disposal of PFHxS-containing products, these compounds may enter wastewater treatment plants (WWTP) via industrial or urban waste. A multi-media assessment of perfluoroalkyl acids in the Canadian environment found PFHxS in all samples, and the highest environmental levels were found in biotic- and abiotic matrices in urban areas (Gewurtz, et al., 2013). Several studies showed that conventional wastewater treatment has a limited efficiency in removing PFCs such as PFHxS from aqueous waste streams (Boulanger, et al., 2005), PFHxS are either accumulated in sludge or emitted to receiving waters via WWTP effluents (Ma & Shih, 2010); (Huset, et al., 2008); Effluents and sludge from WWTP are important sources of PFHxS emission to the environment. As described in Annex B.4.2.1, PFHxS is mainly expected to be more abundant in the waterphase than PFOS but less than PFBS.

PFHxS has been detected in sewage sludge all around the world (Arvaniti & Stasinakis, 2015). The concentration ranges reported were from 0.01 ng/g to 200 ng/g. In Europe, the majority of sewage sludge is disposed to landfills followed by foul sewer and land spreading used for agricultural purposes, among other uses. A study of German sewage sludge showed concentrations of up to 1.4 ng/g and Spanish sewage sludge concentrations up to 0.1 ng/g dw (Gómez-Canela, et al., 2012). A Swedish study of three waste water treatment plants showed PFHxS levels in outlet water up to 1.9 µg/l (Eriksson, et al., 2017). The same study revealed sewage sludge concentrations of PFHxS up to 0.05 ng/g in the corresponding samples, and that PFHxS showed a net mass increase of 37% in all WWTPs. The hypothesis of this observed net increase is linked to degradation of precursor compounds that are not yet analysed for (Eriksson, et al., 2017). A recent Nordic study did not detect PFHxS in any of the samples analysed (n=12 where 2 from Norwegian WWTPs and with a LOD 0.04 ng/g dw) (Kärrman, et al., 2019). This Nordic study also analysed for different precursors such as mono and diPAPs, and highest measured precursor in Norwegian sludge was 11.64 ng/g dw of 6:2/8:2 diPAP.

Another recently published Norwegian report from waste water treatment plants showed mean sludge concentrations of 8.46 ng/g dw for 50 samples (Blytt, et al., 2013). The min-max values for PFHxS from this study was <0.52 – 37 ng/g dw. In a study from 2013 (Blytt et al. 2013), 15 sludge samples were analysed for PFHxS and with a LOD 0.010 mg/kg dw (=10 µg/g=10000 ng/g dw) PFHxS was not detection above LOD in any of the samples.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

A recent Norwegian environmental monitoring report showed that PFHxS was the predominant PFAS compound in sewage sludge and was detected in very high concentrations (1600-2300 µg/kg dw) (Konieczny, et al., 2016). However, compared with other reported levels in the literature the results seem questionable (Konieczny, et al., 2016). The results in this study however contrast both with earlier (Blytt, et al., 2013) and later (Kärrman & Kallenborn, 2018) monitoring data from the same WWTP. The results from 2016 should therefore be interpreted with some caution.

Screening of PFASs in the Oslo-area, Norway, showed that the levels of PFHxS in landfill leachate samples exceeded PFOS, the reported levels were up to 120 ng/l (PFHxS) and 95 ng/l (PFOS) (Konieczny, et al., 2016). Furthermore, the highest levels of PFHxS in urban biota from Oslo was seen in livers from rats living in the sewage system, with values up to 400 µg/kg dw. PFHxS was also detected in cod liver, common crabs and periwinkle, seagull eggs and seagull blood from the Oslo fjord (Herzke, et al., 2017). Data from the urban environment has been collected since 2013¹⁵. Soil from these urban sites in and surrounding Oslo, have been shown to have levels below or close to the detection limit. However, in the same studies, the detection frequency is high for some species. PFHxS has been regularly detected in earthworm, red fox, fieldfare eggs and sparrowhawk eggs, with the highest concentrations found in earthworms, generally ranging from 1-5 ng/g ww, with one sample measured at 40 ng/g ww (Herzke, et al., 2017). For fieldfare, red fox and sparrow hawk, values were generally below 1 ng/g ww. The reports also include rats and tawny owl, but here both the detection frequencies and concentrations are often low, with 0-20% detections for most years, except for 2017, where the tawny owl eggs had detectable PFHxS in 6 out of 7 samples. Soil and earthworms were generally collected at the same sites, as well as to some degree fieldfare, but the other biota samples could not be sampled in the same place. (Herzke, et al., 2017; Herzke, et al., 2015; Herzke, et al., 2016; Herzke, et al., 2014).

B.4.3.4 Point sources

In the literature there are examples of local point sources of PFHxS contamination, both in Europe and elsewhere. The Council of Chemists of the Province of Treviso (Council of Chemists of the Province of Treviso , 2017) supplied the following case of contamination as an annex to the draft POPs risk profile for PFHxS.

In 2013 a screening on PFAS carried out by the National Research Council (CNR) of Italy, brought to light a case of contamination in Veneto Region (Italy) (Polisello & Valsecchi , 2013). The contamination involved ground and surface water and some fresh water wells for human use. A document from CNR; (Polisello & Valsecchi , 2013) reported the presence of PFHxS at levels ranging from below quantification limit (< 5 ng/L) to 36 ng/L (max) in drinking water distributed in some surveyed municipalities, mainly in the provinces of Vicenza and Verona. The average concentration was 32.5 ng/L in drinking water. For other municipalities investigated in the CNR's report, concentrations of PFHxS were mostly below quantification

¹⁵ <http://www.miljodirektoratet.no/no/Tema/Miljoovervakning/Naturovervakning/Giftfritt-miljo/Miljogifter-i-terrestrisk-og-bynart-miljo/Rapporter-fra-programmet-Miljogifter-i-terrestrisk-og-bynart-miljo/>

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

limits (< 5 ng/L). These low levels are consistent with a paper presenting a survey on the occurrence of PFAS in the main river basins in Italy (Valsecchi, et al., 2015) accounting for low levels of PFHxS, mostly under quantification limits.

The report from the (Regione del Veneto, 2016) ascribes the discovered PFAS contamination mainly to discharges of PFAS from a chemical plant (Miteni SpA) where perfluorinated compounds are actively synthesized, including PFHxS related substances as reported in UNEP documents (UNEP, 2017) and in the website of MITENI SpA (2016). According to (WHO, 2017) the area involved spanned more than 200 km² and the report suggested two main pathways for the spread of contamination. Wastewater from the factory responsible for the pollution was emitted into a creek and the surrounding ground water or that effluent from the WWT of the factory was emitted to a canal that drained into a river. Human exposure due to contaminated drinking water is discussed further in Annex B. 9.4.4.1 Drinking water.

PFHxS was the main PFAS constituent in the waste effluent from a semiconductor fabrication plant in Taiwan. Wastewater from the wafer photolithographic process itself and the final waste effluent of the plant contained high concentrations of PFHxS (9.93 mg/L) and (0.13 mg/L) respectively (Lin, et al., 2009). The amount of final waste effluents was estimated to be >5000 tonnes/day and a corresponding mass of PFHxS generated each day from the semiconductor manufacturing process was estimated to be >0.68 kg. In the same study, raw waste effluent from an electronic/optoelectronic fabrication plant was analysed for content of PFASs. The main constituent in this effluent was PFOA but PFHxS was only found in few samples at low levels < 2 µg/L.

A recent article by (Cui, et al., 2018) demonstrated elevated PFHxS concentrations in surface waters of four surrounding rivers and Lake Baiyangdian in China. Beside PFOA was PFHxS the predominant PFAS detected in most water samples with concentration of up to 0.15 mg/L. A photographic film production plant located along Fu River was suggested as the main pollution source. The authors estimated the riverine flux of PFHxS to lake Baiyangdian to 37.35 kg/y.

A company located in Norway has formulated, tested and supplied fire-fighting products for several decades. Annually environmental monitoring of surface water and biota has been performed and monitoring data for 2017 showed that PFOS and PFHxS has been detected in all analysed water samples. PFHxS water concentration up to 4300 ng/L were found in a ditch close to the site which can be attributed to run-off from contaminated soil (COWI AS, 2017). Furthermore, monitoring in 2016 reported PFHxS concentration up to 580 ng/kg ww in sea snails (*Patella vulgaris*) sampled from the seashore closed to the site.

B.4.3.4.1 Fire training sites/ emissions from the use of fire-fighting foams

PFHxS is present in old and in new fire-fighting foams, see Annex A.2.9 for more details. Similar to previous experience on the contamination caused by fire-fighting foams containing PFOS, PFHxS from fire-fighting foams also poses a significant pollution potential.

Studies from all around the world show that the use of AFFFs in fire-fighting training, real incidences, as well as accidental releases of AFFF, cause emissions of substantial amounts of PFHxS, its salts and PFHxS-related compounds to the environment [e.g., (Backe, et al., 2013; Houtz, et al., 2013; Baduel, et al., 2017; Barzen-Hanson, et al., 2017; Bräunig, et al., 2017; Lanza, et al., 2016);].

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

The draft POPs risk profile for PFHxS (UNEP/POPS/POPRC.14/2, 2018) has this description of cases where AFFF contamination has caused elevated levels of PFHxS in the environment:

"48. PFHxS is found in soil, water and a variety of biota (see UNEP/POPS/POPRC.14/INF/4, Tables 1.1 – 1.5) in the vicinity of fire-fighting training areas following historical (and ongoing) use of PFHxS-containing foams (Braunig et al., 2017; Filipovic et al., 2015). (...)

77. Numerous studies have reported environmental contamination due to use of AFFF based on fluorosurfactants (reviewed in (Dauchy, et al., 2019)). PFHxS and/or PFHxS related compounds may be found in these foams either as an unintentional contamination due to the use of PFOS or as an intentionally added ingredient most likely in the form of perfluorohexane sulfonamide (FHxSA) ((Barzen-Hanson, et al., 2017); D'Agostino & Mabury, 2017). (...)"

The following text describes some selected monitoring results from areas where the use of fire-fighting foam containing PFHxS has polluted the surroundings.

A spatial analysis of the occurrence of selected PFASs in US drinking water shows that the number of (military) fire training areas in a water system significantly increased the levels of PFHxS in the drinking water ($p = 0.045$). Furthermore, this study showed that each military fire training site was associated with a 20% increase in PFHxS ($p = 0.002$) (Hu, et al., 2016).

A recent study from France by (Dauchy, et al., 2019) describes the PFAS contamination soil and groundwater around a large fire-fighting training area that has been active for more than three decades. PFOS was the predominant PFSA in the soil surface layer followed by PFHxS. The ground water samples showed the highest PFAS concentrations in monitoring wells located at the fire-fighter training site. PFHxS levels up to 2860 ng/l were detected inside the fire-fighting training area, and PFHxS levels up to 122 ng/l were detected in a spring water well outside the fire-fighting training area.

An Australian study by (Bräunig, et al., 2017) also showed that leaching of perfluoroalkyl acids (PFAAs) from a fire-fighting training area that had been in use since the 1970s had spread underneath parts of a nearby town and caused extensive contamination of a groundwater aquifer. PFOS was the predominant PFAA in all investigated matrices (water, soil, grass, chicken egg yolk, serum of horses, cattle and sheep, as well as human serum), followed by PFHxS. PFOS and PFHxS were detected in most water samples and at the highest concentrations of all PFAAs investigated. PFHxS water concentrations up to 6 µg/L were found, whereas the PFOS water concentrations ranged up to 14 µg/L (Bräunig, et al., 2017). Furthermore, a study of the uptake of different PFAAs in soil, earthworms and wheat grass by the same author (Braunig, et al., 2019) showed that even though PFOS was the predominating PFAA in the soil, PFHxS was the predominating PFAA in wheat grass (Braunig, et al., 2019).

The spreading of PFHxS from fire-fighting training area to drinking water can pose a significant problem to human health. A recent Swedish study by (Li, et al., 2018) found that firefighting foam used at an airfield since the mid-1980s contaminated the drinking water to such an extent that PFHxS levels up to 1700 ng/L were detected in the municipal drinking water. This drinking water had been distributed to one-third of households in Ronneby, Sweden (Li, et al., 2018). As described in Annex B.9.4.5.3 the human blood serum levels of

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

PFHxS from people drinking this water were the highest ever reported in Sweden, (277 ng/mL, range 12–1660) (Li, et al., 2018). Similar results from Cologne, Germany have been presented by (Weiß, et al., 2012).

Former use of PFHxS contaminated fire-fighting foams can still be a source of contamination of the surrounding environment. (Filipovic, et al., 2014) studied a former Swedish airfield that had been abandoned since 1994. PFHxS was detected at significant levels in soil, groundwater, tap water and surface water samples at the abandoned site. Furthermore, PFOS and PFHxS were the dominating PFASs in the surface waters taken from the lakes in the vicinity of the fire drill sites. PFHxS was detected in 48% of muscle tissue samples from different fish species, whereas PFOS was detected in 100% of the fish muscle samples from these lakes (Filipovic, et al., 2014).

Furthermore, a recent Norwegian study also detected elevated levels of PFHxS in a sand trap and an oil separator at a local fire station (Slinde & Høisæter, 2017). It is unclear if fire-fighting training activities have taken place at the fire station.

B.4.3.5 Biota

In a recent study performed by (Groffen, et al., 2017) PFAAs have been detected in eggs of great tits near a perfluorochemical plant (3M) in Antwerp, Belgium. The PFSA concentration measured at the site of the plant were among the highest ever reported in bird eggs. PFHxS concentrations near the plant were in a range of 37-355 ng/g ww with a mean of PFHxS of 162 ng/g ww. The levels at adjacent sites decreased with distance from the plant, and were <LOQ to 5.6 ng/g ww at 1 km from the plant. No PFHxS were detected at two sampling points further away from the plant.

According to (Cui, et al., 2018) were PFHxS (mean 87.5 ng/g) and PFOS (35.9 ng/g) the most prevalent compounds detected in aquatic organisms (including i.a. several fish species, crabs, shrimps, ducks) with a detection frequency of 50 %. Four free-range ducks raised around Baiyangdian Lake and ten duck eggs collected from two local duck farms were also analyzed. The results showed high concentrations of PFHxS in duck blood (438 ng/g), liver (289 ng/g), meat (86 ng/g) and eggs (mean 31 ng/g ww).

Analysis of pooled liver samples from fish caught off the UK coast in 2018 has provided the following statistics for PFHxS concentrations (wet weight): Median measured concentration in Dab (*Limanda limanda*) was 0.115 µg/Kg (95-percentile 0.210 µg/Kg, n = 70); Median measured concentration in European plaice (*Pleuronectes platessa*) was 0.0956 µg/Kg (maximum = 0.124 µg/Kg, n = 5); Measured concentrations in Whiting (*Merlangius merlangus*) were below the Level of Detection of 0.05 µg/Kg (n=4) (UK Environment Agency, 2019a)

PFAS have been analyzed in eggs of three species of seabirds (common eider, European shag and European herring gull) from remote bird colonies in Norway (Huber, et al., 2015). PFHxS concentrations in the range of 0.2–1.6 ng/g were found. In a recent study, PFAS were determined in peregrine falcon eggs collected in South Greenland between 1986 and 2014 (Vorkamp, et al., 2018). PFHxS was detected in all samples in concentrations between 0.4-18 ng/g dw with a mean of 3.7 ng/g dw. A non-linear decrease over the study period was observed with a relative maximum in the early 1990s following by an increase until 2004/2005 where after a decrease has been observed.

Profiles of seven PFAS were compared among three species of top predators (harbour porpoises, harbour seals and whitebeaked dolphins) from the Danish North Sea (Galatius, et

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

al., 2013). The seals had higher total body burdens of PFAS (758 ng/g ww) than the dolphins (440 ng/g ww) and the porpoises (356 ng/g ww). The body burdens are probably positively correlated with feeding taking place closer to the shore and thus closer to contamination sources. Furthermore, seals had higher proportions of PFHxS in the livers (mean 16.3 ng/g ww). The authors suggested that the relatively short-chained PFHxS is more rapidly excreted in cetaceans. These findings are also corroborated by other studies of North Sea and Baltic harbour seals, with PFHxS concentrations in the range of mean 2.7-16.3 ng/g ww from several locations in Danish waters (Dietz, et al., 2012) and 0.7-10.5 ng/g ww in different organs and tissues of harbour seals from the German Bight (Ahrens, et al., 2009) were measured. Liver samples from 95 Harbour Porpoises (*Phocoena phocoena*) stranded or bycaught in UK coastal waters from 2012-17 contained a median measured PFHxS concentration of 0.424 µg/Kg (95-percentile 2.801 µg/Kg) (wet weight) (UK Environment Agency, 2019a)

Lower PFHxS concentration has been found in liver and muscle tissue of marine mammals (seal, dolphin, porpoise and whale species) from the North Atlantic and West Greenland, collected between 1984 and 2009. PFHxS concentration ranged between 0.1 and 0.7 ng/g ww (Rotander, et al., 2012). (Kallenborn R, et al., 2004) detected PFHxS in liver tissue of mink whale and long-finned pilot whale in the North Atlantic in the range of <0.4-1.1 ng/g ww.

Otters from populations in Sweden and Norway were analysed for PFAS (Roos, et al., 2013). PFOS was the dominating compound, but PFHxS was also detected in > 95 % of all analysed liver samples, with concentration of 0.7-12 ng/g ww in samples from Northern Sweden, 0.7-64 ng/g ww in samples from Southern Sweden and 1.5-7.6 ng/g ww in samples from South-west Norway. Further a temporal trend study was performed on otters from southern Sweden collected between 1972 and 2011. Although the mean concentrations of PFHxS were higher during the last years of the time trend compared to earlier, the range was large and no statistically significant time trend for PFHxS was seen.

In terrestrial mammals PFHxS has been detected in pooled liver samples of roe deer collected between 1989 and 2010 in Germany. PFHxS was detected in 21 % of the samples in the range of < 0.5-2.0 ng/g (Falk, et al., 2012).

B.4.3.6 Arctic/ remote areas

PFHxS is detected in the Arctic. The draft POPs risk profile for PFHxS has this description of the levels of PFHxS in the Arctic (UNEP/POPS/POPRC.14/2, 2018):

" 72. Due to detection of PFHxS in Arctic air and snow, long-range transport of PFHxS and/or PFHxS-related compounds through the atmosphere may occur (Theobald, et al., 2007) as cited in (Butt, et al., 2010); (Stock, et al., 2007); (Genualdi, et al., 2010); (Butt, et al., 2010) (Wong, et al., 2018); (Bohlin-Nizzetto, et al., 2017)). A recent study reporting a significant increase in concentrations of PFHxS ($p < 0.006$) during the period 2009 - 2015 in Arctic air both in Canada and Norway indicating that an increase in long-range transport has occurred (Rauert, et al., 2018a). PFHxS was also recently detected in air at remote locations in the Latin American and Caribbean region (Rauert, et al., 2018b). Furthermore, higher PFHxS levels were detected in coastal water of Greenland compared to seawater, a finding that was attributed to precipitation in the form of rain, snow and/or ice melting at the Greenlandic mainland (Busch, et al., 2010). An atmospheric source could involve neutral PFHxS related compounds as with those reported for PFBS and PFOS ((Martin, et al.,

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

2006); (D'Eon, et al., 2006). A number of studies show evidence that PFAS precursors are transported through air and degrade to e.g. PFBS, PFOS (Stock, et al., 2007); (Dreyer, et al., 2009); (Del Vento, et al., 2012) and most likely also PFHxS. This argument is strengthened by the detection of increasing amounts of PFHxS during snow melt (Codling, et al., 2014); (Meyer, et al., 2011)) and detection of PFHxS in rain water (Eschauzier, et al., 2010). See section 2.2.2 for further details. The potential for PFHxS to undergo long-range environmental transport via air is further supported by the detection of PFHxS in lichen from the Antarctic Peninsula. Lichen accumulates pollutants from air and is used as bioindicators for air pollution (Augusto, et al., 2013). PFHxS has also been detected in the feathers of an accipiter bird in rural areas of Tibet (Li, et al., 2017).

73. Recent studies of polar bears from Norwegian Arctic showed that levels of PFSA (Σ PFSA₂; PFHxS and PFOS) were found in the highest concentration compared to other already regulated POPs. Total concentration (ng/g ww) of Σ PFSA₂ were 264.35±12.45 (PFHxS 30 ng/g ww; PFOS 233 ng/g ww), Σ PCB were 39.98±3.84 while Σ PBDE were 0.18±0.01 (Bourgeon, et al., 2017); personal communication with Heli Routti). Hence in these studies the concentration of PFHxS is similar to the total PCB concentrations. In general, it is between 2–18 times more PFOS than PFHxS detected in animals from the Norwegian Arctic, and the amount of PFHxS is 2 – 7 times higher compared to PFOA (Miljeteig, et al., 2009); (Bytingsvik, et al., 2012); (Aas, et al., 2014); (Routti, et al., 2017)."

"78. For a number of studies, exposure in limited areas (such as snowpack, melt water) can be attributed to long-range environmental transport (Zhao et al., 2012; Routti et al., 2017; Codling et al., 2014; Kwok et al., 2013; Yeung et al., 2017; Li et al., 2017). For example, PFHxS has been detected in snowpack in a remote area of northern Sweden (Codling et al., 2014), in surface- snow and water at Svalbard, Norway (Kwok et al., 2013) and in marine Arctic and Antarctic surface waters (Zhao et al., 2012). In a study by Yeung et al., 2017, PFHxS was detected in Arctic snow/meltpond water as well as in ocean water.

79. Furthermore, recent studies report that PFHxS is found at the highest concentration among species- and is the third most abundant PFAS in polar bears (Tartu et al., 2017a; Routti et al., 2017; Norwegian Environment Agency 2017d, M-817/2017; Table 1.3 in UNEP/POPS/POPRC.14/INF/4). Similarly, for polar bears from Hudson Bay, Canada, PFHxS was second only to PFOS in concentration in the liver (Letcher et al., 2018). In plasma from polar bears at Svalbard (Norway), PFHxS levels were in the range 4.9–70 ng/g wet weight (ww) for the time period 2000–2014 (Routti et al., 2017). The concentrations in polar bears from Svalbard are similar to those reported for humans living at the proximity of a fluorochemical manufacturing plant in China (which in turn are an order of magnitude higher than in general populations in China) (Fu et al., 2015). Concentration of PFHxS in polar bears levelled off during the period 2003–2009, the levels increased towards the end of the time series (2014) with an average annual increase of 5%. However, the increase was not significant and with 95% probability the annual change varies between -1% per year to +11% per year (Routti et al., 2017 and personal communication with the author). Furthermore, the authors propose that the fast drop in PFAS concentration following the phase out of C6-8 perfluoroalkyl sulfonates was due to decreased air transport of volatile precursors, while the recent increase in PFHxS levels is most likely due to the much slower oceanic transport of PFASs (Routti et al., 2017). However, a study of PFHxS levels in Norwegian Arctic air recently revealed that significant increasing amounts (< 0.007 – 2.2 pg/m³; p<0.006) has been detected during the period 2009 – 2015 (Rauert et al., 2018)

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

and these results correspond with the observed increase in polar bears levels described in (Routti, et al., 2017) above. In the Routti study, levels of PFHxS in liver from Arctic foxes collected during 1997-2014 were in the range <0.05–139 ng/g ww. PFHxS concentrations in Arctic foxes decreased 11% per year from 2002 to 2014, and the annual change with 95% probability was between -17% to -5%. PFHxS trends for both polar bears and Arctic foxes were similar prior and after they were corrected to the climate-related variation in feeding habits and food availability, the first reflecting the actual trends in the animals and the latter one reflecting the trends in their food web.

81. A number of studies have reported time-trends for PFHxS in various species and matrixes. However, there are some discrepancies in these data and trends are both increasing (Routti, et al., 2017); (Holmstrom, et al., 2010), decreasing (Lam, et al., 2015); (Huber, et al., 2012)), and without any significant trend (Ullah, et al., 2014); (Roos, et al., 2013). In a systematic review of trend studies most data on PFHxS showed no significant change, while an increasing or decreasing trends were observed in a few matrices and regions (Land, et al., 2018). However, as mentioned above the trend of PFHxS in polar bears in the European Arctic (Svalbard, Norway) is increasing (although non-significant within 95% of the confidence interval) in the time-period 2010 – 2014, while the trend in the Arctic fox from the same area is decreasing (Routti, et al., 2017), and personal communication with the author). The increasing trend in polar bears (Routti, et al., 2017) corresponds well with a recent study reporting increasing trends in Arctic air during the same time-period (Rauert, et al., 2018a). Hence, the temporal trend in each case is most likely dependent of emission sources, food choices (terrestrial, marine) and location (urban versus rural) among other factors."

B.4.3.7 Summary on monitoring and trends

Elevated PFHxS levels are found in urban areas and near point sources. Increasing or unchanging temporal trends of PFHxS are found in most biota samples. Point sources such as fluoropolymer, photolithographic and semiconductor factories may be important sources of emissions of PFHxS to the environment. PFHxS from current and old use of fire-fighting foams pollutes the surroundings of fire training sites, leaks to the ground water and may pollute drinking water. Furthermore, PFHxS is detected in marine waters, and an increase of perfluoroalkyl acids in the marine environment could be attributed to human activities. Urban monitoring data that indicates elevated levels of PFHxS in densely populated, urban environments. PFHxS is detected in wildlife including bird eggs from marine and terrestrial environment and in marine mammals representing top predators. The levels of PFHxS in Arctic air samples significantly increased in the period 2009-2015. It is most likely that PFHxS-related substances are transported to remote areas where they are transformed to PFHxS. Furthermore, the PFHxS-levels in polar bears seems to increase.

B.4.4. Bioaccumulation

MSC's agreement document (ECHA, 2017b) for the identification of perfluorohexane-1-sulphonic acid and its salts as substances of very high concern because of their vPvB (Article 57 e) properties, has the following conclusion on why PFHxS and its salts should be identified as very bioaccumulating (vB):

"The reported BCFs and BAFs for PFHxS are below the numerical criteria 2000/5000 in REACH Annex XIII, but it is worth noting that one of the BAF values (European chub, BAF plasma) is close to the threshold of 2000 (log BAF of 3.3 equivalent to a BAF of 1995).

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

The latter value suggests that the substance is a borderline B for some aquatic species. In addition, due to the surface active properties of the substance the appropriateness of the available BCF test and the usefulness of its result may be questioned. Further, PFHxS are expected to quickly be excreted in fish via gill permeation like the other PFSA and PFCAs, due to its expected notable water solubility. PFHxS, like other PFSA and PFCAs, do not follow the behaviour of traditional hydrophobic compounds with partitioning into fatty tissues, but instead bind to proteins in blood and liver. Hence, bioconcentration in gill breathing organisms and the accumulation in lipids is not the most relevant endpoint to consider for these types of substances. Field studies show that air-breathing organisms are more likely to bioaccumulate PFHxS and other PFAS compared to water breathing organisms. Therefore, the numerical bioaccumulation (B)/(vB) criteria defined for aquatic species in the REACH regulation Annex XIII (sections 1.1.2 and 1.2.2) are not suitable to assess the bioaccumulation potential of PFHxS.

REACH Annex XIII (section 3.2.2) defines information which shall be taken into account in the B assessment and can and should be used to draw conclusions in a weight-of-evidence approach. In addition to BCF-data, such data are based on Section 3.2.2(b) of Annex XIII to REACH, for example, data on the bioaccumulation potential in terrestrial species, such as elevated levels in endangered species. PFHxS were found in terrestrial species as well as in endangered species as shown in section 3 for the polar bear. The highest concentrations of PFHxS detected in wildlife have been observed in the arctic top predator polar bear (>500 µg/kg in polar bear liver). This finding and the high concentrations of PFHxS found in humans exposed to contaminated drinking water (up to 1790 µg/L in blood serum) show that exposure to PFHxS have the potential to result in high concentrations in biota including humans. These findings indicate a bioaccumulation potential and are of high concern.

Furthermore, Annex XIII (section 3.2.2 (b)) requires to consider data from human body fluids or tissues and to take the toxicokinetic behaviour of the substance into account.

Both gestational and lactational exposure in humans have been shown for PFHxS, which are of special concern as the foetus and newborn babies are highly vulnerable to exposure by xenobiotic substances. On top of that, data from human body fluids clearly provide quantitative proof of the bioaccumulation of PFHxS: Elimination half-lives in humans range from 7-8 years and above. Data from time trend studies on human samples indicate that the bioaccumulation of PFHxS even exceeds that of PFOS.

Finally, Annex XIII (section 3.2.2 (c)) foresees that the potential for biomagnification in food chains of a substance is assessed, as part of a weight-of-evidence approach. It is not possible to draw a conclusion on trophic magnification for PFHxS due to limited reliability of the available data. However, the available field data provide biomagnification factors (BMFs) for several predator/prey relationships for PFHxS. In air breathing predators the resulting BMFs are larger than 1, especially for polar bears suggesting a potential of biomagnification that is supported by monitoring data.

The elimination half-life of PFHxS in mammalian species are similar to that of PFOS in mice, male rats, pigs, monkeys and humans. The elimination half-lives observed for PFHxS in pigs, monkeys and humans are the longest observed for any PFAS, followed by those for PFOS. The main reason why e.g. PFOA was considered to meet the B-criterion of REACH was that it was concluded to bioaccumulate in humans based e.g. on its presence in human blood of the general population, the long elimination half-life in human blood of 2-4 years

and that the levels increase with age. This holds true also for PFHxS but they have an elimination half-life in human blood of ca 7-8 years (or longer), which is at least 2-4 times longer than the elimination half-life of PFOA.

Depending on the type of substance, the process driving the bioaccumulation will differ, from hydrophobic partitioning to species and gender specific ADME-properties. Elimination half-lives are recognised as relevant bioaccumulation metrics and PFHxS has in comparison with PBT/vPvB and POP-substances among the longest human elimination half-lives reported.

*The information summarised above is in high accordance with the bioaccumulation data on PFOS, the bioaccumulation potential of which corresponds to "vB" as it is included under the Stockholm Convention on persistent organic **pollutants** (POPs). A read-across to PFOS (Annex I) is performed as part of the weight-of-evidence." (ECHA, 2017b)*

B.4.5. Secondary poisoning

Not relevant for this dossier.

B.5. Human health hazard assessment

This dossier is based on PFHxS's established vPvB properties. Assessment of human health effects are therefore not relevant. Nevertheless, for information, we include here the adverse effects described in the draft POPs risk profile (UNEP/POPS/POPRC.14/2, 2018)

"130. In rodents, liver effects such as increased liver weight, marked hepatocellular hypertrophy, steatosis and necrosis has been observed from PFHxS exposure. Effect on liver lipid and lipoprotein metabolism and altered serum cholesterol, triglycerides and lipoproteins has been observed in both rodents and humans. PFHxS activates peroxisome proliferating receptor (PPAR)-alpha, however, effects on liver are also observed in mice without PPAR-alpha, showing mechanisms of action independent of PPAR-alpha. In addition, effect on reproduction (decreased live litter size) has been observed in mice following PFHxS exposure.

131. Neurotoxic and neurodevelopmental effects have been observed in controlled laboratory experiments in mice and rats, and some studies indicate association between behavioural inhibition in children and certain PFASs (and PFHxS) exposure prenatally and in childhood. Effects on the endocrine system, including in particular the thyroid hormone system have been reported cross-species (bird, rat, polar bear and human). Furthermore, several epidemiology studies indicate that the naïve and developing immunesystem might be vulnerable to certain PFASs and PFHxS exposure, observed as associations between serum PFHxS levels and reduced effect of vaccines and higher incidences of infections and asthma in children."

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

PFHxS was identified as a Substance of Very High Concern by the ECHA Member State Committee 15 June 2017, because of the vPvB properties.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

As explained in the SVHC support document (ECHA, 2017a) relevant information on toxicokinetics and bioaccumulation in humans is used in a weight-of-evidence approach to justify that PFHxS fulfils the vB criterion.

The draft POPs risk profile for PFHxS provides this updated overview of data on toxicokinetics (UNEP/POPS/POPRC.14/2, 2018):

"63. (...) The reported half-life of PFHxS in humans varies between 5.3 and 35 years (Li, et al., 2018; Zhang, et al., 2013; Fu, et al., 2016; Olsen, et al., 2003), which is the longest of all PFASs for which data are available. The half-life of 35 years was estimated from paired blood urine samples for men and older females based on urine as the only elimination pathway (Zhang, et al., 2013). The half-life of PFHxS is comparable to the longest human elimination half-lives recorded for known PBT/vPvB- and POP-substances such as some PCBs (ECHA, 2017a). The elimination half-life of PFHxS, PFOS and PFOA in serum of 26 retired fluorochemical production workers (22 males and 2 females) has been reported (Olsen, et al., 2007). Half-lives for PFHxS, PFOS and PFOA were 8.5, 5.4, and 3.8 years, respectively. Hence, the half-life of PFHxS is approximately 1.5 times longer than for PFOS. Elimination half-life in other species has also been reported (Sundström, et al., 2012). However, pharmacokinetic studies in non-humans have demonstrated that serum elimination half-lives of PFHxS can vary considerably between species (Sundström, et al., 2012; Numata, et al., 2014) and, in some cases, between genders within species (Hundley, et al., 2006; Sundström, et al., 2012), but are generally much shorter than the reported human serum elimination half-lives. Furthermore, serum elimination times in humans are affected by female menstruation as well as child-birth (Gomis, et al., 2017).

64. The species-specific and sex-specific elimination of PFHxS is highly expressed in the study by Sundström et al (Sundström, et al., 2012). Male and female rats were investigated in terms of serum elimination and results showed that females much more efficiently eliminated PFHxS than male rats. Furthermore, rats and mice appeared to be more effective at eliminating PFHxS than monkeys (Sundström, et al., 2012). See Table 3 UNEP/POPS/POPRC.14/INF/4) for comparison of half-lives. PFHxS is highly bound to plasma proteins (Kim, et al., 2017; Jones, et al., 2003) and pharmacokinetic studies have revealed that certain PFASs interact with proteins (e.g. albumin, liver fatty acid binding proteins, organic anion transporters) and that their clearance is species-, gender- and chain length-dependent (Andersen, et al., 2008; Ng & Hungerbühler, 2014).

65. The ability to strongly bind to blood proteins and the low clearance and slow excretion in the urine were recently proposed as the best predictors for a chemical's bioaccumulation potential and long half-life (Tonnelier, et al., 2012). In a study of pigs fed a diet contaminated with PFASs, PFHxS was found to have the slowest urinary excretion as well as the highest serum half-life among the investigated PFASs (Numata, et al., 2014). In addition, blood plasma contained the largest amount of unexcreted PFHxS. Interestingly, studies on cows revealed a different pattern of PFHxS with regard to partitioning to blood, liver and edible tissues (Kowalczyk, et al., 2013). In dairy cows, muscle tissue contained the highest concentration of PFHxS indicating a lower tendency for PFHxS to accumulate in plasma than was seen for pigs (Numata, et al., 2014). Furthermore, in the dairy cow study, PFHxS was detected in urine as well as milk during the experimental period showing a higher rate of elimination in cows than in pigs. These studies indicate that both elimination and tissue distribution is species-specific for PFHxS and other PFASs. It was later discussed whether ruminants such as cows have the possibility to biodegrade PFHxS and other PFASs

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

by ruminal microorganisms in the rumen, but this study was inconclusive (Kowalczyk, et al., 2015).

66. The tissue distribution of PFHxS in humans is similar to what is observed in other mammals such as pigs and dairy cows (Numata, et al., 2014; Kowalczyk, et al., 2013; Perez, et al., 2013). In a Spanish human autopsy study PFHxS was found in all studied human (general public) organs/tissues: liver, kidneys, bone, brain and lungs, with highest levels observed in lungs and kidney, and was most frequently detected in lungs (43%) (Perez, et al., 2013). The highest concentrations of PFHxS are found in blood, liver, kidney and lung. Transfer to breast milk appears to be a significant route of elimination during breastfeeding. Time-trend studies indicate that the human bioaccumulation potential of PFHxS may be larger than that of PFOS (ECHA, 2017a)."

Data from the POPs draft risk profile (UNEP/POPS/POPRC.14/2, 2018) referenced above are available in the Appendix 2 of this dossier, see Table 49 for data specifying half-lives.

B.5.2. Acute toxicity

Not relevant for this dossier.

B.5.3. Irritation

Not relevant for this dossier.

B.5.4. Corrosivity

Not relevant for this dossier.

B.5.5. Sensitisation

Not relevant for this dossier.

B.5.6. Repeated dosed toxicity

Not relevant for this dossier.

B.5.7. Mutagenicity

Not relevant for this dossier.

B.5.8. Carcinogenicity

Not relevant for this dossier.

B.5.9. Toxicity for reproduction

Not relevant for this dossier.

B.5.10. Other effects

Not relevant for this dossier.

B.5.11. Derivation of DNEL(s)/DMEL(s)

Derivation of DNELs and DMELs is not relevant for this dossier since the proposed restriction of PFHxS and PFHxS related substances is based on the vPvB-properties.

B.6. Human health hazard assessment of physicochemical properties

Not applicable

B.7. Environmental hazard assessment

This topic is not assessed, as PFHxS and PFHxS-related substances are vPvB-substances.

B.8. PBT and vPvB assessment

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

PFHxS and its salts were included on the list of substances of very high concern in July 2017. The substances were identified as very persistent and very bioaccumulative (vPvB) according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH). See Annex B.4.1 and B.4.4 for more details.

As PFHxS-related substances degrade to PFHxS in the environment (see section 1.2 of the report) these substances must be regarded as vPvB-substances as well (ECHA, 2017c).

B.8.2. Emission Characterisation

PFHxS is found everywhere in the environment including remote areas and endangered species such as polar bears. Monitoring results from Europe and the rest of the world report elevated PFHxS levels in urban areas and near point sources. The occurrence in the environment is a result of anthropogenic manufacture, use and disposal of substances, mixtures and articles containing PFHxS and its related compounds, since they do not occur naturally. PFHxS is not removed from polluted water via wastewater treatment plants. Taking into account that PFHxS is expected to have an environmental half-life of more than 42 years, at least 98% of an emission in one year persists into the next.

According to (Boucher, et al., 2019), the majority of the emissions of PFHxS is expected to come from historic production in United States, Western Europe, and Japan that occurred in the period before the phase-out of POSF-based products. However, the lack of quantitative data makes these assumptions uncertain (Boucher, et al., 2019). It is therefore still unclear to what extent current manufacturing and use of PFHxS, its salts and PFHxS-related substances will contribute to current and future releases of PFHxS to the environment.

Information on the emissions of PFHxS and PFHxS-related substances in the EU is presented in sections 1.1.5.2 - 1.1.5.5 in this report. The table below summarises the emissions of PFHxS in the EU.

Table 19: Summary of the emissions of PFHxS in the EU expressed in kg/year

	Yearly emissions in kg	Comment
Emissions via WWTP	1 793	Mainly coming from industrial sources
	219	Coming from domestic sources and industries not using PFAS
Emissions via landfills	Not quantifiable	Leachate concentrations ranging from < LOD – 8900 ng/L but leachate volumes unknown
Emissions via AFFF	0.035 – 0.245	Negligible compared to emissions via WWTP

B.9. Exposure assessment

As described in section 1.1.6 of the report, exposure of PFHxS and PFHxS-related substances occurs from both local point sources and via diffuse emissions via wastewater treatment plants, housedust, food and drinking water. A recent article by (Boucher, et al., 2019) predicts that the exposure to PFHxS will remain for decades. Also, acknowledging the very persistent nature of PFHxS (see sections 1.1.1 of the report and Annex B.4.1) and the fact that PFHxS-related substances degrade to PFHxS (see section 1.1.2 of the report), human and environmental exposure to PFHxS from current and potential future emissions will remain for a very long time. The exposure of humans and the environment to PFHxS will most probably increase if the emissions are not reduced. Measures to reduce the ongoing emissions to PFHxS are therefore necessary.

B.9.1. General discussion on emissions and exposure

As described in section 1.1.2 of the report, there are currently no REACH registrations of PFHxS or PFHxS-related substances. Some PFHxS-related substances are, however, notified in ECHAs databases (see Table 7). PFHxS is the ultimate degradation product of PFHxS-related substances. This very persistent substance will have a very long residence time in the environment. It will build up over time and can be widespread in various environmental media (Land, et al., 2018; Routti, et al., 2017; Rauer, et al., 2018a). (Boucher, et al., 2019) predicts that elevated environmental concentrations of PFHxS will remain for decades and be spread to remote areas, cfr. section 1.1.6 of the report. The PFHxS levels in wildlife might also increase in the future. This has already been observed in Polar Bear (Routti, et al., 2017). PFHxS has been detected in humans globally with high blood serum levels detected in people consuming PFHxS contaminated drinking water.

The draft POPs risk profile for PFHxS has the following general description of PFHxS-exposure (UNEP/POPS/POPRC.14/2, 2018).

" 6. PFHxS is distributed in the environment including in urban cities, rural areas and in regions that produce or use PFHxS or its precursors in the processing or manufacture of commercial products. It is also found in Arctic regions far away from any sources of release. Worldwide monitoring of water, air, sediment and biota (including humans) at remote locations have detected the presence of PFHxS. At Svalbard, Norway, an annual change has been observed in PFHxS levels in polar bears most likely due to transport through water and air to the Arctic. The highest levels of PFHxS measures in biota, are found in polar bears. Direct transport through ocean currents is likely the main mechanism of transport to remote regions, in addition to atmospheric transport of PFHxS and its precursors. PFHxS has been detected in air, snow, meltwater, rainwater and lichen, indicating that atmospheric transport of precursors that may degrade to PFHxS locally, has occurred. Furthermore, PFHxS as well as FHxSA have been detected in leachates from landfills receiving waste from many sources, indicating possible uses of PFHxS precursors in consumer products.

7. Exposure of the general population takes place by consumption of food, drinking water, by inhalation of indoor air and respiratory and oral uptake of dust containing PFHxS, its salts and PFHxS-related compounds. PFHxS has been detected in human blood and breast milk in many regions, and is together with perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA) and perfluorononanoic acid (PFNA) one of the most frequently detected and predominant PFASs in human blood. The foetus is exposed to PFHxS via the umbilical cord

blood, and breast milk may be an important source of exposure for the infant. In women post-menarche and males, PFHxS levels increase with age, and in general, the highest levels have been observed in men.

8. In regions where regulations and phase-outs have been implemented, human concentrations of PFOS, perfluorodecane sulfonic acid (PFDS), and PFOA are generally declining, while previously increasing concentrations of PFHxS have begun to level off. However, there are also observations of no decline or increasing levels of PFHxS in the same regions, most often connected to households receiving PFHxS contaminated drinking water, but in a few cases also in individuals that get their exposure from unknown sources. Limited data are available on levels and trends of PFHxS in humans in Asia where production continued after the 3M phase out.

(...)

10. PFHxS is ubiquitous in environmental compartments such as surface water, deep-sea water, drinking water, waste-water treatment plants and leachates from landfills, sediment, groundwater, soil, the atmosphere, dust, as well as biota (including wildlife), and humans globally. (...)"

Monitoring results from Europe and the rest of the world show that elevated PFHxS levels can be found in urban areas and near point sources, such as fluorine producing industry and fire-fighting training sites. See Annex B.4.3 for more details on this.

B.9.2. Manufacturing

PFHxS including its salts and PFHxS-related substances are not registered under REACH meaning they should not be manufactured or imported in quantities above one tonne per year in the EU. The Annex XV report for the Identification of a Substance of Very High Concern for PFHxS (ECHA, 2017b) notes that one European company (in Italy) was known to be marketing the PFHxS potassium salt. During consultation carried out with the Italian company as part of preparing this dossier, the Italian company (Miteni, which was the major manufacturer of fluorinated substances in the EU) identified that it stopped manufacturing PFHxS in 2013 and that production of PFC decreased in the period 2011 – 2013 from 778 tonnes to 383 tonnes (Regione del Veneto, 2014). However, the company's website offered PFHxS as a product in 2018. On 26 October 2018, Miteni's management decided to declare bankruptcy and to suspend production activities by the end of the year. This was announced on 31 October 2018.

B.9.3. Other sources (unintentional releases)

As described in Annex A, no no current uses of PFHxS (including its salts and PFHxS-related substances) have been identified in the EU other than fire-fighting foams, textiles and import of PFOS in continuing (exempted) use as mist suppressants for non-decorative hard chromium (VI) plating were identified for PFHxS including its salts and PFHxS-related substances in this survey. PFHxS is detected in wastewater treatment plants and the environment.

Estimating the PFHxS-emissions per use area is not possible since there seem to be no information about intended uses in the EU. Except for the AFFF there is no information on the content of PFHxS including its salts and PFHxS-related substances in mixtures and

articles in the EU. In order to still estimate the emissions of PFHxS including its salts and PFHxS-related substances emissions from wastewater treatment plants were analysed.

Emissions of PFHxS from wastewater treatment plants in the EU

PFHxS has been measured and reported in several literature sources. Concentrations of PFHxS in wastewater treatment plants have been investigated to estimate emissions to the environment from new or unknown intentional uses (as such, in articles or formulations) or due to PFHxS including its salts and PFHxS-related substances being present as an impurity together with other PFASs.

The fate of PFHxS in sewage treatment plants is ambiguous and not fully understood. PFHxS is generally not well adsorbed to sludge and thus usually not detected in sludge. However, some authors have been able to detect low quantities. The highest concentration detected by (Gomez-Canela et al, 2012) was 1.4 ng/g dry weight sludge, while (Bossi, Strand, Sortkjær, & Larsen, 2008) found 10,7 ng/g dry weight in Danish sewage sludge. See also appendix B.4.3.3 – Urban Terrestrial Environment.

PFHxS enters the WWTP in the aqueous phase, and no significant removal occurs during primary clarification, while this is less clear for precursors (Schultz et al, 2006). Perfluoroalkyl sulfonates are sparingly volatile and not susceptible to biodegradation. While it might be argued that there could be removal of PFHxS by sorption onto the biofilm of the trickling filter, the higher molecular weight sulfonates, including PFOS and PFDS, do not show the same behaviour. No further reduction in mass flow occurs during activated sludge or any subsequent treatment stage before discharge (Schultz et al, 2006). In some cases, higher effluent concentration compared to the influent concentration are detected (Stasinakis et al, 2013; Eriksson, et al., 2017). This could arise from PFHxS-related substances (precursors) degrading to PFHxS in the wastewater treatment plant.

The adsorption to sludge is influenced by the organic contents and the presence of divalent and trivalent ions in sludge (Wang et al, 2015) and (Zhang, Yan, Li, & Zhou, 2015) noted that the adsorption properties of sludge in different processes may differ and thus the removal of PFASs through sorption may also vary significantly. This could possibly explain the ambiguity of PFHxS in sludge and the difference in partitioning behaviour.

PFHxS has been detected in sludge from Bavarian wastewater treatment plants from 2008 to 2011. The concentration trend of PFHxS was decreasing and in 2012 and 2013 PFHxS was not anymore detected in the sludge (Ulrich et al, 2016). Gomez-Canela et al (2012) also detected PFHxS in three Bavarian wastewater treatment plants but considering the trends and timeframe these concentrations should not be relevant anymore. Next to German sludge also Spanish sludge was analysed. Only in three out of twelve Spanish sludge samples PFHxS could be detected in concentrations equal or below 0.1 ng/g. Other sources have also reported concentrations of PFHxS in sludge below the detection limit (Stasinakis et al, 2013; Filipovic & Berger, 2015; Kärrman, et al., 2019). It can be concluded that PFHxS is not very well adsorbing to sludge and that most of it would pass through the wastewater treatment plant unmodified. Sludge is therefore not considered a major pathway for emissions of PFHxS to the environment, while this is less clear for PFHxS-related substances. See also Annex B.4.3.3 for more details.

Since sludge from the wastewater treatment plant is not the dominant pathway for PFHxS the focus has been put on the effluent. Concentration of PFHxS in wastewater treatment

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

plants have been collected from several publications (Huset, et al., 2008; Ahrens, et al., 2009b; JRC, 2012; Filipovic & Berger, 2015; Eriksson, et al., 2017; Kärrman, et al., 2019; Stasinakis et al, 2013). A total of 124 data points were extracted from these publications covering domestic but also industrial and commercial input to wastewater treatment plants.

The average concentration of PFHxS in wastewater treatment plants is 37.1 ng/L. This average value is driven by some high values compared to the majority of the data points as the median value is 2.6 ng/L. A closer look at the higher values reveal that they might be related to chemical plants and/or tank cleaning operations, however they were not considered outliers and are therefore included in the average. A similar strategy as for the C9-C14 PFCAs restriction report (ECHA, 2017) has been followed. In the EU a municipal sewage treatment capacity of about 775 million resident equivalents is available (Neumann, 2013). That is equal to 77,500 default WWTP according to the Technical Guidance Document on Risk Assessment Part II (10,000 inhabitant equivalents; capacity per day 2000m³). A default wastewater treatment plant with an effluent concentration of 37.1 ng/L would emit 74.2 mg PFHxS per day, all wastewater treatment plants in the EU would together emit 5.75 kg PFHxS per day or 2.10 tonnes PFHxS per year.

Splitting the data (n=124) on effluent concentrations of PFHxS demonstrated that the 10% highest concentrations were responsible for approximately 90% of the emissions. See Table 50 for details. (The fact that these figures do not add up to 2.1 tonnes is due to rounding in the calculations.)

Table 20: Overview of the concentrations of PFHxS in WWTP effluents

	All data points	10% highest	90% lowest
Number of data points	124	13	111
Min (ng/L)	0	31.6	0
Median (ng/L)	2.55	180.2	2.2
Max (ng/L)	921.9	921.9	30.9
Average (ng/L)	37.1	316.2	4.31
Yearly emissions (kg PFHxS per year)	2 098	1793	219

This shows that the emissions are not so evenly distributed as expected and that point sources are a major contribution. A possible explanation for this could be the use of AFFF close to the sampling locations during the sampling campaign or that industries manufacturing or using fluorochemicals have PFHxS its salts or PFHxS-related substances as such or as impurity in their products. Note however that those higher emission values are dated 2011 or earlier meaning that actions like on the PFOS might also already have reduced the PFHxS emissions nowadays.

This path has been investigated by looking for correlations between PFHxS, PFOS and PFBS using the effluent concentration data from JRC (2012) where all three substances were measured in 90 wastewater treatment plants. A moderately positive correlation between PFHxS and PFOS was found (R=0.77). The correlation between PFHxS and PFBS was lower but still moderately positive (R=0.67). This is not surprising as PFHxS is chemically closely related to both PFBS and PFOS. PFHxS is a known impurity of the PFOS manufacture (See Annex A) and there is evidence of PFHxS being generated as well during PFBS manufacture. Miteni for example has claimed to stop manufacturing PFHxS in 2013 and only produces PFBS but PFHxS was present in its wastewater after this date.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Several literature sources have estimated an emission factor for PFHxS per inhabitant (Banjac et al., 2015; Huset et al., 2008; Eriksson et al., 2017). These range from 0.53 to 15 µg/day/inhabitant. The amount of data is limited and spans over an order of magnitude. Using the average as was done for the effluent concentrations would bear high uncertainties. Therefore, the minimum and maximum concentrations are selected to define a range. The associated emissions on EU level taking into account ca. 500 million inhabitants will subsequently range from 0.1 – 2.7 tonnes PFHxS per year.

The estimated emission of 2.1 tonnes PFHxS by using the effluent concentrations of wastewater treatment plants fall within this range which strengthens the assessment.

Filipovic et al (2015) have demonstrated that tap water could be an important source of PFAS in wastewater treatment plants due to recirculation. See also Annex B.9.4.4.1. This will certainly have an impact on the concentrations of PFHxS in wastewater treatment plants only treating domestic wastewater but will be negligible for the calculation of the total emissions due to the major contribution of point sources.

Emissions of PFHxS from landfills in the EU

Several authors have reported emissions of PFHxS from landfills (Eggen et al, 2010); (Fuentes et al, 2017); (Hamid et al, 2018). This means that even after service life PFHxS can still enter into the environment. The approximate number of landfills in the EU-27 is 8400 (ECHA, 2012). According to the Landfill Directive (99/31/EC), Annex I section 2 leachate is to be treated according to local standards before discharges. As demonstrated in the section above, PFHxS is not very well adsorbing to sludge and most of it would pass through the wastewater treatment plant unmodified. This means that PFHxS present in landfill leachate will be emitted to the receiving environment. Concentration of PFHxS in landfill leachates in the EU range from < LOD to 8900 ng/L (Fuentes et al., 2017). Since leachate volume is highly dependent on climate (in particular, rainfall and subsequent infiltration into landfill), and may vary substantially from month to month, and from year to year (Gallen et al, 2017) it is difficult to estimate the load of PFHxS being emitted via landfill leachates in the EU.

Emissions of PFHxS from the use of AFFF in the EU

The use of AFFF is somewhat special and discussed separately in the following paragraph. The total amount of PFHxS including its salts and PFHxS-related substances being used in AFFF is depending on the number and type of fires occurring, training and testing of fire-fighting systems. Some companies are trying to go fluorine free while others are still having stocks which might or might not be used in the future.

However, there is now more awareness about the hazard of PFHxS and other fluoro chemicals and recommendations are (e.g. (Eurofeu, 2018)) that:

- Fluorine foams should not be used during training and testing;
- Municipal fire departments do not need fluorine foams; and
- Industry sites that have stocks should only use fluorine foams when really needed. First an assessment of the type of fire is required to evaluate if fluorine containing foams are needed.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Note that these are only recommendations from the sector and are not mandatory or enforced by any means.

The amount of stocks and their renewal are discussed in Annex A.2.9. Renewal of the stocks can happen for two reasons, either the foam has passed its expiry date or the foam has been used to extinguish a fire, training and or testing purposes. In the first case the expired foam should be collected and treated appropriately. Although following very poor product management advice from suppliers and manufacturers the extinguisher service agents and end-users have been dumping PFAS foam wastes directly to the ground (e.g., mining vehicle on-site test firing and wash-out) or to sewer (in the case of service agents refilling retail extinguishers) in the mistaken belief, based on supplier's advice, that the products will fully degrade or that wastewater treatment plants (WWTPs) will be able to capture and/or treat the PFAS wastes (IPEN, 2018).

In case the foam has been used to extinguish a fire, several possibilities arise:

- Either the foam was used in an area without firewater collection (e.g. road fire, offshore locations),
- used in a domestic area where the firewater would flow into the sewer system or
- at industrial sites where containment options are potentially available.

In the first case 100% of the PFHxS including its salts and PFHxS-related substances would enter the environment. Either in the ground which would lead to leaching to groundwater or via run-off into a nearby water stream. If the foam is used at an offshore location it would directly go to the marine compartment.

In the second case the firewater would go into the sewer system and pass in a municipal wastewater treatment plant. Unfortunately, except if special measures are taken, which is often not the case, PFHxS would just go through the system and completely released with the effluent. It could even be that the PFHxS concentrations would further increase due to the degradation of the PFHxS-related substances during the biological treatment.

In the third case, a fire at an industrial facility, the firewater can be contained and collected although this depends on the country and obligations for the installations. Secondly the firewater should not be treated in standard wastewater treatment plants as they will not remove the PFHxS and just discharge it altogether with the effluent. Currently only expensive options are available for treatment of firewater with fluorosurfactants: incineration or treatment with activated carbon. Other options are being tested and are almost ready to be commercialised (e.g. resins and ultrasound foam fractioning).

Although technically speaking there might be options to contain and treat firewater contaminated with PFHxS including its salts and PFHxS-related substances it seems that economically it's often not the case and also legally not mandatory to do so. In the end the substance is most likely going to end up in the environment.

One could assume that fluorine foams should not be used anymore in the first and second case and should only be used in the third case if really necessary.

Based on all the arguments above, trying to quantitatively estimate the current and future emissions to the environment is highly uncertain as no one can predict:

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

- When and where a fire might occur,
- if the recommendations are put into practise and
- what type of fluorine foams is used (including or excluding PFHxS its salts and PFHxS-related substances).

However, as a worst-case assumption one could assume that the emissions of PFHxS are equal to the replenishment rate calculated in Annex A.2.9.2 meaning between 39 g and 245 g of PFHxS are emitted across the whole of the EU per year via the use of AFFF. Compared to the amount of PFHxS emitted via wastewater treatment plants this is almost negligible.

It is expected that emissions via AFFF are decreasing as more and more companies like the Norwegian offshore industry, Heathrow airport or states like Queensland in Australia are switching to fluorine free foams for fire-fighting. Consultation with a major F3 producer (see Annex G) suggests that, while the F3 market may be around 60-70% of the market in Australia owing to increasing regulation and phasing out of PFAS, it is only around 20% in New Zealand where this strong regulation is not in force. Information was requested on the EU market as part of consultation for preparation of this dossier, but this has not been forthcoming.

B.9.4. Human exposure

Human exposure to PFHxS is also discussed in section 1.1.7 of the report in this dossier.

The draft POPs risk profile for PFHxS provides this updated overview of data on human exposure (UNEP/POPS/POPRC.14/2, 2018):

"82. Exposure pathways for PFASs, including PFHxS, include indoor dust, diet, drinking water and indoor/outdoor air (ECHA, 2017a) Table 1.4 and 1.6 to 1.8 in UNEP/POPS/POPRC.14/INF/4). PFHxS, along with PFOS and PFOA, is the most frequently detected PFAS in blood-based samples from the general population worldwide (ECHA, 2017a), annex II, Table 14; Table 1.10 in UNEP/POPS/POPRC.14/INF/4) and present in the umbilical cord blood and breast milk (Kärrman, et al., 2007; Gützkow, et al., 2012) PFHxS is transferred to the foetus through the placenta in humans and is excreted via lactation. Breast milk may therefore be an important source of exposure to breast-fed infants. Lifestyle factors contribute to the exposure; microwavable food intake and low frequency of indoor dust removal by vacuuming are connected to higher serum levels of PFHxS and other PFASs (Siebenaler, et al., 2017), as are increased use of stovetop Teflon cookware and preheated packaged foods, and increased use of carpet for floor covering (Hu, et al., 2018) and use of stain repellants (Kingsley, et al., 2018)."

Besides the direct exposure to PFHxS itself, humans are exposed to a range of PFHxS-related substances, present in articles and mixtures that can be metabolised to PFHxS in the human body. According to BIPRO (2018), the production of PFHxS-related substances is considerably larger than the production of PFHxS itself.

For details of most of the individual biomonitoring studies referenced below see tables in Appendix 2. In addition, many of the studies are summarised in the MSC SVHC Support document (ECHA, 2017a) and in the Draft Risk Profile for PFHxS under the Stockholm Convention (UNEP/POPS/POPRC.14/2, 2018).

B.9.4.1. Occupational exposure

Several studies of occupationally exposed workers in manufacturing plants around the world, investigated levels of PFHxS in dust, blood, serum and urine (Wang, et al., 2010; Ehresman, et al., 2007; Olsen, et al., 2003; Fu, et al., 2016; Gao, et al., 2015; Fu, et al., 2015). Some studies also analysed food and drinking water in, or in the vicinity of, the plants (see Annex B.9.4 and tables in Appendix 2) (Gao, et al., 2015; Fu, et al., 2015). The concentrations of PFHxS in serum (mean/geometric mean/median) were in the range of 5-863 ng/mL. In urine the geometric mean/median was found to be 1.7 ng/mL. The geometric means of concentrations of PFHxS in dust were in the range of 18.6-25820 ng/g. Gao and co-workers (Gao, et al., 2015) found that indoor dust (67.3%) and diet (31.6%) were the largest sources to PFHxS exposure for the workers in a Chinese fluorochemical manufacturing plant.

B.9.4.2. Workers exposure

Occupational exposure can lead to high serum levels of PFHxS. One study investigated PFHxS levels in fire-fighters' serum (Rotander, et al., 2015). The levels found were in the range of 49-326 ng/mL.

B.9.4.3. Consumer exposure

Humans may also be exposed to PFHxS via indoor environment, mainly through dust or particulate matter. Studies investigating PFHxS levels in dust in homes, offices, furniture stores and hotels, found median levels of PFHxS in the range of 0.1-2100 ng/g (Huber, et al., 2011; D'Hollander, et al., 2010; Kubwabo, et al., 2005; Strynar & Lindstrom, 2008; Konieczny, et al., 2016). Significant positive associations between concentrations of PFCs in house dust and the corresponding serum concentrations underline the importance of indoor environment as an exposure pathway for PFCs (Haug, et al., 2011).

One study investigated PFHxS levels in carpets treated with Scotchgard™ regularly for the last 20 years in a Canadian household. The carpet in the family room contained ~3000 ng/g PFHxS and blood levels in the family varied from 27.3-423 ng/mL, with the youngest child having the highest levels (Beesoon, et al., 2012).

Siebenaler and co-workers (Siebenaler, et al., 2017) reported that microwavable food intake and low frequency of indoor dust removal by vacuuming are connected to higher serum levels of PFHxS and other PFASs.

Furthermore fully or partially carpet covered floors have been associated with 37.2% increase in serum PFHxS concentrations in children (Hu, et al., 2018) and serum PFHxS concentrations in children enrolled in the Health Outcomes and Measures of the Environment (HOME) Study at the 8-year visit were 33% higher among those who reported having ever used stain repellents compared with those who reported never using stain repellents (Kingsley, et al., 2018).

Exposure for PFHxS from the home environment can lead to concentrations of PFHxS in blood (plasma/serum/whole blood) similar or above those observed in occupational settings (ECHA, 2017a).

B 9.4.4. Indirect exposure of humans via the environment

B. 9.4.4.1 Drinking water

Drinking water consumption from sources near or in contaminated areas is considered to be one of the most important exposure pathways of PFASs for humans in these areas. Several human biomonitoring studies have concluded that exposure to PFHxS via drinking water can lead to much higher blood serum levels compared to control groups, as observed in USA, Germany, Sweden and Italy (Wilhelm, et al., 2009; Li, et al., 2018; Hu, et al., 2016; Ingelido, et al., 2018). In Sweden exposure to PFHxS via drinking water led to 180-times higher blood serum levels (median) compared to the reference group (Li, et al., 2018).

PFHxS levels in blood in German, Swedish and Italian populations with contaminated drinking water were found to be (median/geometric mean) in the range of 0.5-277 ng/mL (Wilhelm, et al., 2009; Li, et al., 2018; Glynn, et al., 2012; Hölzer, et al., 2008; Ingelido, et al., 2018). Contamination of tapwater with PFHxS at low levels (the mean was in the range of n.d. - 2 ng/L) has been observed world wide (Mak, et al., 2009; Kaboré, et al., 2018; Zafeiraki, et al., 2015; Boiteux, et al., 2012; Ericson, et al., 2009) see Table 42 in Appendix 2 for details. In the USA a survey showed that in 23 US States PFHxS was detected in the drinking water serving 5.5 million people (EWG, 2010-2015). In Sweden, surveys indicate that one third of the population get their drinking water from a water source affected by PFASs, including PFHxS (Banzhaf, et al., 2017).

The mean of PFHxS in contaminated drinking water was in the range of 4.6-1770 ng/L (Li, et al., 2018; Council of Chemists of the Province of Treviso, 2017). Data from a contaminated area in Uppsala in Sweden, showed that the PFHxS levels in ground/drinking water varied from 16 ng/L (upstream of the airport) to 690 ng/L (downstream of the airport). The concentration in the communal water well was 83 ng/L (Gyllenhammar, et al., 2015). In the city of Ronneby in Sweden, people have been exposed to even higher levels of PFHxS via drinking water (1700 ng/L in 2013) from a nearby military airport (Li, et al., 2018).

B. 9.4.4.2 Dietary intake

Several studies have analysed PFHxS in a large variety of food items. The results show that the presence of PFHxS in food varies greatly and ranges from the pg/kg to µg/kg level.

The draft POPs risk profile for PFHxS provides this updated overview of data on dietary intake of PFHxS (UNEP/POPS/POPRC.14/2, 2018):

"83. A number of studies have reported presence of PFHxS in food items (EFSA, 2012; Gebbink, et al., 2015; Noorlander, et al., 2011; Food Standards Australia New Zealand, 2016); Table 1.7 in UNEP/POPS/POPRC.14/INF/4). In a Swedish study, decreasing human dietary exposure in the period 1999–2010 from food stuff was observed (from 55 to 20 pg/kg bw/day), with egg and fish contributing most to human dietary exposure of PFHxS (Gebbink, et al., 2015). In a Dutch study, crustaceans, lean fish, flour and butter (44, 23, 18 and 16 pg/g dw, respectively) had highest levels of PFHxS, low levels (<10 pg/g dw) were also found in fatty fish, industrial oil, bakery products and chicken (Noorlander, et al., 2011). Levels of PFHxS in 2948 human food samples on the European marked quantified PFHxS in samples from vegetables (2%), fruits (21%), meat (1%), fish and other seafood (2%) and drinking water (12 %) (EFSA, 2012). A study from Northern-Norway Mother-Child

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Contaminant Cohort Study (2007–2009) determined that high consumers of game had elevated levels of PFHxS, with “a 20% difference between the highest and lowest intake group” (Berg, et al., 2014). A study using data from the US National Health and Nutrition Examination Survey (NHANES) 2013–2014 for children aged 3–11 years-old found that higher levels of PFHxS in serum were associated with consumption of fruits and juices (Jain, 2018). There is data indicating that food packaging materials constitute a source of human PFHxS exposure (Hu, et al., 2018) as well as canned food (Averina, et al., 2018).

84. A study from Australia and New Zealand of PFHxS in food and water samples from contaminated sites, found highest PFHxS amounts in cattle meat (13.31 µg/kg), rabbit meat (4.94 µg/kg) and eggs (4.27 µg/kg). Other foods with high concentrations were crustaceans, fish liver and sheep meat and occasionally in some vegetables (e.g. spices, berries) (Food Standards Australia New Zealand, 2016)."

A Norwegian study (Hansen, et al., 2016) showed that human consumption of stationary fish from contaminated waters near an airport was associated with increased serum PFAS concentrations, particularly PFOS, PFHxS and PFNA.

A study from Sweden (Vestergren, et al., 2012) compared dietary exposure to PFASs in the Swedish population in 1999, 2005 and 2010. They found that the highest levels of PFHxS were measured in meat, eggs and fish products (2.5-39 ng/kg) and that these three food groups contributed most (60-70 %) to the total dietary intake of PFHxS in the Swedish population in 2010. However, the study also showed that although the levels in cereals and fruits are relatively low, the contribution of these items to the total dietary intake of PFASs can be substantial. This was seen in another study from four countries in Europe (Belgium, Czech Republic, Italy and Norway), where the results showed that foods of plant origin (e.g. fruit and vegetables) are most important for the dietary exposure to PFHxS as well as for PFOA and PFHxA (Klenow, et al., 2013)

The European Food Safety Authority (EFSA) has based on the available data calculated the dietary exposure for several PFASs, including PFHxS (EFSA, 2012). The median chronic dietary exposure to PFHxS in average consumers (adults) ranged from 0.05 (lower-bound, LB) to 1.22 (upper-bound, UB) ng/kg b.w. per day. The corresponding median values among high consumers (95 percentile) ranged from 0.13 (LB) - 2.25 (UB) ng/kg b.w. per day. It should be noted that the results just indicate a range within which the real exposure potentially lies (EFSA, 2012).

B.9.4.5. Combined human exposure assessment

B.9.4.5.1 General information

The combined human exposure assessment considers exposure from all sources (both sources of consumer exposure and indirect exposure of humans via the environment as described in section B. 9.4.3 and B.9.4.4). The internal dose, e.g. assessed using biomonitoring data, reflects an integrated exposure over time comprising various sources and pathways.

Exposure to PFHxS is complex and from multiple sources. Thus, blood/serum concentrations represent an integrated measure of exposure, irrespective of the source and specific substances, e.g. PFHxS-related substances that can be metabolised into PFHxS. In addition,

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

breast milk and cord blood represent an integrated measure of exposure for infants and toddlers. This is possible due to the long half-life of PFHxS in humans.

B.9.4.5.2 Cord blood and breast milk

The draft POPs risk profile for PFHxS provides this updated overview of data on cord blood and breast milk (UNEP/POPS/POPRC.14/2, 2018):

"87. (...) The PFHxS detection rate was above 98% in pregnant women in birth cohorts from Shanghai, Northern Norway, Greenland and two from Denmark (Bjerregaard-Olesen, et al., 2017). PFHxS was detected in every sample of maternal and umbilical cord whole blood and plasma in a study of women and their newborn children (n=7) from Arctic Russia (Hanssen, et al., 2013).

88. Furthermore, PFHxS was detected in umbilical cord blood (ECHA, 2017a)(annex II, Table 14; Table 1.11 in UNEP/POPS/POPRC.14/INF/4) and seems to be transmitted to the embryo to a larger extent than what was reported for PFOS (Kim, et al., 2011; Gützkow, et al., 2012; Pan, et al., 2017).

89. Infants are also exposed to PFHxS through breast milk, however, PFHxS seems to be less efficiently transferred from mothers' blood to breast milk compared to PFOS (Kim, et al., 2011; Mogensen, et al., 2015). After the first six months infants' serum concentrations increased 4- to 3.5-fold for PFOS and PFHxS, respectively, in relation to cord blood (Fromme, et al., 2010; Winkens, et al., 2017). PFHxS was detected in more than 70% of breast milk samples analysed from Japan, Malaysia, Philippines, and Vietnam at mean concentrations ranging from 6.45 (Malaysia) to 15.8 (Philippines) pg/mL (Tao, et al., 2008). Other studies report levels ranging from <0.005 to 0.3 ug/L (ECHA, 2017a)(annex II, Table 14); Table 1.12 in UNEP/POPS/POPRC.14/INF/4). Breastfeeding can be an efficient route of PFHxS elimination from the maternal blood. Comparisons of serum concentrations of women who did or did not breastfeed their infants showed that breastfeeding significantly decreases maternal serum concentrations of PFHxS, PFOS, and PFOA (Bjermo, et al., 2013; Brantsæter, et al., 2013; Papadopoulou, et al., 2015). Commonly a reduction of 3% in the mother's serum for PFOS and PFOA and 1% for PFHxS per month of breastfeeding has been observed (Kim, et al., 2011). In a Swedish monitoring study, PFHxS was analysed in breast milk samples from Stockholm and Gothenburg. In Stockholm, the concentrations of PFHxS, (low pg/mL range), have increased over the whole time-period (1972–2015), although if only considering the last 10 years there seemed to be a decrease during the last 10 years both in Stockholm and Gothenburg (Nyberg, et al., 2017). PFHxS were detected in all children age 3–11 from NHANES 2013–2014, at concentrations similar to those of NHANES 2013–2014 adolescents and adults. This suggest prevalent exposure to PFHxS or its precursors among U.S. population and 3-11 years old children, most of whom were born after the phase out of PFOS in the United States in 2002 (Ye, et al., 2018)."

B.9.4.5.3 Blood

A large number of studies have investigated PFHxS in blood, however the studies vary a great deal (number of measurements, portion of blood analysed, part of population etc) making it difficult to draw conclusions on country specific differences. It is however clear that PFHxS is detected in human blood globally.

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Several studies, included in the MSC support document, investigated levels of PFHxS in whole blood, serum and plasma. The median concentrations of PFHxS in the general population measured in whole blood were in the range of 0.2-2.92 µg/L (Kannan, et al., 2004; Kärrman, et al., 2006; Ericson, et al., 2007). Whereas in serum mean/median concentrations were in the range of 0.6-4.3 µg/L (Hansen, et al., 2001; Kannan, et al., 2004; Lin, et al., 2009; Jönsson, et al., 2010; Nelson, et al., 2010; Ji, et al., 2012; Maisonet, et al., 2012; Toft, et al., 2012; Bjermo, et al., 2013; Zhang, et al., 2013) (Jönsson, et al., 2014; ATSDR, 2018). The risk profile for PFHxS for the Stockholm Convention refers to some additional studies with human serum concentrations (median or geometric mean) within the same order of magnitude (range of 0.22-5.94 µg/L) as reported in MSC support document (see tables in Appendix 2 for references).

Populations that were exposed to higher levels of PFHxS due to contamination had median serum values in the range of 2.98-277 µg/L (Stein & Savitz, 2011; Jakobsson, et al., 2014; Li, et al., 2018; Ingelido, et al., 2018). A median serum concentration of 764 µg/L PFHxS (range <LOD to 19837 µg/L) has been reported after occupational exposure at a fluorochemical plant in China. The serum levels of PFHxS and PFOA in this study increased with service life (Fu, et al., 2016). In another study from a fluorochemical manufacturing plant in the same district, serum concentrations of PFHxS in family members of occupational workers were in the range 4.33-3164 µg/L (Fu, et al., 2015).

B.9.4.5.4 Other tissues

As described under the toxicokinetics Annex B.5.1, PFHxS is found in all studied organs and tissues (Perez, et al., 2013).

B.9.4.6 Temporal trends

The following text is a citation from the MSC support document for the identification of PFHxS and its salts as Substances of Very High Concern (ECHA, 2017a):

"The available studies indicate increasing concentrations of PFHxS in humans, even though the increase in some studies appear to start to level off. Several of these studies also report initially increasing levels of PFOS and PFOA which are followed by decreasing levels during more recent years.

The data by (Haug, et al., 2009), (Jönsson, et al., 2009), (Sundström, et al., 2011) and (Glynn, et al., 2012), which all include individual data for PFHxS and PFOS for a number of years, are presented in the figure below" (see Figure 10).

"The concentrations of PFHxS follow the concentrations of PFOS, but at a lower level. However, the concentration gap between the two appear to decrease for both serum (Glynn, et al., 2012) and milk (Sundström, et al., 2011). Actually, in the study by (Glynn, et al., 2012) the concentration difference in blood serum between PFHxS and PFOS is almost gone at the last measurement 2010."

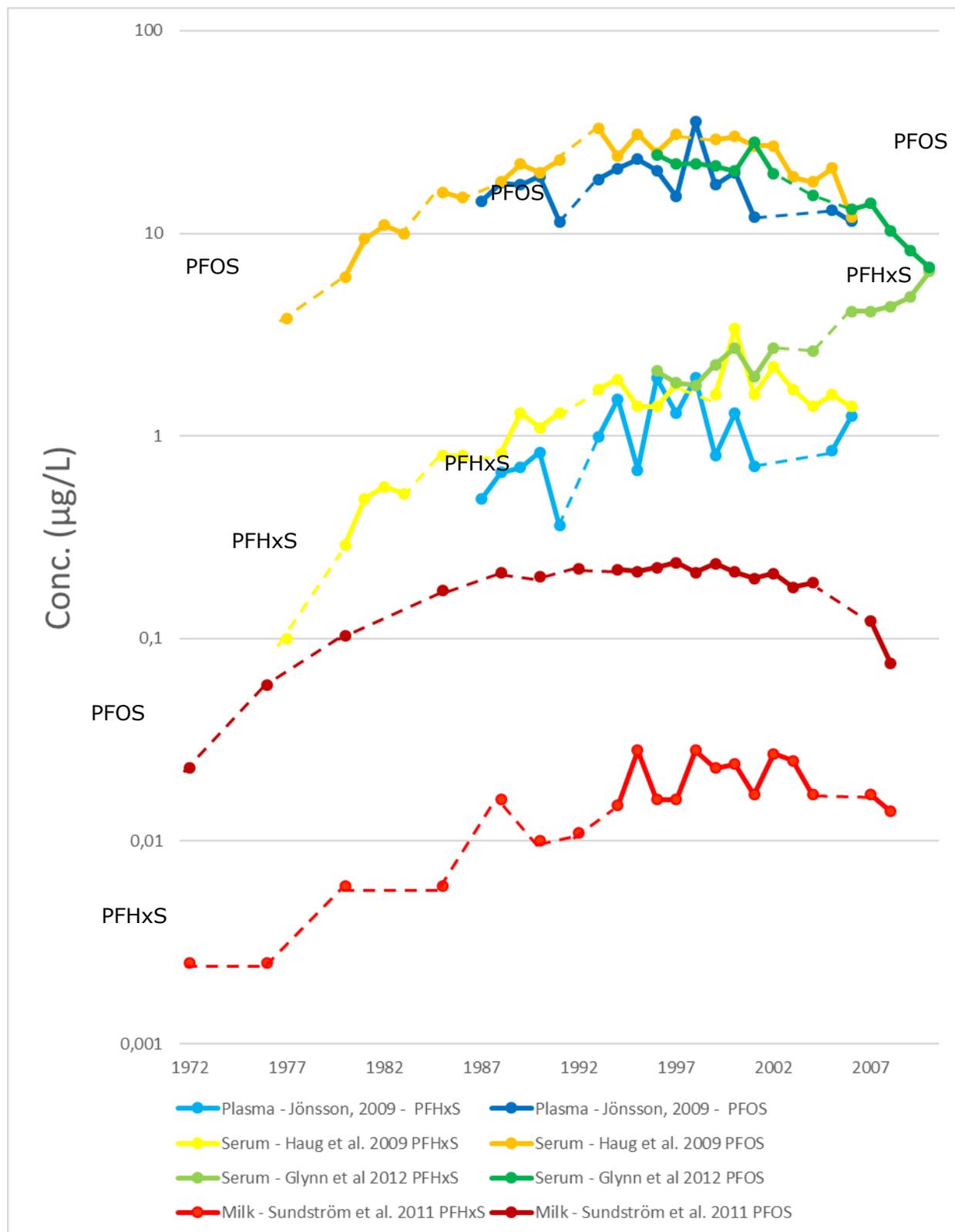


Figure 10: Concentrations of PFHxS and PFOS in human plasma, serum and milk.

Data from Haug et al. 2009, Jönsson 2009, Sundström et al. 2011, and Glynn et al. 2012. (ref MSC support document)

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

The draft POPs risk profile for PFHxS provides this updated overview on temporal trends (UNEP/POPS/POPRC.14/2, 2018):

"91. In the area of Arnberg, Germany, there was a large environmental contamination incident of PFAS in 2006. Wilhelm and co-workers, 2009, evaluated the levels of some PFASs, including PFHxS, in human blood sampled before the contamination (during the period 1977–2004), and the PFHxS plasma levels had increased steadily ($p < 0.001$) from 1977 to 2004. This was in contrast to PFOS and PFOA which remained fairly stable with a small increase during the first 10–15 years followed by a decrease from about 1990–1995. The total median concentration of PFHxS for the entire time period was 1.7 $\mu\text{g/L}$ (range 0.5–4.6 $\mu\text{g/L}$)." (Wilhelm, et al., 2009).

"93. (...) No temporal patterns were observed for PFHxS in archived serum samples from two German cities from 1980–2010 (Yeung, et al., 2013), which is similar to observation from American Red Cross adult blood 2000–2010 (Olsen, et al., 2012). No decline in PFHxS serum levels were observed in Californian women age 50–80 years in the period 2011 to 2015 in contrast to other PFASs which significantly declined (Hurley, et al., 2018), this was also evident after removing participants with known drinking water exposure. In a longitudinal study of men conducted in Northern Norway, concentrations of PFOS and PFOA were highest during 1994–2001 and 2001, respectively, whereas PFHxS levels increased to 2001, however did not decrease between 2001 and 2007 (Nøst, et al., 2014). In a study of blood spots from newborn in New York, USA from 1997 to 2007, PFHxS levels (and PFOS and PFOSA) increased and peaked around year 2000 and then declined. Levels of PFOS and PFOSA declined well below 1997 levels, but PFHxS levels were only slightly lower than 1997 levels (Spliethoff, et al., 2008). In pooled human sera from the Australian population, PFHxS levels ranged from 1.2 to 5.7 ng/mL (08/09) and from 1.4 to 5.4 ng/mL (10/11) but overall the median levels of PFHxS have not significantly changed from 2002 (Toms, et al., 2014). In a systematic review excluding data from occupational exposure and or populations exposed to point sources such as contaminated drinking water, the concentrations of PFOS, PFDS, and PFOA in humans are generally declining, and increasing concentrations of PFHxS have started to level off in recent years (Land, et al., 2018). However, in a study reconstructing past human exposure by using serum biomonitoring data from USA and Australia using a population based pharmacokinetic model, significant declines were observed for PFOS and PFOA but no trend was observed for PFHxS (Gomis, et al., 2017). Furthermore, the concentrations of PFHxS in serum followed a different age pattern than PFOS indicating that global exposure to PFHxS is still ongoing and has not significantly declined since the early 2000s.

94. (...) In the (Fu, et al., 2016) study serum concentrations of PFHxS in occupational workers were in the ranges of <LOD to 19,837 ng/mL (median=764 ng/mL). The serum levels of PFHxS in the exposed workers showed an obviously increasing trend with length of service. Concentrations in urine ranged from <LOD–77.1 ng/mL (median=1.7 ng/mL)." (see Figure 11 below)

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

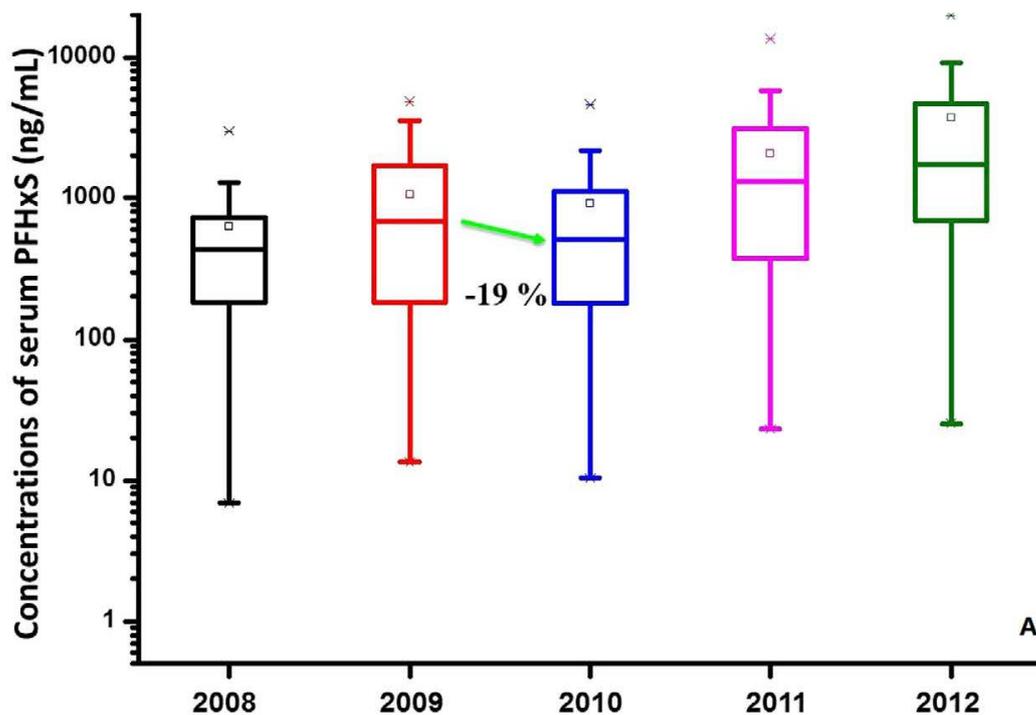


Figure 11: Temporal trends of PFHxS serum concentrations in occupational workers from 2008 to 2012.

The boxes represent 25 and 75 percentiles, and three horizontal bars represent the 5, 50, and 95 percentiles; "x" denotes outliers. Fu et al., 2016.

B.9.5. Environmental exposure

Environmental exposure is discussed in section 1.1.6 of the report. Furthermore, European monitoring results on PFHxS are presented in Annex B.4.3.

The draft POPs risk profile for PFHxS describes the following releases to the environment (UNEP/POPS/POPRC.14/2, 2018).

"41. To date, limited research has been conducted to specifically study the releases of PFHxS, its salts and PFHxS-related compounds in the environment, resulting in a lack of quantitative information on releases, although various studies have detected the ubiquitous presence of PFHxS in the environment (for details, see section Environmental levels and trends below). The occurrence of PFHxS and its related compounds in the environment is a result of anthropogenic production, use and disposal, since they are not naturally occurring substances.

(...)

44. (...) In general, manufacturing processes constitute a major source of PFHxS, its salts and PFHxS-related compounds to the local environment, e.g., in elevated levels of PFHxS in water and the population close to a production plant in Minnesota, the United States (Oliaei et al., 2012). In addition, some uses of PFHxS, its salts and PFHxS-related compounds may result in direct environmental releases. For example, the use of relevant AFFFs in fire-fighting training and real incidences, as well as accidental releases, contribute a substantial amount of PFHxS, its salts and PFHxS-related compounds in the environment (e.g., Backe et al., 2013; Houtz et al., 2013; Ahrens et al., 2015; Baduel et al., 2017; Barzen-Hanson et al., 2017; Bräunig et al., 2017; Lanza et al., 2017). In contrast, some other uses of PFHxS, its salts and PFHxS-related compounds may lead to releases to indoor environments such as from dust (Norwegian Environment Agency, Report M-806/2017c). One example is releases of PFHxS, its salts and PFHxS-related compounds from treated carpets to household dusts (Beesoon et al., 2012)."

B.9.6. Overall exposure assessment

Even though PFHxS including its salts and PFHxS-related substances are not registered under REACH, there is an ongoing exposure of humans and the environment to PFHxS from diffuse and point sources. The continuous emissions of PFHxS combined with the very persistent nature of the substance is expected to lead to increasing exposure if the emissions are not reduced.

PFHxS is detected in human blood globally. Several human biomonitoring studies demonstrates that exposure to PFHxS via drinking water can lead to elevated blood serum levels compared to control groups. In addition, food and exposure in the home environment can lead to elevated concentrations of PFHxS in human blood similar to or above those observed in occupational settings.

B.10. Risk characterisation

It is not relevant to perform quantitative risk assessments of vPvB substances. The overall aim for vPvB substances is to minimise the exposures and emissions to humans and the environment (REACH Annex I, section 6.5).

DRAFT BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

For information we include the concluding statement from the draft POPs risk profile for PFHxS (UNEP/POPS/POPRC.14/2, 2018), which gives a qualitative risk characterisation to humans and the environment:

"133. PFHxS is emitted into the environment from human activities e.g. from manufacturing processes, product use and disposal and management of waste. PFHxS is persistent, bioaccumulative and has the potential to undergo long-range environmental transport, making emissions of this substance a transboundary pollution problem including in remote areas. Globally, the occurrence and distribution of PFHxS is shown for humans, wildlife and the environment. Detections include measurements in the Arctic and Antarctic.

134. PFHxS is one of the most frequently detected PFAS in human blood in the general population and has a very long half-life in humans (range 5.3–35 years). Furthermore, PFHxS has been detected in human umbilical blood, serum and breast milk. High concentrations of PFHxS have been detected in soil, ground and drinking water near airports or fire-fighting training sites, sludge and wastewater from waste water treatment plants, as well as in the vicinity of PFAS/PFHxS production/usage plants and in leachate from landfills.

135. Available scientific literature suggests that there is a risk for adverse effects on the general population, in particular for children and population groups that are exposed to elevated levels of PFHxS and other PFASs through drinking water.

136. The concern for adverse effects relates to observed effects on the liver, thyroid hormone system, reproduction, as well as neurotoxic and neurodevelopmental effects has been shown. Furthermore, effects on lipid and lipoprotein metabolism add to the concern both for humans and Arctic animals.

137. Recent data from polar bear studies at Svalbard (Norway) revealed increasing levels of PFHxS in plasma. Furthermore, studies of polar bears have shown possible alteration in thyroid hormones due to exposure of some PFASs (including PFHxS). Altogether, these studies indicate that there is a risk for adverse effects in wildlife.

138. Based on the persistence, bioaccumulation, toxicity in mammals including humans and the widespread occurrence in environmental compartments including at remote regions, it is concluded that PFHxS, its salts and PFHxS related compounds are likely, as a result of their long-range environmental transport, to lead to significant adverse human health and environmental effects such that global action is warranted.

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

PFHxS and its salts have previously been identified as very persistent and very bioaccumulating substances by the ECHA member states committee (see Annex B.8.1). Since PFHxS-related substances degrade to PFHxS in the environment the concerns also apply to these substances (see Annex B.1.4). The high persistency of these substances implies that ongoing emissions of these substances will build up over time if no risk reducing measures are introduced.

Since these substances persist and accumulate in humans and wildlife they may be impossible to remove if serious health concerns should be documented in the future. A union-wide restriction is therefore needed to reduce the emissions of PFHxS, its salts and their related substances to the environment and to reduce human exposure to a minimum.

According to REACH Article 60 (3) the risks to the environment cannot be adequately controlled for PBT or vPvB substances. No safe concentrations or threshold (PNEC) can be determined for vPvB-substances.

PFHxS is widely dispersed in the environment and is found in remote regions. Humans are also exposed to PFHxS. Human exposure to PFHxS occurs. Several human biomonitoring studies have demonstrated elevated levels of PFHxS in blood serum, related to exposure to PFHxS via drinking water. Furthermore, food and exposure via articles in the home environment can lead to elevated concentrations of PFHxS in human blood similar to or above those observed in occupational settings.

No current intentional uses of PFHxS, its salts or related substances within the EU could be documented during the stakeholder consultation. The substances enter Europe via imported articles. PFHxS substances are a known impurity of PFOS. Whilst the production and use of PFOS and PFOS-related substances was restricted by the inclusion of PFOS on Annex B of the Stockholm Convention in 2009, there are a number of acceptable purposes and specific exemptions of PFOS and related substances listed in the Annex. The dominant potential source of PFHxS could be the import of PFOS and continuing (exempted) uses for PFOS.

Furthermore, PFHxS may be used as technical substitutes to PFOS and PFOA. Regulatory actions to reduce the exposure to PFOA and PFOS may result in increased use of PFHxS or related substances if no regulatory measures are taken. An important aspect of the present restriction proposal is to avoid a future substitution to PFHxS and its related substances when other PFASs are restricted.

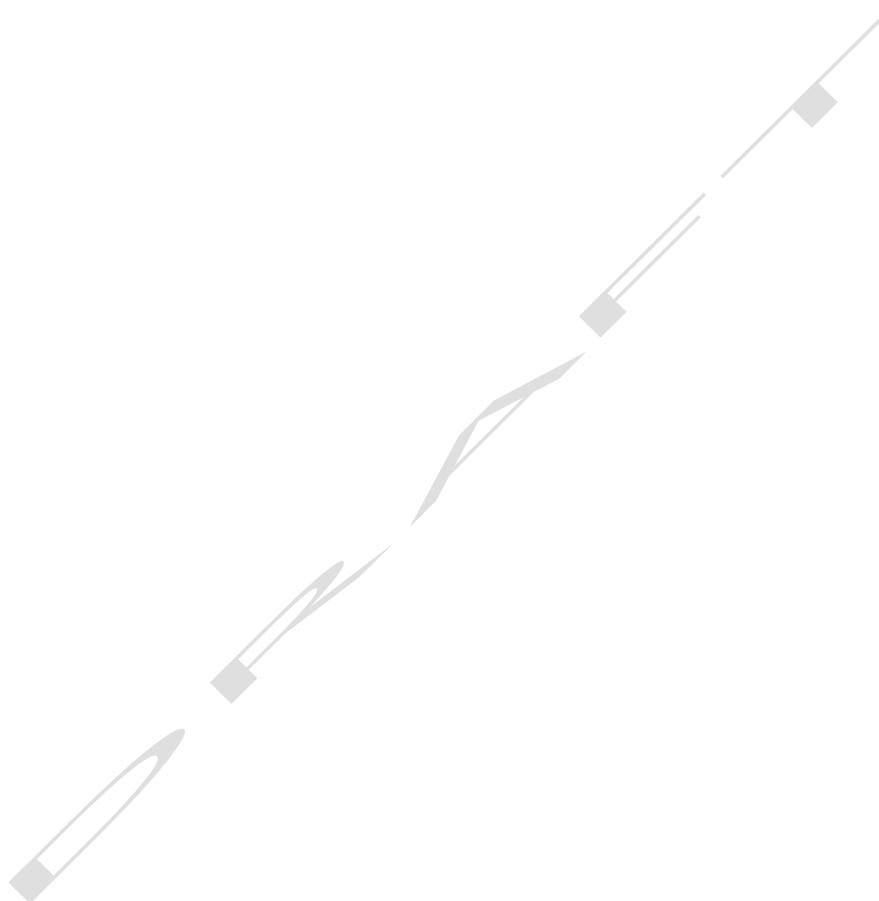
PFHxS enters the inner market via imported articles and is distributed to all parts of the European environment via air and water transport. National regulatory action will therefore not adequately manage the risks of PFHxS and PFHxS-related substances. Risk management measures need to be taken on a Union-wide basis. This need is also acknowledged by the fact that PFHxS and its salts are identified as Substances of Very High Concern, and therefore should be substituted wherever possible.

An alternative to the restriction would be to list the substances in Annex XIV to REACH. Since there are no registrations of PFHxS, the effects of this measure are expected to be marginal. Furthermore, the authorisation procedure does not apply to imported articles. Hence, listing these substances on Annex XIV could lead to ongoing emissions and to an unacceptable risk for human health and the environment due to the vPvB properties of these substances.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

A global regulation on PFHxS seems to be necessary since these substances are transported globally via air, water and articles. At their meeting in September 2018, POPRC decided that PFHxS are to lead to significant adverse human health and environmental effects such that global action is warranted. The committee also decided to prepare a risk management evaluation that includes an analysis of possible control measures for PFHxS (POPRC, 2018b). A European restriction will be an important step to reduce the risks from PFHxS and PFHxS-related substances within the inner marked, and to analyse the EU impact of a global regulation.

In conclusion, a restriction on PFHxS, its salts and PFHxS-related substances is the most appropriate way to limit the risks for human health and the environment on an EU level.



Annex D: Baseline

The Baseline sets out a scenario for what is likely to occur should no additional actions be taken on the use of PFHxS (and related substances). As with other PFAS substances that have come under scrutiny (in particular C9-C14 PFCA), a number of regulatory actions to reduce PFAS in general and some specific compounds (notably PFOA and PFOS) are of relevance because PFHxS (and related substances) can be (and are) used as technical substitutes for these substances in a number of applications. There is, then, the potential for use of PFHxS (and related substances) to increase once such measures take effect.

Amongst the binding measures of most importance and influence in the EU in this regard are:

- the Restriction on PFOA, PFOA salts and PFOA-related substances under REACH. The restriction was submitted by Norway and Germany in 2014 and will become binding in the EU for non-derogated uses in 2020;
- the outcome of considerations to add PFOA to the Annexes of the Stockholm Convention;
- restrictions on PFOS (and related substances) under the POPs Regulation (EU) 2019/1021 and under the Stockholm Convention.

Other regulatory activities in other parts of the world include those listed in Box 1.

Box 1: Examples of regulatory activities in other countries

USA

On January 15, 2015, US EPA proposed a Significant New Use Rule (SNUR) under the Toxic Substances Control Act to require manufacturers (including importers) of some long-chain PFAS chemicals, including as part of articles, and processors of these chemicals to notify EPA at least 90 days before starting or resuming new uses of these chemicals in any article. This notification would allow EPA the opportunity to evaluate the new use and, if necessary, take action to prohibit or limit the activity. The SNUR is effective from July 15, 2016 (US EPA, 2015).

It is noteworthy, however, that the POPRC Risk Profile identifies that the manufacturing (including importing) or processing of one salt of PFHxS (tridecafluorohexanesulfonic acid, compound with 2,2'-iminodiethanol (1:1); CAS No: 70225-16-0) for use as a component of an etchant, including a surfactant or fume suppressant, used in the plating process to produce electronic devices is not be considered a significant new use subject to reporting under the SNUR (POPs Review Committee, 2018).

CANADA

The Restriction Dossier on C9-C14 PFCAs (ECHA, 2017) identifies that in October 2016, the Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012, were published in Canada. These amendments prohibit PFOA, its salts and precursors and articles containing them, unless present in manufactured items. The amendments provide time-limited exemptions for photo media coatings, water based inks and ongoing permitted uses for aqueous film-forming foams used in firefighting applications.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

From the analysis of uses in Annex A, no current uses or sources of PFHxS (including its salts and PFHxS-related substances) have been identified in the EU other than the following:

- Fire-fighting foams: older fire-fighting foams (AFFF) containing PFAS produced using the electrochemical fluorination (ECF) manufacturing process. The stakeholder consultation has confirmed that PFAS based AFFF are now based on C6 telomer technologies which do not contain PFHxS as an impurity. However, Annex A estimates that the current EU stockpile of foams currently maintained at refineries, tank farms, chemical works and other installations contains around 0.5-3 kg PFHxS impurity of which an estimated 39-245 g is consumed or replaced annually;
- Textiles, carpet, leather and upholstery: imported finished textile articles such as overcoats, capes, cloaks, anoraks, windcheaters, outdoor gear and, potentially, other articles for which PFOS was previously used as a waterproofing/stain resistant textile treatment (which might include leather and carpets) - Estimated 66 kg per annum imported on waterproof jackets from China, Vietnam and Bangladesh and an unknown quantity in other applications such as outdoor gear in 2013. More recent data on PFHxS in imported outdoor gear suggests negligible use of PFHxS today but continuing PFOA use at present. Furthermore, the ban on PFOA might lead to increasing use of PFHxS in textiles; and
- Import of PFOS and continuing (exempted) uses as mist suppressants for non-decorative hard chromium (VI) plating. Submissions from EU Member States to the Stockholm Convention suggest 50 kg of PFOS total use per year (equivalent to 2 to 7 kg PFHxS, its salts and PFHxS-related substances (assuming that this PFOS contains such impurities)).

The dominant potential source of PFHxS in the above in terms of quantity is the import of PFOS and continuing (exempted) uses. The Business as Usual (BAU) scenario and the Socio-Economic Assessment (SEA) is based on available emissions data.

As described in chapter 1.3 and in Annex B, there are no data on the specific uses that allows use-specific emissions estimation. Estimation based on WWTP suggests a total annual emission of 2.1 tonnes PFHxS in the EU based on measured quantities in waste water. 1.79 tonnes of this is associated with WWTP handling industrial waste water which is high in the substances of interest (approximately 10% of the total emissions) and 0.22 tonnes from the other (approximately 90% of the total emissions) of WWTP with lower levels (with these comprising both industrial and public waste water sources). For the estimate of 1.79 tonnes from industrial sources, all water samples were taken in 2010/2011 and so best reflect the 'industrial' situation in 2010/2011. This time period coincides with action on PFOS under Directive 76/769/EEC which applied from 2008 onwards. This action may have acted to reduce the industrial component (1.79 tpa) of the total (2.1 tpa) emissions. (The fact that the figures for industrial and other sources do not add up to 2.1 tonnes is due to rounding of the numbers in the calculations.)

In terms of future emissions, under the baseline BAU scenario there is the potential for emissions to increase above the estimated current level of 0.22 tonnes per annum once

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

restrictions on PFOA come into force in the EU (in 2020), internationally via the Stockholm Convention, and also other in other states (See Box 1 for example).

Here there is evidence that PFHxS has been (and is being) used as a substitute for PFOS and PFOA in a number of applications around the World. PFHxS (and related substances) are known to be technically feasible substitutes for PFOA (and PFOS) in a number of applications (Kemi, 2017), including several where current use of PFHxS appears minimal. Examples include:

- **Textiles:** It is reported that water-proofing textile finishes based on PFHxS-based compounds have recently been developed by at least Hubei Hengxin Chemical Co., Ltd. (CAS numbers. 68259-15-4 (tridecafluoro-N-methylhexanesulphonamide), 68555-75-9 (tridecafluoro-N-(2-hydroxyethyl)-N-methylhexanesulphonamide), and 67584-57-0 (2-[methyl[(tridecafluorohexyl)sulphonyl]amino]ethyl acrylate)) and Wuhan Fengfan Surface Engineering Co., Ltd. from China (Huang et al., 2015; Hengxin, 2018), as alternatives to PFOS-based compounds (Huang et al., 2015). The industrial activities with C-6 waterproofing agent for textiles in the Taihu Lake region in China might be a potential source of PFHxS where recent production and use of PFHxS as an alternative to PFOS and PFOA has been reported (Ma et al., 2017). In 2010, it was estimated that the production of surface treatment products containing PFHxS- or perfluorobutane sulfonic acid (PFBS)-related compounds in China would reach 1000 tonnes per year in the next 5–10 years (Huang et al., 2010); no recent update of this estimate is currently available.
- **Semiconductors:** The POPs secretariat (2018) report that during the POPRC-13 meeting on the Stockholm Convention in 2017, an industry representative noted that PFHxS, its salts and PFHxS-related compounds are currently being used as replacements to PFOS, PFOA and their related compounds in the semiconductor industry. This information is further strengthened by published information that indicates that PFHxS is used in the semiconductor industry in Taiwan province of China (Lin et al., 2010). PFHxS (133,330 ng/L), together with PFOS (128,670 ng/L), was one of the primary contaminants at a semiconductor fabrication plant waste water effluent site. Both PFSA are present in the effluent in similar amounts showing that PFHxS is a primary substance in this process and are not unintentionally present at this site.

Emissions: The POPs secretariat (2018) cite a recent paper that reports concentrations in rivers in China. Estimated load of PFHxS to these rivers was 21.6 tonnes in 2016, up from 0.09 tonnes in 2013 (Pan et al., 2018).

The potential for increased use of PFHxS is also confirmed by a Chinese manufacturer that currently advertises PHxSF as “*one of the most essential raw materials for preparing fluorine containing surfactants. The fluorine containing surfactant can be widely used in textile, leather, papermaking, pesticide, electroplating, oilfield, fire control, photosensitive material, synthetic material and other fields*” (Made in China.com).

Few data are available to predict the extent of the increase. However, as noted above, an estimated 66 kg per annum of PFHxS was imported on waterproof jackets from China, Vietnam and Bangladesh (and an unknown quantity in other applications such as outdoor

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

gear) in 2013. As reported in Table 10 in Annex A, measurements in outdoor gear for 2016 suggest negligible use of PFHxS compared with other PFAS such as PFOA (where the latter was found in 67-100% of articles tested). This negligible use is equivalent to the import of 17.4 kg of PFHxS in 2016 (which is also assumed to be the current emission from this source).

Both of these estimates are based on the average quantity of PFHxS measured in all articles sampled including those that contained no PFHxS at all (providing averages of 260.4 µg/kg of imported article in 2013 and 69 µg/kg in 2016). Articles which do contain PFHxS have, on average, 520.7 µg/kg PFHxS. UN COMTRADE data are available for the commodity of 'overcoats, car coats, capes, cloaks, anoraks, incl. ski jackets, windcheaters' (Commodity numbers 6201 and 6202) (UN COMTRADE). These data suggest that, in 2013 some 252 042 tonnes of articles were imported into the EU from China, Vietnam and Bangladesh. Thus, a shift to the use of PFHxS on such articles once controls on PFOA come into effect would have the effect of increasing annual import of PFHxS on textiles to 131.2 kg (520.7 µg/kg * 252 042 000 kg = 131.2 kg)– a doubling of imports relative to estimated imports in 2013 and 7.5 times relative to estimated imports in 2016.

Conservatively taking the lesser of these factor increases (x2) as indicative of the potential shift to PFHxS as a result of controls on PFOA, it is assumed in that, under the baseline, the estimated 0.22 tonnes per annum of estimated current emissions of PFHxS increase to 0.44 tonnes per annum from 2020 onwards under the BAU. Table 4 summarises these annual emissions.

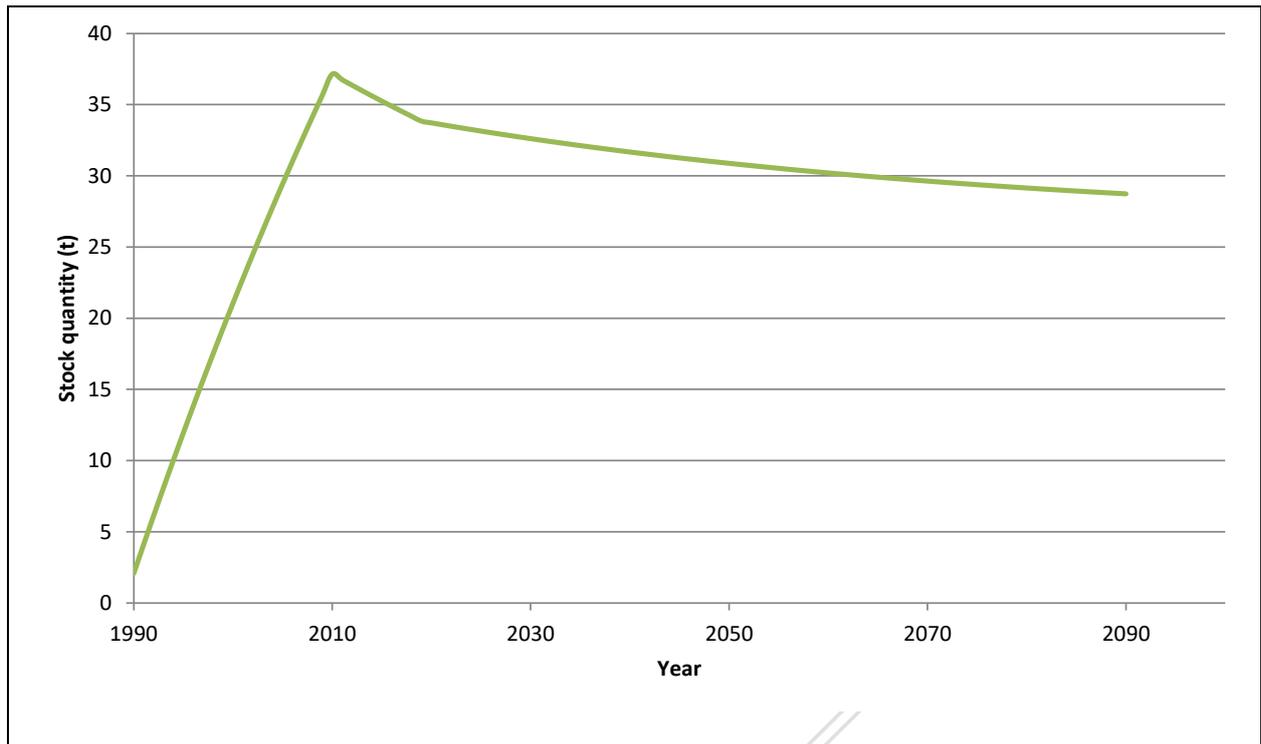
(Copy of Table 4: Summary of estimated emissions under the Baseline (BAU))

Time period	Annual emission of PFHxS (tonnes/year)
1990-2010	2.1
2011-2019	0.22
2020 onwards	0.44

The Annex XV report identifying PFHxS as a SVHC (ECHA, 2017a)) concludes that PFHxS is stable under environmental conditions and abiotic degradation is expected to be as low as for the chemically similar substance PFOS, which has a half-life of >42 years. Applying a half-life of 42 years to the annual emissions set out in Table 4 provides a means to model a projected contribution to environmental loading or environmental stock at an EU level since 1990. Figure 6 provides the stock profile for PFHxS under the baseline (BAU).

This provides for a current (2019) environmental stock quantity of 34 tonnes for the purposes of the baseline and the assessment of options in the impact assessment (Annex E).

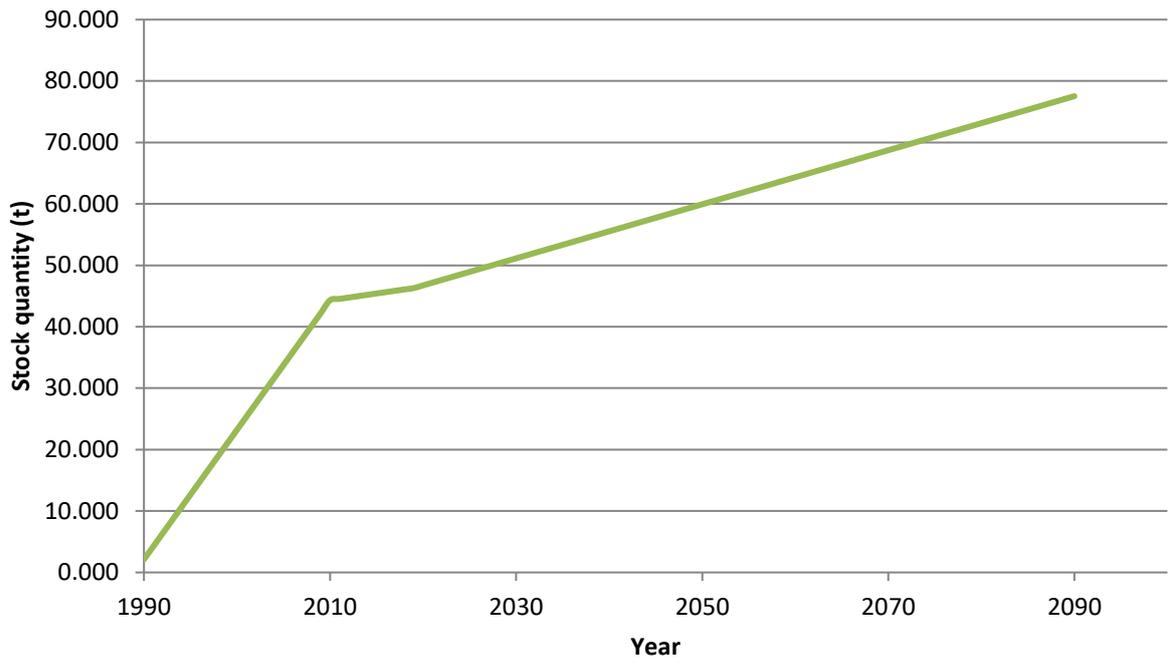
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES



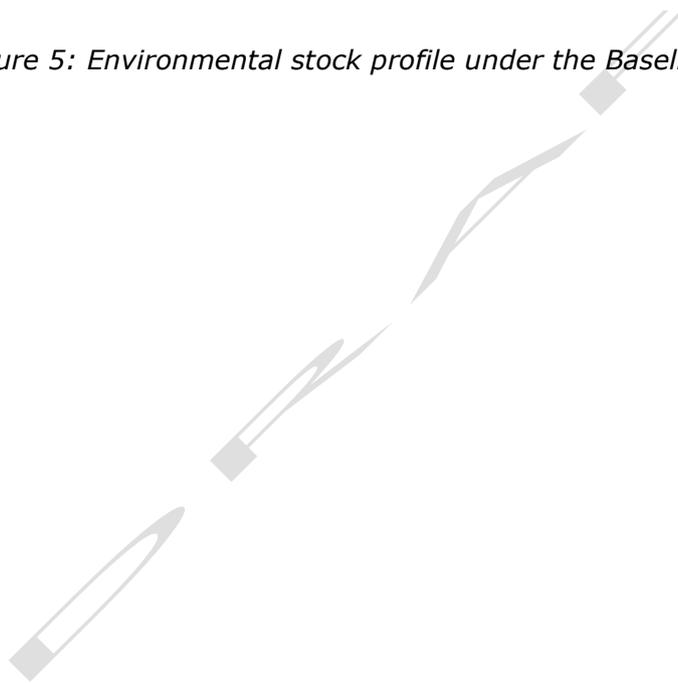
(Copy of Figure 6: Environmental stock profile under the Baseline (BAU) (Half life 42 years))

There is considerable uncertainty about the half life of PFHxS. No degradation has been observed under environmental conditions for PFHxS, see Annex B.4.1 for details. As a result of this the baseline scenario probably underestimates the environmental stock quantities. Because of this we have included a figure that shows the environmental stock profile without degradation, see Figure 5.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES



(Copy of Figure 5: Environmental stock profile under the Baseline (BAU) (no degradation))



Annex E: Impact Assessment

E.1. Risk Management Options

E.1.1. Proposed option for restriction

The proposed restriction comprises a ban on the use of PFHxS, its salts and its related substances with some derogations. The specific text of the proposed restriction is provided as Table 1.

The proposal is for a restriction on both manufacturing, placing on the market and use of PFHxS, its salts and its related substances in the EU. This includes the import of PFHxS, its salts and its related substances in mixtures and articles above the proposed threshold of 25 ppb for the sum of PFHxS and its salts or 1000 ppb for the sum of PFHxS related substances.

These restrictions will apply 18 months after entry into force, except for fire-fighting foams and fire-fighting foam concentrates where the restriction will apply after three months. The restriction will complement the decreasing trend in the use of PFHxS, its salts and its related substances in, for example, textile based outdoor gear while at the same time blocking a switch towards increased use of PFHxS. Such an increase may otherwise occur when controls on PFOA under REACH (and potentially under the Stockholm Convention) apply from 2020. This is because PFHxS is known to be a potential substitute for PFOA in a number of applications.

The restriction proposal also includes recycled material and articles made from recycled materials. This is in line with the Commission's regulation (EU) 2017/1000 on PFOA. As the Commission states in its detailed explanation for PFOA, 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. In addition (as the Commission also states for PFOA), substances with POP properties like PFHxS, its salts and its related substances, in line with the objectives of Regulation (EC) No 2019/1021, should not be recycled. This is also consistent with proposals made for restrictions on the C9-C14 PFCAs.

Also consistent with proposed restrictions on the C9-C14 PFCAs, articles placed on the market before the proposed restriction entries into force (i.e. second-hand articles) are excluded from the scope. This is for two main reasons:

1. The second-hand market is difficult to control, in many cases this involves one single article donated or sold by one consumer to, for example, a non-profit organisation, which in turn is purchased by another consumer. It would not be practical to revoke single articles from the market.
2. To use, for example, a jacket as long as possible before it turns into waste is a sustainable management of resources.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

(Copy of Table 1 Text of proposed restriction on PFHxS, its salts and PFHxS-related substances)

<p>XX. Perfluorohexane sulfonic acid (PFHxS) (linear or branched), its salts and related substances¹⁶:</p> <ul style="list-style-type: none">a. Perfluorohexane sulfonic acids with the formula $C_6F_{13}SO_3H$ and their salts;b. Any substance having a perfluoroalkyl group C_6F_{13}- directly attached to a sulfur atom.	<ol style="list-style-type: none">1. Shall not be manufactured or placed on the market as substances on their own from [<i>date - 18 months after the entry into force of this Regulation</i>]2. Shall not from [<i>date - 18 months after the entry into force of this Regulation</i>] be used in the production of or placed on the market in:<ul style="list-style-type: none">(a) another substance, as a constituent,(b) a mixture,(c) an article or any parts thereof,in a concentration equal to or above 25 ppb for the sum of PFHxS and its salts or 1000 ppb for the sum of PFHxS related substances.3. The restriction in point 2 (c) on the placing on the market shall not apply to articles first placed on the market before [<i>date - 18 months after the entry into force of this Regulation</i>].4. Point 2 shall not apply to<ul style="list-style-type: none">(a) substances or mixtures containing PFHxS as an impurity in PFOS¹⁷ in applications of PFOS which are derogated from the prohibitions in Article 3 of Regulation (EC) No 2019/1021;(b) concentrated fire-fighting foam mixtures that were placed on the market before [<i>date - 3 months after the entry into force of this Regulation</i>] and are to be used, or are used in
--	--

¹⁶ PFHxS related substances are substances that, based upon their structural formulae, are considered to have the potential to degrade or be transformed to perfluorohexane sulfonic acid (linear or branched). See section 2.2 of the report for more details.

¹⁷ Perfluorooctane sulfonic acid and its derivatives (PFOS) $C_8F_{17}SO_2X$ (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)

	<p>the in the production of other fire-fighting foam mixtures.</p> <p>5. Point 1 and 2 shall apply from [<i>date - 3 months after the entry into force of this Regulation</i>] for fire-fighting foams and fire-fighting foam concentrates.</p>
--	---

A global regulation on PFHxS seems to be necessary since these substances are transported globally via air, water and articles. A European restriction will be an important step to reduce the risks from PFHxS and PFHxS-related substances within the inner market, and to analyse the EU impact of a global regulation.

E.1.2. Discarded restriction options

Two potential restriction options related to PFHxS present in currently derogated uses of PFOS have been considered and discarded. These include:

1. A restriction on the production of PFHxS during manufacture of PFOS or PFBS.
2. A requirement to remove all fire-fighting foams from stocks which exceed the 25ppb limit for mixtures.

E.1.2.1. A restriction on the production of PFHxS during manufacture of PFOS or PFBS.

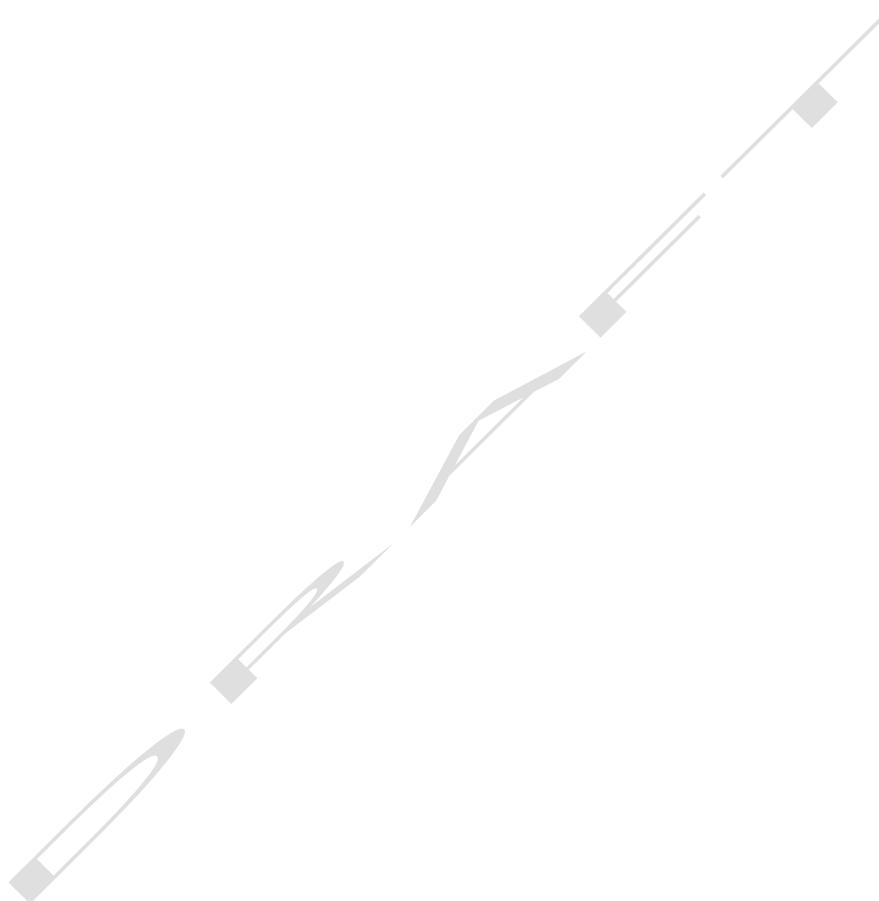
The first discarded option is a restriction on the production of PFHxS during manufacture of PFOS or PFBS. As detailed in Annex A.2.1, PFHxS may be unintentionally formed when PFBS or PFOS or their related substances are produced. Production of fluorotelomers such as PFBSs are based on electrochemical fluorination rather than synthesis via telomerisation. The latter manufacturing approach does not result in the manufacture of PFHxS, its salts and PFHxS-related substances. Thus, restricting the manufacturing process to the use of telomerisation only could provide a means of addressing the unintentional manufacture of PFHxS and hence its ongoing emission into the environment and associated human and environmental exposures. This restriction option however, could also impact the manufacturing of substances beyond the scope of this restriction and would not have effect on the intentional production of PFHxS. As a result of this this restriction option is discarded.

E.1.2.2. A requirement to remove all fire-fighting foams from stocks which exceed the 25ppb limit for mixtures.

The second discarded restriction option is a requirement to remove all fire-fighting foams which exceed the 25ppb limit for mixtures from stock. This restriction option would require testing and destruction by incineration of existing stocks of PFAS based foams, estimated at around 31 240 tonnes. As described in Table 17, this option would reduce the annual PFHxS emissions by a maximum of 0,245 kg per year. The risk reducing potential of this option is not proportional to the societal costs it would encompass.

E.1.3. Other Union-wide risk management options than restriction

As with the C9-C14 PFCAs, there is a potential need for managing the stock of PFHxS in for example landfills and other parts of the technosphere. This is, however, outside the scope of this restriction (and REACH), but if such EU-wide regulatory measures were considered, it would be a complement to this restriction and not dual control.



E.2. Alternatives

As described in Annex A.2.11 the following possible use areas for PFHxS have been examined:

- Fire-fighting foams: older fire-fighting foams (AFFF) containing PFHxS as an impurity;
- Textiles, carpet, leather and upholstery: imported finished textile articles; and
- Import of PFOS and continuing (exempted) uses: mist suppressants for non-decorative hard chromium (VI) plating.

No intentional present use of PFHxS in the EU has been identified. As a result of that there is no need for alternatives at this point. Alternatives are already being used. This is similar to the Annex XV restriction report for C₉-C₁₄ PFCAs including their salts and precursors (BAuA, 2017), where some uses of the substances have not been identified in the EU.

For completeness the alternatives for the uses listed above that has already been taken into use or could have been taken into use, are discussed below. As described in Annex A.2.8, the limit values of PFOA in articles for textiles are soon to be applied which are likely to promote a switch to alternatives also for imports, in which PFHxS may be an alternative if this restriction is not implemented.

E.2.1. Description of the use and function of the restricted substance(s)

E.2.1.1 Fire-fighting foams

Fires are classified into two classes (Class A and Class B) in accordance with the burning material. Class A fires are fires involving fibrous materials (ECHA, 2017b) and Class A fire-fighting foams are fluorine free (IPEN, 2018). Class B fires involve liquid hydrocarbon fires and these foams may contain fluorotelomer-based surfactants. These foams are used for hydrocarbon fires in aviation, industrial, military and municipal applications (ECHA, 2017).

E.2.1.1.1. Use of PFHxS and PFHxS-related substances

PFHxS and PFHxS-related substances may be intentionally present in some fire-fighting foams as the production and use of foams based on PFHxS still takes place in China (ECHA, 2017b), with commercial names including VF-230, VF-9126 and VF-9128 (Huang, et al., ND). Furthermore, PFHxS and PFHxS-related substances can be present as an impurity from the manufacturing process of fluorosurfactants or as a degradation product from fluorosurfactants present in some fire-fighting foams. See also the description of the use of PFHxS in fire-fighting foams in Annex A.2.9.

In terms of the quantities of PFHxS present as an impurity in these foams, measurements of the levels of PFHxS as an impurity in foam concentrates (excluding measurements at/below the limit of detection) in Germany suggest a range of between 31 and 98 µg/kg (ppb) of PFHxS and an average of 59 µg/kg (ppb) PFHxS in foam concentrates, with this range generally confirmed by the (Kemi, 2015b) study. In this study, one of the fire-fighting foams supplied directly from manufacturers contained PFHxS, and six did not. In samples

supplied by users, PFHxS was detected in three of the seven fire-fighting samples. This indicates probable contamination of the user's existing equipment by PFHxS from previous fire-fighting products.

E.2.1.1.2. Function of fluorosurfactants

Fluorosurfactants have been used in fire-fighting foams due to their intrinsic substance properties (see Annex A.2.3). Consultation with foam suppliers indicates that the use of fluorosurfactants allows the fire-fighting foam to be forcefully applied and this allows the foam to come through the foam surface to shred contained fuel from the bubbles. Fluorosurfactants have also been used in aqueous film-forming foams (AFFFs) due to their aqueous, surface tension lowering properties (Buck et al, 2011) and oleophobic (oil repellent) properties (stakeholder consultation). The thin filming properties of fluorosurfactants which produce a thin aqueous layer between the flammable liquid and the foam for fires, such as in large hydrocarbon fires in tanks and secondary containment fires, has also been mentioned during the stakeholder consultation as a property of fluorosurfactants that may be required from AFFFs.

Information received from stakeholder consultation also indicates that the fluorosurfactant content of AFFFs is typically 3-4%. The formulation of AFFFs has evolved over the years with this resulting in increasing purity.

E.2.1.1.3. Technical properties required

The stakeholder consultation also identified a number of technical criteria that need to be fulfilled by AFFFs for use in Class B fires. Properties required for AFFFs are good foam cohesion, good burn-back resistance, rapid knockdown characteristics, good flow properties, low viscosity, low freezing properties and specific weight. The shelf life of the AFFFs is also a criterion that has to be met, with fluorine containing fire-fighting foams having shelf lives typically between 10 years and 20 years (to a maximum of 30 years) from information received from stakeholder consultation.

E 2.1.2 Textiles, carpet, leather and upholstery

E.2.1.2.1. Use of PFHxS and PFHxS-related substances

The use of PFHxS and PFHxS-related substances in the textiles has not been confirmed through stakeholder consultation with three associations stating that their members do not use these substances in the EU. Fluorosurfactants are used in textiles for their oil and water repellency and are used in durable water repellents and Personal Protection Equipment (PPE).

The use of PFHxS and PFHxS-related substances has previously been identified in imports of textile articles from outside EU. The quantity of PFHxS in articles has decreased over time. In 2013, PFHxS was detected in five articles (Greenpeace, 2014) whilst in 2016, on tests on multiple articles, only one article contained PFHxS in tests performed by Greenpeace (Greenpeace, 2016). This is further discussed in Annex A.2.8. There is also consumer demand for more environmentally friendly alternatives, such as in outdoor wear which is driving the phase out of PFASs. A consumer study by Hill et al. (2017) proposes that the use of PFAS chemistry for outdoor apparel provides oil repellence beyond what the

consumer requires. One manufacturer reported that their DWR textiles will be PFAS free by 2020 (ECHA, 2017).

E.2.1.2.2. Function and technical properties required

Durable water repellents are liquid repelling hydrophobic polymers. These form a continuous polymer fibre around the fibres in the outer layers which allows for liquid repellency, for example droplets of rain. The fabric used in clothing also allows the textile to remain water vapour permeable which allows the transport of water vapour from the inside to the outside which allows the clothing to 'breathe' (Schellenberger et al, 2018). The addition of fluorosurfactants allows lower surface tension of the coating which in turn aids the functionality for wetting, flow and levelling (OECD, 2012). The fluorinated polymer is also attached to the textile fiber so that it remains fixed after repeated washings (ZDHC, 2012). Fluorosurfactants are used in Protective Personal Equipment (PPE) due to their repellency properties. The surface energy of the fibre surface needs to be lower than the surface tension of the liquid (polar and non-polar liquids) for repelling liquids and the surface energy of the perfluorinated chains are very low. This low surface energy allows repellency of polar liquids (such as water) and non-polar liquids (such as oil) which is a required functionality in protective personal clothing. (Schellenberger et al, 2018).

E 2.1.3 Semi-conductors

E.2.1.3.1. Use of PFHxS and PFHxS-related substances

The UN BAT/BEP Guidance for the use of PFOS in the semiconductor industry discusses that fluorinated substances and polymers are used in different manufacturing processes with the exact composition of these substances not disclosed. Fluorinated surfactants are required for formulations with use in photoresists and anti-reflective coatings (UNEP-POPS, 2017).

The use of PFOS in the semiconductor industry for photo-resist and anti-reflective coatings and as an etching agent for compound semiconductors is exempted under part 3 of Annex B of the Stockholm Convention on POPs.

The use of PFHxS-related compounds in Taiwan in the semiconductor industry as a replacement of PFOS and PFOA, as etching agents for compound semiconductors and ceramic filters and as photo-resistant and anti-reflective coatings has been reported as discussed in Annex A.2.6. According to industry, there are no known alternatives to PFOS currently available for all the exempted uses of PFOS in the semiconductor industry. However, the use of PFOS is decreasing due to new photolithography technologies (UNEP, 2013). The use of PFHxS and PFHxS-related substances in the European semiconductor industry has not been confirmed in the stakeholder consultation.

E.2.1.3.2. Function and technical properties required

There is limited information on the use and the function of PFHxS and PFHxS-related substances in semi-conductors. PFOS has been used for photoresistors and anti-reflective coatings in semiconductors for reducing the surface tension and for reflectivity in etching solutions (KEMI, 2015), (UNEP, 2013).

E 2.1.4 Metal plating

E.2.1.4.1. Use of PFHxS and PFHxS-related substances

The use of PFOS for metal plating in closed loops in the EU is still reported to occur and is an acceptable use under POPs Regulations (UNEP, 2008). EU recently reported that some EU/EEA countries still uses PFOS in closed-loop systems for hard metal plating (UNEP, 2019a). Fluorosurfactants (including PFOS) are reported by UNEP to be used in chrome plating; as agents for preventing haziness of plated copper; as non-foaming surfactants in nickel-plating baths; as agents added to tin-plated baths; and as agents for aiding the electroplating of polymers onto steel. PFOS was previously used in decorative chrome plating; however, this is no longer the case due to new technology being employed (UNEP, 2013).

The diethanolammonium salt of PFHxS has been reported to be used for metal plating. Limited data are available to evaluate the degree to which the remaining salts in this group are used. Nevertheless, it is noted that use of the three potassium salts in this group was reported in 2012 in Denmark (Australian Government, 2015). POPRC identified a number of patents that suggested that PFHxS, its salts and various PFHxS-related compounds may have been used in metal plating as mist suppressants (POPs Review Committee, 2018). The report identified that it was likely that at least Hubei Hengxin from China had marketed the potassium salt of PFHxS for metal plating.

The use of PFHxS and PFHxS-related substances in metal plating in the EU has not been confirmed from stakeholder consultation.

E.2.1.4.2. Function and technical properties required

The main function of fluorinated substances is as wetting and suppressing agents in metal plating. The diethanolammonium salt of PFHxS was reported to be used as a component of etchants for electroplating according to UNEP.

In chrome plating, PFOS and PFOS derivatives have been used as they lower the surface tension of the plating solution with a single foamy barrier which reduces the airborne loss of chromium (VI) from the plating bath to reduce exposure to chromium (VI) which is a carcinogenic agent. PFOS is still used for this purpose as other mist suppressants degrade more rapidly under working conditions (UNEP-POPs, 2016).

Fluorosurfactants are used in other metal plating applications due to their technical properties (UNEP-POPs, 2016). They regulate foam and improve stability for preventing haziness of plated copper; used to reduce surface tension in nickel-plating for non-foaming surfactants; used to ensure uniform thickness in tin plating; and they are used to impart a positive charge and for aiding in the electroplating of polymers onto steel for surface protection.

E.2.2. Identification of potential alternative substances and techniques fulfilling the function

A summary of present alternatives that have been identified and assessed are described in the following table. Many of these are already in use. No intentional identified uses of PFHxS

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

and PFHxS-related substances have been identified in the EU. For most potential uses, alternatives exist and are discussed for completeness.

Table 21: Summary of alternatives identified

Use	Alternatives assessed	Conclusion
Fire-fighting foams	Fluorine free foams (recommended alternative)	Preferred alternative to be used when feasible
	Fluorotelomer-based short-chain chemistry (6:2 FTS)	This should only be used where it is not possible to use fluorine free foams due to the potential environmental impact
Textiles	Fluorine free alternatives	Fluorine free alternatives are available for water repellency. For oil repellency, there are currently no known fluorine free alternatives
	Fluorotelomer-based short-chain chemistry (6:2 FTOH)	This should only be used where it is not possible to use fluorine free alternatives due to the potential environmental impact
Semi-conductors	Fluorine containing alternatives	Only fluorine containing alternatives have been identified from UNEP-POPS documents with no information obtained from stakeholder consultation.
Metal plating	Fluorotelomer-based short-chain chemistry (6:2 FTS) and other fluorine containing alternatives	This should only be used where it is not possible to use fluorine free alternatives due to the potential environmental impact
	Fluorine free alternatives	Fluorine free alternatives are available for hard plating and decorative plating. No information was received from stakeholder consultation

E.2.2.1 Manufacturing

Alternative techniques are also available for manufacturing fluorinated substances. Electrochemical fluorination was previously used by 3M to manufacture PFOA and PFOS although other manufacturers continued to use this process to manufacture PFOS and PFOA (Buck et al, 2011). This manufacturing route resulted in a mixture of both linear and branched perfluorinated isomers of the raw materials, homologues of the raw materials alongside PFCs and other substances. In the electrochemical synthesis of PFOS, the main starting material used has been POSF ($C_8F_{17}SO_2F$) with the possibility of PFHxS being formed as a by-product. For the electrochemical fluorination of PFOA, sulfonic acids are not used ($C_7F_{15}COF$) has been reported as being used (Buck et al, 2011), so PFHxS contamination is not an issue.

An alternative manufacturing route for perfluoroalkyl substances which is currently in use is telomerisation. This is used for the synthesis of fluorotelomers which are further discussed later in this section. Stakeholder consultation has confirmed that PFHxS is not an issue for this manufacturing route.

E.2.2.2 Fire-fighting foams

For most AFFF applications, literature review and consultation find that alternatives exist. No intentional uses of PFHxS and PFHxS-related substances have been identified in fire-fighting foams in the EU. POPRC has stated (UNEP/POPS/POPRC.14/6) that fluorine free foams are the most favoured alternative because they provide a longer-term solution to the wider issues associated with use of PFAS as a whole. Other alternatives are shorter chain fluorine alternatives (fluorotelomer-based products) and the use of non-chemical techniques (UNEP, 2013).

For fluorine free foams, product names are discussed here as there is limited information available on the exact composition with selected information only available in Safety Data Sheets. Fluorine free foams are the recommended alternatives for fire-fighting foams. Publicly available information is available on some of the composition of C6 fluorine foams, although information on the exact composition of these foams is not available. 6:2 FTS substances are used in modern fire-fighting foams (Kemi, 2015b) and this substance is the focus of assessment for fluorotelomer-based short-chain chemistry. C6 fluorotelomers that may have been used in AFFFs include fluorotelomers based on 6:2 fluorotelomer sulfonamide alkylbetaine and 6:2 fluorotelomer sulfonamide aminoxide (Wang et al, 2013).

The non-chemical alternatives to foams that have been identified from stakeholder consultation are glass beads and Teflon/intumescent polystyrene spheres (Dryfoam). These alternatives are considered to be only suitable for small scale fires as blankets. Compressed air foams could also be used for class B fires (although compressed air is also now used with foams), although further testing for some applications is required. For small scale fires, water mist could also be potentially used.

E.2.2.3 Textiles

No identified uses of PFHxS and PFHxS-related substances in textiles have been identified in the EU. PFHxS has been previously identified in imports of textiles in the EU, as discussed in Annex A.2.8.

Euratex states that C6 fluorine chemistry is required for specific uses in the textile sector, such as PPE and technical textiles. Performance chemistry is required for complying with safety standards and also for meeting other technical criteria (EURATEX, 2018).

Potential alternatives to PFHxS and PFHxS-related substances have been identified through the literature including fluorine free alternatives. Literature review has identified that alternatives for certain uses exist and these are discussed. Midwor has stated, in their research project investigating alternatives, that dendrimers and silicone (Polydimethylsiloxane) are alternatives to C6 fluorine substances for water repellents, however, for oil repellents no alternatives have yet been identified (Midwor, 2018).

The use of PFHxS and PFHxS-related in textiles has not been confirmed during stakeholder association, with three associations indicating that these substances are not used by their members. Specific alternatives including fluorine free alternatives that are currently used could not be identified from stakeholder consultation.

E.2.2.4 Semi-conductors

The use of PFHxS and PFHxS-related substances in semi-conductors has not been confirmed in the EU. As a result of this the identified alternatives discussed here are not discussed further in this report.

Alternatives to PFOS and related substances in the semiconductor industry have been discussed in the UN BAT/BEP guidance for use of PFOS and related chemicals under the Stockholm Convention (UNEP-POPS, 2017). Photoresists and anti-reflective products which do not use PFOS are commercially available, although no information on the composition of the alternatives is available. Some of the alternatives use fluorinated substances, although the exact composition is not available. For etching applications, short-chain perfluoroalkyl substances are known to be used as PFOS alternatives. There is no information available on alternative techniques.

Table 22: Alternatives available for semi-conductors (UNEP-POPS, 2017)

Use/Product	Producer	Web reference
Photoresists		
GKR Series KrF	Fujifilm Holdings America	http://www.fujifilmusa.com/products/semiconductor_materials/photoresists/krf/index.html
Various Product Names	TOKYA OHKA KOGYO	http://tok-pr.com/catarog/Deep-UV_Resists/#page=1
ARCs		
ARC® Coatings	Brewer Science Inc.	http://www.brewerscience.com/arc
AZ® Aquatar®-VIII Coating	EMD Performance Materials	http://signupmonkey.ece.ucsb.edu/wiki/images/b/bb/AZ_Aquatar_VIII-A_45_MSDS.pdf
Source: (UNEP-POPS, 2017).		

E.2.2.5 Metal plating

The use of PFHxS and PFHxS-related substances in metal plating in the EU has not been identified in the EU through extensive stakeholder consultation (as discussed in Annex G). ECHA (2017a) discuss that for alternatives for PFOS can also be used for PFHxS with semiconductors discussed, although the non-fluorinated alternatives are considered not to be as effective for hard plating. Alternatives to PFOS and related substances in metal plating have been discussed in the UN BAT/BEP guidance for use of PFOS and related chemicals under the Stockholm Convention (UNEP-POPS, 2017).

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 23: Alternatives available for metal plating (UNEP-POPS, 2017)

Substance	Trade Name	Manufacturer
Hard plating		
6:2 Fluorotelomer sulfonate (6:2 FTS)	ANKOR® Dyne 30 MS ANKOR® Hydraulics ANKOR® PF1 Fumetrol® 21 Fumetrol® 21 LF 2 HelioChrome® Wetting Agent FF PROQUEL OF Wetting Agent CR	Enthone Enthone Enthone Atotech Atotech Kaspar Walter Maschinenfabrik GmbH & Co. KG Kiesow Dr. Brinkmann Atotech
Other fluorinated substances	Chromnetzmittel LF Netzmittel LF Non Mist-L RIAG Cr Wetting Agent CL-Chromeprotector BA Antifog V4	CL Technology GmbH Atotech Uyemura RIAG Oberflächentechnik AG CL Technology GmbH Chemisol GmbH & Co. KG
Alkylsulfonate	TIB Suract CR-H	TIB Chemicals AG
Decorative plating		
6:2 Fluorotelomer sulfonate (6:2 FTS)	ANKOR® Dyne 30 MS Cancel ST-45 FS-600 High Foam FS-750 Low Foam Fumetrol 21 SLOTOCHROM CR 1271 UDIQUÉ® Wetting Agent PF2 Wetting Agent CR	Enthone Plating Resources, Inc. Plating Resources, Inc. Plating Resources, Inc. Atotech SchlötterGalvanotechnik Enthone Atotech
Other fluorinated substances	Chromnetzmittel LF Antifog CR CL-Chromeprotector BA	CL Technology GmbH Chemisol GmbH & Co. KG CL Technology GmbH
Alkylsulfonate	TIB Suract CR-H	TIB Chemicals AG
Oleo amine ethoxylates	ANKOR® Wetting Agent FF	Enthone
Source: (UNEP-POPS, 2017)		

Alternative technologies available for hard plating identified include the following (UNEP-POPS, 2017): mesh or blankets to be placed on top of baths for controlling mist and aerosol emissions; add on air pollution control devices; high velocity oxygen fuel process and alternative processes such as Topocrom (www.topocrom.com). No further information is available on these alternatives. Alternative technologies identified for decorative chrome plating is the use of Cr(III) instead of Cr (VI) (UNEP-POPS, 2017).

E.2.3. Risk reduction, technical and economic feasibility, and availability of alternatives

In this section, mainly the alternatives for PFHxS and PFHxS-related substances in fire-fighting foams and textiles are described in detail. No intentional uses of PFHxS and PFHxS-related substances have been identified in the EU. PFHxS has been detected in fire-fighting foams and may also be an issue for imports (as discussed in Annex A.2.9.) and has been previously measured in textile imports (as discussed in Annex A.2.8.). A general overview is presented for other uses as discussed in Annex A.2.11.

E.2.3.1. Assessment of fluorine free alternatives for fire-fighting foams

E.2.3.1.1. Availability of fluorine free foams

Silicone-based surfactants, hydrocarbon-based surfactants, synthetic detergent foams and protein based foams have been previously discussed as potential fluorine free alternatives (European Chemicals Agency, 2017a). Information on the exact composition of the surfactants of the fluorine free foams is generally not publicly available. The RE-HEALING™ foam range from Solberg contains hydrocarbon surfactant, water, solvent, sugar, preservative and a corrosion inhibitor (KemI, 2015a).

Solberg RE-HEALING™ foam (fluorine free) has been identified as being used in onshore and offshore oil and gas facilities in Norway. One association has also confirmed the use of fluorine free foams for small scale fires of less than 9 metres in diameter, further discussed in Annex E 2.2.2. Fluorine free foams are also used at a number of airports including London Heathrow, London Gatwick, Copenhagen, Dubai and Stuttgart and Stockholm Arlanda and Oslo Gardermoen. Other fluorine free foams have been identified as being available. These include fluorine free foams from Angus Fire (Respondal ATF, JetFoam, Bio Ex) and Auxquimia (Unipol FF™). Consultation indicates that recent tests in Texas also confirm their ability to effectively put out Class B refinery fires (pers. comm, Arcadis) (Lastfire, 2018).

No information is available for tonnages of these foams and their active ingredients. As a result, trade names have to be used here for fluorine free foams. Regarding the composition of these foams, limited publicly available information is available. Stakeholder consultation has also indicated that fluorine free formulations are constantly evolving with the new generation (5 generation) of fluorine free foams also using compressed air alongside the fluorine free foam.

E.2.3.1.2. Human health risks related to fluorine free foams

There is a lack of information on the human health risks from fluorine free foams. The available data sheets for fluorine free foams indicate the foam can cause serious eye irritation and skin irritation (Angus Fire, 2018) and (Solberg, 2015).

There is some limited substance information in safety data sheets for the composition of the fluorine free foams and human health hazards. In Solberg RE-HEALING foam RF3, 1-propanaminium, 3-amino-N-(carbocymethyl)-N,N-dimethyl-, N-coco acyl derivs.,

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

hydroxides, inner salts)<20%), tris (2-hydroxyethyl) ammonium dodecylsulfate (<20%) and 2-(2-butoxyethoxy) ethanol (<20%) are the major components by weight % (Solberg, 2015). Information on their human health hazards is presented in Table 24 based on their REACH registration dossiers on ECHA's webpages. According to the registration dossier on ECHA's webpages for 1-propanaminium, 3-amino-N-(carbocymethyl)-N, N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts; the substance is classified as Skin Irrit. 2 and Eye Irrit. 2. According to the CLP entry for tris (2-hydroxyethyl) ammonium dodecylsulfate, the substance is classified as Skin Irrit.2 and Eye Irrit. 2. There is no registration dossier available for this substance as the substance is only pre-registered under REACH. For 2-(2-butoxyethoxy) ethanol, according to the registration dossier available on ECHA's webpages the substance is classified as Eye. Irrit 2.

In Respondol ATF 3/3, propylene glycol butyl is present in the largest concentration (4-10%). This substance is classified as Eye Irrit. 2 and Skin Irrit. 2. Information on the health hazards for this substance is presented in Table 24 based on its registration dossier on ECHA's webpages. The substance is not classified as a skin and respiratory sensitiser.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 24: Human related PBT properties for PFHxS and fluorine-free foams

Substance	Persistent	Bioaccumulative	Toxic
PFHxS and PFHxS-related substances	very Persistent (ECHA 2017)	Very Bioaccumulating (ECHA 2017) Yes; $t_{1/2} > 7$ years (human). Bioaccumulates in air-breathing mammals	(PFHxS) Acute Tox. 4; H302 Acute Tox. 4; H312 Acute Tox. 4; H332 Skin Corr. 1B; H314
RE-HEALING™ Foam RF3 3%; RE-HEALING™ RF6 6%	Not considered to be persistent	Not considered to be bioaccumulating	Foam RF3 3%: Eye Irrit. 2; H319 Skin Sens 1; H317 RF6 6%: Skin Mild Irrit. 3; H316 Eye Irrit. 2B; H320
1-propanaminium, 3-amino-N-(carbocymethyl)-N, N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts	No data available	Not expected to bioaccumulative	Skin Irrit. 2 and Eye Irrit. 2. The substance is not classified for acute oral and dermal toxicity based on a read-across approach with a $LD_{50} > 2000$ mg/kg bw. The substance is also considered as a skin sensitiser based on patch test results. The substance is also likely not to be classified as gene mutant based on in vitro Ames test on Salmonella Typhimurium and in vivo tests on L5178Y TK ± mouse lymphoma. The NOAEL for reproductive toxicity for the substance is 1000 mg/kg bw
Tris (2-hydroxyethyl) ammonium dodecylsulfate	No data available	No data available	Skin Irrit.2; H315 Eye Irrit. 2; H319
2-(2-butoxyethoxy) ethanol	Not considered to be persistent	Does not bioaccumulate	Eye. Irrit 2; H319 and is not classified for other toxicological endpoints such as acute toxicity, acute inhalation, and acute dermal toxicity
Respondol ATF 3/3 foam	Readily biodegradable	Not expected to be bioaccumulating	Eye Irrit. 2; H319 Skin Irrit. 2; H315
Propylene glycol butyl ether	No data available	Limit potential for bioaccumulation (log Kow of 1.15)	Eye Irrit. 2; H319 Skin Irrit. 2; H315 Not classified for acute toxicity with a LD_{50} of > 2000 mg/kg/bw. Not classified for genetic toxicity, carcinogenicity, and reproductive toxicity
Sources: (Angus Fire, 2018; ECHA, 2017b; Solberg, 2018; Solberg, 2013)			

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

E.2.3.1.3. Environmental risks related to fluorine free foams

There is a lack of information on the environmental risk for fluorine free foams. According to the available safety data sheets, fluorine free foams are considered not to be persistent, bioaccumulating nor toxic (PBT) or to be very persistent or very bioaccumulative (vPvB). The fluorine free foams may, however, be classified as toxic to aquatic life (Solberg, 2015).

Aquatic toxicity is not available for PFHxS and PFHxS-related substances, although toxicity is expected to increase with increasing carbon length. As discussed in Annex E.2.3.1.2, information on some substances used in fluorine free foams is available from Safety Data Sheets. 1-propanaminium, 3-amino-N-(carbocymethyl)-N,N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts, according to its registration dossier on ECHA's webpages has no potential for bioaccumulation and is readily biodegradable in aquatic environments. The substance is also not classified as being persistent in soil. 2-(2-butoxyethoxy) ethanol is not classified as being toxic to the environment according its registration dossier on ECHA's webpages.

For Respondol ATF 3/3, propylene glycol butyl is readily biodegradable and is not classified for aquatic toxicity according its registration dossier available on ECHA's webpages.

Table 25: Ecotoxicity data for selected fluorine free foams

Substance/Foam	Endpoint	Result	Reference
PFHxS and PFHxS-related substances	Aquatic toxicity is not available for PFHxS and PFHxS-related substances. Data is available for Perfluorobutanesulfonic acid (PFBS; C4)	Toxicity is expected to increase with carbon length	POPRC (2018)
	PFBS: 72h ErC50 (Pseudokirchneriella subcapitata)	651 mg/L	Registration dossier
	PFBS: 48h EC50 (Daphnia Magna)	1937 mg/kg	
RE-HEALING™ Foam RF3 3%; RE-HEALING™ RF6 6%	96h LC50 (Salmo Gairdneri/Oncorhynchus Mykiss)	42 mg/l	Solberg (2013) Solberg (2015)
	48h EC50 (Daphnia Magna)	644 mg/l	
	96h EC50 (Selenastrum Capricornutum)	>6.9 mg/l	
Respondol ATF 3/3 foam	24h EC50 (Daphnia Magna)	139 ppm	Angus Fire (2018)
	48h EC50 (Daphnia Magna)	100 ppm	
Sources: (Angus Fire, 2018; UNEP/POPS/POPRC.14/2, 2018; Solberg, 2015; Solberg, 2013)			

E.2.3.1.4. Technical and economic feasibility of fluorine free foams

Information received from stakeholder consultation has shown that fluorine free foams are currently in use. This is an indication of the technical and economic feasibility of these foams.

The technical properties of the foams are dependent on the application and the type of fire. Fluorine free foams are successfully used on small Class B fires (<9 meters in diameter). According to industry, the technical feasibility of fluorine free foams on large scale storage fires has been highlighted as a potential issue. For example, one association has indicated that they have not successfully tested fluorine free foams on fires in the oil and gas sector that were over 9 metres in diameter; similarly, they have been unable to use these foams successfully for fires in tanks of 100 metres and above due to the thin filming property of fluorinated substances. From additional information received from consultation, this thin film is temperature dependent and requires a positive spreading coefficient which is dependent on a number of other factors. However, conclusions on the infeasibility of using fluorine free foams for large scale fires could be due to the lack of testing. For storage tank fires (as part of the LASTFIRE project), fluorine free foams have been successfully used on a tank fire of 11 metres in diameter. The LASTFIRE project is a consortium of oil and storage companies which reviews associated risks with fires and develops best industry practices (LASTFIRE, 2016). One focus of LASTFIRE is testing fluorine free foams. Consultation has indicated that a test carried out 2018 in Texas as part of the LASTFIRE project on a test refinery fire confirmed the ability to effectively extinguish such fires (pers. comm, Arcadis, (Lastfire, 2018)).

Consultees have noted though that fluorine free foams are not generally used in the military due to MIL-F-24385 standard for fire-fighting foams in the United States (pers. comm, Arcadis). There have recently been changes to legislation in the United States for airports. This change in legislation is to allow the use of fluorine free fire-fighting foam in airports. AFFFs which conform to the military specifications have been typically used in airports in the United States (Chemical Watch, 2018b).

The Institute for Fire and Disaster Control Heyrothsberge in Germany tested six fluorine-free alcohol resistant fire-fighting foams and one PFAS-containing foam for their ability to extinguish fires of five different polar liquids that can be constituents of biodiesel (Keutel & Koch, 2016). The authors conclude that there are fluorine-free foams available which show a similar performance compared with PFAS-containing foams.

Regarding the effectiveness of fluorine free foam more generally, it is reported that this is dependent on the formulation and the equipment for application. Application rates for fluorine free foams can be similar to application rates for AFFFs from industry consultation. Furthermore, according to some stakeholders, there is also no decrease in performance compared to AFFFs.

E.2.3.1.5 Substitution costs

According to industry (stakeholder consultation), fluorine free foams have previously been generally more expensive than AFFFs, with cost estimates varying from fluorine free foams

being 30 - 60% more expensive than PFAS containing AFFFs. The cost of AFFFs has varied between €3 and €11 per litre depending on the foam, with this suggesting that the price of fluorine free alternatives could vary from €4 to €18 per litre. As this substitution has already taken place, there are no new costs connected to the proposed restriction.

However, recent evidence has suggested that the fluorine free alternatives are now not more expensive than AFFF. The typical market cost per litre for AFFF varies from <\$2.5 to >\$7.5 depending on purity with the cost of fluorine free foams can vary from \$2.5 per litre to <\$5 per litre (IPEN, 2018). This also supports information that the latest generation (5 generation, now coming on line) of foams may actually be less expensive than fluorinated foams (stakeholder consultation). It can be concluded, based on this that fluorine free foams are now generally less expensive than AFFFs.

In addition, the cost of the equipment used for foam spraying may vary although no information is available on this difference. According to industry (stakeholder consultation), there is also no 'drop in' replacement so equipment will need to be tested for compatibility. However, the Norwegian Oil & Gas association, in their response to ECHA's call for evidence commented that issues related to safety critical chemicals and equipment were raised and solved when substituting to fluorine free foams.

E.2.3.1.6. Conclusion on fluorine free foams

Fluorine free foams are commercially available on the market and the indications for cost is that the price of these foams are decreasing and that they are now potentially cheaper than shorter-chain fluorotelomer based foams compared for a business as usual scenario. The use of fluorine free foams has been demonstrated as they are in use in the oil and gas airport and at a number of airports worldwide. However, concerns have been raised during the stakeholder consultation for the ability of these foams for large scale fires which may be due to lack of testing. The human health effects of these foams are that they are skin and eye irritations. The environmental impacts of fluorine free foams are also potentially less severe than shorter-chain fluorotelomer based foams. From available information these foams are not classified as PBT or vPvB- substances.

E.2.3.2. Assessment of fluorotelomer-based short-chain chemistry for fire-fighting foams

E.2.3.2.1. Availability of fluorotelomer-based short-chain chemistry for fire-fighting foams

Short chain fluorotelomers are available, although they give rise to environmental concerns, are not recommended as an alternative and should only be used where alternatives do not exist for the use. In their evaluation of PFOS, POPRC state that the use of other PFASs in fire-fighting foams is "*not a suitable option from an environmental and human health point of view*" (UNEP, 2018).

C6 fluorotelomer chemistry has been used to replace C8 chemistry. In fire-fighting foams, this has involved replacing the mixture of 6:2 and 8:2 fluorotelomers with pure 6:2 fluorotelomers. C6 fluorotelomers that may have been used in AFFFs include fluorotelomers based on 6:2 fluorotelomer sulfonamide alkylbetaine and 6:2 fluorotelomer sulfonamide aminoxide (Wang et al, 2011). The use of 6:2 FTS has been discussed as being used (Kemi, 2015b) although consultation indicates that this could also be a result of breakdown from

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

other products. The fluorosurfactants used are regarded as confidential (KemI, 2015a). In C6 fluorotelomer chemistry, 6:2 fluorotelomer sulfonate (6:2 FTS) has previously been found as a product in AFFFs which degrades to 5:3 acid ($F(CF_2)_5CH_2CH_3COOH$), Perfluoropentanoic acid (PFPeA) and Perfluorohexanoic acid (PFHxA) and is further discussed in Annex E.2.3.1.3 (Wang et al, 2013) dependent on the environmental conditions.

According to industry, PFHxS and PFHxS-related substances are not an issue during the manufacturing of fluorotelomers as the synthesis route is by telomerisation and not electrochemical fluorination which may give rise to PFHxS and other substances during the manufacturing process.

E.2.3.2.2. Human health risks related to alternative fluorotelomer-based short- chain chemistry

According to the REACH registration dossier on ECHA's webpages for 6:2 FTS (CAS No: 27619-97-2; EC No: 248-580-6), no metabolism is expected for 6:2 FTS based on tests in male rat liver S9 (ECHA, 2018). The substance, based on a read across approach for 1-Octanesulfonic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-, potassium salt, is classified as acutely harmful (category 4). The LD50 for acute oral toxicity is between 300 and 2000 mg/kg bw based on the read across approach from tests performed on female Wistar rats. The LD50 for acute dermal toxicity is greater than 2000 mg/kg bw based on the read across approach from tests performed on female Wistar rats.

In its registration dossier, 6:2 FTS is classified as skin corrosive 1B and serious eye damage category 1. This is based on a previously performed in vitro corrositex® assay. In the in vitro skin corrosion OECD TG 435, there was evidence of dermal corrosion of the substance at 30% in water. The substance is not classed as a skin sensitiser based on tests performed in mice using local lymph node assay. For repeated dose toxicity, the substance is classified in the registration dossier as STOT RE 2 (H373: May cause damage to organs through prolonged or repeated exposure). The repeated dose toxicity studies performed on Wistar rats showed a dose related decrease in body weight gain, a decrease in food consumption, dose related effects on creatinine and urea levels, and increased kidney weight. 6:2 FTS is not classified for mutagenicity and reproductive toxicity based on tests performed in the registration dossier.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 26: Human related PBT properties for PFHxS and 6:2 FTS

Substance	Persistent	Bioaccumulative	Toxic
PFHxS and PFHxS-related substances	very Persistent (ECHA 2017)	Very Bioaccumulating (ECHA 2017) Yes; t1/2 >7 years (human). Bioaccumulates in air-breathing mammals	(PFHxS:) Acute Tox. 4; H302 Acute Tox. 4; H312 Acute Tox. 4; H332 Skin Corr. 1B; H314
6:2 FTS	Yes, not metabolised	No, but the fate of all produced metabolites is presently not known	Skin corrosion/irritation and can cause serious eye damage CLH entries: Acute Tox. 4 Skin Corr. 1B Eye Dam .1 STOT RE 2 Repeated dose NOEL: 15 mg/kg bw in rats. Dose related decrease in body weight gain, a decrease in food consumption, dose related effects on creatinine and urea levels, and increased kidney weight Genotoxicity: In vivo: Tests reported in the registration dossier were negative. Negative for mutagenicity in bacterial cell. Positive test for induction of structural numerical chromosome aberrations in mammalian cell culture Carcinogenicity: no data Reproduction toxicity: (i) NOEL = ≥45 mg/kg bw/day for fertility and developmental toxicity (ii) NOEL = 15 mg/kg bw/day for maternal toxicity
Sources: (ECHA, 2018; ECHA, 2017b)			

E.2.3.2.3. Environmental risks related to alternative fluorotelomer-based short-chain chemistry

Studies performed on 6:2 fluorotelomer-based substances have suggested that the substances undergo similar degradation processes. These short chain products are persistent in the environment (Wang et al, 2013). Short chain fluorotelomers will degrade to perfluorohexanoic acid (PFHxA), perfluoropentanoic acid (PFPeA) and the 5:3 fluorotelomer acid, CF₃(CF₂)_nCH₂CH₂COOH dependent on the environmental conditions.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

The aerobic biotransformation of 6:2 FTS Potassium salt has been studied in activated sludge. The biotransformation of the 6:2 FTS salt is slow with 63.7% of the salt still remaining after 90 days. The stable transformation products of the 6:2 FTS salt after 90 days were 5:3 acid (0.12%), PFPeA (1.5%), PFBA (0.14%) and PFHxA (1.1%). These bio transformed products accounted for 6.3% of the initial molar mass of 6:2 FTS salt (Wang, 2011). The slow degradation of 6:2 FTS may be because of the microbial aerobic de-sulfonation of 6:2 FTS which is required for further biotransformation. This may be a rate limiting step in the microorganisms in activated sludge.

The aquatic toxicity of 6:2 FTS and its degradation products is presented in [Table 27](#).

Table 27: Aquatic toxicity data of 6:2 FTS and its degradation products

Substance	Endpoint	Result [mg/L]	Reference
PFHxS and PFHxS-related substances	Aquatic toxicity is not available for PFHxS and PFHxS-related substances. Data is available for Perfluorobutanesulfonic acid (PFBS; C4)	Toxicity is expected to increase with carbon length	Persistent Organic Pollutants Review Committee (2018)
	PFBS: 72h ErC50 (Pseudokirchneriella subcapitata)	651 mg/L	Registration dossier
	PFBS: 48h EC50 (Daphnia Magna)	1937 mg/kg	
6:2 FTS	96h LC50 (fish) 48h LC50 (daphnia) 72h ErC50 (algae)	>108 >109 >96	Registration dossier
5:3 acid	48h LC50 (daphnia) 72h ErC50 (algae) Fish not detected	>103 53.3	Hoke et al., 2012
PFBA (C4-PFCA)	90d NOEC (fish) 21d NOEC (daphnia)	9.14 1.25	No published data
PFHxA (C6-PFCA)	96h LC50 (fish) 48h LC50 (daphnia) 72h ErC50 (algae)	>99.2 >96.5 >100	Hoke et al., 2012
PFHpA (C7)	48h LC50 (daphnia) 72h EC50 (algae)	>10 000 1896	Australian Government, Department of Health (2018)
PFPeA	96h LC50 (fish) 48h EC50 (daphnia) 72h EC50 (algae)	31.8 >112 81.7	Hoke et al., 2012
PFHxS, its salts and PFHxS-related substances	Limited information on PFHxS, although studies on PFBS and PFOS indicate increase aquatic toxicity with increasing carbon length		UNEP, 2018
Sources: (NICNAS, 2018; ECHA, 2014; ECHA, 2017b; UNEP/POPS/POPRC.14/2, 2018; Hoke, et al., 2012)			

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

E.2.3.2.4. Technical and economic feasibility of alternative fluorotelomer-based short-chain chemistry

C6 fluorotelomers have been used as alternatives to C8 fluorosurfactants in AFFFs and are currently in use. The higher purity C6 foams have been confirmed to be in use from stakeholder consultation. PFHxS has been measured in some of the foams in the KemI (2015a) study, although it is noted that this could be due to contamination from previously used products. This indicates the technical and economic feasibility of short-chain fluorotelomer chemistry.

Information collected from stakeholder consultation has indicated that shorter chain fluorotelomer based chemistry has been more expensive because a higher loading is needed to achieve the same technical function as C8 fluorochemistry.

E.2.3.2.5. Conclusion on alternative fluorotelomer-based short-chain chemistry for fire-fighting foams

Foams based on alternative fluorotelomer based short chain chemistry give rise to concerns. The environmental impact of these foams is potentially more severe than that for fluorine free foams. These short chain products are persistent in the environment and potentially toxic to aquatic life. The fluorotelomer, 6:2 FTS which has been identified in foams also gives rise to human health concerns. This includes for acute toxicity and repeated exposure toxicity. The use of alternative fluorotelomer based short chain chemistry should only be used where no other fluorine free alternative can be used.

E.2.3.3. Assessment of fluorine free alternatives in textiles

E.2.3.3.1. Availability of fluorine free alternatives in textiles

Fluorine free alternatives are commercially available in textiles for some uses and there is a move towards fluorine free alternatives from information received from the stakeholder consultation. Limited information was received during the stakeholder consultation. Selected fluorine free alternatives are summarised in Table 28. It is also difficult for a fluorine free alternative to match the requirement of fluorinated substances (ECHA, 2017a). Stakeholder consultation with one textile association identified that for high performance wear, no fluorine free alternatives have to date achieved the same performance as fluorinated substances to comply to safety standards and provide a certain function such as oil, water, and chemical repellence.

The MIDWOR-LIFE project which evaluated fluorine free alternatives in textiles have stated that dendrimers and silicone (*Polydimethylsiloxane*) are alternatives to C6 fluorine substances for water repellents, however, for oil repellents no alternatives have yet been identified (Midwor, 2018).

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 28: Fluorine free alternatives in textiles

Alternative	Use
Alkyl urethane	Water repellency
Dendrimer- based repellents (such as BIONIC-FINISH® ECO, such as ®RUCO-DRY ECO PLUS (Rudolf Group); AD-9 (Dymeric®))	Dirt, grease and water-repellency
Functionalised polymers; glycols; cationic surfactants	Water repellency
Natural repellents such as bees wax	Impregnation agent in outdoor clothing
Organic silicon compounds; organic acid	Water repellency
Paraffin based repellents	Water repellency
Paraffin waxes, blend of polymers	Water repellency
Polydimethylsiloxanes	Water repellency
Stearic acid	Water repellency
Stearic acid- Melamine repellent chemistries	Water repellency
Sources: (Danish EPA, 2015; Kaufland, (undated); KEMI, 2015; Midwor, 2018; OECD , 2013; Subsport , 2012; Subsport, 2013; Subsport, 2015; Weber, 2016)	

E.2.3.3.2 Human health risks related to fluorine free alternatives in textiles

There is limited information on the human health risks for fluorine free alternatives in textiles as discussed in Annex E.2.3.3.2. For the alternatives listed in Table 28, the compositions of those available are generally not publically available. No further information was obtained from stakeholder consultation on fluorine free alternatives in textiles.

There is some limited information in safety data sheets and registration dossiers for substances, safety data sheets for products available on the market and also from reports on alternatives in textiles which conclude that for many alternatives there is insufficient information to conclude on hazards (Danish EPA, 2015). Information on health hazards where available are discussed in Table 29.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 29: Human related PBT properties for fluorine free alternatives in textiles

Substance	Persistent	Bioaccumulative	Toxic
PFHxS and PFHxS-related substances	very Persistent (ECHA 2017)	Very Bioaccumulating (ECHA 2017) Yes; t1/2 >7 years (human). Bioaccumulates in air-breathing mammals	(PFHxS:) Acute Tox. 4; H302 Acute Tox. 4; H312 Acute Tox. 4; H332 Skin Corr. 1B; H314
BIONIC-FINISH® ECO (Rudolf Group (2012))	No available information	No available information	Eye Irrit. 2; H319 Skin Irrit. 2; H315 Not classified for germ cell mutagenicity, carcinogenicity, reproductive toxicity and STOT exposure; LD50 (oral) >8000 mg/kg (rat)
Natural repellents (such as bees wax)	No available information	No available information	Not classified
Organic silicon compounds; organic acid (such as OC aquasil Tex W™)	No available information	No available information	Organic silicon compound: Eye Irrit. 2; H319 LD50 (oral) >5000 mg/kg (rat) Organic acid: Eye Irrit. 2; H319 STOT SE3; H334 LD50 (oral) >1500 mg/kg
Paraffin waxes, blend of polymers (such as Arkophob FFR liq)	>90% biodegradability (28d, DOC decrease)	Not tested	Non-irritant for eyes and skin
Polydimethylsiloxanes	No available data	No available data	Carcinogenicity: Rat-implant Reproductive toxicity: Rat-Subcutaneous
Stearic acid	No available data	No bioaccumulation	Acute toxicity: LD50 (oral) > 2 000 mg/kg (rat) LD50 (dermal) > 5000 mg/kg (rabbit)
Stearic acid – Melamine repellent chemistries	Not considered to be persistent (melamine)	Low bioaccumulation (melamine)	No hazard identified (melamine)
Sources: (Archroma , 2014; Danish EPA, 2015; ECHA, 2018; ECHA, 2019; ECHA, 2019; ECHA, 2017b; Global Safety Management Inc., 2016; Rudolf Group , 2016; Sigma Aldrich, 2017)			

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

E.2.3.3.3 Environmental risks related to fluorine free alternatives in textiles

There is limited information on the environment risks for fluorine free alternatives in textiles as discussed in Annex E.2.3.3.2.

For dendrimer-based repellents, silicone-based repellents, and other repellents there is a lack of information for an evaluation of the environmental risks (Denmark Environmental Protection Agency, 2015). Paraffin-based repellents are readily biodegradable, not accumulated and have insignificant aquatic toxicity (Danish EPA, 2015).

Table 30: Aquatic toxicity data of fluorine free alternatives in textiles

Substance	Endpoint	Result [mg/L]	Reference
PFHxS and PFHxS-related substances	Aquatic toxicity is not available for PFHxS and PFHxS-related substances. Data is available for Perfluorobutanesulfonic acid (PFBS; C4)	Toxicity is expected to increase with carbon length	Persistent Organic Pollutants Review Committee (2018)
	PFBS: 72h ErC50 (Pseudokirchneriella subcapitata)	651 mg/L	ECHA (2018a)
	PFBS: 48h EC50 (Daphnia Magna)	1937 mg/kg	
BIONIC-FINISH® ECO	48h LC50 (vertebrata)	>100 mg/l	Rudolf Group (2016)
Organic silicon compounds; organic acid (such as OC aquasil Tex W™)	No information	No information	
Paraffin waxes, blend of polymers (such as Arkophob FFR liq)	LC50 (fish)	>100 mg/l	Archroma (2014)
Stearic acid – Melamine repellent chemistries	96h LC50 (Poecilia reticulata)	>4.59 g/L (melamine)	Registration dossier
	48h EC50 (Daphnia Magna)	200 mg/L (melamine)	
Sources: (Archroma , 2014; Danish EPA, 2015; ECHA, 2017b; Rudolf Group , 2016)			

E.2.3.3.4 Substitution costs

Limited information is available for substitution costs to fluorine free alternatives instead of PFHxS from information received during the stakeholder consultation. According to one industry association fluorine free alternatives may be more expensive at the present time; however, this cost is expected to decrease over time.

To give an indication of possible substitution costs of moving to fluorine-free DWR (durable water repellent), an example that gives an indication of costs related to moving from a C6 chemistry based DWR to fluorine-free DWR is introduced. This example has been taken from

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

the background document proposing restrictions on C9-C14 PFCAs including their salts and precursors (ECHA, 2018b).

This is not the correct substitution costs because it relates to moving from PFOA to fluorine-free instead of moving from PFHxS. These substitution costs are not available since there are no users of PFHxS in the EU at the moment. It is still included as an illustrative and best available example. The rising consumer demand for fluorine-free products and the environmental consciousness of the outdoor industry might make this an interesting alternative for some producers despite somewhat higher costs (ECHA, 2018b).

"Costs of fluorine-free options are higher for several reasons. The amount of chemicals/additives used is higher. PFASs-free material has a higher water demand in production, because machines have to be rinsed between batches to avoid cross contamination. The costs for this are allocated to the PFASs-free material. Also different curing temperatures and/or durations are needed. Some suppliers double the curing time for the PFASs-free material and some need to apply an extra pre-wash on the fabric. PFASs-free material shows a wider variety, with silicone based, wax, hydrocarbon and ester as basis." (ECHA, 2018b)

In 2017, the rise in cost for one stakeholder was estimated to 0,33-0,42 EUR (based on 1USD=0,8351 EUR, 2017-09-22) per yard of fabric, or 0,04-0,33 EUR for a backpack; for clothing, the increase was 5-20 US Cent per yard. Roughly estimated the production costs were 2.3 – 3.5 % higher for fluorine-free products. One company switched production of PFOA-based DWR coating to PFAS-free alternatives in 2011. It led to increased prices for the fabric, in 2011, about 0,06-0,18 EUR (based on 1 USD=0,8356 EUR)) were added for the fabric by the supplier, depending on the quality. Another stakeholder reported that the cost rise for PFASs-free DWR, due to smaller volumes, was estimated to be around 0,17-0,33 EUR/yard (ECHA, 2018b).

"One manufacturer for shoes evaluated for which purposes per-and polyfluorinated substances was necessary and for which kind of shoes they were not important. The manufacturer shifted its whole production line and separated waterproof styles and styles where water repellence was not needed (e.g. for sandals). Now PFASs are only used for those shoes that need to meet the highest demands (e.g. special work wear), whereas other articles such as sandals do not need treatment at all. PFASs-free alternatives are used for those shoes that need to be water proof. The company reported that all in all the shift in the production did not induce extra costs. Articles that do not need any impregnation are now made at a lower price, whereas those where fluorine-free alternatives are used are made at a higher price. Thus, the costs for using fluorine-free alternatives are levelled out (chemical watch webinar "Lessons for Safer Chemicals in Products – PFAS", March 14, 2017)." (ECHA, 2018b)

In 2018, the cost for fluorine-free fabric was estimated to be 0,03 EUR/m higher, the difference has evened out. There are no differences in prices for chemicals (ECHA, 2018b).

E.2.3.3.5 Conclusion on fluorine free alternatives in textiles

The use of PFHxS and PFHxS-related substances in textiles cannot be determined, with three industry associations indicating their members do not use these substances. One association commented that there could be a possibility of trace amounts in imported

products and there is already a move towards fluorine free alternatives. Fluorine free alternatives are commercially available for most uses in textiles. It has been established that fluorine free alternatives are available for water repellency, although there may be a lack of fluorine free alternatives for oil repellency. No conclusion is possible for the health and environmental risks due to insufficient information. Fluorine free alternatives have already been taken into use by EU industry. The costs of fluorine free alternatives is that they may be more expensive but the cost is expected to decrease over time.

E.2.3.4. Assessment of fluorotelomer-based short-chain chemistry for textiles

E.2.3.4.1. Availability of fluorotelomer-based short-chain chemistry for textiles

Shorter chain fluorotelomer-based products are already in use in textiles. Other shorter chain fluorine alternatives are also available in textiles, such as PFBS. Where C6 fluorotelomers have been used to replace longer chain fluorotelomers based on n: 2 FTOH ($n \geq 8$), 6:2 FTOH (CAS: 647-42-7; EC: 211-477-1) has been used as an alternative.

Due to the environmental impacts of the fluorotelomer-based short-chain products, fluorine free products are recommended to be used where technically possible.

E.2.3.4.2. Human health risks related to alternative fluorotelomer-based short-chain chemistry

The fluorotelomer 6:2 FTOH is rapidly metabolised to PFCAs (PFBA, PFHxA and PFHpA) and 5:3 fluorotelomer acid as the terminal metabolites, although it is not known if the metabolites leave the body without causing any harm due to the lack of urine measurements (ECHA, 2014). There could also be some fluorine retention in liver and fat of rat gavage. The substance has also shown liver toxicity in repeated dose toxicity studies and higher concentrations of the substance have been toxic for reproductive and developmental effects and have shown only a modest oestrogen effect (ECHA, 2014). One in vitro study that investigated the metabolism and cytotoxicity of selected fluorotelomer alcohols (4:2 FTOH, 6:2 FTOH, 8:2 FTOH and 10:2 FTOH) found that the 6:2 FTOH metabolised to FTOH-sulfate and FTOH-glucuronide, although it was concluded that GSH-conjugates and other metabolites are also formed (Martin et al., 2005 as discussed in ECHA, 2014). In another in vitro study, all the investigated FTOH demonstrated moderate toxicity, although 6:2 FTOH is less cytotoxic than 4:2 FTOH and 8:2 FTOH ($LC_{50} = 3.7 \pm 0.54$ mM, 0.66 ± 0.20 mM and 1.4 ± 0.37 mM respectively) (Martin et al., 2009 as discussed in ECHA, 2014). The relevant PBT human health effects of 6:2 FTOH are discussed below from its REACH registration dossier.

Short chains PFASs have similar effects as those of long chain PFASs in laboratory animals. Effects of short chain PFASs include effects on lipid metabolism, haematological effects, liver toxicity and development/reproductive toxicity (ECHA, 2017). Some short chain PFASs also have a high mobility in water and soil with persistent degradation products which can result in contamination of drinking water; they may also accumulate in edible parts of plants (Brendel et al., 2018). With respect to drinking water levels, the United States has set a health advisory limit of 70 ppt (parts per trillion) for PFOA/PFOS (US EPA, 2018).

Table 31: Ecotoxicity data for PFHxS and 6:2 FTOH

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Substance	Persistent	Bioaccumulative	Toxic
PFHxS and PFHxS-related substances	very Persistent (ECHA 2017)	Very bioaccumulating (ECHA 2017) Yes; t1/2 >7 years (human). Bioaccumulates in air-breathing mammals	(PFHxS:) Acute Tox. 4; H302 Acute Tox. 4; H312 Acute Tox. 4; H332 Skin Corr. 1B; H314
6:2 FTOH	No, in rodents there is rapid metabolism	Fate of the possible metabolites is not known. T _{1/2} humans 100 mins T _{1/2} rats: 30 mins T _{1/2} mouse: 22 min Rapid metabolism for rats when the 5:3 fluoroteleomeric acid is a major metabolite	Eye and skin irritant CLH entries: Acute Tox. 4 STOT Rep. Exp. 2 Repeated dose: NOEL =5 mg/kg/day in rats. Increased liver weight with decreased motor activity for males only at 100 pm for rat inhalation. Carcinogenicity: No data available Reproductive toxicity: (i) NOEL = 25 mg/kg/kg/day for reproductive toxicity. (ii) NOEL 75 mg/kg/day for offspring pup mortality and lower mean F1 male and female pup weights of the surviving litter at 225 mg/kg/day. (iii) Exposure during pregnancy on gestation days 6-20 at doses of 125 and 250 mg/kg/day resulted in increased skeletal variations in the foetuses.
Sources: (ECHA, 2014; ECHA, 2017b)			

E.2.3.4.3. Environmental risks related to alternative fluorotelomer-based short- chain chemistry

Studies performed on 6:2 fluorotelomer-based substances have suggested that the substances undergo similar degradation processes and are transformed to short chain PFASs and PFCAs (such as PFHxA and PFBA) and /or short chain perfluorocarboxylic acids (Wang et al, 2013). These short chain products are persistent in the environment (Wang et al, 2013) and 6:2 FTOH and other short chain fluorotelomers will degrade to perfluorohexanoic acid (PFHxA), perfluoropentanoic acid (PFPeA) and the 5:3 fluorotelomer acid, $CF_3(CF_2)_nCH_2CH_2COOH$ dependent on the environmental conditions.

The fluorotelomer 6:2 FTOH is aerobically biodegraded to 5:3 acid (12%), PFHxA (4.5%) and PFPeA (4.2%) after 84 days in a study performed by Liu et al. (Liu et al, 2010). Another study performed by the same authors found the following degradation products after 180 days in soil (closed system): PFPeA (30%), PFHxA (8%), PFBA (2%), 5:3 acid (15%), 4:3 acid (1%), 6:2 FTOH (3%) and 5:2 sFTOH (7%) (Liu et al, 2010b).

The aerobic biotransformation of 6:2 FTOH has also been studied in activated sludge (Zhao et al., 2013). The primary biotransformation was rapid with 5:2 FTOH the most abundant product, and other products including 5:3 acid, PFHxA and PFPeA. The substance will transform to short chain (C3 to C5) perfluorinated carboxylic acids (ECHA, 2014). These short chain PFCAs are mobile with the potential to reach water bodies and they also have a low absorption potential (ECHA, 2017). They are also persistent in the environment and cannot be biodegraded under abiotic or biotic conditions and can accumulate in plants.

Regarding aquatic toxicity, 6:2 FTOH is moderately toxic and short chain PFCAs have low toxicity.

Table 32: Aquatic toxicity data of 6:2 FTOH, 8:2 FTOH and other metabolites

Substance	Endpoint	Result [mg/L]	Reference
6:2 FTOH	96h LC50 (fish)	4.84	Registration dossier
	48h LC50 (daphnia)	7.84	
	72h EC50 (algae)	4.52	
	21d NOEC (daphnia)	2.16	
5:3 acid	48h LC50 (daphnia)	>103	Hoke et al., 2012
	72h ErC50 (algae)	53.3	
	Fish not detected		
PFBA (C4-PFCA)	90d NOEC (fish)	9.14	No published data
	21d NOEC (daphnia)	1.25	
PFHxA (C6-PFCA)	96h LC50 (fish)	>99.2	Hoke et al., 2012
	48h LC50 (daphnia)	>96.5	
	72h ErC50 (algae)	>100	
8:2 FTOH	96h NOEC (fish)	0.18	Hekster et al., 2003
	48h NOEC (daphnia)	0.16	
	72h NOEC (algae)	0.2	
PFHxS, its salts and PFHxS-related substances	Limited information on PFHxS, although studies on PFBS and PFOS indicate increase aquatic toxicity with increasing carbon length		UNEP, 2018

Sources: (ECHA, 2014; ECHA, 2017b; UNEP/POPS/POPRC.14/2, 2018)

E.2.3.4.4. Conclusion on alternative fluorotelomer based short chain chemistry in textiles

Alternatives based on alternative fluorotelomer based short chain chemistry give rise to concerns. The health impact of 6:2 FTOH with the substance showing liver toxicity and reproductive and development effects. The environmental impact of these foams is also potentially more severe than that for fluorine free alternatives. 6:2 FTOH is moderately toxic to aquatic organisms and its metabolites are expected to be persistent in the environment. No information has been obtained on costs on alternative fluorotelomer based short chain chemistry compared to business as usual from stakeholder consultation.

The use of alternative fluorotelomer based short chain chemistry should only be used where no other fluorine free alternative can be used.

E.2.3.5. Assessment of fluorine free alternatives for other uses

Potential alternatives for other uses of PFHxS related substances are summarised in Table 33. For a number of these alternatives are PFOS alternatives (PFHxS is a known impurity in the production of PFOS) and also alternatives for other long-chained PFAS. For example, in the ECHA REACH Annex XV report for PFHxS, alternatives to PFOS are discussed, as it is likely that the alternatives for uses of PFOS can be alternatives for PFHxS (ECHA, 2017b). No further information on these alternatives and their uses has been obtained from the stakeholder consultation and these alternatives are not assessed further.

Specifically, for semiconductors it is discussed that no substitutes for PFOS with comparable effectiveness have been identified for critical uses. Other fluorine products (PFBS, fluorotelomers or fluorinated polyethers) could be used for non-critical uses (ECHA, 2017b). No fluorine free alternatives have been identified for semiconductors (UNEP-POPS, 2017). No information on uses in semiconductors was received during stakeholder consultation. According to a recent report from the European Commission to the POPs secretariat (UNEP, 2019a), the countries of the European Union do not use substances or mixtures containing PFOS in photo resist and anti-reflective coatings for semi-conductors, as etching agent for compound semi-conductors and ceramic filters. Fluorine free alternatives are available for metal plating. The fluorine substance, 6:2 FTS is also used as an alternative in metal plating; however this gives rise to environmental concerns as discussed in Annex E.2.3.2.3. According to a recent reporting from the European Commission to the POPs secretariat (UNEP, 2019a), there is a continuous need within the EU for PFOS in hard metal plating in closed-loop systems.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 33: Fluorine free alternatives for other potential uses

Alternative	Use
Alkylsulfonate	Metal plating
Aminoethanol	Surface coatings, paints and varnishes
Fatty alcohol polyglycol ether sulphate	Surface treatment
Hydrocarbon surfactants	Photography
Naphthalene derivatives	Various including coatings
Olea amine	Metal plating
Phosphates	Impregnation of paper and cardboard
Polypropylene glycol ethers, such as Propylene Glycol n-Butyl Ether	Surface coatings, paints and varnishes
Silicone products	Photography
Sulfosuccinates	Surface coatings, paints
Synthetic piperonyl compounds: S-Methaprene; Pyriproxyfen; Fipronil Chloropyrifos	Agrochemical (pesticides)
Sources: (ECHA, 2017b; OECD , 2013)	

E.3. Socio-economic impacts

E.3.1 Introduction

The socio-economic analysis provided takes as its starting point the baseline scenario described in Annex D of this restriction report, and then assesses the changes from this baseline that would arise under the proposed restriction.

Owing to the fact that, for PBT and vPvB substances such as PFHxS a 'safe' concentration in the environment cannot be established using the methods currently available. Quantification and valuation of benefits via the assessment of the impacts on environment and human health is not possible in this case. Instead, a cost-effectiveness analysis based on emissions reduction and the total costs of implementing the proposed restriction is more appropriate. In this respect, total costs should include compliance costs, enforcement costs, and other additional social costs (see for example the SEAC Guide (ECHA, 2016)).

Within this type of analysis, emissions reductions normally act as a proxy for the unquantified environmental and human health benefits in terms of a reduced risk. The total costs of the measure are divided by the reduction in emissions to derive a cost per unit of reduction. Where it is possible to estimate a cost per unit of reduction, this can be compared to other past decisions (i.e. to suitable benchmarks) to confirm whether or not it is likely to reflect a net benefit to society.

E.3.2 Economic impacts

E.3.2.1 Costs of alternatives and substitution

In terms of economic impacts, based on the evidence of exhaustive consultation and thorough data searches on PFHxS its salts or related substances in the EU it is concluded that the restriction proposal will have:

- No impacts on EU production of PFHxS, its salts or related substances because no such production exists (i.e. there are no economic impacts);
- No impact on the production of PFAS. Since PFAS production methods have now shifted to C6 fluorotelomer production, there is no longer any production of PFAS containing impurities of PFHxS, its salts or related substances above 25ppb and, as such, there are no economic impacts on manufacturers;
- No impact on the market for PFAS based fire-fighting foams. There is no longer any production of PFAS fire-fighting foams containing impurities of PFHxS, its salts or related substances above 25ppb and, as such, there are no economic impacts;
- No impact on private companies and public bodies maintaining a stockpile of fire-fighting foams. The restriction does not extend retrospectively to fire-fighting foams already purchased and stockpiled for the purpose of fighting fires; and
- No negative impact on importers of finished articles containing PFHxS, its salts or related substances above 25ppb into the EU.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

In relation to the latter (imports of PFHxS in articles such as outdoor gear), as reported in Annex A, more recently there has recently also been a shift away from the use of PFHxS as a waterproofing and protective agent in articles such as outdoor clothing imported from countries such as China, Vietnam and Bangladesh. The restriction would re-inforce this shift and ensure that use of PFHxS in imported textiles does not increase (again) as a result of the changes brought about by the restriction on PFOA.

This action could actually provide a benefit to some EU brands and retailers of articles such as outdoor gear. As is identified in the dossier on C9-C14 PFCAs (BAuA, 2017), there is consumer demand for more environmental friendly products, in for example the outdoor industry, which is driving a phasing out of PFAS in general. A manufacturer of outdoor clothes reported to the PFCAs consultation that durable water repellent (DWR) textiles will be PFASs free by 2020 and PFASs-free DWR textiles are available. Similarly, a retailer stated that 80% of own brands were PFASs free in the spring/summer collection 2017 and more than 90% in the autumn/winter collection. The stakeholder was aiming for 100% PFASs-free of own brands by 2018.

The proposed restriction on PFHxS should assist manufacturers and retailers who are pursuing such objectives by reinforcing their own requirements regarding the presence of PFAS in articles.

PFHxS could (in theory) be used as an alternative to PFOS in applications such as semiconductors and metal plating. Stakeholders in these areas have repeatedly been contacted and have provided no information that confirms such use. The indication, then, is that the restriction will have no impact on these uses.

E.3.2.2. Administrative costs

In the consultation for the C9-C14 PFCAs (BAuA, 2017) some companies in the outdoor textile industry indicated that they intended to send some of their products to independent laboratories for testing once a restriction was implemented. The same is likely to be the case for PFHxS.

In the C9-C14 PFCA dossier (BAuA, 2017) costs of €241 were estimated for such testing but it was identified that part of the testing costs would be shared with the testing needed to comply with the PFOA restriction. Specific testing costs for PFHxS have not been identified, however, they can be expected to be similar to those of PFCAs or possibly less as testing would be shared also with PFCAs. The C9-C14 PFCA dossier estimates administrative costs due to testing could be €89 less for a company who comply with both the PFOA restriction and the C9-C14 PFCA restriction at once.

E.3.2.3. Comparison with other similar PBT and vPvB, PFAS cases

In cases with other similar PBT and vPvB substances, where concentrations have reached the recommended guidance level, for example PFAS in drinking water in Sweden (from fire-fighting foam), it has been proven (Swedish Chemicals Agency, 2016), to be a cost-effective measure to regulate these substances in beforehand rather than paying for the abatement and substitution cost afterwards.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Avoidance of future emissions of PFHxS into the environment is important to reducing impacts on the environment and human health. There are numerous examples in the literature of the costs of remediating sites where contamination of groundwater and soil has occurred due to the past use of PFASs at industrial sites, at airports, as part of training activities in the use of fire-fighting foams, and due to the need to put out fires. Although these examples are not specific to PFHxS, they provide an indication of the potential for significant costs should there be a need to undertake such remediation activities specific to PFHxS, its salts and PFHxS-related substances in the future due to the high levels of contamination that have been identified globally (For examples, see tables in Appendix 2).

Weber (2016) provides information on the costs of addressing unacceptably high levels of PFAS in drinking water due to PFAS pollution in the Ruhr and its tributaries. The costs of upgrading wastewater treatment works with, for example activated carbon filters, to reduce exposures cost are estimated to have cost around €100 million with the works taking several years. In addition, the mismanagement of industrial sludges from the Netherlands and Belgium was found to have resulted in a series of contaminated sites with the region. More specifically PFOS/PFAS contamination was identified as an issue for Dusseldorf, with sources including major fires where AFFFs were used, the airport, fire-fighting practice areas and at chromium plating facilities. The total remediation estimate for contamination at the airport was indicated as potentially reaching costs of €100 million, the remediation costs associated with foams used to put out a fire were greater than €10 million, and the costs of soil exchange for a site in Baden-Wurtemberg were estimated at between €1-3 billion (Weber, 2016).

Alling et al (2017) presented two case studies for remediation of PFAS contaminated fire-fighting sites in Norway. These report costs of up to 50 million NOK (€5.1 million) at Evenes airport and over 30 million NOK (€3.1 million) at Oslo Gardermoen Airport.

E.3.2.4. Enforcement Cost

Average enforcement costs have been identified in connection to the restriction on lead compounds in PVC (ECHA, 2016) for EU28 member state agencies to ensure compliance with EU regulation. ECHA assessed the administrative cost of member states to comply with restrictions to be approximately €55 600 per year. This number could be seen as an indication of the magnitude of the enforcement costs associated with the PFHxS restriction. However, enforcement costs are likely to be lower than this because many of the enforcement actions and costs would overlap with those associated with the PFOA (and also C9-C14 PFCAs) restriction. Here, an inspection and testing regime for PFOA, PFHxS (and C9-C14 PFCA) in articles at the same time is likely to be less expensive than separate inspection and testing regimes. Thus, part of the costs can already be attributed to the enforcement of the PFOA-restriction (and potentially the C9-C14 PFCAS).

E.3.2.5. Competition

It is not anticipated that the restriction will have any negative competition effects as the restriction applies to all actors. In any case, there is no manufacture and use of PFHxS, its salts or related substances in the EU to produce such an effect. As the restriction includes thresholds for imported articles, EU manufacturers of products will not be at a disadvantage on the internal market.

E.3.3. Human health and environmental impacts

E.3.3.1. Human health impacts

The potential harm to humans from PFHxS, its salts and PFHxS-related substances follows from the PBT or vPvB properties of these substances. The main potential exposure pathways are intake via food and drinking water and through exposure to house dust. No human absorption data is available but monitoring data demonstrate the presence of PFHxS in human blood and serum. Some of these detected PFHxS levels in human blood and serum have also been seen to increase or level off despite decreasing uses in manufacture and production over time. PFHxS has also been observed in human breast milk (see Annex B.5 for a full description of the data and studies).

Due to their vPvB properties, minimizing the use of PFHxSs is an urgent priority. There are indications that PFHxS is likely to lead to significant adverse human health effects. Furthermore, since these substances persist and accumulate in humans and wildlife they may be impossible to remove if serious health concerns should be documented in the future (see Annex B.5).

No monetary valuation of human health impacts is possible because a quantitative cause and effect relationship between PFHxS levels and different health endpoints has not yet been defined.

E.3.3.2. Environmental impacts

As set out in the baseline in Annex D, emissions are conservatively estimated as 0.22 tonnes per annum in 2019, down from 2.1 tonnes per annum in 2010 owing to the action taken on PFOS from 2008 onwards reducing industrial emissions down to the levels measured at public WWTP.

Under the baseline it is anticipated that uses of PFHxS may expand from 2020 onwards owing to the restrictions on PFOA which come into force in the EU in 2020. PFHxS (and related substances) are known to be technically feasible substitutes for PFOA (and PFOS) in a number of applications (Kemi, 2017), including several where current use of PFHxS appears (see Annex D). Based on an increase of PFHxS use in outdoor clothing from an average 260.4 µg/kg across imported outdoor clothing articles in 2013 (the average accounts for articles where PFHxS was not detected) to 520.7 µg/kg (the average for PFHxS treated articles), the baseline estimates a doubling in emissions from 0.22 to 0.44 tonnes per annum after 2020.

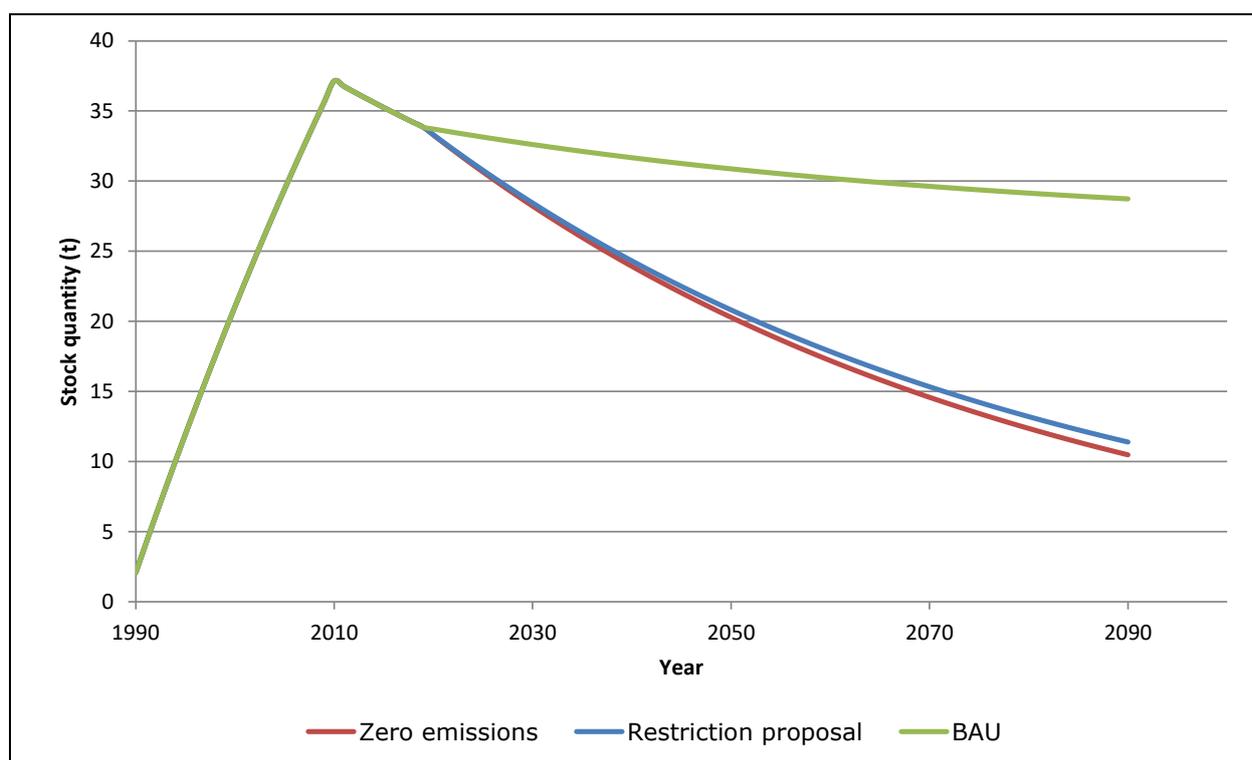
Applying the same estimation method, the threshold for PFHxS in the restriction proposal is 25ppb (i.e. 25 µg/kg) which, when compared 260.4 µg/kg used in the baseline, suggests emissions after 2020 at 9.6% (taken as 10%) of those for 2019, i.e. an annual emission of 0.02 tonnes per annum PFHxS after 2020. Emissions under the Baseline (BAU) and under the Restriction are summarised in Table 5.

As described above, the Annex XV report identifying PFHxS as a SVHC (ECHA, 2017a) concludes that PFHxS is stable under environmental conditions and abiotic degradation is

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

expected to be as low as for the chemically similar substance PFOS, which has a half-life of >42 years.

Applying a half-life of 42 years to the annual emissions under the baseline (BAU) and under the restriction scenario provided in Table 5 allows projection of environmental stocks of PFHxS under each scenario. For reference purposes we have also included a zero emissions from 2020 scenario. This is provided in Figure 7. The figure shows the change in environmental stock after 1990. Possible stock from releases prior to 1990 is not included in this figure. This stock has not been estimated and will not be affected by this restriction.



(Copy of Figure 7: Environmental stock profile under the Baseline (BAU) and Restriction scenarios (half life 42 years) Figure 7: Environmental stock profile under the Baseline (BAU) and Restriction scenarios (half life 42 years))

Owing to the persistence of PFHxS (half-life >42 years) even a relatively small annual emission can quickly produce a large stock in the environment. It is this attribute (together with the bioaccumulation and toxicity) that sets such substances apart from other, less persistent, substances for which half-lives are short enough for there to be no (or negligible) residue from one year to the next. Thus, for a non-persistent substance (i.e. the 'normal' case) the environmental stock is taken as broadly equalling the annual emissions (because no or negligible emissions from one year persist into the next).

For an extremely persistent substance such as PFHxS around 98% of an emission in year n persists into year $n+1$. Thus, an annual emission of 1 ton produces an environmental stock of 1 ton in year 1 and 1.98 tonnes in year 2 (because the emission from the first year persists into the second). As such, where in the 'normal case' of a non-persistent substance

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

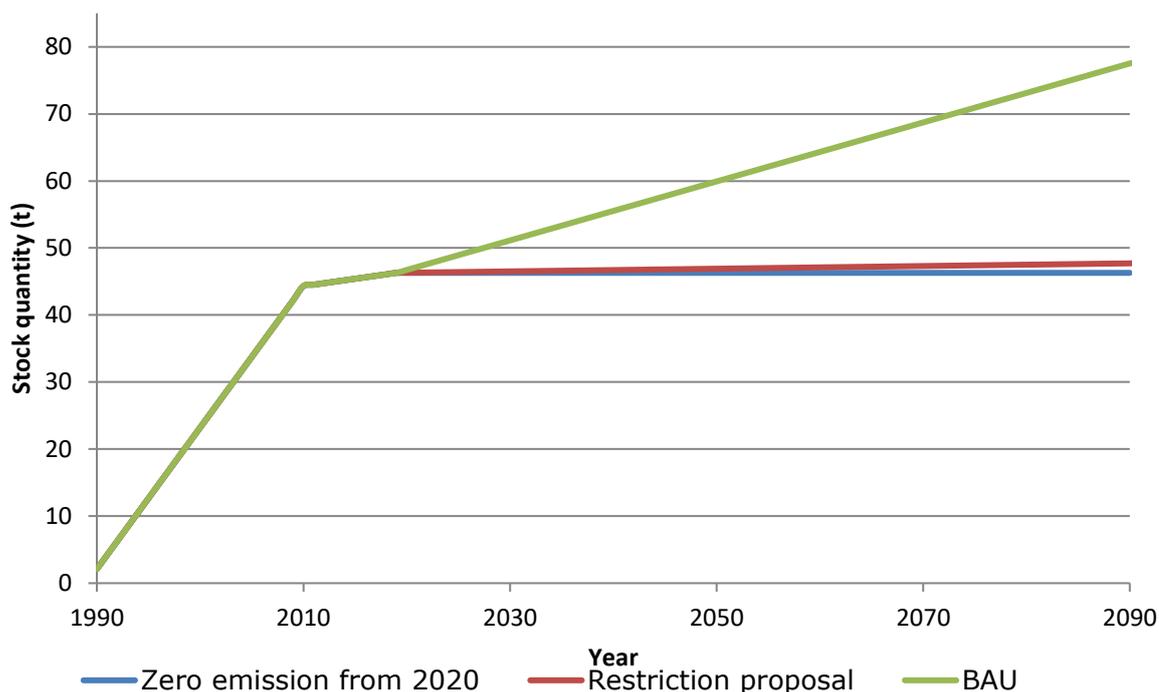
the environmental stock is taken as equalling the annual emissions (and the same for emissions reductions) the same does not apply to extremely persistent substances such as PFHxS.

In the case of emissions of PFHxS provided in Figure 7: Environmental stock profile under the Baseline (BAU) and Restriction scenarios (half life 42 years), it is estimated that 2.1 tonnes of annual emissions from 1990-2010 produced a total environmental stock quantity peaking at around 37.1 tonnes in 2010 when action to restrict PFOS and the resulting changes in manufacture and use of associated PFASs (such as PFHxS) took effect. The actions under the restriction resulted in annual estimated emissions of 0.22 tonnes per annum and a new trajectory towards reduced environmental stocks of PFHxS. Stocks reduced to an estimated 33.8 tonnes at present (2019).

It is argued in this dossier that the restrictions on PFOA that apply from 2020 represent a fork in the trajectory for environmental stocks of PFHxS. The evidence presented in Annex D on the baseline BAU scenario suggests that there will be increased use of PFHxS once the PFOA restriction applies and that this will have the effect of increasing the annual emissions from 0.22 to 0.44 tpa. Whilst maintaining the downward trajectory in environmental stock instigated by action of PFOS, the rate of reduction is slowed such that, under the BAU, from an environmental stock of 33.8 tonnes at present stocks are reduced to only 32.6 tonnes by 2030 and 31.7 tonnes in 2040.

In contrast, by preventing a switch from PFOA to PFHxS and by setting thresholds to reduce the quantity of PFHxS in imported articles (and mixtures), the restriction proposal accelerates the rate of the downward trajectory. Here it is estimated that from an environmental stock of 33.8t at present stocks are reduced to 28 tonnes by 2030 and 24 tonnes in 2040.

However, the very persistent nature of PFHxS and the fact that no degradation of PFHxS has been observed under environmental conditions, imply that the predictions above probably underestimate the real situation. Because of that we have included Figure 8 that shows the baseline, a zero emission situation and the restriction proposal from 2020 in a situation with no degradation. The figure shows the change in environmental stock after 1990. Possible stock from releases prior to 1990 is not included in this figure. This stock has not been estimated and will not be affected by this restriction.



(Copy of Figure 8: Environmental stock profile under the Baseline (BAU) and Restriction scenarios (no degradation))

In the case with no degradation as shown in Figure 8, it is estimated that 2.1 tonnes of annual emissions from 1990-2010 produced a total environmental stock quantity of around 44.3 tonnes in 2010 when action to restrict PFOS and the resulting changes in manufacture and use of associated PFASs (such as PFHxS) took effect. The actions under the restriction on PFOS resulted in annual estimated emissions of 0.22 tonnes per annum and a new trajectory towards reduced growth in environmental stocks of PFHxS. The stock from emissions between 2010 and 2019 is estimated to be 46.3 tonnes at present (2019).

It is argued in this dossier that the restrictions on PFOA that apply from 2020 represent a split in the trajectory for environmental stocks of PFHxS. The evidence presented in Annex D on the baseline BAU scenario suggests that there might be increased use of PFHxS once the PFOA restriction applies and that this will have the effect of increasing the annual emissions from 0.22 to 0.44 tpa. Whilst maintaining the trajectory in environmental stock instigated by action of PFOS, the rate of emission is increased such that, under the BAU, from an environmental stock of 46.3 tonnes at present stocks are increased to 51.1 tonnes by 2030 and 55.5 tonnes by 2040.

In a situation with zero emissions from 2020 the environmental stock is expected to level out at 46.3 tonnes. By preventing a switch from PFOA to PFHxS and by setting thresholds to reduce the quantity of PFHxS in imported articles (and mixtures), the restriction proposal is expected to reduce the emissions to 0.02 tonnes per year. If the proposed restriction is implemented, the stock will only be slightly larger than in the situation with zero emissions.

In this case the stock is estimated to increase to 46.5 tonnes by 2030 and 46.7 tonnes by 2040.

E.3.4. Other impacts, practicality and monitorability

E.3.4.1 Social and wider economic impacts

The social and wider economic impacts of the restriction are considered to be negligible. This is due to the fact that there is no manufacture or use of PFHxS in the EU at present. The impacts on the presence of PFHxS as an impurity in mixtures and articles should also give rise to only negligible impacts. With respect to initial concerns with regard to fire-fighting foams, alternative methods of producing PFAS such that PFHxS impurities do not arise are already in place. Furthermore, the stakeholder consultation indicates that the market is already moving to alternative fluorine-free fire-fighting foams. With the shift towards fire-fighting foams that do not contain PFHxS only a small quantity of PFHxS remains in existing stock as an impurity (estimated in Annex A as 0.5 to 3 kg) and only a small proportion of these stocks are used or disposed of per year (estimated as 39-245g PFHxS per year in Annex A). Similarly, use of PFHxS in DWR textiles is, currently, very limited (see Annex A) and the restriction merely reinforces this.

E.3.4.2. Distributional impacts

The distributional impacts of the proposed restriction are considered to be negligible, given that no manufacture or intentional use has been identified in the EU, and the restriction does not require the destruction of existing stocks of fire-fighting foams that may contain PFHxS as an impurity. In principle the most impacted set of actors could have been manufacturers and retailers of DWL clothing and outdoor gear. As noted in Annex E.3.2.1, however, there is consumer demand for more environmental friendly products, in for example the outdoor industry, which is driving a phasing out of PFAS in general and evidence that manufacturers and retailers are trying to meet this demand with targets for PFAS free DWR. The proposed restriction on PFHxS should assist manufacturers and retailers who are pursuing such objectives by reinforcing their own requirements.

E.3.4.3. Practicality and monitorability

E.4.4.3.1. Implementability and manageability

This restriction proposal meets the requirements regarding practicality and monitorability, as its requirements are similar to those proposed for C9-C14 PFCAs. The frameworks put in place with respect to the PFCAs, PFOA and PFOS will also be relevant to implementation of this restriction.

Given that no intentional use of PFHxS or PFHxS-related substances has been identified in the EU and that alternative technologies or substances are available, the proposed transition time of 18 months should also be feasible for all actors. Indeed, as indicated in Annex G and in the restriction proposal on C9-C14 PFCAs, consultation indicates that relevant EU actors have already foreseen the need to move away from PFASs more generally, and are therefore already using fluorine free alternatives or alternative technologies.

E.4.4.3.2. Monitorability

Several analytical methods which can be used to measure PFHxS and PFASs in general in almost all environmental media are reported in the literature. Although no standardised analytical methods exist today, it is in principle possible to use the method specified within the Technical Specification (CEN/TS) for "Determination of extractable perfluorooctanesulphonate (PFOS) in coated and impregnated solid articles, liquids and fire fighting foams - Method for sampling, extraction and analysis by LCqMS or LC-tandem/MS" to determine the levels of ionic forms of PFHxS, its salts and PFHxS related substances. For volatile neutral PFHxS related chemicals, Herzke et al (2012) have reported detection of PFHxS and related compounds using a different analytical instrumentation (GC/PCI-MS) (Herzke, et al., 2012). The level of quantification in both mentioned methods is 0.06 ppb. This allows quantification of PFHxS and related compounds in levels below the proposed limit values.

Even though no standardised EU method exists, other institutes have complied standardised methods for monitoring PFHxS and related substances. The U.S. Department of Defence released guidelines for standardising the measurement of PFASs (include PFHxS) in groundwater and soil in 2017. These are not U.S. EPA guidelines; however, they have helped in the standardisation of the accurate quantification of PFAS for measuring concentrations in drinking water using U.S EPA Method 537. This method uses solid phase

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

extraction followed by liquid chromatography/tandem mass spectrometry. PFHxS has a detection level of 0.002 ppb in the reagent water (U.S EPA, 2009).

In Germany, there is a norm (DIN 38407) for analysing selected polyfluorinated compounds (which includes PFHxS) in water, sewage and sludge (Deutsches Institut für Normung e.V. (DIN), 2011). For this method, unfiltered water is spiked with mass-labelled internal standards and extracted with solid phase extraction. The samples are then analysed using liquid chromatography coupled to a mass spectrometer. This method is applicable for concentrations which are higher than 0.01 ppb in water and 0.025 ppb in treated sewage.

In order to detect PFHxS related compounds with the existing methods, suitable commercially available PFHxS internal standards (and other C6-PFAS) have to be used. This approach presupposes that the exact structure and CAS number of the precursor are known. A number of precursors and related substances to PFHxS have a CAS number and will be possible to monitor using these methods (see also Appendix 1 that lists identified PFHxS-related substances). The monitorability of precursors and related substances of PFHxS where the exact structure is unknown will be more challenging than for other perfluorinated compounds like for instance PFOA. PFOA related substances without known structure can be monitored by conversion of these substances to PFOA by oxidation performed with hydroxyl radicals (Houtz and Sedlak, 2012). Oxidation of PFHxS related substances will result in a mixture of PFHxS, other PFASs, PFHxA and other PFCAs. Performing a direct calculation of concentrations of PFHxS-related compounds may therefore be complicated.

As identified by the proposed restriction for C9-C14 PFCAs, a monitoring strategy is also required to monitor the implementation and success of the restriction. It is proposed here that this be developed to be consistent with and complementary to the strategy put forward for the PFCAs, for cost-effectiveness reasons. This includes the strategy finally agreed with respect to time trend monitoring and monitoring of emissions suited to very persistent substances, for example with respect to emissions from waste water treatment facilities. This should be aimed at assessing the extent to which there are continuing emissions from articles in use within the EU. In this case, there may also be a need for additional monitoring of emissions at facilities where there has been use in the past, including airports and fire-fighting training facilities.

As proposed for PFCAs, time trend monitoring should include sampling from the environment, from animals and from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring. However, it should be recognised that it may take a very long time period in order to detect downward trends in concentrations, due to the persistence of PFHxS and related substances and the potential for on-going releases from environmental sinks such as sediment and soil.

E.3.4.4 Enforceability

For other restrictions, ECHA has estimated that the administrative costs to member states of complying with and enforcing a restriction are approximately €55 600 per annum. This figure appears low for a case where there is a need for random sampling and testing of a range of imported articles over a year. Thus, this number should be considered more as an indicative cost to authorities.

As the costs of enforcing this restriction may be able to be shared with the costs of enforcing other restrictions on perfluorinated substances (PFOA and PFCAs), however, it is likely that the costs could be lower rather than higher.

Enforcement activities involving inspections and testing can be arranged so as to target the occurrence of PFOS, PFOA, C9-C14 PFCA and PFHxS and related substances in articles at the same time, with this improving the cost effectiveness of such activities (as for any environmental monitoring). Thus, the enforcement costs specific to PFHxS should be moderate in magnitude.

As noted above, there are no standard analytical methods to measure the content of PFHxS and PFHxS-related substances in articles and mixtures available at this present time although there are methods currently in development for PFOA and related substances. Also in the United States, method development research is ongoing for standard analytical methods for testing PFASs in water and solids (U.S. EPA, 2018). Analytical methods exist that can be used to measure PFHxS and PFHxS-related substances which could be used for standardisation. These are further discussed in Annex E.3.4.3. The method developed by Herzke et al is applicable to measure PFHxS and related substances in textiles (Herzke, et al., 2012). Determination of PFHxS and related substances in textiles is quantified by $\mu\text{g}/\text{m}^2$, and the level of quantification for analysis in textiles is reported to be $0.015 \mu\text{g}/\text{m}^2$ which allows quantification of levels below the proposed restriction.

The establishment of an EU standard method could make the implementation of these routine tests easier, however, this could be costly and time consuming. As methods exist in the literature for measuring PFHxS and there is ongoing work on standard methods for PFASs (including PFOS), this is not expected to be an issue for the enforcement of the restriction.

E.4. Proportionality (comparison of options)

PFHxS and its salts are substances of very high concern owing to their PBT/vPvB properties. The SVHC report concludes that:

- PFHxS accumulates in humans
- PFHxS is present in human blood of the general population
- Time trend studies indicate that the human bioaccumulation potential of PFHxS may even be larger than that of PFOS.
- The human elimination half-life for PFHxS is > 7 years which is the longest of all perfluoroalkyl and polyfluoroalkyl substances (PFAS) for which data are available. It is also comparable to the longest human elimination half-lives recorded for known PBT/vPvB- and POP-substances such as some PCBs.
- There is evidence that PFHxS preferentially bioaccumulates in air-breathing mammals, including endangered species and humans
- PFHxS accumulates in the air-breathing food chains at least as much as PFOS and more than the long-chained PFCAs which have already been identified as vB on the Candidate List.
- Elevated levels of PFHxS have been measured in both humans (up to 1790 µg/L in blood serum) and wildlife (>500 µg/kg in polar bear liver) showing that exposure to PFHxS has the potential to result in high levels in biota.

Due to the extreme persistency of the substances, every emission contributes to the environmental stock of the substances. REACH promotes the reduction of impacts of such substances by requiring the minimisation of emissions and environmental and relevant human exposure (Annex I para 6.5 of REACH).

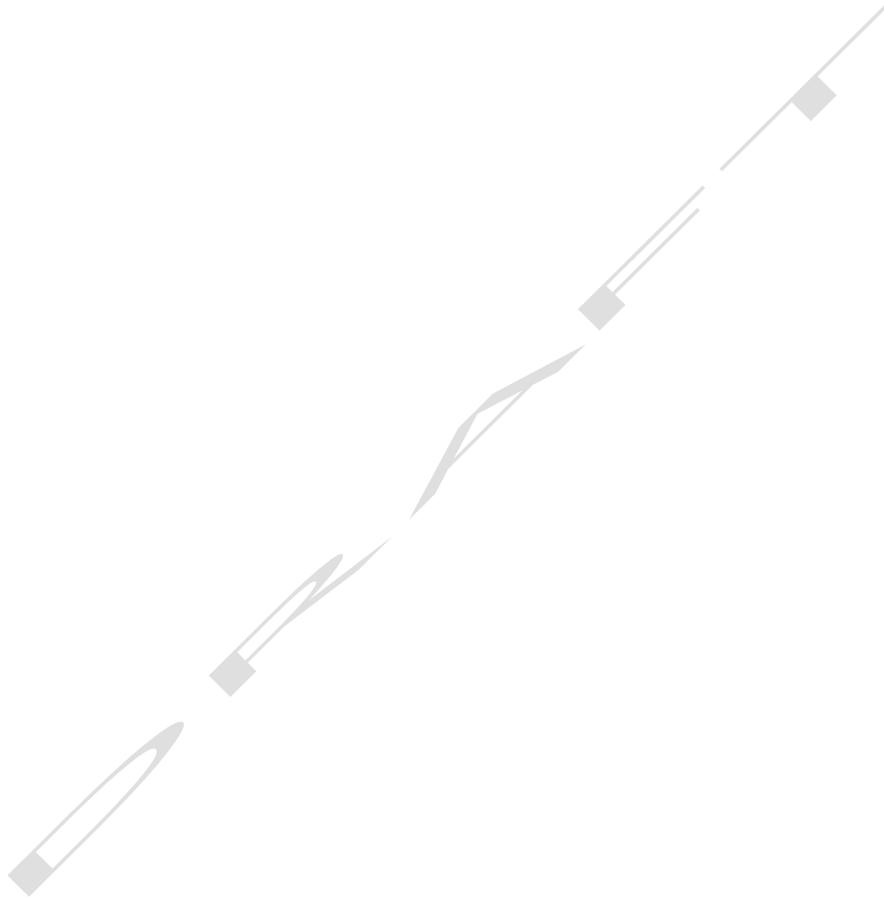
SEAC's guide *Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC* discusses use of cost-effectiveness analysis approach based on compliance cost per unit (e.g. kg) reduction.

Annex E.4.1.2 estimated annual average equivalent stock 'emissions' reductions of 2.5 tonnes per annum and 4.2 tonnes per annum respectively for the 2021-2030 and 2021-2040 periods. However, as no significant costs are anticipated for this there is no sensible dividend available to calculate cost effectiveness in €/kg.

In terms of proportionality, the SEAC guidance (ECHA, 2014b) describes efforts to define benchmarks for the proportionality/disproportionality of actions to reduce uses/emissions of PBTs/vPvBs. After the VU (Vrije Universiteit Amsterdam) project for the development of a benchmark for regulatory decision making under REACH for PBTs/vPvBs reported a very wide 'grey zone' (with margins in the order of magnitude somewhere between €1000 and €50,000 per kg PBT substituted, remediated or reduced emission) within which measures may be either proportionate or disproportionate, SEAC concluded that it was not (yet) able to set (what would be a formal) benchmark. However, based on the evidence collected so far on the costs of the proposed restriction, see chapter 2.4.1 Economic impacts, the costs are expected to be well below the €1000 per kg lower margin of the identified 'grey zone'. This is an indication that the restriction proposal is proportionate.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Given the lack of identified intentional uses of PFHxS, its salts and PFHxS-related substances within the EU, the costs are expected to be minimal to EU actors. Authorities will incur costs from undertaking monitoring and enforcement activities, but there should be the potential for these to be organised in a cost-effective manner by undertaking activities in a joint manner across PFOA, C9-C14 PFCA and PFHxS substances. This restriction proposal is therefore considered to be proportionate.



Annex F: Assumptions, uncertainties and sensitivities

There are uncertainties and assumptions which could affect the results of this SEA. However, these are not anticipated to be sufficient to alter the direction of the conclusions and, where this potential existed in principle, this has been mitigated in the analysis by a conservative treatment of data and emissions.

F.1. Data collection and uses

The data collection exercises have identified no current manufacture or uses of PFHxS, its salts or related substances in the EU. It is, however, possible that other users exist but that this has been missed in the data collection process. The potential for this has been mitigated by repeated attempts to engage potential users and user groups as well as reviews of the international literature and data (including on PFOS) to identify potential uses. There have been several other studies undertaken to identify and consult with potential users (including the BiPRO, 2018 study) before the extensive consultation and ECHA call for evidence (see Annex G) was launched specifically for evidence presented in this (current) dossier. Through these efforts every possible opportunity to provide a response has been provided to potential users but all of these have either identified no use or no interest (also implying no use).

F.2. Imports of PFOS

As reported in Annex A, PFHxS may be present as an impurity in PFOS used in applications exempted under Regulation (EU) 2019/1021. Reports submitted by parties pursuant to Article 15 of the Stockholm Convention indicates that 50 kg of PFOS use was imported for use in the EU in 2014¹⁸ (UNEP, 2015).

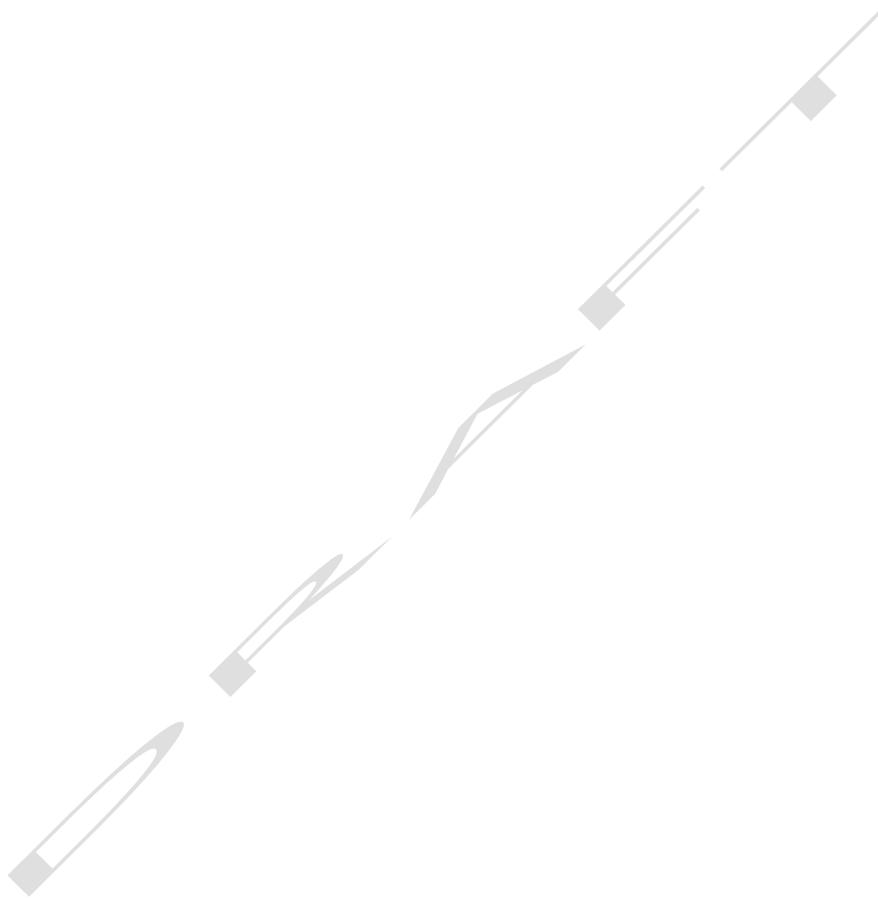
F.3. Substitution after the C8-PFOA restriction applies

The restriction on PFOA, PFOA-related substances and its salts applies from 4 July 2020 with certain derogations. The case for the restriction rests partially on the likelihood that the restrictions on PFOA will trigger substitution with PFHxS for some uses (particularly in textiles). Annex D provides the evidence for this which, we argue, is good evidence. The case for the restriction presented in this SEA, however, does not depend entirely on this potential increase in use because the thresholds to be implemented on articles (and mixtures) would still provide a reduction in imports of PFHxS, its salts and PFHxS-related substances in imported articles.

¹⁸ Note that not all parties provide quantitative data and instead report 'minimal' or similar wording.

F.4.Environmental and health effects

There are some uncertainties with regard to the effects on the environment and human health. One such uncertainty is the cause and effect relationship between PFHxS and different health impacts and outcomes. But as described in Annex E.3.3 these uncertainties together with the very persistent nature of PFHxS also provide a strong motivation for a restriction on PFHxS, its salts and PFHxS-related substances.



Annex G: Stakeholder consultation

G.1. Launch

The stakeholder consultation was launched on 3 July 2018. Emails were sent out to the identified stakeholders providing information about the survey and practical information on how to respond. The email included a link to a dedicated webpage¹⁹ containing a description of the survey, the set of questionnaires, the letter of confirmation from the Norwegian Environment Agency and a note describing the handling of confidential data.

A simplified email and questionnaire were sent out to companies in Russia (with the introductory email in Russian) and in China, along with the link to the full survey.

In total, around 250 different stakeholders were contacted.

G.2. Reminders and extensions

The initial deadline for responding to the survey was 29 July 2018, but there was a first extension until 5 August 2018. A reminder and information on the extension of the deadline was sent out on 25 July to the stakeholders that had not yet responded.

A few requests for an additional extension of the deadline were received and a further extension to 10 August 2018 was granted.

Available information has indicated that the Italian company Miteni was a likely manufacturer/supplier of PFHxS and/or related substances. As part of the desk-based research, it was also found that PHxSF is listed as part of WeylChem Group's product portfolio, of which Miteni is part (WeylChem Group, 2018). Additional efforts were therefore put into contacting Miteni. Contact was made both in English and in Italian, by email and by phone.

G.3. Call for Evidence

The Call for Evidence was launched by ECHA on 11 July 2018 with the deadline for responding set as 22 August 2018.

G.4. Responses

G.4.1. Stakeholder consultation

Twenty-two responses were received as part of the stakeholder consultation: six from authorities, seven from industry associations, six from companies and three from NGOs and others.

¹⁹ <http://rpaltd.co.uk/pfhxs-consultation>

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

None of the governmental bodies that responded had any data on use of PFHxS or related substances and, of the three NGOs that responded, only ChemTrust provided some information. ChemTrust forwarded their response to the stakeholder consultation for C4-C7 PFAS, which did not include specific information on PFHxS or the PFHxS-related substances.

All of the industry associations stated that, to their knowledge, these substances are not used amongst their members or even within the sector. Out of the six companies that responded, two reported that they do not use the substances and one stated that they were prioritising the provision of information to other restriction proposals. The responses are described below.

Miteni, which only provided some information by phone, claimed that they do not manufacture these substances, and have not done so for more than 15 years. They still had a small amount of PFHxS in stock which they provided to a testing and monitoring company. No written response has been provided by Miteni and further attempts to contact Miteni's representatives, by both email and phone, did not succeed. Miteni filed for bankruptcy on 9 November 2018.

Equinor, the largest offshore operator in Norway, explained that they have been phasing out the use of these substances over the last five years, and that this process is almost completed. They also say that there are fluoro-free alternatives available on the market today and that substitution should be easy for most installations.

The Outdoor Industry Association responded that this chemistry and its alternatives are used in the outdoor industry although no more specific information was provided. However, this response supports concern that these substances may be used as waterproofing agents on textiles and other outdoor gear and hence be imported into the EU on such articles.

Fedustria (textiles) stated that their members do not use PFHxS and PFHxS-related substances. AFIRM also stated that their members do not use these substances.

Dainippon Ink and Chemicals Inc. (Japan), was the only company that filled in the complete questionnaire. This company claimed that they did not directly use any of the target substances, but PFHxS may be present as an unintentional impurity in some of their final products. The company also manufactures less than 7 tonnes of flame retardants for polycarbonate every year, with an average content of PFHxS of 0.1% or less. They have no emissions to water or air, and the solid waste that leaves the plant is subsequently incinerated. They claim that there are no alternatives, and their response to a restriction under the Stockholm Convention would be to cease production of the materials as there are no technically feasible alternatives that would not also have PFHxS present as an impurity.

G.4.2. Follow-up consultation with selected stakeholders

G.4.2.1 Call for Evidence

BAuA and UBA provided monitoring data and reference to a few studies underpinning the "significant threshold" to ground water and the acceptable lifetime drinking water guideline values in Germany.

Norsk Olje & Gass's (The Norwegian Oil and Gas Association) and its members (operators) have substituted PFAS and most are now using fluoro-free AFFFs; the substitution process

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

took around 5-7 years. Their only concern with a restriction was the technical or economic difficulties that may arise if the concentration limit is set too low. Norwegian operators have identified fluorine-free alternatives that are feasible from a technical and safety point of view. These products have a higher cost, but this has been accepted. Operators have participated in the development of these product to make them suitable for their operations. Most operators have substituted their old fire-fighting foams, some fields still use fluorinated foams. Among these are older fields soon to be decommissioned. For new installations fluorine-free fire-fighting foams are implemented in the design phase.

The German Mineraloelwirtschaftsverband states that when fuels contain biofuel, all refineries and fuel depots must use fire-fighting foams containing PFAS, since other types of foam are destroyed by the biofuels. They claim that all substitution tests have failed, and provided results from their testing of different AFFFs. In relation to PFHxS, some PFHxS have been measured in foams tested by the German Mineraloelwirtschaftsverband. A summary of these is provided in Table 34.

Table 34: Data from Mineraloelwirtschaftsverband on PFHxS content of fire-fighting foams

Manufacturer	Foam	Type	Date of analysis	Lab A µg/kg	Lab B µg/kg	Lab C µg/kg
Company A	Foam A1	AFFF alcohol resistant, frost resistant	Lab A, B: September 2010; Lab C: 2008	36	< 10	89
Company B	Foam B1	AFFF alcohol resistant, frost resistant	Sep-10	31	< 10	
Company B	Foam B2	AFFF alcohol resistant, frost resistant	Sep-11	< 30	0	
Company B	Foam B3	AFFF alcohol resistant, frost resistant	Lab A: May 2010; Lab B: August 2010	< 10	< 100	
Company B	Foam B4	AFFF alcohol resistant, frost resistant	May-11	< 30	0	
Company B	Foam B6	AFFF alcohol resistant, frost resistant	Aug-13	< 50	98	67
Company C	Foam C1	AFFF alcohol resistant, frost resistant	Sep-10	34	< 10	0
Company C	Foam C2	AFFF	Oct-09	0	< 100	0

Source: Mineraloelwirtschaftsverband response to ECHA call for evidence

G.4.2.2 Interviews

Follow up interviews were conducted with seven selected stakeholders.

AFIRM, a textile association confirmed that PFHxS and PFHxS-related substances are not viewed as a significant issue for leading brands in the western apparel and footwear industry and members of AFIRM are generally not concerned with this restriction. There is also a move in the sector towards fluorine free alternatives from short chain PFAS substances.

A manufacturer of fluorotelomer products confirmed that they have never manufactured or used PFHxS-related substances and they do not use electrochemical fluorination for synthesis.

Equinor confirmed the use of fluorine free foams on offshore facilities and that the whole substitution process took 5 - 7 years. Concern was raised that if a very low limit was imposed then draining of tanks containing fluorine free foams may be needed to remove all traces of previously used foams.

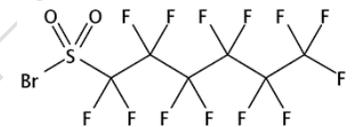
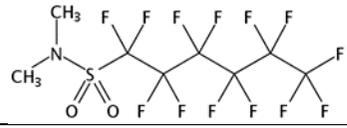
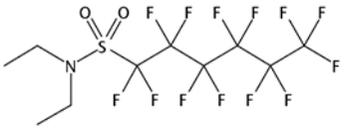
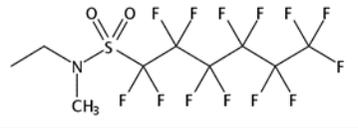
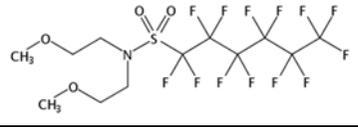
The German Mineraloelwirtschaftsverband stated that there have been issues with fluorine free foams with larger fires. The banning of impurities would have a detrimental effect as described under "transition" and a derogation as for PFOA would be a satisfactory approach to addressing any potential issues.

A manufacturer of fluorine free foams stated that fluorine free foams are a technically feasible alternative and that Scandinavian countries have experienced a fairly quick transition from AFFFs.

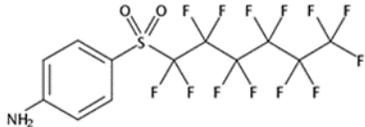
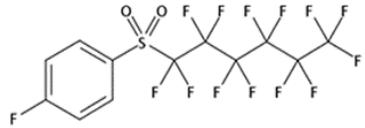
Lastfire were also interviewed about fluorine free foams and it was stated that the majority of these companies are trying to move away from these substances and find alternatives. Companies are using higher purity C6 foams and also fluorine free foams. These fluorine free foams are viewed as the most attractive and reasonable alternative, although it is difficult to test these foams on a large scale. There would be impacts of a restriction, however, if it impacted on existing stockpiles of foams. In this respect, it is likely to take a further 3 to 5 years for the transition to higher purity or fluorine free foams to take place.

Appendix 1 List of identified CAS numbers that fall within the scope of the proposal

Table 35 PFHxS, salts and related substances (per 2018-08-24)

CAS	Name	Structure
111393-39-6	1-Hexanesulfonyl bromide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
1270179-82-2	1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N,N-dimethyl-	
1270179-93-5	1-Hexanesulfonamide, N,N-diethyl-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
127133-66-8	2-Propenoic acid, 2-methyl-, polymers with Bu methacrylate, lauryl methacrylate and 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl methacrylate	
129813-71-4	Sulfonamides, C4-8-alkane, perfluoro, N-methyl-N-(2-oxiranylmethyl)	
141607-32-1	β -Alanine, N-[3-(dimethylamino)propyl]-N-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-	
1427176-17-7	1-Hexanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-methyl-	
1427176-20-2	1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N,N-bis(2-methoxyethyl)-	

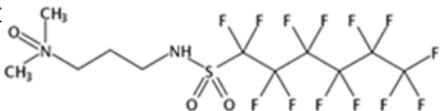
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
147029-28-5	Benzenamine, 4-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-	
148240-80-6	Fatty acids, C18-unsatd., trimers, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl esters	
148684-79-1	Sulfonamides, C4-8-alkane, perfluoro, N-(hydroxyethyl)-N-methyl, reaction products with 1,6-diisocyanatohexane homopolymer and ethylene glycol	
149652-30-2	Benzene, 1-fluoro-4-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-	
160305-97-5	Benzoic acid, 2,3,4,5-tetrachloro-6-[[3-(hydroxyphenyl)amino]carbonyl]-, perfluoro-C6-8-alkanesulfonates (esters), monopotassium salts	
160336-17-4	2-Propenoic acid, butyl ester, polymers with 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl acrylate	
160901-25-7	Sulfonamides, C4-8-alkane, perfluoro, N-ethyl-N-(hydroxyethyl), reaction products with 2-ethyl-1-hexanol and polymethylenepolyphenylene isocyanate	
160901-26-8	Sulfonamides, C4-8-alkane, perfluoro, N-ethyl-N-(hydroxyethyl), reaction products with 2-ethyl-1-hexanol, Me Et ketone oxime and polymethylenepolyphenylene isocyanate	
161074-58-4	Fatty acids, C18-unsatd., trimers, 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl esters	
1645842-67-6	Sulfonamides, C4-8-alkane, perfluoro, N-(3-chloro-2-hydroxypropyl)-N-methyl	
1645852-10-3	Siloxanes and Silicones, di-Me, Bu group- and 3-[(2-methyl-1-oxo-2-propen-1-yl)oxy]propyl group-terminated, telomers with acrylic acid, di-Me, Me 3-mercaptopropyl siloxanes, Me acrylate, Me methacrylate and 2-[methyl[(perfluoro-c4-8-alkyl)sulfonyl]amino]ethyl acrylate, 2,2'-(1,2-diazenediyl)bis[2-methylpropanenitrile]-initiated	
1648534-82-0	2-Propenoic acid, polymers with lauryl acrylate and 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl acrylate	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
1648539-69-8	Poly(oxy-1,2-ethanediyl), α -[2-(methylamino)ethyl]- ω -hydroxy-, N-[(perfluoro-C4-8-alkyl)sulfonyl] derivs., C12-16-alkyl ethers	
1648540-20-8	2-Propenoic acid, 2-(methylamino)ethyl ester, N-[(perfluoro-C4-8-alkyl)sulfonyl] derivs., polymers with propene	
171561-95-8	Benzene, 1-nitro-4-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-	
178094-71-8	1-Hexanesulfonamide, N-[3-(dimethyloxidoamino)propyl]-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, potassium salt (1:1)	
178535-22-3	Sulfonamides, C4-8-alkane, perfluoro, N-ethyl-N-(hydroxyethyl), polymers with 1,1'-methylenebis[4-isocyanatobenzene] and polymethylenepolyphenylene isocyanate, 2-ethylhexyl esters, Me Et ketone oxime-blocked	
179005-06-2	Sulfonamides, C4-8-alkane, perfluoro, N-[3-(dimethyloxidoamino)propyl], potassium salts	
179005-07-3	Sulfonamides, C4-8-alkane, perfluoro, N-[3-(dimethyloxidoamino)propyl]	
1893-52-3	2-Propenoic acid, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl ester	
192662-29-6	Sulfonamides, C4-8-alkane, perfluoro, N-[3-(dimethylamino)propyl], reaction products with acrylic acid	
222716-67-8	Sulfonamides, C4-8-alkane, perfluoro, N-ethyl-N-(hydroxyethyl), reaction products with poly(Bu acrylate) and polyethylene-polypropylene glycol mono-Bu ether	
254889-10-6	Pyridinium, 1-[[1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]-, inner salt	

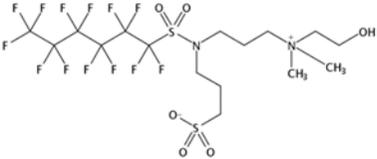
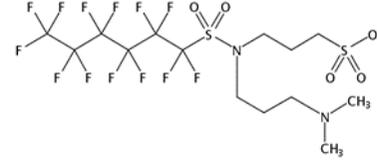
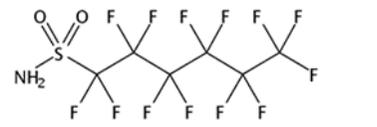
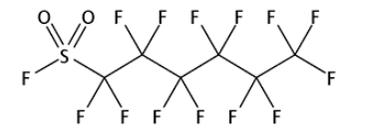
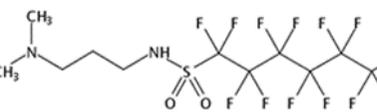
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
30295-56-8	1-Hexanesulfonamide, N-[3-(dimethyl- 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
306973-47-7	Sulfonamides, C4-8-alkane, perfluoro, N-(hydroxyethyl)-N-methyl, reaction products with 12-hydroxyoctadecanoic acid and 2,4-TDI, ammonium salts	
306974-19-6	Sulfonamides, C4-8-alkane, perfluoro, N-methyl-N-[(3-octadecyl-2-oxo-5-oxazolidinyl)methyl]	
306974-28-7	Siloxanes and Silicones, di-Me, mono[3-[(2-methyl-1-oxo-2-propen-1-yl)oxy]propyl group]-terminated, polymers with 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl acrylate and stearyl methacrylate	
306974-45-8	Sulfonic acids, C6-8-alkane, perfluoro, compds. with polyethylene-polypropylene glycol bis(2-aminopropyl) ether	
306974-63-0	Fatty acids, C18-unsatd., dimers, 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl esters	
306975-62-2	2-Propenoic acid, 2-methyl-, dodecyl ester, polymers with 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl acrylate and vinylidene chloride	
306975-84-8	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, polymer with 1,6-diisocyanatohexane, N-(hydroxyethyl)-N-methylperfluoro-C4-8-alkanesulfonamides-blocked	
306975-85-9	2-Propenoic acid, 2-methyl-, dodecyl ester, polymers with N-(hydroxymethyl)-2-propenamides, 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl methacrylate, stearyl methacrylate and vinylidene chloride	
306976-25-0	1-Hexadecanaminium, N,N-dimethyl-N-[2-[(2-methyl-1-oxo-propen-1-yl)oxy]ethyl]-, bromide (1:1), polymers with Bu acrylate, Bu methacrylate and 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl acrylate	
306976-55-6	2-Propenoic acid, 2-methyl-, 2-methylpropyl ester, polymer with 2,4-diisocyanato-1-methylbenzene, 2-ethyl-2-(hydroxymethyl)-1,3-propanediol and 2-propenoic acid, N-ethyl-N-(hydroxyethyl)perfluoro-C4-8-alkanesulfonamides-blocked	

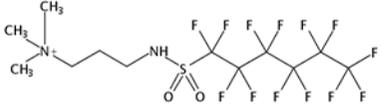
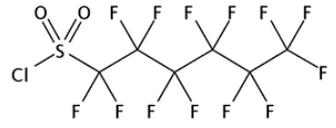
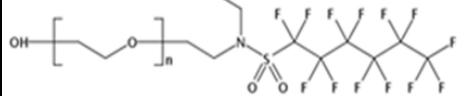
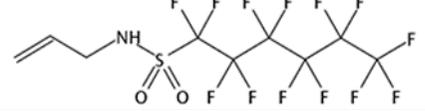
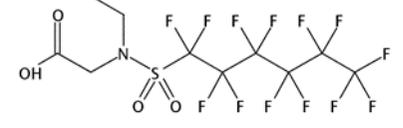
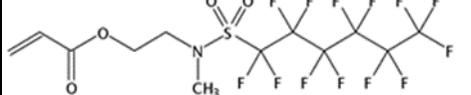
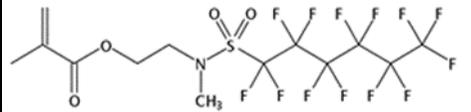
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
306977-10-6	2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, telomer with 2-[ethyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl methacrylate and 1-octanethiol, N-oxides	
306977-58-2	2-Propenoic acid, 2-methyl-, 3-(trimethoxysilyl)propyl ester, polymers with acrylic acid, 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl acrylate and propylene glycol monoacrylate, hydrolyzed, compds. with 2,2'-(methylimino)bis[ethanol]	
306978-04-1	2-Propenoic acid, butyl ester, polymers with acrylamide, 2-[methyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl acrylate and vinylidene chloride	
306978-65-4	Hexane, 1,6-diisocyanato-, homopolymer, N-(hydroxyethyl)-N-methylperfluoro-C4-8-alkanesulfonamides- and stearyl alc.-blocked	
306979-40-8	Poly(oxy-1,2-ethanediyl), α -[2-(methylamino)ethyl]- ω -[(1,1,3,3-tetramethylbutyl)phenoxy]-, N-[(perfluoro-C4-8-alkyl)sulfonyl] derivs.	
306980-27-8	Sulfonamides, C4-8-alkane, perfluoro, N,N'-[1,6-hexanediy]bis[(2-oxo-3,5-oxazolidinediy)methylene]]bis[N-methyl-	
34455-03-3	1-Hexanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-(2-hydroxyethyl)-	
355-46-4	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
3871-99-6	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, potassium salt (1:1)	PFHxS K-salt
38850-52-1	1-Propanaminium, 3-[(carboxymethyl)[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]-N,N,N-trimethyl-, inner salt	

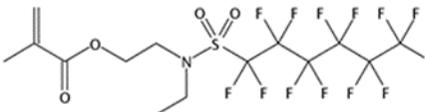
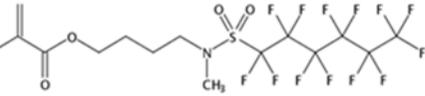
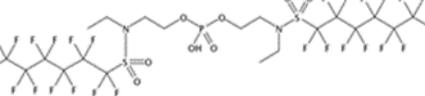
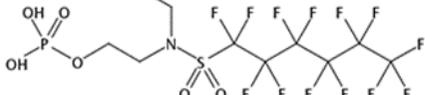
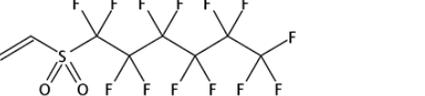
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
38850-58-7	1-Propanaminium, N-(2-hydroxyethyl)-N,N-dimethyl-3-[[3-sulfopropyl][(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]-, inner salt	
38850-60-1	1-Propanesulfonic acid, 3-[[3-(dimethylamino)propyl][(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]-	
41997-13-1	1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
423-50-7	1-Hexanesulfonyl fluoride, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
504396-13-8	2-Propenoic acid, 2-methyl-, 2-[ethyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl ester, polymers with polyethylene glycol acrylate Me ether	
50598-28-2	1-Hexanesulfonamide, N-[3-(dimethylamino)propyl]-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
507225-08-3	Siloxanes and Silicones, di-Me, 3-hydroxypropyl group-terminated, reaction products with Me Et ketone oxime, 2-mercaptoethanol, 2-[methyl[(perfluoro-C3-8-alkyl)sulfonyl]amino]ethyl acrylate, polymethylenepolyphenylene isocyanate and polypropylene glycol	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
52166-82-2	1-Propanaminium, N,N,N-trimethyl-3-[[1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]-, chloride (1:1)	 <p>• Cl⁻</p>
55120-77-9	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, lithium salt (1:1)	PFHxS Li-salt
55591-23-6	1-Hexanesulfonyl chloride, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
56372-23-7	Poly(oxy-1,2-ethanediyl), α-[2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl]-ω-hydroxy-	
67584-48-9	1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-2-propen-1-yl-	
67584-53-6	Glycine, N-ethyl-N-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-, potassium salt (1:1)	 <p>• K</p>
67584-57-0	2-Propenoic acid, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl ester	
67584-61-6	2-Propenoic acid, 2-methyl-, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl ester	

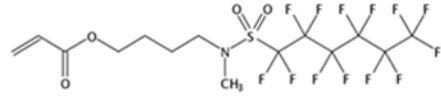
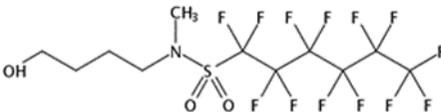
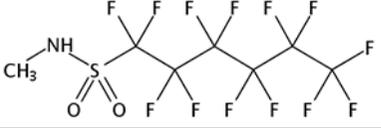
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
67906-70-1	2-Propenoic acid, 2-methyl-, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl ester	
67906-71-2	2-Propenoic acid, 2-methyl-, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl ester, polymer with octadecyl 2-propenoate and 2-propenoic acid	
67939-61-1	2-Propenoic acid, 2-methyl-, 4-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]butyl ester	
67939-92-8	1-Hexanesulfonamide, N,N'-[phosphinicobis(oxy-2,1-ethanediyl)]bis[N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
67969-65-7	1-Hexanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-[2-(phosphonoxy)ethyl]-	
680187-85-3	Hexane, 1-(ethenylsulfinyl)-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
680187-86-4	Hexane, 1-(ethenylsulfonyl)-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-	
68081-83-4	Carbamic acid, N,N'-(4-methyl-1,3-phenylene)bis-, bis[2-[ethyl[(perfluoro-C4-8-alkyl)sulfonyl]amino]ethyl] ester	
68227-87-2	2-Propenoic acid, 2-methyl-, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]amino]ethyl ester, telomer with 2-[ethyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-	

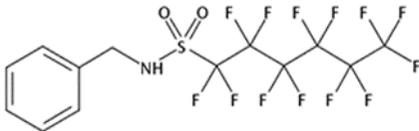
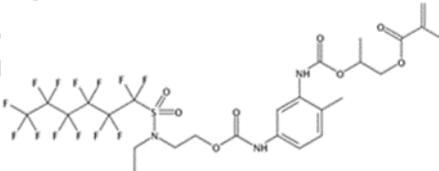
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
	methyloxirane polymer with oxirane di-2-propenoate, 2-methyloxirane polymer with oxirane mono-2-propenoate and 1-octanethiol	
68227-94-1	2-Propenoic acid, 2-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl ester, polymer with 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, α-(2-methyl-1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), α-(2-methyl-1-oxo-2-propen-1-yl)-ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]poly(oxy-1,2-ethanediyl), 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and α-(1-oxo-2-propen-1-yl)-ω-methoxypoly(oxy-1,2-ethanediyl)	
68227-96-3	2-Propenoic acid, butyl ester, telomer with 2-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, α-(2-methyl-1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,4-butanediyl), α-(2-methyl-1-oxo-2-propen-1-yl)-ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]poly(oxy-1,4-butanediyl), 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and 1-octanethiol	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
68227-98-5	2-Propenoic acid, 4-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]butyl ester	
68228-00-2	2-Propenoic acid, ethyl ester, polymer with 4-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]butyl 2-propenoate, 4-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]butyl 2-propenoate, α-(2-methyl-1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,4-butanediyl), α-(2-methyl-1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), α-(2-methyl-1-oxo-2-propen-1-yl)-ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]poly(oxy-1,4-butanediyl), α-(2-methyl-1-oxo-2-propen-1-yl)-ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]poly(oxy-1,2-ethanediyl), 4-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]butyl 2-propenoate, 4-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]butyl 2-propenoate and 4-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]butyl 2-propenoate	
68239-74-7	1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-(4-hydroxybutyl)-N-methyl-	
68259-08-5	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, ammonium salt (1:1)	PFHxS NH4-salt
68259-15-4	1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-methyl-	
68259-38-1	Poly[oxy(methyl-1,2-ethanediyl)], α-[2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl]-ω-hydroxy-	

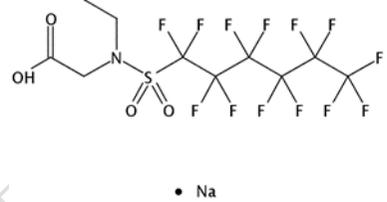
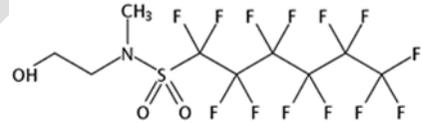
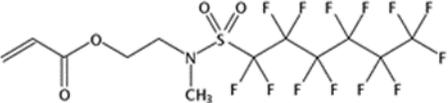
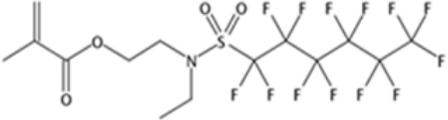
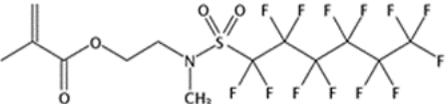
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
68298-09-9	1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-(phenylmethyl)-	
68298-74-8	2-Propenoic acid, 2-methyl-, 2-[[[[5-[[[2-[ethyl[(tridecafluorohexyl)sulfonyl]amino]ethoxy]carbonyl]amino]-2-methylphenyl]amino]carbonyl]oxy]propyl ester (9CI)	
68298-78-2	2-Propenoic acid, 2-methyl-, 2-[[[[5-[[[2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]amino]ethoxy]carbonyl]amino]-2-methylphenyl]amino]carbonyl]oxy]propyl ester, telomer with butyl 2-propenoate, 2-[[[[5-[[[2-[ethyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethoxy]carbonyl]amino]-2-methylphenyl]amino]carbonyl]oxy]propyl 2-methyl-2-propenoate, 2-[[[[5-[[[2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethoxy]carbonyl]amino]-2-methylphenyl]amino]carbonyl]oxy]propyl 2-methyl-2-propenoate, 2-[[[[5-[[[2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethoxy]carbonyl]amino]-2-methylphenyl]amino]carbonyl]oxy]propyl 2-methyl-2-propenoate, 2-[[[[5-[[[2-[ethyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethoxy]carbonyl]amino]-2-methylphenyl]amino]carbonyl]oxy]propyl 2-methyl-2-propenoate, 2-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and 1-octanethiol	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
68299-21-8	Benzenesulfonic acid, [[[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]methyl]-, sodium salt (1:1)	
68299-39-8	2-Propenoic acid, 2-methyl-, 4-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]butyl 2-propenoate, 2-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl 2-propenoate, 4-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]butyl 2-methyl-2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, α-(2-methyl-1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,4-butanediyl), α-(2-methyl-1-oxo-2-propen-1-yl)-ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]poly(oxy-1,4-butanediyl), 4-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]butyl 2-methyl-2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 4-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]butyl 2-methyl-2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 4-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]butyl 2-methyl-2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and 1-octanethiol	
68329-56-6	2-Propenoic acid, eicosyl ester, polymer with 2-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl 2-propenoate, hexadecyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and octadecyl 2-propenoate	
68391-09-3	Sulfonic acids, C6-12-alkane, perfluoro, potassium salts	

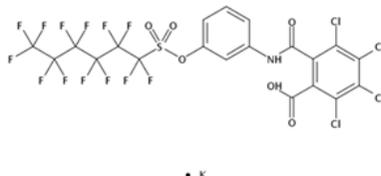
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
68555-70-4	Glycine, N-ethyl-N-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-, sodium salt (1:1)	
68555-75-9	1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-(2-hydroxyethyl)-N-methyl-	
68555-90-8	Polymer based on 67584-55-8	<p>Polymer based on:</p> 
68555-91-9	2-Propenoic acid, 2-methyl-, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptafluorooctyl)sulfonyl]amino]ethyl ester, polymer with 2-[ethyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate and octadecyl 2-methyl-2-propenoate	<p>Polymer based on:</p> 
68555-92-0	2-Propenoic acid, 2-methyl-, 2-[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptafluorooctyl)sulfonyl]methylamino]ethyl ester, polymer with 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate and octadecyl 2-methyl-2-propenoate	<p>Polymer based on:</p> 

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
68568-77-4	2-Propenoic acid, 2-methyl-, 2-[ethyl[(1,1,2,2,3,3,4,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]amino]ethyl ester, polymer with 2-chloro-1,3-butadiene, 2-[ethyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate and 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate	
68586-13-0	2-Propenoic acid, 2-[[heptadecafluorooctyl)sulfonyl]methylamino]ethyl ester, polymer with 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, α -(2-methyl-1-oxo-2-propenyl)- ω -hydroxypoly(oxy-1,2-ethanediyl), α -(2-methyl-1-oxo-2-propenyl)- ω -[(2-methyl-1-oxo-2-propenyl)oxy]poly(oxy-1,2-ethanediyl), 2-[methyl[(pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate and 2-[methyl[(undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate (9CI)	
68586-14-1	2-Propenoic acid, 2-[[[(1,1,2,2,3,3,4,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl ester, telomer with 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, α -(2-methyl-1-oxo-2-propen-1-yl)- ω -hydroxypoly(oxy-1,2-ethanediyl), α -(2-methyl-1-oxo-2-propen-1-yl)- ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]poly(oxy-1,2-ethanediyl), 2-[methyl[(1,1,2,2,3,3,4,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and 1-octanethiol	<p>Polymer based on:</p>
68608-13-9	Sulfonamides, C4-8-alkane, perfluoro, N-ethyl-N-(hydroxyethyl), reaction products with TDI	
68608-14-0	Sulfonamides, C4-8-alkane, perfluoro, N-ethyl-N-(hydroxyethyl), reaction products with 1,1'-methylenebis[4-isocyanatobenzene]	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
68649-26-3	1-Octanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-N-(2-hydroxyethyl)-, reaction products with N-ethyl-1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-1-butanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoro-N-(2-hydroxyethyl)-1-heptanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-(2-hydroxyethyl)-1-hexanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,5-undecafluoro-N-(2-hydroxyethyl)-1-pentanesulfonamide, polymethylenepolyphenylene isocyanate and stearyl alc.	
68797-76-2	2-Propenoic acid, 2-methyl-, 2-ethylhexyl ester, polymer with 2-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and 2-oxiranylmethyl 2-methyl-2-propenoate	
68815-72-5	Benzoic acid, 2,3,4,5-tetrachloro-6-[[[3-[[[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]oxy]phenyl]amino]carbonyl]-, potassium salt (1:1)	
68867-60-7	2-Propenoic acid, 2-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl ester, polymer with 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and α -(1-oxo-2-propen-1-yl)- ω -methoxypoly(oxy-1,2-ethanediyl)	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
68867-62-9	2-Propenoic acid, 2-methyl-, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]amino]ethyl ester, telomer with 2-[ethyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 1-octanethiol and α -(1-oxo-2-propen-1-yl)- ω -methoxypoly(oxy-1,2-ethanediyl)	
68877-32-7	2-Propenoic acid, 2-methyl-, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]amino]ethyl ester, polymer with 2-[ethyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-methyl-2-propenoate and 2-methyl-1,3-butadiene	<p>Polymer based on:</p>
68891-98-5	Chromium, diaquatetrachloro[μ -[N-ethyl-N-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]glycinato- κ O: κ O']]- μ -hydroxybis(2-propanol)di-	
68909-15-9	2-Propenoic acid, eicosyl ester, polymers with branched octyl acrylate, 2-[[heptadecafluorooctyl)sulfonyl]methylamino]ethyl acrylate, 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethyl acrylate, 2-[methyl[(pentadecafluoroheptyl)sulfonyl]amino]ethyl acrylate, 2-[methyl[(tridecafluorohexyl)sulfonyl]amino]ethyl acrylate, 2-[methyl[(undecafluoropentyl)sulfonyl]amino]ethyl acrylate, polyethylene glycol acrylate Me ether and stearyl acrylate	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
68957-32-4	Glycine, N-ethyl-N-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-	
68957-53-9	Glycine, N-ethyl-N-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-, ethyl ester	
68957-58-4	1-Propanaminium, N,N,N-trimethyl-3-[[1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]-, iodide (1:1)	
68957-61-9	1-Hexanesulfonamide, N-[3-(dimethylamino)propyl]-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, hydrochloride (1:1)	
70225-16-0	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, compd. with 2,2'-iminobis[ethanol] (1:1)	PFHxS, 2,2'-iminodiethanol salt (1:1)
70248-52-1	1-Propanaminium, N,N,N-trimethyl-3-[[1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]-, sulfate (2:1)	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
70776-36-2	2-Propenoic acid, 2-methyl-, octadecyl ester, polymer with 1,1-dichloroethene, 2-[[[(1,1,2,2,3,3,4,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl 2-propenoate, N-(hydroxymethyl)-2-propenamide, 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate and 2-[methyl[(1,1,2,2,3,3,4,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate	<p>Polymer based on:</p>
70900-36-6	2-Propenoic acid, 2-methyl-, 2-[[[[2-methyl-5-[[[4-[methyl[(tridecafluorohexyl)sulfonyl]amino]butoxy]carbonyl]amino]phenyl]amino]carbonyl]oxy]propyl ester (9CI)	
70900-40-2	2-Propenoic acid, 2-methyl-, 2-[[[[5-[[[4-[[[(1,1,2,2,3,3,4,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]butoxy]carbonyl]amino]-2-methylphenyl]amino]carbonyl]oxy]propyl ester, telomer with butyl 2-propenoate, 2-[[[(1,1,2,2,3,3,4,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl 2-propenoate, 2-[[[[2-methyl-5-[[[4-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]butoxy]carbonyl]amino]phenyl]amino]carbonyl]oxy]propyl 2-methyl-2-propenoate, 2-[[[[2-methyl-5-[[[4-[methyl[(1,1,2,2,3,3,4,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]butoxy]carbonyl]amino]phenyl]amino]carbonyl]oxy]propyl 2-methyl-2-propenoate, 2-[[[[2-methyl-5-[[[4-[methyl[(1,1,2,2,3,3,4,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]butoxy]carbonyl]amino]phenyl]amino]carbonyl]oxy]propyl 2-methyl-2-propenoate, 2-[[[[2-methyl-5-[[[4-[methyl[(1,1,2,2,3,3,4,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]butoxy]carbonyl]amino]phenyl]amino]car	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
	bonyl]oxy]propyl 2-methyl-2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and 1-octanethiol	
71487-20-2	2-Propenoic acid, 2-methyl-, methyl ester, polymer with ethenylbenzene, 2-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,7-pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(1,1,2,2,3,3,4,4,5,5,5-undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate and 2-propenoic acid	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
73772-32-4	1-Propanesulfonic acid, 3-[[3-(dimethylamino)propyl][(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]-2-hydroxy-, sodium salt (1:1)	
73772-33-5	1-Hexanesulfonamide, N-[3-(dimethylamino)propyl]-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, acetate (1:1)	
73772-34-6	1-Hexanesulfonamide, N-[3-(dimethylamino)propyl]-1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-[2-[2-(2-hydroxyethoxy)ethoxy]ethyl]-	
76848-59-4	Benzene, 1-chloro-4-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-	
76848-68-5	1H-Benzimidazolium, 1,3-diethyl-2-methyl-5-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-, 4-methylbenzenesulfonate (1:1)	
80621-17-6	1-Propanesulfonic acid, 3-[methyl[3-[[3-(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]propyl]amino]-, sodium salt (1:1)	

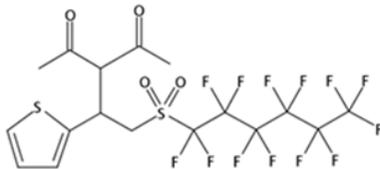
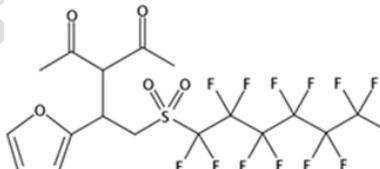
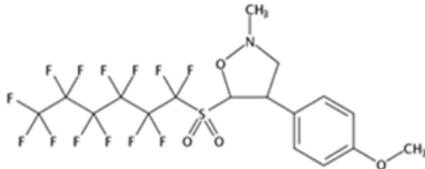
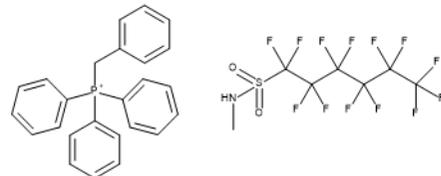
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
81190-38-7	1-Propanaminium, N-(2-hydroxyethyl)-3-[(2-hydroxy-3-sulfopropyl)[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]-N,N-dimethyl-, hydroxide, sodium salt (1:1:1)	<ul style="list-style-type: none"> • Na • OH-
82382-12-5	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, sodium salt (1:1)	PFHxS Na-salt
85665-64-1	1-Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-(2-hydroxyethyl)-N-propyl-	
85665-66-3	Glycine, N-propyl-N-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-, potassium salt (1:1)	<ul style="list-style-type: none"> • K
86525-30-6	1-Hexanesulfinic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, zinc salt (2:1)	
86525-43-1	Thiophene, 2-[2-[(tridecafluorohexyl)sulfonyl]ethenyl]-	
86525-48-6	Furan, 2-[2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethenyl]-	

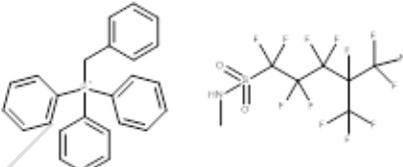
Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
86525-51-1	Benzene, 1-methyl-4-[2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethenyl]-	
86525-52-2	Benzene, 1-methoxy-4-[2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethenyl]-	
89863-48-9	Thiophene, 2-[1-(phenylthio)-2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethyl]-	
89863-49-0	Furan, 2-[1-(phenylthio)-2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethyl]-	
89863-50-3	Benzene, 1-methyl-4-[1-(phenylthio)-2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethyl]-	
89863-55-8	Thiophene, 2-[1-(nitromethyl)-2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethyl]-	
89863-56-9	Furan, 2-[1-(nitromethyl)-2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethyl]-	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
89863-63-8	2,4-Pentanedione, 3-[1-(2-thienyl)-2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethyl]-	
89863-64-9	2,4-Pentanedione, 3-[1-(2-furanyl)-2-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]ethyl]-	
91081-99-1	Sulfonamides, C4-8-alkane, perfluoro, N-(hydroxyethyl)-N-methyl, reaction products with epichlorohydrin, adipates (esters)	
93416-31-0	Isoxazolidine, 4-(4-methoxyphenyl)-2-methyl-5-[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]-	
93572-72-6	Sulfonic acids, C6-12-alkane, perfluoro	
944578-05-6	Sulfonamides, C4-8-alkane, perfluoro, N-[4,7-dimethyl-4-[(1-methylpropylidene)amino]oxy]-3,5-dioxa-6-aza-4-silanon-6-en-1-yl]-N-ethyl	
NA	Benzyl(triphenyl)phosphonium, salt with 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N-methyl-1-hexanesulfonamide	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

CAS	Name	Structure
NA	Benzyl(triphenyl)phosphonium, salt with 1,1,2,2,3,3,4,5,5,5-decafluoro-N-methyl-1-(trifluoromethyl)-4-pentanesulfonamide	 <p>The image shows two chemical structures. On the left is the benzyl(triphenyl)phosphonium cation, consisting of a central phosphorus atom bonded to three phenyl rings and one benzyl group. On the right is the 1,1,2,2,3,3,4,5,5,5-decafluoro-N-methyl-1-(trifluoromethyl)-4-pentanesulfonamide anion, a long-chain perfluorinated sulfonamide with a trifluoromethyl group at the 1-position and a methyl group on the nitrogen.</p>

Appendix 2 Human and environmental monitoring data

Table 36 Concentrations in humans of PFHxS, and when available in the same study also PFOS, PFOA, PFUnDA, PFDoDA, PFTrDA and PFTeDA (copy of human data in Table 18 in SVHC support document, (ECHA, 2017a))

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
		PFHxS	PFOS	PFOA	PFUnDA	PFDoDA	PFTrDA	PFTeDA			
Blood plasma											
Belgium	1998, 2000	<1/<1 (<1) 0%	11.1/10.4 (4.9 - 19) 100%	4.1 (<1 - 7.6) 75%	-	-	-	-	Female: n = 4 Male: n = 16 Arithm. mean/media n, (range) % positive	(Kannan et al., 2004)	2
USA	2002	4.1/2.9 (0.2 - 23) 100%	42.8/42 (16 - 83) 100%	27.5/25.2 (14 - 56) 100%	-	-	-	-	n = 70 New York City		
Sweden	2004	2.4, 3.0, 4.0, 2.3, 1.4	17.3, 18.9, 34.1, 17.3, 14.8	2.6, 2.1, 4.5, 5.1, 2.2	-	-	-	-	Female 36 years, Male 27 years, M41, F29, F24	(Kärrman et al., 2006)	2
USA	2004-2005	EDTA 25 ± 25 12 (5 - 80) Heparin 25 ± 26 12 (6 - 82)	EDTA 134 ± 198 69 (14 - 880) Heparin 137 ± 207 74 (13 - 915)	EDTA 1039 ± 2085 230 (19 - 7440) Heparin 1040 ± 2081 214 (19 - 7420)	-	-	-	-	Employes at 3M; production, corporate, research Arithm. mean ± SD, median, (range) PFHxS: n = 16 PFOS: n = 18	(Ehresman et al., 2007)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
									PFOA: n = 12		
Germany	2006	1.0 ± 1.1/0.8 (<LOD - 9.1 79/80	5.2 ± 3.4/4.6 (1.6 - 26.2) 80/80	5.2 ± 2.1/4.8 (2.0 - 11.5) 80/80	-	-	-	-	<i>Children</i> Siegen (ref); n = 80	(Holzer et al., 2008)	2
		1.4 ± 1.5/1.2 (0.5 - 13.4) 90/90	5.4 ± 2.9/4.9 (2.4 - 20.6) 90/90	24.6 ± 12.9/22 (6.7 - 96.6) 90/90					Arnsberg; n = 90		
		0.7 ± 0.4/0.6 (<LOD - 2.1) 151/153	6.2 ± 6.2/5.2 (1.0 - 70.7) 153/153	3.2 ± 1.5/2.8 (0.7 - 9.2) 153/153					Arnsberg; n = 164		
		1.2 ± 0.6/1.1 (<LOD - 5.7) 162/164	2.8/5.8 (1.7 - 16.7) 164/164	26.7 ± 13.8/23 (5.4 - 99.7) 164/164					<i>Men</i> Brilon (ref); n = 103		
		2.4 ± 1.0/2.2 (0.7- 5.4) 103/103	12.4 ± 11.5/9.7 (1.7 - 92.5) 103/103	6.4 ± 2.8/5.8 (1.1 - 15.3) 103/103					Arnsberg; n = 101		
		2.7 ± 1.1/2.5 (0.7 - 8.7) 101/101	11.8 ± 6.1/10.5 (2.7 - 36.2) 101/101	28.5±12.9 (6.1-77.5) 101/101					Arithm. mean ± SD/ geometric mean, (range) no.>LOD		

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)				Remarks	Reference	Reliability			
Sweden	1987	0.49/0.30 (0.28 - 0.90)	14.43/13.1 (8.28 - 21.81)	2.46/2.60 (1.75 - 3.02)	-	-	-	-	n=3	(Jönsson et al., 2009)	2
	1988	0.66/0.65 (0.41 - 0.89)	17.75/21.3 (8.55 - 25.83)	3.70/3.72 (1.23 - 6.85)					n = 8		
	1989	0.70/0.64 (0.49 - 1.51)	17.37/16.7 (11.12 - 25.0)	2.68/2.63 (1.54 - 4.20)					n = 9		
	1990	0.70/0.64 (0.49 - 1.51)	19.12/16.7 (10.69 - 32.3)	2.31/1.78 (1.56 - 4.12)					n = 4		
	1991	0.83/0.81 (0.44 - 1.26)	11.42	1.70					n = 1		
	1993	0.83/0.81 (0.44 - 1.26)	18.46	4.90					n = 1		
	1994	0.36 0.99	20.91/20.9 (20.19 - 21.6)	3.89/3.89 (3.73 - 4.05)					n = 2		
	1995	1.52/1.52 (1.13 - 1.90)	23.24/22.1 (15.69 - 33.0)	5.03/4.64 (3.65 - 7.18)					n = 4		
	1996	0.68/0.68 (0.52 - 0.82)	20.46/19.5 (11.07 - 36.7)	3.92/3.81 (2.32 - 6.33)					n = 8		
	1997	0.68/0.68 (0.52 - 0.82)	15.22/17.4 (10.02 - 18.2)	3.92/3.81 (2.32 - 6.33)					n = 3		
	1998	1.93/1.93	35.50	17.34/17.3 (16.75 - 17.9)	3.70/2.97 (2.81 - 5.32)				n = 1		
	1999	1.93/1.93	18.98/16.7						n = 2		

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
	2000	(0.52 - 1.70)	(10.24 - 27.6)	5.51					n = 8		
	2001	1.29/0.88 (0.73 - 2.26)	13.08/10.4 (3.65 - 27.5)	2.50/2.50 (1.88 - 3.11)					n = 1		
	2006	1.93	11.46/10.2 (4.07 - 20.0)	3.27 - 3.32 (1.40 - 5.08)					n = 15		
	2007	0.80/0.80 (0.49 - 1.11)		2.22					n = 10		
		1.300/1.29 (0.65 - 2.64)		2.69/2.51 (1.19 - 4.65)					All n = 80 were females		
		0.71		3.08/2.93 (1.29 - 5.24)					Arithm. mean/median, (range),		
		0.85/0.89 (0.16 - 1.54)									
		1.25/0.93 (0.33 - 2.35)									
Germany	1997-20004	1.7 (0.5 - 4.6)	18.8 (8.1 - 150.7)	6.1 (1.7 - 40.7)	-	-	-	-	Median, (range) n = 30	(Wilhelm et al., 2009)	2
Germany	2006	2.7	25	10	-	-	-	-	Median (range)	(Holzer et al., 2011)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
		(0.4 - 17)	(1.1 - 650)	(2.1 - 170)							
									n = 105 (99 M and 6 F, age 14-88 y)		
Norway	2007-2008	0.28 (0.04 - 1.64)/ 0.20 (0.04 - 1.13)	4.99 (1.63 - 17.7)/ 1.52 (0.04 - 6.49)	1.12 (0.36 - 4.24)/ 0.88 (0.04 - 3.23)	0.16 (0.04 - 0.54)/ 0.04 (0.04 - 0.19)	-	0.04 (0.04 - 0.23)/ 0.04 (0.04 - 0.25)	-	Median, (range) n = 123 Mother/ umbilical cord sampled immediately after birth	(Gützkov et al. (2012))	2
Norway	2003-2004	0.76/0.60 (0.43 - 0.86) Two samples <LOQ (0.05)	13.7/12.8 (10.1 - 16.6)	2.35/2.11 (1.54 - 2.93)	-	-	-	-	n = 487 mothers, blood sample taken at w. 17 of gestation. Mean/median, (IQR)	(Brantsaeter et al., 2013)	
Blood serum											
USA	2000	4.3 (<LOD - 21.4) (LOD ~1.5, LOQ = 5)	25.7 (6.7 - 81.5) (LOD ~1.7, LOQ = 5)	5.2 (<LOQ - 35.2) (LOD ~1, LOQ = 5)	-	-	-	-	Median (range) n = 65 Non- industrially exposed	(Hansen et al., 2001)	2
USA	1998	180 (145-223) 5-1880 14 (11-18) 1-210	941 (787-1126) 91-10600 136 (114-161) 15-946	899 (722-1120) 21-6160 49 (39-62) 6-298	-	-	-	-	Chemical plant employees n = 126 Geometric mean (95% CI) (range)	(Olsen et al., 2003)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
									Film plant employees n = 60 Geometric mean (95% CI) (range)		
India	2000	1.6/1.6 (<1 - 1.8) 36%	2.3/2.5 (<1 - 3) 55%	<3/<3 (<3) 0%	-	-	-	-	Arithm. mean/media n, (range) % positive Female: n = 11 Male: n = 34	(Kannan et al., 2004)	2
		1.6/1.5 (<1 - 2.9) 41%	1.7/1.3 (1 - 3.1) 50%	3.5/3.5 (<3) 3%							
Italy	2001	1.3/1.3 (<1 - 1.4) 37.5%	4.4/3.5 (<1 - 8) 87.5%	<3/<3 (<3) 0%	-	-	-	-	Female: n = 8 Male: n = 42		
		1.7/1.7 (<1 - 2.1) 33%	4.3/4.2 (<1 - 10.3) 90.5%	<3/<3 (<3) 0%							
Japan	2002	3.3/3.3 (<2.6 - 4.7) 23%	20.1/18.3 (6.3 - 40.3) 100%	12.3/12.3 (<6.8 - 12.3) 8%	-	-	-	-	Female: n = 13 Male: n = 25		
		4.2/3.7 (<2.6 - 4.7) 27%	14.1/12.4 (4.1 - 38) 100%	<6.8/<6.8 (<6.8) 0%							
USA	2000	3.6/2.8 (<1.3 - 13.2) 85%	32.5/28.9 (<1.3 - 91.7) 91%	4.7/4.4 (<3 - 7.3) 46%	-	-	-	-	Female: n = 46 Male: n = 29		
		4.3/3.3 (<1.3 - 13.6) 76%	32.9/26.2 (<1.3 - 124) 93%	5.7/4.4 (<3 - 14.7) 45%							

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
Sweden	2004	4.7 ± 2.9 4.0 (1.8 - 11.8) 12/12	20.7 ± 10.5 18.7 (8.2 - 48.0) 12/12	3.8 ± 1.0 3.8 (2.4 - 5.3) 12/12	0.40 ± 0.35 0.28 (0.20 - 1.5) 12/12	-	-	-	Mean ± SD, Median, (range), Number >LOD n = 12 primiparous women	(Kärrman et al., 2007)	2
USA	1998-2004	290/19 3 (16 - 1295) 182/11 7 (10 - 791)	799/626 (145 - 3490) 403/295 (37 - 1740)	691/408 (72 - 5100) 262/148 (17 - 2435)	-	-	-	-	Retirees from the 3M company n = 26 <i>Initial conc.</i> Arithm. mean/ median (range) <i>Final conc.</i> Arithm. mean/ median (range)	(Olsen et al., 2007)	2
Canada	2004-01 - 2005-06	4.13 ± 11.43 (1.44 - 3.06) (46.5%) 4.05 ± 12.30 (1.33 - 2.66) (45.5%) 5.05 ± 12.92 (1.4 - 2.77) (20%)	18.31 ± 10.95 (10.8 - 22.9) (100%) 16.19 ± 10.43 (9.19 - 20.22) (100%) 7.19 ± 5.73 (3.92 - 9.11) (100%)	2.54 ± 1.65 (10.8 - 22.9) n = 101 (100%) 2.24 ± 1.61 (1.33 - 2.64) (100%) 1.94 ± 1.54 (1.09 - 2.37) (100%)	-	-	-	-	Maternal serum at 24- 28 weeks n = 101 Maternal serum at delivery n = 101 Umbilical cord blood n = 105 Mean ± SD (range) (% of detection)	(Monroy et al., 2008)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
Sweden	1977	0.10	3.8	0.58	<0.050	<0.050	0.067	-	Pooled samples from Males 40-50 y	(Haug et al., 2009)	2
	1980	0.29	6.1	1.3	0.069	0.056	<0.050				
	1981	0.49	9.4	1.4	0.097	<0.050	0.073				
	1982	0.56	11	1.4	0.13	0.055	0.088				
	1983	0.52	10	1.5	0.28	<0.050	0.090				
	1985	0.80	16	2.2	0.27	<0.050	0.13				
	1986	0.80	15	2.6	0.61	0.062	0.18				
	1988	0.82	18	2.7	0.19	0.051	0.085				
	1989	1.3	22	3.1	0.31	<0.050	0.088				
	1990	1.1	20	3.3	0.29	<0.050	0.11				
	1991	1.3	23	3.4	0.17	0.054	0.072				
	1993	1.7	33	5.2	0.27	0.051	0.11				
	1994	1.9	24	4.1	0.22	<0.050	0.092				
	1995	1.4	31	4.4	0.21	<0.050	0.13				
	1996	1.4	25	4.0	0.20	<0.050	0.10				
	1997	1.8	31	4.2	0.21	<0.050	0.15				
	1999	1.6	29	4.0	0.17	0.070	0.13				
	2000	3.4	30	4.5	0.24	0.084	0.12				
	2001	1.6	27	4.9	0.24	0.054	0.16				
	2002	2.2	27	3.9	0.30	0.21	0.053				
2003	1.7	19	3.8	0.23	0.23	<0.050					
2004	1.4	18	3.4	0.18	0.063	0.11					
2005	1.6	21	3.5	0.25	0.065	0.20					
2006	1.4	12	2.7	0.14	<0.050	0.071					
USA	1999-2000, 2003-2004	0.95 ±	3.11 ±	1.51 ±	-	-	-	-	Adolescents (≥12 - <20 years; n = 474) Adults (≥ 20 years; n = 969) Arithm. mean ± SEM	(Lin et al., 2009)	2
		0.10	0.05	0.05							
		0.60 ±	3.19 ±	1.48 ±							
		0.04	0.04	0.04							
Norway	2008/2009	1.6	27	50	0.96	2.0	0.26	1.2	Median, (range) Ski wax technicians World Cup in skiing n = 13 A: After season I (March)	(Freberg et al., 2010)	2
		(0.83 - 6.2)	(11 - 91)	(20 - 174)	(0.32 - 3.4)	(0.51 - 9.1)	(0.11 - 1.0)	(0.26 - 4.4)			
			24	53	0.88	1.2	0.17	0.40			
		(0.84 - 6.2)	(8.7 - 86)	(15 - 73)	(0.16 - 3.5)	(0.32 - 7.3)	(0.009 - 0.65)	(0.03 - 2.10)			
		26	57	0.88	1.3	0.21	0.36				
		(10 - 86)	(20 - 162)				(0.11 - 2.9)				

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)						Remarks	Reference	Reliability
		(0.80 - 6.4)			(0.21 - 3.3)	(0.46 - 8.3)	(0.06 - 0.76)			
Germany	2007-2009	0.6/0.5 (1.3) 43/44	3.5/3.2 (6.8) 44/44	2.6/2.4 (5.5) 44/44	-	-	-	B: Before season II (November) C: After season II (March)	(Fromme et al., 2010)	2
		0.6/0.5 (1.5) 37/38	3.5/3.2 (6.1) 38/38	2.3/1.9 (5.2) 38/38				Arithm. mean/median (95 perc.) n>LOQ		
		0.4/0.3 (0.9) 45/47	3.2/2.9 (6.3) 47/47	1.7/1.5 (3.9) 47/47				Mother Pregnancy At delivery 6 months after delivery		
		----- 0.3/0.2 (0.9) 24/33	- 1.1/1.0 (2.2) 33/33	1.7/1.4 (3.7) 33/33				Fetus/infant Cord blood 6 months after birth 19 months after birth		
		0.7/0.6 (1.6) 39/40	3.3/3.0 (8.1) 40/40	8.0/6.9 (19.5) 40/40						
		0.7/0.6 (1.2) 24/24	2.2/1.9 (4.6) 24/24	5.1/4.6 (11.4) 24/24						
Canada	2005-12 - 2006-06	2.1 (<0.25 - 43) 233/252	9.0 (<0.25 - 35) 251/ 252	2.1 (<0.25 - 18) 227/ 252	-	-	-	Pregnant women, week 15-16 Arithm. mean (range) Detected/ total	(Hamm et al., 2010)	2
USA	1999-2000, 2003-2004	2.2 (<0.1/ <0.3 - 64.1)	22.6 (2.1 - 87.2)	4.4 (0.4 - 21.7)	-	-	-	Children age 12-1 years n = 571 Median (range)	(Hoffman et al., 2010)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
USA	2003-2004	1.8 (0.2 – 27.1)	21.0 (1.4 – 392)	3.9 (0.1 – 37.3)	-	-	-	-	Age 20 – 80 years of age n = 860 Median (range)	(Nelson et al., 2010)	2
Korea	2008-08 – 2009-03	0.55 (0.46 – 0.85)	2.93 (2.08 – 4.36)	1.46 (1.15 – 1.91)	0.60 (0.50 – 0.99)	< 0.27	0.24 (0.17 – 0.31)	<0.27	Median (25 perc – 75 perc.) Pregnant women n = 44 Fetal cord n = 43	(Kim et al., 2011)	2
USA	2005-2006	9.3 ± 13.7	22.9 ± 12.5	66.3 ± 106.1	-	-	-	-	Arithm. mean ± SD n = 10546 Children age 5-18 y	(Stein & Savitz, 2011)	2
Taiwan	2004	0.035 (0.035 – 0.420)	5.50 (0.11 – 48.36)	1.71 (0.75 – 17.40)	-	-	-	-	Cord blood Median (range) n = 244	(Wang et al., 2011)	2
Sweden	1996	1.61/ 2.44/ 2.24	22.7/ 27.3/ 23.3 24.8/	2.18/ 2.92/ 2.69 3.07/	0.189/ 0.212/ 0.163	<0.1/ <0.1/ <0.1 <0.1/	<0.15/ <0.15/ <0.15/	<0.25/ <0.25/ <0.25 <0.25/ <0.25/ <0.25	n = 19, 3 pools n = 62, 3 pools	(Glynn et al., 2012)	2
	1997	2.30/ 1.55/ 1.63	20.3/ 20.7 20.2/ 23.1/ 23.0	2.26/ 2.54 2.22/ 2.66/ 2.35	0.228/ 0.154/ 0.261	<0.1/ <0.1 <0.1/ <0.1/ <0.1	<0.15/ <0.15/ <0.15/	<0.25/ <0.25/ <0.25 <0.25/ <0.25/ <0.25	n = 74, 3 pools		
	1998	1.16/ 1.99/ 2.19	20.0/ 21.5/ 23.0 18.7/ 22.0	2.38/ 3.11/ 2.49 2.65/ 2.50	0.168/ 0.223/ 0.202	<0.1/ <0.1/ <0.1 <0.1/ <0.1	<0.15/ <0.15/ <0.15/	<0.25/ <0.25/ <0.25 <0.25/ <0.25/ <0.25	n = 17, 3 pools		
	1999	2.00/ 2.95/ 1.80	28.1	3.05	0.153/ 0.262/ 0.144	<0.1 <0.1/ <0.1/ <0.1	<0.15/ <0.15/ <0.15/	<0.25/ <0.25/ <0.25/ <0.25	n = 20, 2 pools		
	2000	2.40/ 3.03	17.0/ 18.7/ 23.2	2.17/2.59/ 2.98	0.198/ 0.201/ 0.32	<0.1/ <0.1 <0.1/ <0.1 <0.1/	<0.15/ <0.15/ <0.15/	<0.25/ <0.25/ <0.25 <0.25/ <0.25/ <0.25	n = 9, 1 pool		
	2001	1.96	16.0/ 16.6/ 13.6	2.12/ 2.12/ 2.15	0.228/ 0.272/ 0.274	<0.1/ <0.1 <0.1/ <0.1 <0.1/	<0.15/ <0.15/ <0.15/	<0.25/ <0.25/ <0.25 <0.25/ <0.25/ <0.25	n = 31, 3 pools		
	2002	3.04/ 2.87	12.2/ 10.7	2.11/ 1.89/ 1.70	0.274	<0.1/ <0.1 <0.1/ <0.1 <0.1/ <0.1	<0.15/ <0.15/ <0.15/	<0.25/ <0.25/ <0.25 <0.25/ <0.25/ <0.25	n = 32, 3 pools n = 30, 3 pools		

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
	2007		15.1/	2.41/	0.303/	<0.1/	<0.15/	<0.25/ <0.25/	n = 29, 3		
	2008	2.16/ 3.82/ 1.85	18.3/ 8.80 11.1/ 9.25/ 10.4	2.42/ 1.36 2.01/ 1.69/ 2.58	0.299/ 0.180 0.240/	<0.1/ <0.1 <0.1/ <0.1	<0.15/ <0.15 <0.15/	<0.25 <0.25/ <0.25/	pools n = 30, 3		
	2009	3.87/ 5.26/	7.14/ 8.68/ 8.89	1.54/ 2.40/ 1.80	0.175/ 0.241		<0.15/ <0.15		pools n = 30, 3		
	2010	3.24 4.48/ 4.68/ 3.20 5.05/ 3.92/ 4.12 4.00/ 4.58/ 5.95 5.83/ 5.63/ 7.95	7.61/ 5.11/ 7.62	1.96/ 1.71/ 1.39	0.245/ 0.225/ 0.185 0.208/ 0.254/ 0.262 0.281/ 0.247/ 0.285 0.311/ 0.232/ 0.188		<0.15/ <0.15/ <0.15 <0.15/ <0.15/ <0.15 <0.15/ <0.15/ <0.15 <0.15/ <0.15		pools n = 30, 3		
Korea	2008	1.51 (0.92 - 2.34)	7.96 (5.58 - 12.10)	2.74 (2.04 - 3.64)	1.75 (1.11 - 4.58)	0.92 (0.21 - 1.13)	0.39 (0.27 - 0.57)	<0.05	n = 633 Median, (25 th - 75 th percentiles)	(Ji et al., 2012)	2
Sweden	2009-2010	0.78 (0.38 - 2.5)	6.9 (3.7 - 19)	1.9 (1.2 - 3.3)	<0.1 (<0.1 - 0.83)	-	-	-	Median, (range) Male: n = 50	(Jönsson et al., 2010)	2
Canada	2008	45.2, 27.5, 77.1, 32.3, 215, 423, 222	15.2, 17.7, 19.9, 16.4, 78.4, 108, 72.3	3.68, 2.55, 4.96, 2.40, 9.02, 9.23, 6.84	-		<0.05, <0.05, <0.05, <0.05, <0.05, <0.05, <0.05	<0.05, <0.05, <0.05, <0.05, <0.05, <0.05, <0.05	Family members; M-52, F-48, M-23, M.21, F-18, M-17, M-15	(Beesoon et al., 2012)	2
United Kingdom	1991-1992	1.6 (0.2 - 54.8) ----- ----- 1.5	19.6 (3.8 - 112) ----- ----- 16.9 (11.1 - 42.9)	3.7 (1.0 - 16.4) ----- ----- - 3.5 (1.2 - 8.3)	-	-	-	-	Median, (range) N = 447 Maternal conc. ----- Overall	(Maisonet et al., 2012)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)						Remarks	Reference	Reliability
		(0.7 - 3.6)	20.1 (3.8 - 112)	3.8 (1.0 - 15.7)				----- Maternal pregnancy BMI		
		(0.2 - 54.1)	(11.3 - 47.6)	3.7 (1.9 - 6.5)				Underweight		
		1.9	19.2	3.6				Normal		
		(0.7 - 17.5)	(9.4 - 74.2)	(2.1 - 11.1)				Overweight		
		1.4	17.3	3.5				Obese		
		(0.9 - 4.4)	(8.5 - 94.5)	(1.3 - 16.4)				Missing		
		1.6	-----	-----				----- Maternal age at delivery (y)		
		(0.5 - 54.8)	-	-				<25		
		-----	(9.2 - 32.6)	(1.8 - 8.6)				25 - 29		
		-----	32.6	3.8				≥30		
		1.6	20.7	(1.2 - 16.4)				Missing		
		(0.8 - 6.2)	(6.5 - 112)	19.6				----- Maternal education		
		1.6	(3.8 - 74.2)	(1.0 - 15.7)				<0 level		
		(0.6 - 54.8)	-----	-----				0 level		
		1.7	-	-				<0 level		
		(0.2 - 49.8)	8.2 (8. - 94.5)	3.6 (1.3 - 16.4)				Missing		
		-----	19.6	16.4				----- Maternal race		
		-----	(8.5 - 112)	3.7				White		
		6	20.4	(1.6 - 8.6)				Nonwhite		
		(0.4 - 54.8)	(3.8 - 69.2)	3.9				Missing		
		1.6	-----	(1.0 - 15.7)				----- Previous live births		
		(0.5 - 37.3)	-	-				0		
		1.7	19.9	3.8				≥1		
		(0.2 - 54.1)	(6.5 - 112)	(1.1 - 16.4)				Missing		
		-----	14.6	16.4				----- Smoking during pregnancy		
		-----	25.6	2.3				Yes		
		-----	-----	(1.0 - 3.5)				No		
		1.6	-	-----				Missing		
		(0.2 - 54.8)	21.5	-						
		1.4	(6.5 - 94.5)	4.4						
			18.2	(1.5 - 16.4)						

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)						Remarks	Reference	Reliability
		(0.3 - 2.8)	(3.8 - 74.2)	3.1 (1.0 - 13.8)				----- <i>Low birth weight</i> Yes		
		----- 1.8	----- 17.2	----- -				No		
		(0.4 - 54.8)	(7.6 - 39.6)	3.4 (1.2 - 7.5)				Missing		
		----- 1.5	----- 20.9	----- 3.9				----- <i>Preterm delivery</i> Yes		
		(0.2 - 49.8)	(4.3 - 112)	(1.0 - 16.4)				No		
		----- 1.6	----- 18.0	----- 3.2				Missing		
		(0.2 - 9.5)	-	(1.1 - 11.1)				----- <i>Breast-feeding in first 4 weeks</i> Yes		
		----- 1.7	----- 21.8	----- -				No		
		(0.3 - 54.8)	(4.3-112)	4.1 (1.0 - 11.1)				Missing		
		----- 1.4	----- 19.6	----- 3.7				----- <i>Menarche (years)</i> <11.5 >11.5		
		(0.4 - 24.9)	(3.8-94.5)	(1.1 - 16.4)						
		----- 1.7	----- 23.9	----- -						
		(0.3 - 37.3)	(10.9 - 112)	4.7 (2.5 - 8.5)						
		----- 1.6	----- 19.6	----- 3.7						
		(0.2 - 54.8)	(3.8 - 94.5)	(1.0 - 16.4)						
		----- 1.7	----- 18.2	----- 3.7						
		(0.9 - 37.3)	(8.5 - 39.6)	(1.0 - 16.4)						
		----- 1.6	----- -	----- 3.7						
		(0.2 - 54.8)	(3.8 - 112)	(2.1 - 6.7)						
		----- 1.6	----- 19.9	----- -						
		(0.2 - 54.8)	(3.8 - 112)	-						
		----- 1.6	----- 18.2	----- 3.7						
		(0.2 - 54.8)	(7.6 - 94.5)	(1.0 - 15.7)						
		----- 1.7	----- 19.9	----- 3.9						
		(0.2 - 54.8)	(3.8 - 112)	(1.1 - 16.4)						
		----- 1.7	----- 19.9	----- 3.9						

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
		(0.6 - 7.1) ----- ----- 1.7 (0.3 - 7.3) 1.6 (0.2 - 54.8)									
Greenland	2002-2004	2.8/2.2 (1 - 21) 100% >LOD	51.9/44.7 (12 - 161) 100% >LOD	4.8/4.5 (2 - 14) 100% >LOD	1.7/ 1.3 (0.2 - 13) 94.4% >LOD	0.2/ 0.1 (0.04 - 2) 80.6% >LOD	-	-	Mean/media n, (range) n = 199 men	(Specht et al., 2012)	2
Poland		1.2/1.2 (0.4 - 4) 100% >LOD	18.6/18.5 (8 - 40) 100% >LOD	5.1/4.8 (2 - 16) 100% >LOD	0.3/ 0.3 (0.2 - 0.7) 11.6% >LOD	0.1/ 0.1 (0.04 - 0.2) 8.4% >LOD	-	-	n = 197 men		
Ukraine		0.4/0.3 (0.03-3) 99.5% >LOD	8.1/7.6 (3-30) 100% >LOD	1.8/1.3 (0.3-35) 92.1% >LOD	0.3/ 0.2 (0.1 - 1) 51.2% >LOD	0.3/ 0.3 (0.02 - 0.5) 12.3% >LOD	0.1/ 0.1 (0.04 - 0.1) 3% >LOD	-	-	n = 208 men	
Greenland	2011	2.2	44.7	4.5	-	-	-	-	Median n = 196	(Toft et al., 2012)	2
Poland		1.2	18.5	4.8					Median n = 189		
Ukraine		0.3	7.6	1.3					Median n = 203		
Sweden	2010-2011	1.95 (0.73 - 10.29)	11.20 (3.89 - 25.41)	2.25 (0.76 - 5.01)	0.33 (0.11 - 0.86)	-	-	-	Median, (p5 - p95) n = 270 Adults (18 - 80 years)	(Bjeremo et al., 2013)	2
China	2010	2.6/1.2 (<LOD - 16) 84/86	31/19 (1.4 - 180) 86/86	3.1/2.3 (0.26 - 29) 86/86	0.21/ 0.18 (<LOD - 0.82) 84/86	-	-	-	Arithm. mean/media n, (range) No. >LOD n = 86	(Zhang et al., 2013)	2
Sweden	2013	258/17 90	291/1737 500/881	16/92 26/47	-	-	-	-	n = 79 Median/max	(Jakobsson et al., 2014)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
		478/86 6							75 th /95 th percentile	(Jönsson, 2014)	
Sweden	2013	0.53 0.79 1.10 1.61 2.29	1.30 2.11 3.14 3.86 5.25	0.79 1.24 1.85 2.51 3.59	0.05 0.10 0.14 0.20 0.29	<0.03 <0.03 <0.03 <0.03 0.06	<0.01 0.01 0.03 0.04 0.07	<0.01 <0.01 <0.01 0.01 0.02	5 th percentile 25 th perc. 50 th perc. 75 th perc. 95 th perc.	(Jönsson, 2014)	2
		0.66 0.98 1.24 1.80 3.48	1.76 2.89 4.12 5.11 7.53	1.03 1.38 1.700 1.95 2.39	<0.04 0.08 0.13 0.17 0.31	<0.03 <0.03 <0.03 <0.03 0.06	<0.01 <0.01 0.02 0.03 0.05	<0.01 <0.01 <0.01 <0.01 0.02	Female: n = 104 Male: n = 97		
China	2012	1.21± 0.63 1.22 9/9	19.8 ± 10.7 18.7 9/9	3.53 ± 2.09 2.88 9/9	0.72 ± 0.34 0.68 9/9	0/9	-	-	Reference group (n=9)	(Zhou et al., 2014)	2
		726 ± 578 542 39/39	11400 ± 6760 10400 39/39	43.5 ± 27.3 41.0 39/39	18.2 ± 8.87 17.3 39/39	3.87 ± 4.20 2.60 39/39	-	-	Fishery employee (n=39)		
		189 ± 106 150 7/7	3150 ± 754 3540 7/7	12.5 ± 4.01 11.7 7/7	6.11 ± 2.61 6.72 7/7	1.17 ± 0.95 1.02 7/7	-	-	Fishery family (n=7)		
									Mean ± SD Median Number detected		
USA		1.5-3.9	14.7-55.8	2.1-9.6	-	-	-	-	Mean values in the general population resulting from various studies	(ATSDR, 2015)	2
Blood – whole											

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
Brazil	2003	5.4/2.2 (<0.6 - 15.3) 52.9%	10.7/8.4 (4.3 - 35) 1005	<20/<20 (<20) 0%	-	-	-	-	Whole-blood data were converted to a serum basis by multiplying by a factor of 2. Mean/media n, (range) % positive Female: n = 17 Male: n = 10	(Kannan et al., 2004)	2
		1.0/0.8 (0.6 - 1.9) 100%	13.5/12.7 (6.8 - 24) 100%	20/<20 (<20) 0%							
Colombia	2003	0.2/0.2 (<0.4) 0%	8.0/7.3 (4.6 - 13) 100%	6.1/5.6 (3.7 - 9.2) 100%	-	-	-	-	Female: n = 25 Male: n = 31		
		0.2/0.2 (<0.4 - 0.9) 10%	8.5/8.1 (6.2 - 14) 100%	6.2/5.9 (3.9 - 12.2) 100%							
Malaysia	2004	2.4/2.3 (1.2 - 4.2) 100%	11.7/12.7 (7.6 - 17) 100%	<10/<10 (<10) 0%	-	-	-	-	Female: n = 7 Male: n = 16		
		1.8/1.4 (1.2 - 6.8) 100%	13.2/13.1 (6.2 - 18.8) 100%	<10/<10 (<10) 0%							
Poland	2003	1.3/1.2 (0.5 - 2.6) 100%	33.3/33.8 (16 - 60) 100%	21.9/23.2 (9.7 - 34) 100%	-	-	-	-	Female: n = 15 Male: n = 10		
		1.3/1.2 (<0.4 - 1.8) 90%	55.4/40.9 (21 - 116) 100%	20.5/18.4 (11 - 40) 100%							
South Korea	2003	3.8/2.9 (0.9 - 20) 100%	15.1/11.3 (3.0 - 61.3) 100%	88.1/30.9 (<15 - 256) 19%	-	-	-	-	Female: n = 25 Male: n = 25		
		4.1/3.4									

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
		(1.3 - 9.6) 100%	27.1/27.1 (6.6 - 92) 100%	35.5/26.8 (<15 - 71.4) 25%							
USA	2002	4.2/1.1 (<1 - 32) 55%	66/81 (11 - 130) 100%	23/20 (15 - 39) 100%	-	-	-	-	Female: n = 11 Male: n = 19		
		4.0/2.2 (<1 - 20) 95%	73.2/72.0 (19 - 164) 100%	41.6/38.1 (11 - 88) 100%							
Sweden	2004	1.7 (0.4 - 28.4) 40/40	17.7 (1.7 - 37) 40/40	2.7 (LOD(0.5) - 12.4) 40/40	0.2 (<0.1 - 0.6)	-	-	-	Median, (range), number detected n = 40 (men; age 19-46 years) n = 26 (their mothers; age 46-75 years)	(Karrman et al., 2006)	2
		1.2 (0.4 - 2.5) 26/26	16.9 (4.6 - 32.8) 26/26	2.1 (0.8 - 4.1) 26/26	0.1 (<0.1 - 0.7)						
		2.2, 2.6, 2.9, 2.0, 1.2	14.2, 15.2, 27.8, 15.0, 11.3	2.0, 1.7, 3.8, 3.9, 1.2	Total 42/66	-	-	-	Female 36y, Male 27y, M41, F29, F24		
USA	2004-2005	<i>EDTA</i> 19 ± 12 16 (5 - 32) <i>Heparin</i> 19 ± 12 15 (5 - 36)	<i>EDTA</i> 69 ± 104 46 (8-449) <i>Heparin</i> 68 ± 105 47 (7 - 450)	<i>EDTA</i> 535 ± 1050 106 (8-3730) <i>Heparin</i> 535 ± 1035 110 (9 - 3670)	-	-	-	-	Employees at 3M; production, corporate, research Arithm. mean ± SD, median, (range) PFHxS: n = 7 PFOS: n = 17 PFOA: n = 12	(Ehresman et al., 2007)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
Spain	2006	3.56 ± 2.97 2.92 (0.65 - 20.0)	7.64 ± 3.54 7.60 (0.76 - 16.2)	1.80 ± 0.66 1.65 (0.79 - 3.13)	0.34 ± 0.19 0.20 (nd - 0.84)	-	-	<0.44	n = 48 Arithm. mean ± SD, median, (range)	(Ericson et al., 2007)	2
Sweden	2007/20 08	<0.30 <0.30 <0.30 1.9 1.6 - 2.1 3.3 - 4.3 1.4 0.78 - 1.5 0.96 - 3.3 1.70 1.7 - 1.9 1.6 - 2.0 1.6 1.5 - 1.8 - - 2.0 - 2.4 1.2 - 1.3 - 0.69 - 0.82 - 1.4 1.2 - 1.6 1.2 - 1.9	0.28 00.30 - 0.39 0.34 - 0.36 24 23 - 26 21 - 25 14.9 12 - 14 12 - 17 13 11 - 13 10 - 11 14 14 - 15 - - 24 - 26 22 - 27 - 8.1 - 8.2 - 7.2 7.0 - 8.0 7.0 - 9.0	4.8 6.3 - 17 17 - 20 8.50 10 - 20 19 - 23 151 146 - 150 134 - 153 127 114 - 131 101 - 122 10 12 - 22 - - 253 - 276 249 - 268 - 100 - 106 - 474 528 - 520 468 - 520	0.11 0.14 - 0.39 0.30 - 0.46 0.18 0.36 - 0.55 0.31 - 0.47 0.79 1.0 - 2.2 1.1 - 2.5 1.0 0.73 - 1.2 1.2 - 1.4 0.35 0.38 - 0.75 - - 2.4 - 2.8 1.2 - 6.1- 11 10 - 13 7.3 - 12	-	-	-	Ski wax technicians World Cup in skiing n = 8 A: pre- season (Sep) B: during World Cup season (Dec-Mar) C: post season (Apr- Aug) = No sample was provided	(Nilsson et al., 2010)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
Human milk											
Sweden	2004	0.085 ± 0.047 0.070 (0.031 - 0.1722) 12/12	0.201 ± 0.117 0.166 (0.060 - 0.470) 12/12	Not available Not available (<0.209 - 0.492) 1 ^a /12	(<0.008) 0/12	-	-	-	Arithm. mean ± SD, Median, (range), Number >LOD n = 12 primiparous women ^a Eleven additional samples were >LOD(0.01) but the blank level (0.209) was >50% of the detected concentratio ns.	(Karrman et al., 2007)	2
Sweden	Uppsala 1996 Uppsala 1997 Uppsala 1998 Uppsala 1999 Uppsala 2000 Göteborg 2001 Uppsala 2002 Lund 2003 Lycksele 2003-2004	0.037 0.030 0.040 0.044 0.028 0.028 0.051 0.025 0.016	0.209 0.207 0.219 0.213 0.191 0.258 0.194 0.153 0.123	<0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a <0.209 <0.209	-	-	-	-	^a Levels were >LOD(0.01) but the blank level (0.209) was >50% of the detected concentratio ns.		
Germany	2007-2009	- (<0.02 - 0.3) 6/201	0.04 (<0.3 - 0.11) 145/201	- (<0.15 - 0.25) 4/201	-	-	-	-	Median, (range), No. >LOQ n = 201	(Fromme et al., 2010)	2
Sweden	1972 1976 1980	<0.005 <0.005 0.006	0.023 0.059 0.103	0.019 0.041 0.060	-	-	-	-	n = 75 n = 78 n = 116	(Sundström et al., 2011)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
	1984/1985	0.006	0.172	0.078					n = 102		
	1988	0.016	0.211	0.148					n = 20		
	1990	0.010	0.202	0.106					n = 20		
	1992	0.011	0.222	0.111					n = 20		
	1994	0.015	0.219	0.106					n = 20		
	1995	0.028	0.214	0.139					n = 20		
	1996	0.016	0.224	0.111					n = 20		
	1997	0.016	0.237	0.138					n = 20		
	1998	0.028	0.212	0.128					n = 20		
	1999	0.023	0.234	0.120					n = 20		
	2000	0.024	0.213	0.124					n = 20		
	2001	0.017	0.198	0.098					n = 20		
	2002	0.027	0.210	0.118					n = 20		
	2003	0.025	0.179	0.098					n = 15		
	2004	0.017	0.188	0.100					n = 20		
	2007	0.017	0.122	0.086					n = 20		
	2008	0.014	0.075	0.074					n = 18		
France	2007	0.049/ 0.050 (0.040 - 0.066) 48/48	0.092/0.07 9 (<0.05 - 0.330) 43/48	0.082/0.07 5 (<0.05 - 0.224) 47/48	-	-	-	-	Arithm. mean/media n, (range), Number >LOD n = 48,	(Antignac et al., 2013)	2
Urine											
Canada	2008	<0.05, <0.05, 0.052, 0.054, 0.324, 0.318, 0.248	0.175, <0.05, <0.05, <0.05, 0.390, 0.074, <0.05	<0.05, <0.05, <0.05, <0.05, <0.05, <0.05, <0.05	-	-	<0.05, <0.05, <0.05, <0.05, <0.05, <0.05, <0.05	<0.05, <0.05, <0.05, <0.05, <0.05, <0.05, <0.05	Family members; M-52, F-48, M-23, M.21, F-18, M-17, M-15	(Beesoon et al., 2012)	2
China	2010	0.0024 /0.001 1 (<LOD -0.035) 84/86	0.037/0.02 5 (0.002 - 0.184) 86/86	0.122/0.02 3 (0.0035 - 1.869) 86/86	0.00042/ 0.00030 (<LOD - 0.0024) 84/86	-	-	-	Arithm. mean/media n, (range) No. >LOD n = 86	(Zhang et al., 2013)	2
China	2012	0.042 ± 0.004 0.042 2/9	0.016 ± 0.007 0.018 5/9	0.019 ± 0.01 0.016 5/9	-	-	-	-	Reference group (n=9)	(Zhou et al., 2014)	2

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
		0.55 ± 0.57 0.45 33/39	8.0 ± 9.0 4.7 39/39	0.13 ± 0.095 0.11 39/39					Fishery employee (n=39)		
		0.065 ± 0.068 0.055 4/7	2.5 ± 1.5 2.4 7/7	0.038 ± 0.022 0.043 7/7					Fishery family (n=7)		
									Mean ± SD Median Number detected		
Stool (µg/kg)											
Canada	2008	<2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50	<2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50	<2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50	<2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50	<2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50, <2.50	<2.50, <2.50, <2.50, <2.50, 4.80, <2.50, 7.80, 9.10	<2.50, <2.50, <2.50, <2.50, <2.50, 3.20, <2.50	Family members; M-52, F-48, M-23, M.21, F-18, M-17, M-15	(Beesoon et al., 2012)	2
Other human tissues (µg/kg)											
Spain	2008	1.8/1.2 (<2.4-13.8) (5%)	-/- (<3) (0%)	60.2/20.9 (<3-234) (55%)	-/- (<0.3) (0%)	16.6/5.1 (<0.98-169) (70%)	15.8/0.3 (<0.6-311) (5%)	-/- (<0.001) (0%)	Arithm.mean /median (range) (% detected) Bone (rib)	(Perez et al., 2013)	2
		3.2/2.3 (<4.5-14.4) (5%)	4.9/1.9 (<3-20.6) (10%)	-/- (<2.4) (0%)	-/- (<18) (0%)	13.2/1.5 (<1.3-102) (25%)	9.9/1.4 (<2.9-167) (10%)	24.8/1.4 (<3-336) (30%)	Brain		
		20.8/18	75.6/55 (<6-269) (45%)	2.0/1.5 (<3-11.9) (95%)	7.1/1.5 (<3-55.4) (10%)	14.7/4.5 (<2.3-91.4) (15%)	-/ (<6) (0%)	6.2/30.8 (<0.002-?) (25%)	Kidney		
			102/41.9	13.6/4.0	-/-			-/-			

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Date	Concentration (µg/L)							Remarks	Reference	Reliability
		(<4.2-37) (5%)	(<3-405) (90%)	(<3-98.9) (45%)	(<0.003) (0%)	2.4/1.5 (<1.45-20.2) (5%)	2.1/<0.001 1 (<0.001-32) (10%)	(<0.001) (0%)	Liver		
		4.6/1.8 (<3-20.6) (10%)	29.1/28.4 (<3-61.8) (89%)	29.2/12.1 (<6-87.9) (42%)	2.8/1.4 (<2.7-20.4) (11%)	20.7/<4.8 (<4.8-253) (11%)	139/6.9 (<3-1582) (42%)	9.8/1.5 (<2.9-82.8) (16%)	Lung		
		8.1/5.7 (<3.3-47.6) (32%)							Autopsy samples, age 28-83y (mean 56 y). Varying cause of death.		

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 37 (copy of Table 1.1. from additional data to POPs draft risk profile for PFHxS) Measured levels of PFHxS in aquatic biota

Organism	Tissue	Year	Country	Study site/ Type of location	Range (µg/kg)	Mean (µg/kg)	Comment	Reference
Marine water organisms								
Atlantic croaker	Homogenate	2004	United States	Charleston Harbour, South Carolina	n.d.			Houde et al., 2006
Fish	Homogenate	2009	Republic of Korea	Estuarine and Coastal areas, Urban/industrial	0.020–1.2	0.28		Naile et al., 2013
Crab	Homogenate	2009	Republic of Korea	Estuarine and Coastal areas, Urban/industrial	0.039–3.3	0.30		Naile et al., 2013
Gastropod	Homogenate	2009	Republic of Korea	Estuarine and Coastal areas, Urban/industrial	0.16–1.1	0.45		Naile et al., 2013
Bivalve	Homogenate	2009	Republic of Korea	Estuarine and Coastal areas, Urban/industrial	0.073–1.4	0.47		Naile et al., 2013
Fish (Arctic cod, Capelin, Sand lance)	Homogenate	2007–2009	Canadian Arctic	Remote	n.d.		Pooled samples and some individual	Braune et al., 2014
Bentic fish (various)	Homogenate	2007–2009	Canadian Arctic	Remote	n.d.–0.22 ng/g		Pooled samples and some individual	Braune et al., 2014
Pigfish	Homogenate	2004	United States	Sarasota Bay, Florida		4.1		Houde et al., 2006
Pinfish	Homogenate	2002/03	United States	Charleston Harbour, South Carolina		n.d.		Houde et al., 2006
Pinfish	Homogenate	2004	United States	Sarasota Bay, Florida		4.6		Houde et al., 2006
Red drum	Homogenate	2002/03	United States	Charleston Harbour, South Carolina		<0.5		Houde et al., 2006
Sheephead	Homogenate	2004	United States	Sarasota Bay, Florida		n.d.		Houde et al., 2006
Spotted seatrout	Homogenate	2002/03	United States	Charleston Harbour, South Carolina		1.1		Houde et al., 2006
Spotted seatrout	Homogenate	2004	United States	Sarasota Bay, Florida		0.6		Houde et al., 2006
Spotfish	Homogenate	2002/03	United States	Charleston Harbour, South Carolina		0.6		Houde et al., 2006
Polar cod	Liver	2004	Norway	Svalbard, Barents Sea	n.d.–0.07	0.04		Haukas et al., 2007
Rainbow trout	Muscle		Sweden	Baltic Sea	<0.011–0.040	0.013		Glynn et al., 2012
Fish various	Whole body		Canada	Hudson Bay	n.d.–0.22			Braune et al., 2014
Fish	Muscle/liver		Australia	Urban/industrial	n.d./0.70–1.2			Thomson et al., 2011b

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Organism	Tissue	Year	Country	Study site/ Type of location	Range (µg/kg)	Mean (µg/kg)	Comment	Reference
Various aquatic organisms		2007	United States, Savannah, Georgia	Urban	<0.1–3.4 ng/g		Sawtooth pen clam, white shrimp, eel, oyster toadfish, snapper, catfish, Atlantic croaker, southern kingfish, southern stingray, silver perch, spot, inshore lizardfish, tomtate, sea robin, Black sea bass, largemouth bass, Atlantic sharp-nose shark, bonnethead shark	Kumar et al., 2009
Various fish	Liver	2004	Netherlands	North Sea, Western Scheldt, Skagerak	<3–27 ng/g		Various marine fish	Van Leeuwen & Boer, 2006
Various shellfish and crustaceans	Liver	2004	Netherlands	North Sea, Western Scheldt, Skagerak	<3–<6 ng/g			Van Leeuwen & Boer, 2006
Fresh water organisms								
Atlantic croaker	Homogenate		United States	Charleston Harbour, South Carolina	n.d.			Houde et al., 2006
Big head carp	Muscle	2011	China	Lake Tangxun, urban/industrial	0.19–3.57	1.15		Zhou et al., 2014
Grass carp	Muscle	2011	China	Lake Tangxun, urban/industrial		4.58		Zhou et al., 2014
Silver carp	Muscle	2011	China	Lake Tangxun, urban/industrial	0.81–3.33	1.59		Zhou et al., 2014
Common carp	Muscle	2011	China	Lake Tangxun, urban/industrial	15.5–74.0	31.2		Zhou et al., 2014
White amur bream	Muscle	2011	China	Lake Tangxun, urban/industrial	0.83–3.16	1.84		Zhou et al., 2014
Yellow catfish	Muscle	2011	China	Lake Tangxun, urban/industrial	6.19–12.2	9.92		Zhou et al., 2014
Cod	Whole blood		Poland	Baltic Sea, Gulf of Gdansk	0.05–0.80	0.10		Falandysz et al., 2006
Herring	Liver	2005/2006	Sweden	East and West coast		0.22	Pooled sample	Bignert et al., 2008
Herring	Liver	2007/2008	Sweden	East and West coast		2.2	Pooled sample	Bignert et al., 2008
Herring	Liver	2009	Sweden	East and West coast		1.3	Pooled sample	Bignert et al., 2008
Biota	Various	2013-2015	Vietnam	River	<0.0–0.95 ng/g	0.06	Fish, crab, prawn, snail,	Lam et al., 2017

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Organism	Tissue	Year	Country	Study site/ Type of location	Range (µg/kg)	Mean (µg/kg)	Comment	Reference
Fish	Various	2010	Czech Republic	River Labe, Vltava and Bilina	0.007–0.121 ng/g	0.032	Pooled and individual	Svihlikova et al., 2015
Bentic invertebrates	Whole	2010/2011	Canada	Arctic	n.d.			Lescord et al., 2015
Pelagic invertebrates	Whole	2010/2011	Canada	Arctic	n.d.			Lescord et al., 2015
Char	Various	2010/2011	Canada	Arctic	n.d.–2.0			Lescord et al., 2015
Various fish	Liver	2004	Netherlands		<3–<4		Eel and pike	Van Leeuwen & Boer, 2006
Rainbow trout	Muscle		Sweden	Baltic Sea	<0.011–0.040	0.013		Glynn et al., 2012
Fish	Edible tissue (muscle)	2016/2018	China	Baiyangdian Lake, recipient water from rivers containing emission from production facilities.	0.02–39.77 ng/g ww		Carp, bream, snakehead, stone maroko, and loach	Cui et al., 2018
Crab	Edible tissue	2016/2018	China	Baiyangdian Lake, recipient water from rivers containing emission from production facilities.	0.9–1.43 ng/g ww		Crab	Cui et al., 2018
Shrimp	Whole body	2016/2018	China	Baiyangdian Lake, recipient water from rivers containing emission from production facilities.		32.94 ng/g ww		Cui et al., 2018
Rice field eel	Edible tissue (muscle)	2016/2018	China	Baiyangdian Lake, recipient water from rivers containing emission from production facilities.		25.69 ng/g ww		Cui et al., 2018
Turtle	Edible tissue (muscle)	2018	China	Baiyangdian Lake, recipient water from rivers containing emission from production facilities.		0.02 ng/g ww		Cui et al., 2018

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 38 (copy of Table 1.2. from additional data to POPs draft risk profile for PFHxS) Measured levels of PFHxS in amphibians and birds

Organism	Tissue	Year	Country	Study site/Type of location	Range (µg/kg)	Mean (µg/kg)	Comments	Reference
Amphibians								
American alligators	Plasma	2008/2009	United States	Merrit Island National Wildlife Refuge	<0.008–161	7.955		Bangma et al., 2017
American alligators	Tail muscle	2015	United States	South Carolina	0.051–0.272 ng/g	0.0816–0.099 ng/g	Median	Tipton et al., 2017
Chinese alligators	Serum	2009	China	Anhui Research Center for Chinese Alligator Reproduction	0–1.5 ng/g dw	0.2 ng/g dw		Wang et al., 2013
Birds								
Albatross	Liver	2011	Canada	Midway Atoll, North Pacific Ocean	0.32–0.81			Chu et al., et al., 2015
Albatross	Muscle	2011	Canada	Midway Atoll, North Pacific Ocean	0.14–0.44			Chu et al., et al., 2015
Albatross	Adipose	2011	Canada	Midway Atoll, North Pacific Ocean	n.d.–0.18			Chu et al., et al., 2015
Herring Gull	Egg	2012/2013	United States/Canada	Great Lakes	0.01–1.44			Letcher et al., 2015
Caspian tern	Egg	2013/2014	United States/Canada	Great Lakes	n.d.–4.61		Range of three colonies	Su et al., 2017
Murres and fulmars	Liver	Various	Canada	Arctic			Very low detection of PFHxS	Butt et al., 2007
Murres and Fulmars	Egg	Various	Canada	Prins Leopold Island, Nunavut	<0.01–0.21		Range between two species	Braune and Letcher, 2013
Herring Gull	Egg	2009–2014	United States/Canada	Urban (industrial)/rural	<0.1–2.7		Range between locations. Big difference in concentration between Urban/industrial and rural	Gewurtz et al., 2016
Various	Egg		Australia	Urban/industrial	<0.50–6.8		Ibis and gull eggs	Thomson et al., 2011b
Great tits	Egg (n=11)	2011	Belgium, Antwerp	Industrial	36.9–354.6	162.3	Vicinity of a perfluorochemical plant (3 M) in Antwerp, Belgium (PFOS levels in the range 3237–69218 µg/kg)	Groffen et al., 2017

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Organism	Tissue	Year	Country	Study site/Type of location	Range (µg/kg)	Mean (µg/kg)	Comments	Reference
Great tits	Egg (n=11)	2011	Belgium, Antwerp	Industrial	<LOQ-5.6	1.6	1 km Sout East of a perfluorochemical plant (3 M) in Antwerp, Belgium (PFOS levels in the range 55.1-782 µg/kg)	Groffen et al., 2017
Eider duck	Blood		Poland	Baltic Sea, Gulf of Gdansk	400-2900 pg/ml	1100 pg/ml		Falandysz et al., 2006
Northern goshawk	Plasma	2014	Norway	North	<LOD-1.33 ng/ml	0.61 ng/ml		Gomez-Ramirez et al., 2017
White-tailed eagle	Plasma	2014	Norway	North	<LOD-2.37	0.89 ng/ml		Gomez-Ramirez et al., 2017
White-tailed eagle	Feather	2014	Norway	North	<LOD-2.23	0.63 ng/ml		Gomez-Ramirez et al., 2017
Common eider	Egg	2012	Norway	Sklinna, mid, remote	0.49-0.56 ng/g (µg/kg)		Pooled samples	Huber et al., 2015
Common eider	Egg	2012	Norway	Røst, north, remote	0.59-1.58		Pooled samples	Huber et al., 2015
European Shag	Egg	2012	Norway	Sklinna, mid, remote	0.53-0.53		Pooled samples	Huber et al., 2015
European Shag	Egg	2012	Norway	Røst, north, remote	0.65-0.93		Pooled samples	Huber et al., 2015
European herring gull	Egg	2012	Norway	Sklinna, mid, remote	0.23-0.50		Pooled samples	Huber et al., 2015
European herring gull	Egg	2012	Norway	Røst, north, remote	0.40-0.79		Pooled samples	Huber et al., 2015
Duck	Egg	2016	China	Baiyangdian Lake, recepient water from rivers containing emission from production facilities.		30.61 ng/g ww	n=10	Cui et al., 2018
Duck	Meat	2016	China	Baiyangdian Lake, recepient water from rivers containing emission from production facilities.		88.52 ng/g ww	n=4	Cui et al., 2018
Duck	Liver	2016	China	Baiyangdian Lake, recepient water from rivers containing emission from production facilities.		288.78 ng/g ww	n=4	Cui et al., 2018

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Organism	Tissue	Year	Country	Study site/Type of location	Range (µg/kg)	Mean (µg/kg)	Comments	Reference
Duck	Blood	2016	China	Baiyangdian Lake, recipient water from rivers containing emission from production facilities.		438.01 ng/g ww	n=4	Cui et al., 2018

Table 39 (copy of Table 1.3. from additional data to POPs draft risk profile for PFHxS) Measured levels of PFHxS in marine- and terrestrial mammals

Organism	Tissue	Year	Country	Study site/Type of location	Range (µg/kg)	Mean (µg/kg)	Comments	Reference
Marine mammals								
Lichen	-	2009	Antartica		0.11-1.16			Alava et al., 2015
Penguin	Feces	2009	Antartica		<0.45-4.9			Alava et al., 2015
Penguin	Feces	2010	Antartica		2.17-3.77			Llorca et al., 2012
Weddell seals	Plasma		Antartica	McMurdo Sound	n.d.		Not detected	Routti et al., 2015
Ringed seal	Plasma	1990 - 2010	Norway	Svalbard	0.49-2.68		Not sampled every year	Routti et al., 2016
Ringed seal	Liver	1986 - 2010	Greenland	East Greenland	<MDL-0.9		Not sampled every year	Riget et al., 2013
Ringed seal	Liver	1984 - 2006	Greenland	Northwest Greenland	0.1, 0.2, 0.7 ng/g		1984, 1998, 2006 (3 pooled samples/year, pool n=4-5, medians)	Rotander et al., 2012
Ringed seal	Liver	1982 - 2010	Greenland	West Greenland	<MDL-0.4			Riget et al., 2013
Seal	Muscle		Greenland	Western	0.2-0.6			Carlsson et al., 2014
Harbour seal	Liver	2002	Denmark	Various seas and fjords	2.7-16.3		Range of mean from several locations in Denmark	Dietz et al., 2012
Harbour seal	Various		Germany	German Bight	0.66-10.49		Liver, kidney, lung, heart, blood, brain, muscle, thyroid, thymus* and blubber. * had max concentration	Ahrens et al., 2009
Harbour seal	Liver	2002	Germany	Wadden Sea	6.5-32.4 ng/g	16.3		Galatius et al., 2013
Hooded seal	Liver	1990 - 2007		West Ice	0.1, 0.2 ng/g		1990, 2007 (3 pooled samples/year, pool n=4-5, females, medians)	Rotander et al., 2012

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Organism	Tissue	Year	Country	Study site/Type of location	Range (µg/kg)	Mean (µg/kg)	Comments	Reference
Hooded seal, mother	Plasma	2008	Greenland, east	West Ice	0.256–1.89 ng/g	0.845		Grønnestad et al., 2017
Hooded seal, pup	Plasma	2008	Greenland, east	West Ice	0.483–5.01	2.90		Grønnestad et al., 2017
Hooded seal	Mother's milk	2008	Greenland, east	West Ice	0.394	n.d.	n=1	Grønnestad et al., 2017
Fur seal pup	Liver		Antarctica		<0.4		82% frequent detection	Schiavone et al., 2009
Harbour porpoises	Liver	1980 – 2005	Denmark	Danish North Sea	<DL		Found in minority of samples	Galatius et al., 2011
Harbour porpoises	Liver	1992 – 1997	Iceland	West Iceland	0.2, 0.2 ng/g		1992, 1997 (3 pooled samples/year, pool n=5, medians)	Rotander et al., 2012
Harbor porpoises	Liver	1999 – 2002	Denmark	Danish North Sea	<DL–6.3	1.1		Galatius et al., 2013
Pilot Whale	Muscle	1986 – 2013	Faroe Islands		n.d., 0.13, 0.19, 0.11, 0.14 ng/g		1986–1988, 1994–1997, 1998–2002, 2006–2009, 2010–2013	Dessuncao et al., 2017
Pilot Whale	Liver	1986 – 2007	Faroe Islands		0.1, 0.3, 0.4 ng/g		1986, 2001/2002, 2006/2007 (3 pooled samples/period, pool n=3–5, males, medians)	Rotander et al., 2012
Pilot Whale	Liver	1986 – 2016	Faroe Islands		0.08–1.7 ng/g		n=63 (juvenile males)	Andreassen et al., in prep.
Beluga whale	Liver		Alaska, United States	Cook inlet	<0.6–3.55			Reiner et al., 2011
Beluga whale	Liver		Alaska, United States	Eastern Chukchi Sea	<0.0261–0.378			Reiner et al., 2011
Mink whale	Liver		Iceland		<0.4–1.1			Kallenborne et al., 2004
Minke whale	Liver	1998	Greenland	Central, west	0.2 ng/g		1998, 3 pooled samples, pool n=4, females, median.	Rotander et al., 2012
Fin whale	Muscle	1986 – 2009	Iceland	West	<0.2, <0.2 ng/g		1986–1989, 2009 (3 pooled samples/period, pool n=3–5, males, medians)	Rotander et al., 2012
Long-finned pilot whale	Liver		Faroe island		0.39–1.0			Kallenborne et al., 2004

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Organism	Tissue	Year	Country	Study site/Type of location	Range (µg/kg)	Mean (µg/kg)	Comments	Reference
White-beaked dolphin	Liver	1999 – 2002	Denmark	Danish North Sea	<DL 6.8	2.8		Galatius et al., 2013
White-sided dolphin	Liver	2001 – 2006	Faroe Islands		0.4, 0.5 ng/g		2001/2002, 2006 (3 pooled samples/period, pool n=3–5, males, medians)	Rotander et al., 2012
Bottlenose dolphins	Plasma	2004	United States	Sarasota Bay, Florida		115 ± 101 ng/g ww	n=12	Houde et al., 2006
Bottlenose dolphins	Plasma	2004	United States	Charleston Harbour, South Carolina		48 ± 62 ng/g	n=24	Houde et al., 2006
Bottlenose dolphins	Plasma	2003 – 2005	United States	Indian River Lagoon, FL, less urban	2.30–757		Range between juvenile, adult female and adult male. Highest level found in juvenile based geometrical mean.	Fair et al., 2012
Bottlenose dolphins	Plasma	2003 – 2005	United States	Charleston, SC, Urban	4.6–471		Range between juvenile, adult female and adult male. Highest level found in juvenile based geometrical mean.	Fair et al., 2012
Bottlenose dolphins	Blubber	2005	United States	Indian River Lagoon, FL, less urban	0.3–69.3		Range between juvenile, adult female and adult male. Highest level found in adult male based on geometrical mean.	Fair et al., 2010
Bottlenose dolphins	Blubber	2005	United States	Charleston, SC, urban	0.3–22.7		Range between juvenile, adult female and adult male. Highest level found in juvenile based on geometrical mean.	Fair et al., 2010
Otter	Liver	1972 – 2011	Sweden		0.7–12 ng/g Northern Sweden 0.7–64 ng/g Southern Sweden 1.5–7.6 ng/g South-west Norway	2.8, 5.5, and 3.6 ng/g (median respectively)	Northern Sweden, Southern Sweden, South-west Norway	Roos et al., 2013
Terrestrial								
Roe deer	Liver pooled		Germany		<0.5–2.0			Falk et al., 2012
Arctic fox	Various	2011 / 2012	Norway	Svalbard, Arctic remote	0.23–8.4 total range	0.47–5.2 mean range	The range levels represent tissues; liver, blood, kidney, adipose tissue and muscle	Aas et al., 2014
Arctic fox	Liver		Norway	Svalbard, Arctic	<0.05–139			Routti et al., 2017
Polar bear	Liver		Greenland	East Greenland				Bossi et al., 2005

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Organism	Tissue	Year	Country	Study site/Type of location	Range (µg/kg)	Mean (µg/kg)	Comments	Reference
Polar bear	Liver	1999 / 2001	Greenland	East Greenland		140 ng/g ww		Smithwick et al., 2005a
Polar bear	Liver	2001	United States	Chukchi Sea, Alaska	35.2–325 ng/g ww	129 ng/g ww		Smithwick et al., 2005b
Polar bear	Liver	2001	United States	Northwest Territories,	<3.2–261 ng/g ww	44.8 ng/g ww		Smithwick et al., 2005b
Polar bear	Liver	2002	Canada	High Arctic	<3.2–263 ng/g ww	35.9 ng/g ww		Smithwick et al., 2005b
Polar bear	Liver		Canada	South Baffin Island	<3.2–417 ng/g ww	71.4 ng/g ww		Smithwick et al., 2005b
Polar bear	Liver	2002	Canada	South Hudson Bay	<3.2–321 ng/g ww	62.3 ng/g ww		Smithwick et al., 2005b
Polar bear	Liver	1999 / 2001	Greenland	East Greenland	4.39–544 ng/g ww	80.2 ng/g ww		Smithwick et al., 2005b
Polar bear	Liver	1996 / 2002	Norway	Svalbard, Barents Sea	2260–4430 ng/g ww	2940 ng/g ww		Smithwick et al., 2005b
Polar bear	Plasma	1998 – 2008	Norway	Svalbard, Arctic		40.8	Mothers 1998	Bytningvik et al., 2012
Polar bear	Plasma	1998 – 2008	Norway	Svalbard, Arctic		12.0	Cubs 1998	Bytningvik et al., 2012
Polar bear	Plasma	1998 – 2008	Norway	Svalbard, Arctic		32.6	Mothers 2008	Bytningvik et al., 2012
Polar bear	Plasma	1998 – 2008	Norway	Svalbard, Arctic		12.2	Cubs 2008	Bytningvik et al., 2012
Polar bear	Various		Greenland	Scoresby Sound, Central East Greenland.	1.37–30.9		Liver, blood, brain, muscle, adipose	Greaves et al., 2012
Polar bear	Blood		Norway	Svalbard, Arctic	4.9–70	28 median		Routti et al., 2017
Polar bear	Liver	1984 – 1988	Greenland	East Greenland		n.d.	Not sampled every year	Riget et al., 2013
Polar bear	Liver	1989 – 2011	Greenland	East Greenland	<MDL–27.9 ng/g		Not sampled every year	Riget et al., 2013

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Organism	Tissue	Year	Country	Study site/Type of location	Range (µg/kg)	Mean (µg/kg)	Comments	Reference
Polar bear	Serum		Norway	Svalbard-spring	5.5-65.3	28.6	Varies with the season	Tartu et al., 2017
Polar bear	Serum		Norway	Svalbard-autum	11.0-70.7	28.6	Varies with the season	Tartu et al., 2017
Polar bear	Liver		Canada	Southern Hudson Bay	7.1-9.66	8.28 ng/g		Letcher et al., 2018
Polar bear	Liver		Canada	Western Hudson Bay	5.98-8.22	7.09 ng/g		Letcher et al., 2018
Caribou	Liver	2005 - 2016	Canada	Arctic	<0.01-0.11 ng/g ww	0.02 ng/g ww		Gamberg et al., 2018 (in preparation)

Table 40 (copy of Table 1.4. from additional data to POPs draft risk profile for PFHxS) Measured levels of PFHxS in abiota

Matrix	Country / Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Air								
Air	Canada		Arctic lakes (Amituk, Char, and Resolute) on Cornwallis Island, Nunavut, Canada.	Remote, Arctic	<1 pg/m ³		No exact value was given	Stock et al., 2007
Air	Canada	2009	Alert	Remote, Arctic	0.085 pg/m ³			Genualdi et al., 2010
Air	Norway	2016	Zeppelin	Remote, Arctic				Norwegian Environment Agency, 2017a (M-757)
Air	Norway	2016	Birkenes					Norwegian Environment Agency, 2017a (M-757)
Air	Canada	2006-2014	Alert	Remote, Arctic	n.d.-0.62 pg/m ³	0.032 pg/m ³		Wong et al., 2018
Air	Norway	2006-2014	Zeppelin	Remote, Arctic	n.d.-0.35 pg/m ³	0.036 pg/m ³		Wong et al., 2018
Air	France		Paris	Urban	60.4 pg/m			Genualdi et al., 2010
Air	Canada	2009	Alert	Remote, Arctic	0.26 pg/m ³		Polar site	Rauert et al., 2018a
Air	Canada	2013	Alert	Remote, Arctic	NS-2.0 pg/m ³		Polar site	Rauert et al., 2018a
Air	Canada	2015	Alert	Remote, Arctic	1.2 pg/m ³		Polar site	Rauert et al., 2018a
Air	Norway	2009	Ny Ålesund	Remote, Arctic	<0.07 pg/m ³		Polar site	Rauert et al., 2018a
Air	Norway	2013	Ny Ålesund	Remote, Arctic	NS-0.71 pg/m ³		Polar site	Rauert et al., 2018a
Air	Norway	2015	Ny Ålesund	Remote, Arctic	2.2 pg/m ³		Polar site	Rauert et al., 2018a
Air	United States	2009	Hilo, Hawaii	Background	1.6 pg/m ³			Rauert et al., 2018a
Air	United States	2013	Hilo, Hawaii	Background	1.9-5.9 pg/m ³			Rauert et al., 2018a
Air	United States	2015	Hilo, Hawaii	Background	7.6 pg/m ³			Rauert et al., 2018a

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country / Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Air	South America	2015	Sites in Costa Rica, Mexico, Colombia, Brazil and Bolivia	Background	<0.1–3.1 pg/m ³			Rauert et al., 2018b
Air	South America	2015	Sites in Argentina, Chile and Brazil	Urban	NS–2.6 pg/m ³			Rauert et al., 2018b
Air	South America	2015	Site in Mexico	Agriculture	2.4 pg/m ³			Rauert et al., 2018b
Ice, snow and snowmelt								
Snow melt	Antarctica	2014/2015	Livingston Island	Remote	0.35–7.3 pg/L		58% detection frequency	Casal et al., 2017
Snow surface	Antarctica	2014/2015	Livingston Island	Remote	n.d.–23 pg/L		58% detection frequency	Casal et al., 2017
Snowpack	Sweden	2009	North region	Remote	<n.d. to 651 pg/L	25.1 pg/L		Codling et al., 2014
Snow	Norway	2006	Svalbard	Remote	20–30 pg/L			Kwok et al., 2013
Snow	Greenland	2004	East	Remote	8.2–40.2 pg/L),			Reviewed in Butt et al., 2010
Ice cap	Canada		Devon Ice cap	Remote	n.d.		Not detected	McInnis et al., 2017
Rain- and river water								
Rain water	Germany		20 km east of Hamburg	Semi-rural.	n.d.–500 pg/L			Dreyer et al., 2010
Rain water	Netherlands	2008	North Sea coast, 30 km outside Amsterdam	Semi-rural, infiltrated	0.3–25 ng/L	10.0 ng/L		Eschauzier et al., 2010
Rain water	Netherlands	2008	North Sea coast, 30 km outside Amsterdam	Semi-rural.	2.9–21 ng/L			Eschauzier et al., 2010
River water	Netherlands	2008	North Sea coast, 30 km outside Amsterdam	Semi-rural, infiltrated	<0.8–4.0 ng/L	1.4 ng/L		Eschauzier et al., 2010
River water	Germany		Rivers Elbe and lower Weser		0.6–1.0 ng/L		Amount varied by season	Zhao et al., 2015
Water	Australia		Sydney Harbour and Parramatta River estuary	urban/industrial	2.7–4.3 ng/L			Thomson et al., 2011b
Water								
Water	Norway	2006	Svalbard	Surface	20–500 pg/L			Kwok et al., 2013
Ocean water	Greenland	2009	Eastern Greenland	Arctic Ocean	n.d.–14.5 pg/L			Bush et al., 2010

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country / Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Ocean water		2008	Atlantic Ocean	Northern Europe	8.3–53 pg/L			Ahrens et al., 2010
Ocean water	Atlantic	2008	Atlantic Ocean	Atlantic	<4.1–17 pg/L			Ahrens et al., 2010
Ocean water	Southern	2008	Southern Ocean	Southern	<4.1 pg/L			Ahrens et al., 2010
Ocean water	Southern		Between Asia and Antarctica	Surface water	<1–10.2 pg/L			Wei et al., 2007
Ocean water	Greenland	2009	Greenland Sea	Surface water	<6.5–45 pg/L			Zhao et al., 2012
Ocean water	Atlantic	2010	Atlantic Ocean	Surface water	<6.5–61 pg/L			Zhao et al., 2012
Ocean water	Southern	2010/2011	Southern Ocean	Surface water	<6.5 pg/L			Zhao et al., 2012
Ocean water	Greenland	2004	Greenland Sea	East of Greenland	<6–19 pg/L,			Reviewed in Butt et al., 2010
Ocean water	Faroe Islands		Sea		<1 ng/L			Reviewed in Butt et al., 2010
Ocean water	Russian Federation		Baydaratskaya Bay	Arctic	n.d.			Reviewed in Butt et al., 2010
Ocean water	Global		Global	Surface water	n.d.–51 pg/L			Benskin et al., 2012
Ocean water	Arctic ocean		East of Greenland		n.d.–20 pg/L			Caliebe et al., 2005
Ocean water	Arctic					<5–22 pg/L		Yeung et al., 2017
Ocean water	Southern	2012	Between Asia and Antarctica	Surface water	<5–10.2		Mean range from various stations	Wei et al., 2007
Ocean water	Arctic ocean	2011			<66 pg/L		Under detection limit at all sites	Cai et al., 2012
Ocean water	Mediterranean	2014	Western Mediterranean	Surface water	5.4–41.3 pg/L			Brumovský et al., 2016
Ocean and costal	Republic of Korea	2009	Estuarine and coastal areas	Surface water	<0.2–8.7 ng/L	1.7 ng/L		Naile et al., 2013
Ocean and costal	World wide		North and south Atlantic and Pacific, and south	Tropic- and sub tropic surface water	n.d.–1420 pg/L		Close to 100% detection frequency	González-Gaya et al., 2014

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country / Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
			Indian oceans, and the coastal regions					
Ocean and coastal water	World wide		Pacific and Atlantic Oceans	Various depth	0.1–5600 pg/L			Yamashita et al., 2005
Coastal Sea Water	Finland, Denmark		Iceland, Faroe Islands		8–4390 pg/L			Kallenborn et al., 2004
Coastal Sea Water	Sweden	2013	Baltic Sea and Kattegat	2 meters depth	0.11–1.7 ng/L	0.91 ng/L	100 % detection frequency, n=18. Significant correlation with dissolved organic carbon and PFAS was observed.	Nguyen et al., 2017
Fresh water	Canada		Arctic lakes (Amituk, Char, and Resolute) on Cornwallis Island, Nunavut, Canada.	Background location, Southern Norway	n.d.–24 ng/L			Stock et al., 2007
Fresh water								
Fresh water	Canada	2010/2011	Arctic lake	Remote	0.01–30 ng/L			Lescord et al., 2015
Fresh water	Spain	2010	Juca River basin	Urban/industrial	12.1–36.7 ng/L	3.25 ng/L	13% detection frequency	Campo et al., 2016
Fresh water	China	2004	Tributaries of the Pearl River in Guangzhou	River water	<0.13–<0.67			So et al., 2007
Fresh water	China	2004	Sampling points along the Yangtze River Chongqing	River water	<0.005–0.4			So et al., 2007
Fresh water	China	2015	Taihu Lake	Lake	45.9–182 ng/L	69.3 ng/L	Mean PFOS: 20.3 ng/L	Chen et al., 2018
River	Sweden	2013	Baltic Sea and Kattegat	40 cm depth	0.051–18 ng/L	9.0 ng/L	77 % detection frequency, n=40. Significant correlation with dissolved organic carbon and PFAS was observed	Nguyen et al., 2017
Fresh water	France	2012	Nation-wide survey	133 lakes and rivers	<0.02–217 ng/L		Industrial and urban sites had high PFAS levels	Munoz et al., 2015
River	Australia	2011	Brisbane River (Somerset Dam)		0.09–0.13 ng/L	0.11 ng/L		Gallen et al., 2014
River	Australia	2011	Brisbane River (Jindalee)			2.5 ng/L		Gallen et al., 2014

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country / Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
River	Australia	2011	Oxley Creek	High tide	1.7–4.3 ng/L	3.1 ng/L		Gallen et al., 2014
River	Australia	2011	Oxley Creek	Low tide	7.1–17 ng/L	10 ng/L		Gallen et al., 2014
Coastal water	Australia	2011	Morton Bay		0.98–1.3 ng/L	1.1 ng/L		Gallen et al., 2014
Coastal water	Australia	2011	Morton Bay		0.1–0.46 ng/L	0.25 ng/L		Gallen et al., 2014
River water	China	2016	Fuhe River	The range of concentrations include various stations up- and downstream of production plant	0.38–1478 ng/L		Flows into Baiyangdian Lake, production facility upstream of lake possible source of PFHxS PFHxS was the dominating PFAS	Cui et al., 2018
River water	China	2016	Hebei Province, Zhulong River	No known source of PFHxS	0.15 and 0.48 ng/L		n=2, flows into Baiyangdian Lake	Cui et al., 2018
River water	China	2016	Hebei Province, Zhaowangxin River	Receives water from Baiyangdian Lake	383 and 682 ng/L		n=2, flows out of Baiyangdian Lake. PFHxS was the dominating PFAS	Cui et al., 2018
River water	China	2016	Hebei Province, Baigouyin River	No known source of PFHxS	11.8–13.6 ng/L		n=2, flows into Baiyangdian Lake	Cui et al., 2018
Lake water	China	2016	Hebei Province, Baiyangdian Lake north	Various station in the lake	187–978.5 ng/L			Cui et al., 2018
Lake water	China	2016	Hebei Province, Baiyangdian Lake south	Various station in the lake	3.6–900.4 ng/L			Cui et al., 2018
Lake water	China	2009	Thaihu Lake		n.d.–6.92 ng/L			Ma et al., 2018
Lake water	China	2014	Thaihu Lake		4.8–118.5 ng/L			Ma et al., 2018
Sediment								
Sediment	Canada		Arctic lakes (Amituk, Char, and Resolute) on Cornwallis Island, Nunavut, Canada.	Remote region, Arctic	n.d.–3.5 ng/g dw			Stock et al., 2007
Sediment	United States	2007	Savannah, Georgia	Urban	n.d.–0.3 ng/g dw			Kumar et al., 2009
Sediment	Japan	2005	Rivers, (Kumo, Uji, Tenjin, Katsura, Osaka)		<0.1–<1.6			Senthilkumar et al., 2007

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country / Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Sediment	United States	2004	The San Francisco Bay area, California, Corvallis, Oregon, Baltimore, Maryland	Coastal areas	n.d.-0.2			Higgins et al., 2005
Sediment	Republic of Korea	2009	Estuarine and coastal areas	Urban/industrial	n.d.			Naile et al., 2013
Sediment	Spain	2010	Juca River basin	Urban/industrial	n.d.			Campo et al., 2016
Sediment	France	2012	Nation-wide survey (n=129)		<0.2-0.63 ng/g dw			Munoz et al., 2015
Sediment	Czech Republic	2007-2008	Morova River	Industrial	0.12-3.8 µg/kg	0.53 µg/kg	Median 0.34 µg/kg, n=70, detection=60%	Becanova et al., 2016
Sediment	Australia		Sydney Harbour and Parramatta River estuary	urban/industrial	<0.10-0.10			Thomson et al., 2011b
Sediment	Serbia		Canal	urban/industrial	n.d.-0.23		Channel draining waste water	Beškoski et al., 2013
Sediment	Canada	2015	Various sites, Ontario, Hamilton area		0.06-1.1 ng/g		FHxSA <0.06-0.19	D'Agostino and Mabury, 2017
Sediment	Canada	2010/2011	Arctic lake	Remote	0.0-0.95 ng/g			Lescord et al., 2015
Sediment	Vietnam	2013-2015	River	Urban	<0.04-18.3 ng/g		18.3 ng/g highest of all PFAS measured	Lam et al., 2016
Sediment	China	2015	Lake Taihu	Urban	0.044-0.250 ng/g dw	0.145 ng/g dw	Mean PFOS: 0.824 ng/g dw Mean PFBS: 0.002 ng/g dw	Chen et al., 2018
Soil								
Soil	North America		Various	Rural	<LOD-36.5 pg/g			Rankin et al., 2016
Soil	Europe		Various	Rural	<LOD-99.7			Rankin et al., 2016
Soil	Asia		Various	Rural	2.95-14.63			Rankin et al., 2016
Soil	Africa		Various	Rural	<LOD-8.91			Rankin et al., 2016
Soil	Australia		Various	Rural	<LOD-39.57			Rankin et al., 2016
Soil	South America		Various	Rural	<LOD			Rankin et al., 2016
Soil	Antarctica		Various	Rural	<LOD			Rankin et al., 2016

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country / Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Soil	Republic of Korea	2009	Estuarine and coastal areas	Urban/industrial	n.d.			Naile et al., 2013

Table 41 (copy of Table 1.5. from additional data to POPs draft risk profile for PFHxS) Detection in waste water treatment, sludge, impacted biota, AFFF impacted sites and from manufacture

Matrix	Country / Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Waste water treatment, sludge, impacted biota, AFFF impacted sites and from manufacture								
Water	Canada	2015	Various sites-Ontario, Hamilton area	AFFF-impacted	28–150 ng/L		FHxSA 1.0–19 ng/L, FASADA n.d.–0.36, FASAB nd–1.42	D'Agostino and Mabury, 2017
Water	Canada	2015	Various sites-Ontario, Hamilton area	Urban	0.04–0.94 ng/L		FHxSA 0.32 ng/L median	D'Agostino and Mabury, 2017
Water	Canada	2015	Various sites-Ontario, Hamilton area	Urban		2.5 ng/L		D'Agostino and Mabury, 2017
Water	Canada	2015	Various sites-Ontario, Hamilton area	Rural		0.3 ng/L		D'Agostino and Mabury, 2017
Water	Canada	2014	Meretta- and Resolute Lake	AFFF-impacted Arctic lakes	13–30 ng/L		FHxSA 1.2–3.6, FASAB <0.7–0.74	D'Agostino and Mabury, 2017
Ground water	Sweden	2016–2017		Military airport	18 000–92 000 ng/L			Ericson Jogsten and Yeung, 2017
Ground water	Australia		Future Forrestfield rail station site	AFFF use	0.024–0.12 µg/L		Awaiting classification	http://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Ground water	Australia		Future Belmont Station site	AFFF use	n.d.–3.08 µg/L		Classified as possibly contaminated - <i>investigation required</i>	http://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Ground water	Australia		Crown reserve land (lot 800)	AFFF use	n.d.–1.6 µg/L		Awaiting classification	http://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country/ Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Waste water treatment, sludge, impacted biota, AFFF impacted sites and from manufacture								
								2cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Ground water	Australia		Former DFES Headquarters	AFFF use	n.d.-5.11 µg/L		Restriction on ground water use	http://www.parliament.wa.gov.au/publications/taledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Ground water and soil	Australia		Private fire training facility	AFFF use	n.d.-4.66 µg/L ground water 0.8-89.2 µg/kg		Classified as contaminated - <i>remediation required</i>	http://www.parliament.wa.gov.au/publications/taledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Ground water	Australia		Forrestfield Rail yard, Abernethy Road, High Wycombe	AFFF use	n.d.-2.11 µg/L		Being reviewed for classification.	http://www.parliament.wa.gov.au/publications/taledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Ground water	Australia		Fuel refinery	AFFF use	n.d.-2.29 µg/L		Classified as contaminated - <i>remediation required</i>	http://www.parliament.wa.gov.au/publications/taledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Ground water and soil	Australia		Former fuel terminal	AFFF	n.d.-32.5 µg/L ground water n.d.-16 µg/kg		Restriction on ground water use Classified as <i>remediated for restricted use</i>	http://www.parliament.wa.gov.au/publications/taledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Ground water	Australia		Former fuel terminal	AFFF	n.d.-4.2 µg/L		Classified as possibly contaminated - <i>investigation required</i>	http://www.parliament.wa.gov.au/publications/taledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country/Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Waste water treatment, sludge, impacted biota, AFFF impacted sites and from manufacture								
Ground water	Australia		Former fuel terminal	AFFF	n.d.–5.99 µg/L		Classified as contaminated - remediation required	http://www.parliament.wa.gov.au/publications/tables/papers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Soil	Norway	2011	New training field at Evenes Airport (BØF A)	AFFF	<2.1–443 µg/kg		Used from 1987–2005	https://avinor.no/contentassets/c3f5953f2b7d412e9cc973909a53d266/2015-harstad_narvik-undersokelser-av-pfas-i-jord-vann-og-biota.pdf
Soil	Norway	2013	New training field at Evenes Airport (BØFA)	AFFF	<3.0–99.3 µg/kg		Used from 1987–2005	https://avinor.no/contentassets/c3f5953f2b7d412e9cc973909a53d266/2015-harstad_narvik-undersokelser-av-pfas-i-jord-vann-og-biota.pdf
Soil	Norway	2011	Old training field at Evenes Airport (BØFB)	AFFF	12.9–203 µg/kg		Used from 1973–1980	https://avinor.no/contentassets/c3f5953f2b7d412e9cc973909a53d266/2015-harstad_narvik-undersokelser-av-pfas-i-jord-vann-og-biota.pdf
Ground water	Norway		Old training field at Evenes Airport (BØFB)	AFFF	212 µg/L		Used from 1973–1980	https://avinor.no/contentassets/c3f5953f2b7d412e9cc973909a53d266/2015-harstad_narvik-undersokelser-av-pfas-i-jord-vann-og-biota.pdf
Surface water	Norway		Old training field at Evenes Airport (BØFB)	AFFF	<7.5–407 µg/L		Used from 1973–1980	https://avinor.no/contentassets/c3f5953f2b7d412e9cc973909a53d266/2015-harstad_narvik-undersokelser-av-pfas-i-jord-vann-og-biota.pdf
Surface water	Norway		New training field at Evenes Airport (BØFA)	AFFF	<5–3460 µg/L		Used from 1973–1980	https://avinor.no/contentassets/c3f5953f2b7d412e9cc973909a53d266/2015-harstad_narvik-undersokelser-av-pfas-i-jord-vann-og-biota.pdf

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country/Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Waste water treatment, sludge, impacted biota, AFFF impacted sites and from manufacture								
								undersokelser-av-pfas-i-jord-vann-og-biota.pdf
Water	Norway	2015	Rygge airport	AFFF	53–6240 ng/L		Concentration range from various areas surrounding the airport	https://www.forsvarsbygg.no/contentassets/392d6ac269554b578b9634e74641dc6a/tiltaksvurdering-pfas-rygge-flystasjon-1.mars-2016-endig.pdf
Soil	Norway	2015	Rygge airport	AFFF	<3–22.9 µg/kg		Concentration range from various areas surrounding the airport	https://www.forsvarsbygg.no/contentassets/392d6ac269554b578b9634e74641dc6a/tiltaksvurdering-pfas-rygge-flystasjon-1.mars-2016-endig.pdf
Ground water	Norway	2015	Rygge airport	AFFF	66.7–47400 ng/L		Concentration range from various areas surrounding the airport	https://www.forsvarsbygg.no/contentassets/392d6ac269554b578b9634e74641dc6a/tiltaksvurdering-pfas-rygge-flystasjon-1.mars-2016-endig.pdf
Water	Canada	2015		AFFF impacted	38 ng/L	FHxSA 2.4/ 0.32 ng/L (AFFF/Urban)		D'Agostino and Mabury, 2017
Surface water	Sweden	2016–2017	Fortum Waste Solution	Hazardous waste management facility	8.8–250 ng/L			Ericson Jogsten and Yeung, 2017
Surface water	Sweden	2016–2017	Various airports	Airports	4.4–1000 ng/L		Both civil and military	Ericson Jogsten and Yeung, 2017
Surface water	Australia		Perth Airport South Main Drain, Redcliffe and Ascot	Airport	0.02–0.55 µg/L		Classified as <i>possibly contaminated</i> – <i>investigation required</i> .	http://www.parliament.wa.gov.au/publications/taledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Surface water	Australia		Perth Airport North Main Drain and Swan River	Airport		1.8 µg/L	Classified as <i>contaminated</i> – <i>restricted use</i>	http://www.parliament.wa.gov.au/publications/taledpapers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country/ Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Waste water treatment, sludge, impacted biota, AFFF impacted sites and from manufacture								
			foreshore at South Guildford					ers.nsf/displaypaper/4011002cdacb8122de9b89b2482581f00013ce30/\$file/tp-1002.pdf
Waste water	European		90 European Waste Water Treatment Plants			3.4 ng/L	Highest (single) Maximum Concentration 922 ng/L	CONCAWE, report no. 8/16
Waste water	Sweden	2015	Influent/effluent	Waste water treatment park	0.1–1.9 ng/L			Eriksson et al., 2017
Waste water	Sweden		Effluent	Waste water treatment park		Approx. 7 ng/L		Swedish EPA, 2016
Waste water	Norway	2016	Waste water inlet	Waste management	2899–5689 ng/passive sampler			Norwegian Environment Agency, 2017b (M-806)
Water	Norway	2016	Landfill leachates	Waste management	93–96 ng/passive sampler			Norwegian Environment Agency, 2017b (M-806)
Water	Sweden		Landfill leachates	Waste management		Approx. 80 ng/L		Swedish EPA, 2016
Water	United States		Landfill leachates from 6 different sites	Waste management	1.3–3900 ng/L		PFHxS detected	Allred et al., 2014
Water	United States		Landfill leachates from 6 different sites	Waste management	n.d.–89 ng/L		Precursor FHxSAA (perfluorohexane sulfonamino acetic acid)	Allred et al., 2014
Water	United States		Landfill leachates from 6 different sites	Waste management	0.63–1900 ng/L		Precursor MeFHxSAA (N-methyl perfluorohexane sulfonamino acetic acid)	Allred et al., 2014
Water	United States		Landfill leachates from 6 different sites	Waste management	n.d.–51 ng/L		Precursor EtFHxSAA (N-ethyl perfluorohexane sulfonamino acetic acid)	Allred et al., 2014
Water	Australia	2015–2016	Local point source, Oakey, Queensland	Fire-fighting training area	<0.07–6	2.4 µg/L		Bräunig et al., 2017
Sludge	Norway	2016	Sludge	Waste management	110–2700 µg/kg dw			Norwegian Environment Agency, 2017b (M-806)
Sludge	Sweden	2012–2015	Sludge	Waste water treatment park	<0.02–0.07 ng/g			Eriksson et al., 2017

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country/Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Waste water treatment, sludge, impacted biota, AFFF impacted sites and from manufacture								
Leachate	Australia	2014	Landfills	13 landfill sites	<LOD-1900 ng/L		Sites are located across Australia	Gallen et al., 2016
Biosolid	Australia	2014	Waste Water Treatment Plants	16 WWTP	<LOD-7.3 ng/g dw		Sites are located across Australia	Gallen et al., 2016
Leachate	Australia	2014	Landfills	27 landfill sites	56-16000 ng/L	1200 ng/L	100 % detection frequency, PFHxS>PFOS in concentration	Gallen et al., 2017
Sediment	Norway	2016	Oslo Fjord and Mjøsa	Fjord and lake	<0.71 µg/kg dw			Norwegian Environment Agency, 2017b (M-806)
Soil	Australia	2015-2016	Local point source, Oakey, Queensland	Fire-fighting training area	<0.1-74	13 µg/kg dw		Bräunig et al., 2017
Grass	Australia	2015-2016	Local point source, Oakey, Queensland	Fire-fighting training area	1-26	10 µg/kg ww		Bräunig et al., 2017
Egg yolk	Australia	2015-2016	Local point source, Oakey, Queensland	Fire-fighting training area	10-16	13 ng/g		Bräunig et al., 2017
Cow inside plume	Australia	2015-2016	Local point source, Oakey, Queensland	Fire-fighting training area	2-125	52 µg/L serum		Bräunig et al., 2017
Cow outside plume	Australia	2015-2016	Local point source, Oakey, Queensland	Fire-fighting training area	0.5-18	7 µg/L serum		Bräunig et al., 2017
Sheep	Australia	2015-2016	Local point source, Oakey, Queensland	Fire-fighting training area	32-129	63 µg/L serum		Bräunig et al., 2017
Horse	Australia	2015-2016	Local point source, Oakey, Queensland	Fire-fighting training area	18-74	33 µg/L serum		Bräunig et al., 2017
Human	Australia	2015-2016	Local point source, Oakey, Queensland	Fire-fighting training area	39-214	93 µg/L serum		Bräunig et al., 2017
Waste effluent	Taiwan, Province of China		Hsinchu Science Park	Semiconductor fabrication plant		13333 ng/L		Lin et al., 2009a
Pure water	Taiwan, Province of China		Hsinchu Science Park	Semiconductor fabrication plant		24.2 ng/L		Lin et al., 2009a
Photolithographic waste water	Taiwan, Province of China		Hsinchu Science Park	Semiconductor fabrication plant		9930 ng/L		Lin et al., 2009a

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country/Region	Year	Study site	Type of location	Concentration	Mean	Comment	Reference
Waste water treatment, sludge, impacted biota, AFFF impacted sites and from manufacture								
Waste effluent	Taiwan, Province of China		Hsinchu Science Park	electronic/optoelectronic fabrication plant		<2 µg/L		Lin et al., 2009a
Waste water effluent	Taiwan, Province of China		Urban Taipei	Municipal waste water treatment plant I		6.3 ng/L		Lin et al., 2010
Waste water effluent	Taiwan, Province of China		Urban Taipei	Municipal waste water treatment plant II		35 ng/L		Lin et al., 2010
Waste water effluent	Taiwan, Province of China		Urban Taipei, Hsinchu Science Park	Industrial Waste water treatment plant		2226.7 ng/L	A hub for 384 high-tech companies that include 86 optoelectronics, 203 integrated circuit companies and 27 semiconductor fabrication plants	Lin et al., 2010

Table 42 (copy of Table 1.6. from additional data to POPs draft risk profile for PFHxS) Detection in Drinking water

Drinking water	Country/region	Year	Study site	PFHxS range ng/L	Mean ng/L	Comment Sum PFAS (mean (range))	References
Drinking water	Sweden	2013	Outgoing water from Brantafors waterworks in Ronneby		1770	Drinking water was also contaminated with 8000 ng/L PFOS and 100 ng/L PFOA	Li et al., 2018
Drinking water	Sweden	2013	Outgoing water from Kärragården waterworks in Ronneby		4.6	PFOS 27 ng/L and PFHxA 3.6 was also detected	Li et al., 2018
Drinking water	Italy	2013	Various municipalities in province of Treviso		27-36	From 8 municipalities supplied by drawing wells located in the Almisano area, involved in the PFAS contamination plume (from chemical plant (Miteni SpA)).	Annex E submission from Council of Chemists of the Province of Treviso, Italy
Drinking water	France	2009-10	Raw water (surface water, n=99)	<4 to 8	1	% LOD=48, % LOQ=6	Boiteux et al., 2012
Drinking water	France	2009-10	Raw water (ground water, n=163)	<4 to 32	1	% LOD=31, % LOQ=10	Boiteux et al., 2012
Drinking water	France	2009-10	Treated water (surface water, n=26)	<4 to 7	2	% LOD=88, % LOQ=8	Boiteux et al., 2012
Drinking water	France	2009-10	Treated water (surface water, n=15)	<4 to 13	2	% LOD=100, % LOQ=27	Boiteux et al., 2012

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Drinking water	Country/region	Year	Study site	PFHxS range ng/L	Mean ng/L	Comment Sum PFAS (mean (range))	References
Drinking water	Spain		40 different locations from 5 different zones of Catalonia	<0.02-5.3	0.64		Ericson et al., 2009
Tap water	The Netherlands	2013-14	37 water sources	<LOQ-2.3	1.3	Sum PFAS <LOQ to 54 ng/l	Zafeiraki, et al., 2015
Tap water	Greece	2013-14	43 water sources	>LOQ	0	Sum PFAS <LOQ and 5.9 ng/l	Zafeiraki, et al., 2015
Drinking water	Canada and other	2015-16	Bottle water (n=38)	<LOQ-0.67	0.10	Canada and other countries (Burkina Faso, Chile, Ivory Coast, France, Japan, Mexico, Norway, and the United States) in 2015-2016.	Kabore et al., 2018
Drinking water	Canada and other	2015-16	Tap water (n=59)	<LOQ-1.0	0.30	Canada and other countries (Burkina Faso, Chile, Ivory Coast, France, Japan, Mexico, Norway, and the United States) in 2015-2016.	Kabore et al., 2018
Drinking water	Australia	2010	Portable water from 34 locations in Australia	n.d.-14.4		PFHxS were detected in 27% of the samples	Thompson et al., 2011a
Tap water	China	2008	Xiamen and Beijing		0.085		Mak et al., 2009
Tap water	Afghanistan	2007	Kabul		n.d.	PFOA and PFOS were not detected in tap water (LOQ µg/L: 0.03 PFOA, 0.015 PFOS)	Hemat et al., 2010
Tap water	China	2016	Hebei Province, From well		Not detected	n=2	Cui et al., 2018

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 43 (copy of table 1.7 from additional data to POPs draft risk profile for PFHxS) PFHxS levels in food items

Food item	Country/region	Year	N	Median ng/g ww	Mean ng/g ww	PFHxS range ng/g ww	Detection frequency	Comment Sum PFAS (median (range) ng/g ww)	References
Domestic eggs	Netherlands	2013–2014	73	1.1		<0.5–5.2	7	Home produced eggs, sum PFASs :3.5 (<LOQ–31.2), PFASs measured in egg yolk	Zafeiraki et al, 2016
Domestic eggs	Greece	2013–2014	45	<0.5		<0.5	0	Home produced eggs sum PFASs: 1.1 (<LOQ–15) PFASs measured in egg yolk	Zafeiraki et al, 2016
Fatty fish	Netherlands	2009			0.009			herring/eel/mackerel/ salmon	Noorlander et al., 2011
Lean fish	Netherlands	2009			0.023			cod/plaice/pollack/tuna	Noorlander et al., 2011
crustacians	Netherlands	2009			0.044			mussels/shrimp/crab	Noorlander et al., 2011
butter	Netherlands	2009			0.016			salt-free butter/salted butter/low-fat butter	Noorlander et al., 2011
Chicken/poultry	Netherlands	2009			0.003				Noorlander et al., 2011
flour	Netherlands	2009			0.018			whole wheat flour/flour	Noorlander et al., 2011
Bakery products	Netherlands	2009			0.006			cake/almond paste cake/biscuits/brown spiced biscuit/pie	Noorlander et al., 2011
Industrial oil	Netherlands	2009			0.007			margarine/frying fat (industrial oil)/ frying oil (industrial oil)	Noorlander et al., 2011
Meat products	Sweden	1999			0.006			Beef, pork, lamb, poultry, cured/processed meats, sausages	Gebbink et al., 2015
Fish products		1999			0.007			Fresh and frozen fillets of fish, canned fish products, shellfish	Gebbink et al., 2015
Egg		1999			0.034			Hen eggs	Gebbink et al., 2015
Potatoes		1999			0.0002				Gebbink et al., 2015
Soft drinks		1999			0.0002			Soft drinks, mineral water, low alcohol beer, medium-strong beer	Gebbink et al., 2015
Vegetables and vegetable products	13 EU countries	2006–2012	186			0.0028–0.0038	2%	Broccoli, lettuce and melons	EFSA 2012
Fruit and fruit products	13 EU countries	2006–2012	133			0.008-0.2	21%	Only a limited number of fruit samples were analysed for PFHxS	EFSA 2012
Meat and meat products	13 EU countries	2006–2012	683			0.079-2.1	1%	PFHxS was found in one sample of each: sheep, game mammal, poultry	EFSA 2012
Fish and other	13 EU countries	2006–2012				0.043 and 1		Found in one unspecified seafood sample and one fish sample	EFSA 2012

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Food item	Country/region	Year	N	Median ng/g ww	Mean ng/g ww	PFHxS range ng/g ww	Detection frequency	Comment Sum PFAS (median (range) ng/g ww)	References
seafood									
Fish offal	13 EU countries	2006–2012				1.4–4.5	2%		
Crustaceans	13 EU countries	2006–2012	43			0.3–4.9			EFSA 2012
Various	Norway	2010–2011	940	0.71	1.53	0.18–84.7		Consummation of fat fish, canned food and drinks with sugar were positively associated with PFHxS amounts	Averina et al., 2018
Infant formula	United States	2007	21			<1.35–3.59	10%	5 different brands	Tao et al., 2008b
Diary milk	United States	2008	12			<1.35–3.82	8%	11 different brands	Tao et al., 2008b
Shrimp	China	2016	15			32	100%	Samples from area around Baiyangdian Lake, Hebei Province	Cui et al., 2018
Duck egg	China	2016–2018	10			30.61±19.7	100%	Mean and SD. Samples from area around Baiyangdian Lake, Hebei Province	Cui et al., 2018
Duck meat	China	2016–2018	4			88.52±92.71	100%	Mean and SD. Samples from area around Baiyangdian Lake, Hebei Province	Cui et al., 2018

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 44 (Copy of table 1.8 from additional data to POPs draft risk profile for PFHxS) Detection in indoor and outdoor dust and indoor air

Dust	Country/Region	Year of sampling (n)	Type of location	Concentration range µg/kg dw (%>LOD)	Mean µg/kg dw	Comment	Reference
Dust	Norway /Oslo	2017 (n=5)	Furniture store	1600–2300 (100)	1983 µg/kg dw	6:2diPAP was found in equal high amounts 330–3300 µg/ kg dw (mean PFOS 10,75 µg/kg)	Norwegian Environment Agency, 2017 (M-806)
Dust	Norway/ Oslo	2017 (n=5)	Hotel	1600–2100 (100)		6:2diPAP was found in equal high amounts 330–3300 µg/ kg dw	Norwegian Environment Agency, 2017 (M-806)
Dust	Norway	2007/08 (n=7)	Private residences	<1.4-3.1	1.4		Huber et al., 2011
Dust	Norway	2007/08 (n=1)	Office		27.8		Huber et al., 2011
Dust	Norway	2007/08 (n=1)	Storage		1814		Huber et al., 2011
Dust	Norway	2008 (n=41)	Private residences	0.21-142	8.4	Level of PFHxS was negatively correlated with age of residence, and positive correlated with volum of the living room (m ³)	Haug et al., 2011
Dust	Czech Republic	2013 (n=12)	Private home vacuuming	<MQL–9.3 (93.8)			Karazkova et al., 2016
Dust	Canada	2013 (n=15)	Private home vacuuming	n.d.–11.5 (90.0)			Karazkova et al., 2016
Dust	United States	2013 (n=14)	Private home vacuuming	1.4-84.4 (100)			Karazkova et al., 2016
Dust	Canada	2007–2008 (n=18)	Private home	2.9–1300	140	PFOS was found at equal high levels	Beesoon et al., 2011
Dust	United States/ Boston	2009 (n=31)	Office	5.24–18.5 (23)			Fraser et al., 2013
Dust	United States/ Boston	2009 (n=30)	Private home	6.05–430 (40)			Fraser et al., 2013
Dust	United States/ Boston	2009 (n=12)	Vehicle	5.22–108 (46)			Fraser et al., 2013
Dust	Canada, Ottawa	2002/2003 (n=67)	House Dust	(2.3–4305)	Median 23, mean 391.96		Kubwabo et al, 2005
Dust	UK, Australia, Germany and United States	2004 (n=39)	Houshold dust	47.7–632.2) max 43765 (79.5)	185.5	(25 th and 7 th percentile)	Kato et al., 2009
Dust	United States/Ohio and North Carolina	2000–2001 (n=112)	Private homes (n=102) and day care centres (n=10)	(<DL–35,700)	Median 46, mean 874		Strynar and Lindstrom, 2008

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Dust	Country/Region	Year of sampling (n)	Type of location	Concentration range $\mu\text{g}/\text{kg dw}$ (%>LOD)	Mean $\mu\text{g}/\text{kg dw}$	Comment	Reference
Dust	China	2015	Hotel (n=11)	n.d. -7.01 (9)		Fluortelomer alkohols (FTOHs) were predominant PFAS (24.8-678 ng/g)	Yao et al., 2018
Dust	China	2015	Private residents (n=18)	n.d.-18 (61)	2.93		Yao et al., 2018
Air	China	2015	Hotel (n=19)	6.47-40.9 pg/m^3 (100)	11.9 pg/m^3	Fluortelomer alkohols (FTOHs) were predominant PFAS (250-82300 pg/m^3)	Yao et al., 2018
Air	China	2015	Private residents (n=22)	10.4-65.3 pg/m^3 (100)	23.4 pg/m^3		Yao et al., 2018
Dust	China		Manufacturing plant, office 1		2010		Wang et al., 2010
Dust	China		Manufacturing plant, office 2		580		Wang et al., 2010
Dust	China		Manufacturing plant, product storage 1		2040		Wang et al., 2010
Dust	China		Manufacturing plant, product storage 2		25820		Wang et al., 2010
Dust	China		Manufacturing plant, raw material stock room 1		4340		Wang et al., 2010
Dust	China		Manufacturing plant, raw material stock room 2		590		Wang et al., 2010
Dust	China		Manufacturing plant, electrolysis workshop 1		2400		Wang et al., 2010
Dust	China		Manufacturing plant, electrolysis workshop 2		1460		Wang et al., 2010
Dust	China		Manufacturing plant, electrolysis workshop 3		4990		Wang et al., 2010
Dust	China		Manufacturing plant, sulfonation workshop 1		15110		Wang et al., 2010
Dust	China		Manufacturing plant, sulfonation workshop 2		15920		Wang et al., 2010

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Dust	Country/Region	Year of sampling (n)	Type of location	Concentration range $\mu\text{g}/\text{kg dw}$ (%>LOD)	Mean $\mu\text{g}/\text{kg dw}$	Comment	Reference
Dust	China		Manufacturing plant, sulfonation workshop 3		9950		Wang et al., 2010
Dust	China		Manufacturing plant, laboratory building		4740		Wang et al., 2010
Dust	China		Manufacturing plant, road 1		100		Wang et al., 2010
Dust	China		Manufacturing plant, road 2		140		Wang et al., 2010
Dust	China		Manufacturing plant, road 3		1260		Wang et al., 2010

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 45 (Copy of table 1.9 from additional data to POPs draft risk profile for PFHxS) Detection in products

Matrix	Country/Region	Year of sampling (n)	Type of product/material	Concentration mean $\mu\text{g}/\text{kg dw}$ (%>LOD)	Comment	Reference
Consumer products	Czech Republic	2008	Curtain (textile)	2.18	New	Becanova et al., 2016
Consumer products	Czech Republic	2004	Foam (textile)	0.586	Used	Becanova et al., 2016
Consumer products	Czech Republic	2003	Foam (textile)	0.409	Used	Becanova et al., 2016
Consumer products	Czech Republic	1996	Teddy bear cover (textile)	0.439	Used	Becanova et al., 2016
Consumer products	Czech Republic	1986	Table cloth (textile)	0.437	Used	Becanova et al., 2016
Consumer products	Czech Republic	1981	Upholstery material (textile)	2.93	Used	Becanova et al., 2016
Consumer products	Czech Republic	1981	Foam (textile)	1.085	Used	Becanova et al., 2016
Consumer products	Czech Republic	1981	Upholstery material (textile)	0.835	Used	Becanova et al., 2016
Consumer products	Czech Republic	1981	Blanket (textile)	0.219	Used	Becanova et al., 2016
Consumer products	Czech Republic	2010	Carpet-red (floor covering)	0.256	New	Becanova et al., 2016
Consumer products	Czech Republic	2006	Carpet-grey (floor covering)	5.016	Used	Becanova et al., 2016
Consumer products	Czech Republic	2006	Carpet-green (floor covering)	0.448	Used	Becanova et al., 2016
Consumer products	Czech Republic	1981	Persian carpet (floor covering)	3.26	Used	Becanova et al., 2016
Consumer products	Czech Republic	1981	Carpet (floor covering)	1.25	Used	Becanova et al., 2016
Consumer products	Czech Republic	2010	Switch (EEE)	0.054	New	Becanova et al., 2016
Consumer	Czech	2001	Keyboard (EEE)	0.059	Used	Becanova et al.,

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country/Region	Year of sampling (n)	Type of product/material	Concentration mean $\mu\text{g}/\text{kg dw}$ (%>LOD)	Comment	Reference
products	Republic					2016
Consumer products	Czech Republic	1996	TV	0.115	Used	Becanova et al., 2016
Consumer products	Czech Republic	1991	Fridge rubber insulation (EEE)	0.09	Used	Becanova et al., 2016
Building materials	Czech Republic	1986	Chipboard (OSB and wood)	0.207	Used	Becanova et al., 2016
Building materials	Czech Republic	2010	Blow cellulose insulation	0.642	New	Becanova et al., 2016
Building materials	Czech Republic	2006	Mounting and sealing foam	0.662	New	Becanova et al., 2016
Building materials	Czech Republic	2010	Pipe insulation aeroflex	1.43	New	Becanova et al., 2016
Building materials	Czech Republic	2006	Paper insulation	0.372	Used	Becanova et al., 2016
Building materials	Czech Republic	2006	Plaster (facade material)	0.182	Used	Becanova et al., 2016
Building materials	Czech Republic	2010	Window finishing beard (facade material)	0.252	New	Becanova et al., 2016
Building materials	Czech Republic	2006	Window corner bead (facade material)	1.48	Used	Becanova et al., 2016
Building materials	Czech Republic	2006	Drywall (facade material)	24.5	Used	Becanova et al., 2016
Car interior material	Czech Republic	2006	Hyundai textile material	0.147	Used	Becanova et al., 2016
Car interior material	Czech Republic	2006	Hyundai textile material	0.479	Used	Becanova et al., 2016
Car interior material	Czech Republic	2006	Skoda-textil material	0.027	Used	Becanova et al., 2016
Consumer products	Germany	2010 (n=7)	Paper based FCM	0.6 (6)		Kotthoff et al., 2015
Consumer products	Germany	2010 (n=13)	Ski wax	9.3 (35)		Kotthoff et al., 2015

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Matrix	Country/Region	Year of sampling (n)	Type of product/material	Concentration mean $\mu\text{g}/\text{kg dw}$ (%>LOD)	Comment	Reference
Consumer products	Germany	2010 (n=13)	Leather	10.1 (96)		Kotthoff et al., 2015
Consumer products	Norway		Paint	0.53		Herzke et al., 2012
Consumer products	Norway		Paint	0.31		Herzke et al., 2012
Consumer products	Norway		Electrics and electronics	0.06		Herzke et al., 2012
Consumer products	Norway		Carpet (textile)	0.08 $\mu\text{g}/\text{m}^3$		Herzke et al., 2012
Consumer products	Norway		Lether	4.81 $\mu\text{g}/\text{m}^3$		Herzke et al., 2012
Consumer products	Norway		Non-stick wear pans	14.1		Herzke et al., 2012
Consumer products	Norway		Non-stick wear pans	11.9		Herzke et al., 2012
Consumer products	Norway		Non-stick wear pans	1.86		Herzke et al., 2012
Fire-fighting agents	Norway		AFFF	370,000		Herzke et al., 2012
Consumer products	Untied States	2014-15 (n=407)	Paper based FCM	56% of bread and dessert wrappers, 38% of sandwich and burger wrappers and 20% of paperboard contained fluorine (total fluorine) no fluorine was detected in paper cops. PFHxS was detected in 1 of 20 samples analysed with LC/MS/TOF		Schaider et al., 2017

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 46 (Copy of table 1.10 from additional data to POPs draft risk profile for PFHxS) Concentrations of PFHxS in human serum (See also ECHA 2017a, Annex II Table 14)

Location	Year	N	Human serum concentration (µg/L) median (rang, %LOQ) or geometric mean (GM)			Remarks	Reference
			PFHxS	PFOS	PFOA		
Afghanistan, Kabul	2007	43 adults 12 children	Max level 3.0 (22%)	1.2 (0.2–11.8) 100%	Max level 3.0 (24%)	PFOA and PFOS were not detected in tap water (LOQ µg/L: 0.03 PFOA, 0.015 PFOS) Adults (20–43 years old), Children (2.5–9 years old)	Hemat et al., 2010
Arctic Russia	2001	7	0.26 (0.15–0.46)	11.0 (5.56–14.11)	1.61 (0.63–2.48)	Noriisk, Taimyr AO Region of Russia, blood from mothers collected 3 days post-delivery. Noriisk participants mostly consumed store-bought foods (primarily non-local). There was some consumption of tundra reindeer, ptarmigan, and fish (mostly Salmonidae and Coregonidae species)	Hanssen et al., 2013
Australia	2002/02 2006/07 2008/09 2010/11	26 pools 84 pools 24 pools 24 pools	3.6 (2–12.8) 2.9 (<LOD–11.3) 3 (1.2–5.7) 3.3 (1.4–5.4)	25 (19.1–36.1) 14.8 (5–28.5) 11 (5.3–19.2) 9.4 (4.4–17.4)	10.6 (7–14.5) 6.4 (0.8–9.1) 5.1 (2.8–7.3) 4.3 (3.1–6.5)	Pools of human serum, all ages and both sex combined	Toms et al., 2014
Canada	2008–11	1940	GM 1.03 (<LOD–40)	GM 4.56 (<LOD–36)	GM 1.65 (<LOD–16)	Maternal-child cohort study in 10 sites across Canada	Fisher et al., 2016
Canada	2007–2009	1376	GM 3.2 *	GM 11.0*	GM 2.9*	Plasma concentrations of Canadian males, aged 20-79 years, Canadian Health Measures Survey Cycle 1	Health Canada, 2013
Canada	2009–2011	510	GM 2.4*	GM 8.3*	GM 2.6*	Plasma concentrations of Canadian males, aged 20-79 years, Canadian Health Measures Survey Cycle 2	Health Canada, 2013
Canada	2007–2009	1504	GM 1.6*	GM 7.1*	GM 2.2*	Plasma concentrations of Canadian females, aged 20-79 years, Canadian Health Measures Survey Cycle 1	Health Canada, 2013

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Year	N	Human serum concentration (µg/L) median (rang, %LOQ) or geometric mean (GM)			Remarks	Reference
			PFHxS	PFOS	PFOA		
Canada	2009–2011	505	GM 1.3*	GM; 5.7*	GM 2.0*	Plasma concentrations of Canadian females, aged 20-79 years, Canadian Health Measures Survey Cycle 2	Health Canada, 2013
China	2014	100	1.18 (0.61–2.42)	14.23 (0.24–1.04)	3.24 (1.83–5.61)	Maternal serum first trimester Wuhan, China, mean (5 th –95 th percentile)	Pan et al., 2017
China	2008–12	302	764 (<LOD to 19,837)	1725 (50.3–118000)	427 (2.5–32000)	Occupational exposure at a fluorochemical plant (Hexin Chemical Plant, Yingcheng, Hubei province). Serum levels of PFHxS and PFOA increased with length of service.	Fu et al., 2016
China Denmark Greenland Norway	2013–2015 (China) 1996–2002 (Denmark) 2008–2013 (Denmark) 2010–2013 (Greenland) 2007–2009 (Norway)	448 1594 1533 207 391	GM 0.58 (0.55;0.61) GM 1.06 (1.03;1.09) GM 0.44 (0.43;0.45) GM 0.79 (0.73;0.84) GM 0.47 (0.45;0.50)	GM 8.0(7.6;8.3) GM 28.3(27.7;29.0) GM 7.7 (7.5;7.9) GM 10.9 (10.3;11.7) GM 8.0(7.7;8.4)	GM 10.7(10.2;11.1) GM 4.3(4.2;4.4) GM 1.8(1.8;1.9) GM 1.3(1.2;1.4) GM 1.6(1.6;1.7)	Blood sample were taken at gestagenal week 15, 9.7, 12.3, 25.1 and 18.6 weeks in the respective birth cohort from China (Shanghai Birth Cohort), Denmark, (Danish National Birth Cohort and Aarhus Birth Cohort), Greenlandic Birth Cohort and Northern-Norway Mother Child Contaminant Cohort. Log-transformed PFAA concentrations were adjusted for age and parity using analysis of covariance.	Bjerregaard-Olesen et al., 2017
Faroe Island	2006 2011-12, 2007-2008	10 51 51	M 2.38 (0.53-3.71) C 5.94 (3.59–14.3) F (0.5 (0.15–1.35)	M 47.8 (12.66-76.04) C 9.82 (4.40–15.0) F 5.59 (1.82–13.8)	M 3.46 (2.79-5.36) C 0.73 (0.34–1.97) F 1.0 (0.35–3.1)	Male age 47–80 (whaling men) Children age 13 Female age 19–44	Hu et al., 2018
Germany	ESB, 1982-2009	420	0.079–5.10	0.417–116.0	0.092–39.4	Participants (age 20-29 year), mostly students from two German cities, i.e. Münster and Halle. In this study, also PFSA and PFCA precursors (DiPAPs and SamPAPs) were detected in human plasma. PFOS peaked between 1985 and 1990, PFHxS peaked between 2000 and 2005	Yeung et al., 2013

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Year	N	Human serum concentration (µg/L) median (rang, %LOQ) or geometric mean (GM)			Remarks	Reference
			PFHxS	PFOS	PFOA		
Greenland	2010-2013	207	0.70	10.15	1.19	<p>Pregnant Inuit women (18-44 years), blood sampled at gestational week 25.1 (range 7-40 week)</p> <p>In the North region, the levels of PFASs in the blood were associated with both Se and Hg.</p> <p>These data indicate that the pregnant women's burden of PCBs, OCPs, PFASs, Pb and Hg is mainly derived from intake of the traditional food including marine mammals, seabirds, fish and terrestrial species.</p>	Long et al., 2015
Greenland	2002/03	196	2.01 (0.091-20.5)	44.7 (12.3-161)	4.54 (1.52-13.7)	Male Inuit, seafood 2 days/week	Lindh et al., 2012
India, Coimbatore	2000	45	Female 1.6 (<1-1.8, 36%) Male 1.5 (<1-2.9, 41%)	Female 2.5 (<1-3, 55%) Male 1.3 (<1-3.1, 50%)	Female <3.5 (<3, 0%) Male 3.5 (<3-3.5, 3%)	Agricultural and industrial area	Kannan et al., 2004
Italy	2016	250 257 43	2.49 (0.03-9.14) ^a 2.98 (0.09-43.40) ^b 9.16 (2.74-32.30) ^c	5.84 (0.56-119) ^a	1.64 (27.9) ^a	<p>^a not exposed ^b exposed ^c exposed (Lonigo)</p> <p>drinking water exposure, area with fluorochemical plant</p>	Annex E Council of Chemists of the Province of Treviso, Italy

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Year	N	Human serum concentration ($\mu\text{g/L}$) median (rang, %LOQ) or geometric mean (GM)			Remarks	Reference
			PFHxS	PFOS	PFOA		
Japan	2013 2014 2015 2016	83 81 76 88	0.54 (n.d.-1.8) 0.42 (n.d.-1.1) 0.22 (n.d.-0.8) 0.32 (0.071-0.76)	-	-	Select three areas in each year, (40-59 years old and long-time resident) in each survey area	Japan Annex E, Survey of the Exposure to chemical compounds in human (FY 2013 to FY 2016). The Environmental Risk Assessment Office, Environmental Health Department, Ministry of the Environment, Japan has conducted this survey and are open on website below: http://www.env.go.jp/chemi/dioxin/pamph/cd/2017en_full.pdf
Norway	2007-8	123	0.34 (0.04-1.64)	5.37 (1.63-17.7)	1.03 (0.36-4.24)		Gützkow et al., 2012
Norway	2007-9	391	0.44 (<LOD-14.8, 99%)	8.03 (0.3-35.8, 100%)	1.53 (0.28-11, 100%)	Women who completed The Northern Norway Mother-and-Child Contaminant Cohort Study (MISA). Blood samples donated at mean gestational week 18.6 (9-36)	Berg et al., 2014

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Year	N	Human serum concentration (µg/L) median (rang, %LOQ) or geometric mean (GM)			Remarks	Reference
			PFHxS	PFOS	PFOA		
Norway	2010-11	950	0.71 (0.18-84.7, 100%)	6.20 (1.28-99.2, 100%)	1.92 (0.51-14.0, 100%)	445 girls age 16.5 495 boys, age 16.3 Boys had significant higher sum PFOS and sum PFHxS. PFHxS levels were higher in the group that had fat fish >1x week, 1-6 glasses of sugar drinks and canned food 4-6 times per week	Averina et al., 2018
Poland	2002/03	190	1.18 (0.43-3.78)	18.5 (8.20 - 40.2)	4.84 (1.48-16.0)	Male, seafood 1 day/week	Lindh et al., 2012
Sweden, Ronneby	2014-2016	106	277 (12.3-1660)	345 (24.1-1500)	17.5 (2.38-92)	Participants age 4-84 years, 53% females, receiving PFAS contaminated drinking water	Li et al., 2018
Sweden, Ronneby	2014-2016	3418	152 (<0.5-1790)	176 (<0.50- 1870)	10.4 (<0.4-91.9)	Drinking water exposure until 2013, (AFFF training area and military facility located nearby the municipal water source). Levels (ng/L) in outgoing water from waterworks in Ronneby: 1770 PFHxS, 8000 PFOS, 100 PFOA. Highest serum levels in persons that had live 35 years in this area.	Li et al., 2018
Sweden, Karlsham n	2016	242	0.84 (<0.5- 60.1)	4.21 (<0.5- 55.3)	1.59 (<0.4-4.98)	Reference site nearby Ronneby with PFAS clean water source	Li et al., 2018
Ukraine	2002/2003	203	0.34 (<LOD- 3.42)	7.60 (2.77 - 29.9)	1.29 (<LOD- 35.0)	Male, seafood 2 days/week	Lindh et al., 2012
United States	2015	37	GM 3.12 (1.07- 12.55)	GM 4.96 (0.39- 31.35)	GM 1.57 (0.30- 4.07)	Age 22-34 years, Serum PFHxS levels were also elevated in individuals that vacuumed less often, and in individuals that reported consuming more microwavable foods.	Sibenaler et al., 2017
United States	NHANES 2013- 2014	639	0.84 (0.76-0.94)	2.51 (2.03-2.74)	1.81 (1.64-2.01)	Children age 3-11	Jane, 2018
United States	2009	31	GM 1.5 (0.2-13)			In blood serum of some office workers in Boston, exposed to FTOHs	Fraser et al., (2012)

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Year	N	Human serum concentration (µg/L) median (rang, %LOQ) or geometric mean (GM)			Remarks	Reference
			PFHxS	PFOS	PFOA		
United States	2000	654	2.25	34.9	2.70	Red Cross adult blood donors (total, both men and women) Percentage decline from 2000-2001 to 2010 PFHxS (40%), PFOS (76%), PFOA (48%).	Olsen et al., (2012)
	2006	600	1.52	14.5	3.44		
	2010	600	1.34	8.3	2.44		
United States	NHANES 1999–2000 and 2003–2004	2094	GM 2.1 GM 1.9 (0.7–8.3)	GM 30.4 GM 20.7 (9.8–54.6)	GM 5.2 GM 3.9 (1.9–9.8)	All groups together GM (10th and 95th percentile)	Calafat et al., 2007
United States	NHANES 1999–2006	1032	2.0 ± 0.1	4.3 ± 0.2	23.7 ± 0.7	60 years old participants	Fry et al., 2017
Uzbekistan	2002	10	n.d.	0.23 (<0.08–0.89)	n.d.	Urgench, and Khazarasp cities, Uzbekistan, blood from mothers collected 3 days post-delivery. Uzbekistan women featured a variety of items produced locally (e.g., meat, poultry, fish, cereal, fruits, and vegetables)	Hanssen et al., 2013

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 47 (Copy of table 1.11 from additional data to POPs draft risk profile for PFHxS) Levels in cord blood (See also ECHA 2017a, annex II, Table 14)

Location	Year	Cord blood concentration ng/mL Median, (range), % detection (LOD)			Remarks	Reference
		PFHxS	PFOS	PFOA		
Arctic Russia	2001	0.14 (0.08-0.33)	0.49 (0.15-1.12)	4.11 (1.75-6.27)	n=7, Norilsk, Taimyr AO Region of Russia.	Hanssen et al., 2013
Canada, Ottawa	2005-2008	0.5 (n.d.-9.6) 77%	5.0 (n.d.-21.7) 98%	1.6 (0.3-5.2) 100%	N=100	Arbuckle et al., 2013
Canada	2008-2011	<LOD (0.3) Min=n.d. max=1.9 (22.89% above LOD)	<LOD (0.3) Min=n.d. Max=5.8 (63.58% above LOD)	0.35 (GM) Min=n.d. Max=5.6 (47.73% above LOD)	n=1385	Fisher et al., 2016
China, Guangzhou	2013	3.87 (n.d.-20.15) 97.2%	2.99 (n.d.-744.2) 97.51%	1.23 (n.d.-229.36) 96.88%	n=321	Zhang et al., 2017
China, Wuhan	2014	0.46 (0.24-1.04)* 100%	4.38 (1.66-12.54)* 100%	1.41 (0.8-2.63)* 100%	n=100 *(5 th -95 th percentile) See also maternal serums	Pan et al., 2017
Norway	2007-8	0.23 (0.04-1.12)	1.78 (0.04-6.49)	1.03 (0.04-3.23)	n=123	Gützkow et al., 2012

*plasma

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 48 (Copy of table 1.12. from additional data to POPs draft risk profile for PFHxS) Levels in Breast milk (See also ECHA 2017a, annex II, Table 14)

Location	Year	Breast milk concentration ng/ml Median, (range), % detection (LOD)			Remarks	Reference
		PFHxS	PFOS	PFOA		
Cambodia	2000	nd (<0.002-0.019) 13%	0.039 (0.017-0.327) 100%	n.d. (<0.043-0.131) 4%	n=24	Tao et al., 2008b
China	2004	0.004-0.1	0.045-0.36	0.047-210	Range, n=19, all above LOD	So et al., 2006 (Annex E China)
China		0.012-2.52	0.0446-83.1	<0.05-2.19	5 samples from 5 different citys	Yeung et al., 2006
France	2007	0.050 (0.040-0.066) 100%	0.079 (<0.05-0.330) 90%	0.075 (<0.05-0.224) 98%	median, (range), Number >LOD n=48	Antignac et al., 2013
Germany	2007-2009	n.d., (<0.02-0.3) 3%	0.04 (<0.3-0.11) 72%	n.d., (<0.15-0.25) 2%	No. >LOQ n=44 participants (1 samples each month)	Fromme et al., 2010
Indonesia	2001	0.013 (<0.002-0.059) 100%	0.067 (0.025-0.256) 45%	n.d. 0%	n=20	Tao et al., 2008b
Japan	1999	0.006 (<0.002-0.018) 92%	0.196 (0.140-0.523) 100%	0.067 (<0.043-0.170) 92%	n=24	Tao et al., 2008b
Malaysia	2003	0.007 (<0.002-0.013) 85%	0.121 (0.048-0.350) 100%	n.d. (<0.042-0.090) 23%	n=13	Tao et al., 2008b
Philippines	2000/2004	0.007 (<0.002-0.013) 92%	0.104 (0.027-0.208) 100%	n.d (<0.043-0.183) 29%	n=24	Tao et al., 2008b
Republic of Korea	1999-2005	0.007 (0.001-0.016)	0.061 (0.032-0.130)	0.041 (<0.043-0.077)	n=17	Kim et al., 2011
Spain	2007-2008	0.040 (0.02-0.11) 100%	0.11 (<0.05-0.22) 100%	n.d. 0%	n=10	Karrman et al., 2010
Sweden	1972 1976 1980 1984/1985 1988 1990 1992 1994 1995 1996	<0.005 <0.005 0.006 0.006 0.016 0.010 0.011 0.015 0.028 0.016	0.023 0.059 0.103 0.172 0.211 0.202 0.222 0.219 0.214 0.224	0.019 0.041 0.060 0.078 0.148 0.106 0.111 0.106 0.139 0.111	n=75 n=78 n=116 n=102 n=20 n=20 n=20 n=20 n=20 n=20	Sundstrøm et al., 2011

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Location	Year	Breast milk concentration ng/ml Median, (range), % detection (LOD)			Remarks	Reference
		PFHxS	PFOS	PFOA		
	1997	0.016	0.237	0.138	n=20	
	1998	0.028	0.212	0.128	n=20	
	1999	0.023	0.234	0.120	n=20	
	2000	0.024	0.213	0.124	n=20	
	2001	0.017	0.198	0.098	n=20	
	2002	0.027	0.210	0.118	n=20	
	2003	0.025	0.179	0.098	n=15	
	2004	0.017	0.188	0.100	n=20	
	2007	0.017	0.122	0.086	n=20	
	2008	0.014	0.075	0.074	n=18	
Sweden	2004	0.070 (0.031-0.172) 100%	0.166 (0.060-0.470) 100%	Not available (<0.209-0.492)	Median, (range), Number >LOD n=12 primiparous women	Karrman et al., 2007
Sweden Uppsala Uppsala Uppsala Uppsala Göteborg Uppsala Lund Lycksele	1996 1997 1998 1999 2000 2001 2002 2003 2003-2004	0.037 0.030 0.040 0.044 0.028 0.028 0.051 0.025 0.016	0.209 0.207 0.219 0.213 0.191 0.258 0.194 0.153 0.123	<0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a <0.209 ^a	^a Levels were >LOD (0.01) but the blank level (0.209) was >50% of the detected concentrations.	Karrman et al., 2007
United States	2004	0.012 (<0.030-0.161) 51%	0.106 (<0.032-0.617) 95%	0.044 (<0.031-0.161) 88%	n=45	Tao et al., 2008a
Vietnam	2000/2001	0.004 (<0.002-0.027) 73%	0.058 (0.017-0.393) 100%	n.d (<0.043-0.089) 3%	median, (range), Number >LOD n=40	Tao et al., 2008b

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 49 (Copy of Table 3 from additional data to POPs draft risk profile for PFHxS) Comparison of half-lives of PFAS in male and females in a variety of species including human

PFAS		Human (year)				Rat (days)	Mice (days)	Pig (days)	Monkey (days)
PFHxS	M	8.5 (3109 days) Range 2.2-27.0	7.4 (95% CI: 6.0, 9.7)	35	GM 19.9	29.1	31	713	141
	F	12.2 13.3	4.7 (95% CI: 3.9,5.9)	7.7	GM 7.5	1.64	25	713	87
PFOS	M	5.4 (1976 days) Range 2.4-21.7	4.6 (95% CI: 3.7,6.1)	27	GM 60.9	38	43	634	132
	F	4.9 6.8	3.1 (95% CI: 2.7,3.7))	6.2	GM 8.0	62	38	634	110
PFOA	M	3.8 (1378 days) Range 1.5-9.1	2.8 (95% CI: 2.4,3.4)	2.1	GM 4.7	5.6	22	236	21
	F	3.3 3.3	2.4 (95% CI: 2.0,3.0)	2.6	GM 3.1	0.08	16	236	32
References		Olsen et al., 2007 ^a	Li et al., 2018 ^b	Zhang et al., 2013 ^c	Fu et al., 2016 ^d	Sundström et al., 2012 ^e	Sundström et al., 2012 ^e	Numata et al., 2014 ^f	Sundström et al., 2012 ^e

a: Half-life in 26 (24 males and 2 females) fluorplant workers, blood sampled for 5 successive years after retirement (individual half-life given for the two women).

b: Drinking water exposure, up to seven blood samples collected between 2014 to 2016 from 106 individuals.

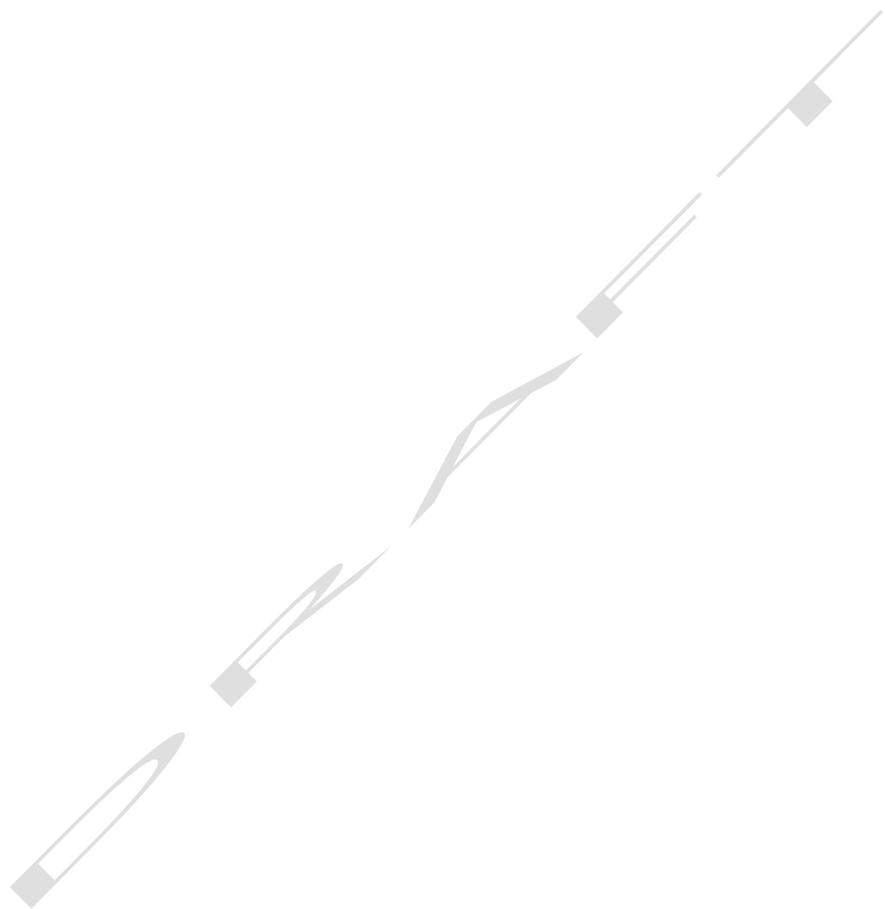
c: Half-life estimated based on paired urine-blood samples and urine as only elimination way from 86 individuals.

d: Half-life in fluorplant workers (n=302) estimated by daily clearance rate by paired blood-urine samples and annual decline in serum levels over 5 years.

e: Clearance profile of PFHxS after a single oral dose; Rats (n=4/sex/group) within 96 h after exposure for 1, 10, or 100mg K+PFHxS/kg body weight. CD-1 mice were sampled at designated times (2, 4, and 8 h post-dose and days 1, 8, 15, 22, 36, 50, 64, and 162 post-dose (n=4/sex/dose group) after exposure to 1 or 20mg K+PFHxS/kg body weight. For rat and mice, blood, liver, kidney, 24h-urine and feces were sampled. Three male and three female cynomolgus monkeys were given intravenous dose of 10 mg/kg PFHxS. Urine was collected up to day 119, and blood sampled at regular intervals up to day 171 post-dose.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

f: Fattening pigs, 10 gilts (female), 10 barrows (castrated male pigs) and 10 prepubescent male pigs) for 21 days they received either PFAA contaminated feed (hay and barley grown on agricultural land added soil improver contaminated with high concentrations with PFAS (PFHxS concentration was 91.3 µg/kg, each animal received 2 kg/feed per day), blood were sampled at day -4 and days 4, 8, 11, 15, and 18 and at slaughter day 21, muscle, fat, liver, kidney, urine, and feces were sampled.



Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Table 50: Effluent concentrations of PFHxS in WWTP

Source	Effluent concentrations of PFHxS in WWTP (ng/L)
Ahrens et al. 2009	21
	0.6
	1.4
	1.4
	0.8
	1
	6.3
	0.3
	1.2
	0
JRC 2012	4.5
	2.4
	2.6
	8.8
	4.7
	180.2
	0
	0
	0
	0
	0
	16.5
	2.7
	921.9
	459.4
	332
	0
	0
	868.5
	15.9
	13.3
	0
	206.7
	0
	0
	1.2
	0
	0
	30.9
	4.2
	137.6
	3
	0
	31.6
	3.6
	2.4
	0
	19.7
	10.9
	7.2
	0
	2.7
	6.3
	0
	5.3
	8.9
	7.8
3.7	
9.1	
14.2	
16.2	
0	
7.5	
2.5	
8.1	
0	
0	
0	
3	
4.9	
18.1	

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Source	Effluent concentrations of PFHxS in WWTP (ng/L)
	0
	0
	0
	34.6
	770.1
	36.3
	21.1
	3.2
	10.5
	1
	21
	8.2
	6.6
	0
	1.2
	2.2
	1.6
	7.4
	0
	2.5
	1.3
	10.1
	2
	3.2
	0.9
	10.1
	4.1
	4.2
Nordic screening report	0.32
	0.38
	1.13
	0.64
	0.1
	2.24
	0.54
	0.57
	0.1
	1.22
	2.28
	4.22
	0.24
Eriksson et al. 2017	1.5
Huset et al. 2008	3
	2.8
	53
	88
	11
	9
	19
Filipovic et al. 2015	4.07
	0.285
	1.52
Stasinakis et al. 2013	1.5

References

3M, 2000. *Letter to Charles Auer. Re: Phase-out Plan for POSF-Based Products. US. s.l.:s.n.*

3M, M. M. a. M. C., 1981. *Mist Suppressant. USA, Patentnr. GB 2077765.*

Aas, C. et al., 2014. Effect of body condition on tissue distribution of perfluoroalkyl substances (PFASs) in Arctic fox (*Vulpes lagopus*). *Environmental Science and Technology*, pp. 48(19):11654-61. Erratum in: *Environ Sci Technol.* 48(22):13558..

Ahrens, L., 2010. Polyfluoroalkyl compounds in the aquatic environment: a review of their occurrence and fate. *Journal of Environmental Monitoring*, 23 September, pp. 20-31.

Ahrens, L. et al., 2009b. Polyfluorinated compounds in waste water treatment plant effluents and surface waters along the River Elbe, Germany. *Mar. Pollut. Bull.*, pp. 1326-1333.

Ahrens, L., Norstrøm, K., Cousins, A. P. & Joseffon, S., 2014. Stockholm Arlanda Airport as a source of per- and polyfluoroalkyl substances to water, sediments and fish. *Chemosphere*, 10 May.

Ahrens, L. et al., 2015. Stockholm Arlanda Airport as a source of per- and polyfluoroalkyl substances to water, sediment and fish. *Chemosphere*, pp. 33-38.

Ahrens, L., Siebert, U. & Ebinghaus, R., 2009. Total body burden and tissue distribution of polyfluorinated compounds. *Marine Pollution Bulletin*, pp. 520-525.

Ahrens, L., Siebert, U. & Ebinghaus, R., 2009. Total body burden and tissue distribution of polyfluorinated compounds. *Marine Pollution Bulletin*, pp. 520-525.

Andersen, M. E. et al., 2008. Perfluoroalkyl Acids and Related Chemistries—Toxicokinetics and Modes of Action. *Toxicological Sciences*, pp. 102(1), 3-14.

Angus Fire, 2018. *Respondol ATF 3/3 Safety Data Sheet, s.l.: s.n.*

Angus Fire, 2018. *Respondol ATF 3/3 Safety Data Sheet.* [Internett]
Available at: <http://angusfire.co.uk/wp-content/uploads/Respondol-ATF-33.pdf>
[Funnet 8 November 2018].

Anon., u.d. *Made in China.com.* [Internett]
Available at: <https://worldyachem.en.made-in-china.com/product/OvqmATeKnbkR/China-Perfluorohexane-Sulphonyl-Fluoride-CAS-No-423-50-7.html>
[Funnet 17 January 2019].

Anon., u.d. *UN COMTRADE.* [Internett]
Available at: <https://comtrade.un.org/data/>

Archroma, 2014. *Arkophob FFR liq Safety Data Sheet.* [Internett]
Available at: https://www.subsport.eu/wp-content/uploads/2015/03/Case-408_MSDS-fluorine-free-alternative-textile-finish.pdf
[Funnet 25 January 2019].

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Armitage, J. M. et al., 2009. Modeling the global fate and transport of perfluorooctane sulfonate (PFOS) and precursor compounds in relation to temporal trends in wildlife exposure. *Environmental Science and Technology*, pp. 43(24), 9274-9280.

Arvaniti, O. S. & Stasinakis, A. S., 2015. Review on the occurrence, fate and removal of perfluorinated compounds during wastewater treatment. *Sci. Tot. Environ.*, pp. 81-92.

ATSDR, 2018. *Toxicological profile for Perfluoroalkyls (Draft for Public Comment)*., Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.: Agency for Toxic Substances and Disease Registry.

Augusto, S., Máguas, C. & Branquinho, C., 2013. Guidelines for biomonitoring persistent organic pollutants (POPs), using lichens and aquatic mosses--a review.. *Environmental Pollution*, pp. 180; 330-8. Review..

Australian Government, 2015. *National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2015): Environment Tier II Assessment for Direct Precursors to Perfluoroheptanesulfonate (PFHpS), Perfluorohexanesulfonate (PFHxS) and Perfluoropentanesulfonate (PFPeS)*, s.l.: s.n.

Averina, M., Brox, J., Huber, S. & Furberg, A.-S., 2018. Perfluoroalkyl substances in adolescents in northern Norway: Lifestyle and dietary predictors. The Tromsø study, Fit Futures 1. *Environment International*, pp. 123-130.

Backe, W. J., Day, T. C. & Field, J. A., 2013. Zwitterionic, Cationic, and Anionic Fluorinated Chemicals in Aqueous Film Forming Foam Formulations and Groundwater from U.S. Military Bases by Nonaqueous Large-Volume Injection HPLC-MS/MS. *Environmental Science and Technology*, 47, pp. 5226-5234.

Baduel, C., Mueller, J. F., Rotander, A. & Coughland, J., 2017. Discovery of novel per- and polyfluoroalkyl substances (PFASs) at a fire fighting training ground and preliminary investigation of their fate and mobility. *Chemosphere*, 20 June, pp. 1030-1038.

Banzhaf, S. et al., 2017. A review of contamination of surface-, ground-, and drinking water in Sweden by perfluoroalkyl and polyfluoroalkyl substances (PFASs). *Ambio*, pp. 335-346.

Barnes, I., Hjorth, J. & Mihalopoulos, N., 2006. Dimethyl Sulfide and Dimethyl Sulfoxide and Their Oxidation in the Atmosphere. *Chemical Reviews*, pp. 940-975.

Barzen-Hanson, K. A. et al., 2017. Discovery of 40 Classes of Per-and Polyfluoroalkyl Substances in Historical Aqueous Film-Forming Foams (AFFFs) and AFFF-Impacted Groundwater. *Environmental Science and Technology*, 18 January, p. 2047–2057.

BAuA, 2017. *Proposal for a Restriction on C9-C14 PFCAs -including their salts and precursors-*, Germany: Federal Institute for Occupational Safety and Health Division 5 - Federal Office for Chemicals.

Becker, A., Gerstmann, S. & Frank, H., 2008. Perfluorooctane surfactants in waste waters, the major source of river pollution. *Chemosphere*, pp. 115-121.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Beesoon, S., Genius, S. J., Benskin, J. P. & Martin, J. W., 2012. Exceptionally High Serum Concentrations of Perfluorohexanesulfonate in a Canadian Family are Linked to Home Carpet Treatment Applications. *Environmental Science and Technology*, pp. 46(23), 12960-12967.

Benskin, J. P., Muir, D. C., Scott, B. F. & Yamashita, N., 2012. Perfluoroalkyl Acids in the Atlantic and Canadian Arctic Oceans. *Environmental Science & Technology*, MAY, pp. 5815-5823.

Berg, V. et al., 2014. Maternal serum concentrations of per- and polyfluoroalkyl substances and their predictors in years with reduced production and use. *Environment International*, pp. 58-66.

BiPRO, 2018. *Investigation of sources to PFHxS in the environment.*, s.l.: s.n.

Bjeremo, H. et al., 2013. Serum concentrations of perfluorinated alkyl acids and their associations with diet and personal characteristics among Swedish adults. *Mol Nutr Food Res*, pp. 2206-2215.

Bjerregaard-Olesen, C. et al., 2017. Maternal serum concentrations of perfluoroalkyl acids in five international birth cohorts. *International Journal of Hygiene and Environmental Health*, Issue 2, Part A, pp. 86-93.

Blytt, L. D., Bruskeland, A. B. & Stang, P., 2013. *Organiske miljøgifter i norsk avløps slam*, Hamar: Norsk Vann Rapport.

Bohlin-Nizzetto, P., Aas, W. & Warner, N., 2017. Monitoring of environmental contaminants in air and precipitation. *NILU report, M-575/2017*, NILU report 17/2017.

Bohlin-Nizzetto, P., Aas, W. & Warner, N., 2017. *Monitoring of environmental contaminants in air and precipitation. Report M-757/2017*, Trondheim: Norwegian Environment Agency.

Boiteux, V., Dauchy, X., Rosin, C. & Munoz, J.-F., 2012. National Screening Study on 10 Perfluorinated Compounds in Raw and Treated Tap Water in France. *Archives of Environmental Contamination and Toxicology*, July, pp. 1-12.

Bossi, R., Strand, J., Sortkjær, O. & Larsen, M., 2008. Perfluoroalkyl compounds in Danish wastewater treatment plants and aquatic environments. *Environment International*, May.

Boucher, J. M. et al., 2019. Toward a Comprehensive Global Emission Inventory of C4–C10 Perfluoroalkanesulfonic Acids (PFSA) and Related Precursors: Focus on the Life Cycle of C6- and C10-Based Products. *Environmental Science & Technology Letters*, Issue 1, pp. 1-7 .

Boulanger, B., Vargo, J., Schnoor, J. & Hornbuckle, K., 2005. Evaluation of perfluorooctane surfactants in a wastewater treatment system and in a commercial surface protection product. *Environ Sci Technol*, pp. 5524-5530.

Bourgeon, S. et al., 2017. Potentiation of ecological factors on the disruption of thyroid hormones by organo-halogenated contaminants in female polar bears (*Ursus maritimus*) from the Barents Sea. *Environmental Research*, pp. 158:94-104.

Brantsæter, A. et al., 2013. Determinants of plasma concentrations of perfluoroalkyl substances in pregnant Norwegian women. *Environ Int*, pp. 74-84.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Braunig, J., Baduel, C., Barnes, C. M. & Mueller, J. F., 2019. Leaching and bioavailability of selected perfluoroalkyl acids (PFAAs) from soil contaminated by firefighting activities. *Science of the Total Environment*, 646, pp. 471-479.

Brooks, S., Pampanin, D., Harman, C. & Dunaevskava, E., 2013. *The Water Column Monitoring Programme 2013: Determining the biological effects of two offshore platforms on local fish populations*, s.l.: Norwegian Institute for Water Research.

Bräunig, J. et al., 2017. Fate and redistribution of perfluoroalkyl acids through AFFF-impacted groundwater. *Science of the Total Environment*, 12 April, pp. 360-368.

Buck et al, 2011. Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. *Integr Environ Assess Manag* 7 (4), 513 - 541. DOI: 10.1002/ieam.25.

Busch, J., Ahrens, L., Sturm, R. & Ebinghaus, R., 2010b. Polyfluoroalkyl compounds in landfill leachates. *Environ. Pollut.*, pp. 1467-1471.

Busch, J. et al., 2010. Polyfluoroalkyl compounds in the East Greenland Arctic Ocean. *J Environmental Monitoring*, pp. 12(6):1242-6..

Butt, C., Berger, U., Bossi, R. & Tomy, G., 2010. Levels and trends of poly- and perfluorinated compounds in the arctic environment. *Science of the Total Environment*, pp. 408(15):2936-65. Review.

Bytingsvik, J. et al., 2012. Perfluoroalkyl substances in polar bear mother-cub pairs: a comparative study based on plasma levels from 1998 and 2008. *Environment International*, pp. 15;49:92-9.

Campo, J., Lorenzo, M., Perez, F. & Barcelo, D., 2016. Analysis of the presence of perfluoroalkyl substances in water, sediment and biota of the Jucar River (E Spain). Sources, partitioning and relationship with water physical characteristics. *Environmental Research*, pp. 503-512.

Casal, P. et al., 2017. Role of Snow Deposition of Perfluoroalkylated Substances at Coastal Livingston Island (Maritime Antarctica). *Environmental Science & Technology*, 30 June, pp. 8460-8470.

Chemical Watch, 2018b. US legislation to allow PFAS alternatives in airport firefighting foams.

Chemicalwatch, 2018. Checks on EU Pic compliance lead to prosecutions. *Chemicalwatch*, 19 Decemper 2018.

Chemicalwatch, 2018. Checks on EU Pic compliance lead to prosecutions. *Chemicalwatch*, 19 Decemper 2018.

Chemicalwatch, 2018. Checks on EU PIC compliance lead to prosecutions. *Chemicalwatch*, 19 Decemper 2018.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

ChemIndex, 2018. *ChemIndex*. [Internett]
Available at: www.chemindex.com/355-46-4-cas.html
[Funnet 11 09 2018].

Codling, G. et al., 2014. The fate of per- and polyfluoroalkyl substances within a melting snowpack of a boreal forest.. *Environmental Pollution*, pp. 191:190-8.

COM, 2010. *Commission Regulation (EU) No 757/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III*. s.l.:s.n.

Conder, J. M. et al., 2008. Are PFCAs bioaccumulative? A critical review and comparison with regulatory criteria and persistent lipophilic compounds. *Environmental Science and Technology*, pp. 42(4), 995-1003.

Council of Chemists of the Province of Treviso , 2017. *Annex to the form for submission of information specified in Annex E to the Stockholm Convention pursuant to Article 8 of the Stockholm Convention filed by:*, s.l.: UNEP.

Council of Chemists of the Province of Treviso, 2017. *Annex to the form for submission of information specified in Annex E to the Stockholm Convention pursuant to Article 8 of the Stockholm Convention filed by:*, s.l.: UNEP.

COWI AS, 2017. *Årsrapport 2017, Gjennomført overvåking for Solberg Scandinavian AS*, s.l.: s.n.

Cui, Q., Pan, Y., Zhang, H. & Sheng, N., 2018. Elevated concentrations of perfluorohexanesulfonate and other per- and polyfluoroalkyl substances in Baiyangdian Lake (China): Source characterization and exposure assessment*. *Environmental Pollution*, Issue 241.

D'Agostino , L. & Mabury, S., 2017. Certain Perfluoroalkyl and Polyfluoroalkyl Substances Associated with Aqueous Film Forming Foam Are Widespread in Canadian Surface Waters. *Environ Sci Technol*, pp. 13603-13613.

Dainippon Ink and Chemicals, I. J., 1979. *Prevention of mist formation over plating baths*. Japan, Patentnr. JP54076443.

Dainippon Ink and Chemicals, I. J., 1988. *N-(dihydroxypropyl) perfluoroalkanecarbonamide and -sulfonamide derivatives as antifogging agents*. Japan, Patentnr. JP63208561..

Danish EPA, 2015. *Alternatives to perfluoroalkyl and polyfluoroalkyl substances (PFAS) in textiles*. [Internett]
Available at: <https://www2.mst.dk/Udgiv/publications/2015/05/978-87-93352-16-2.pdf>
[Funnet 19 December 2018].

Danish EPA, 2015. *Short-chain Polyfluoroalkyl Substances (PFAS)*, s.l.: s.n.

Danish_(Q)SAR_Database, 2018. *Danish (Q)SAR Database*. [Internett]
Available at: [Danish \(Q\)SAR Database](#)
[Funnet 11 09 2018].

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Dauchy, X. et al., 2019. Deep seepage of per- and polyfluoroalkyl substances through the soil of a firefighter training site and subsequent groundwater contamination. *Chemosphere*, pp. 729-737.

Del Vento, S. et al., 2012. Volatile per- and polyfluoroalkyl compounds in the remote atmosphere of the western Antarctic Peninsula: an indirect source of perfluoroalkyl acids to Antarctic waters?. *Atm. Poll. Res.*, pp. 3(4): 450-455.

D'Eon, J., Hurley, M., Wallington, T. & Mabury, S., 2006. Atmospheric chemistry of N-methyl perfluorobutane sulfonamidoethanol, C₄F₉SO₂N(CH₃)CH₂CH₂OH: kinetics and mechanism of reaction with OH. *Environ Sci Technol*, pp. 1862-1868.

D'Eon, J., Hurley, M., Wallington, T. & Mabury, S., 2006. Atmospheric chemistry of N-methyl perfluorobutane sulfonamidoethanol, C₄F₉SO₂N(CH₃)CH₂CH₂OH: kinetics and mechanism of reaction with OH. *Environmental Science and Technology*, pp. 40(6):1862-8.

D'Hollander, W. et al., 2010. Brominated flame retardants and perfluorinated compounds in indoor dust from homes and offices in Flanders, Belgium. *Chemosphere*, pp. 478-487.

Dietz, R., Riget, F. & Galatius, A., 2012. Spatial trends of perfluorochemicals in harbor seals (*Phoca vitulina*) from. *Science of the Total Environment*, pp. 732-737.

DNV GL, 2016. *Miljøforhold i sjøbunnen ved Njord A*, s.l.: DNV.

Dreyer, A., Weinberg, I., Temme, C. & Ebinghaus, R., 2009. Polyfluorinated compounds in the atmosphere of the Atlantic and Southern Oceans: evidence for a global distribution. *Environmental Science and Technology*, pp. 43(17):6507-14..

ECHA, 2012. *Agreement of the Member State Committee on the identification of Bis(pentabromophenyl)ether [Decabromodiphenyl ether] as a Substance of Very High Concern According to Articles 57 and 59 of Regulation (EC) 1907/2006. Adopted on 29 November 2012*, s.l.: s.n.

ECHA, 2012. *Guidance on information requirements and chemical safety assessment Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage*, s.l.: s.n.

ECHA, 2014. *Annex XV Proposal for a Restriction- Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances*, s.l.: s.n.

ECHA, 2014b. *Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC*, s.l.: s.n.

ECHA, 2015. Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals. *Document agreed at RAC-34 and SEAC-28*, 11 September.

ECHA, 2015. *Support document for the identification of PFNA as a substance of very high concern*, s.l.: s.n.

ECHA, 2016d. *Forum Guide on Enforcement for Dossier Submitters*, s.l.: s.n.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

ECHA, 2016. *Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC*, Helsinki: s.n.

ECHA, 2017a. Agreement of the Member States Committee on the identification of Perfluorohexane-1-Sulphonic acid and its salts as Substances of Very High Concern According to Articles 57 and 59 of Regulation (EC) 1907/2007. 15 June.

ECHA, 2017a. *SVHC SUPPORT DOCUMENT FOR IDENTIFICATION OF PERFLUOROHEXANE-1-SULPHONIC ACID AND ITS SALTS AS SUBSTANCES OF VERY HIGH CONCERN BECAUSE OF THEIR VPVB (ARTICLE 57 E) PROPERTIES*, s.l.: s.n.

ECHA, 2017b. Agreement of the Member States Committee on the identification of Perfluorohexane-1-Sulphonic acid and its salts as Substances of Very High Concern According to Articles 57 and 59 of Regulation (EC) 1907/2007. 15 June.

ECHA, 2017b. *Proposal for the Identification of a Substance of Very High Concern on the Basis of the Criteria Set out in REACH Article 57, Perfluorohexane-1-sulphonic acid and its salts, Annex XV dossier, March 2017*, s.l.: s.n.

ECHA, 2017c. *Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.11: PBT Assessment. European Chemicals Agency*, s.l.:
https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f.

ECHA, 2017. *Proposal for a Restriction on C9-C14 PFCAs -including their salts and precursors-*, Germany: Federal Institute for Occupational Safety and Health Division 5 - Federal Office for Chemicals.

ECHA, 2018b. *Background document to the opinion on the Annex XV dossier proposing restrictions on C9-C14 PFCAs including their salts and precursors, ECHA/RAC/RES-O-0000001412-86-219/F, ECHA/SEAC/RES-O-0000001412-86-236/F*, s.l.: s.n.

ECHA, 2018. *REACH registration dossier on 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonic acid (6:2 FTS)*. [Internett]
Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/24637/1>
[Funnet 17 December 2018].

ECHA, 2019. *Melamine REACH registration dossier*. [Internett]
Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/15978/6/1>
[Funnet 25 January 2019].

ECHA, 2019. *Stearic acid REACH registration dossier*. [Internett]
Available at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/15163/6/1>
[Funnet 25 January 2019].

EFSA, 2012. Perfluoroalkylated substances in food: occurrence and dietary exposure. *European Food Safety Authority, EFSA Journal*.

Eggen et al, 2010. Municipal landfill leachates: A significant source for new and emerging pollutants. *Science of The Total Environment, Volume 408, Issue 21, Pages 5147-5157*.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Ehresman, D. J. et al., 2007. Comparison of human whole blood, plasma, and serum matrices for the determination of perfluorooctanesulfonate (PFOS), perfluorooctanoate (PFOA), and other fluorochemicals. *Environmental Research*, p. 176–184.

Eirksson et al, 2017. Contribution of precursor compounds to the release of per- and polyfluoroalkyl substances (PFASs) from waste water treatment plants (WWTPs). , *Journal of Environmental Sciences, Volume 61, Pages 80-90*.

Elmoznino, J., Vlahos, P. & Whitney, M., 2018. Occurrence and partitioning behavior of perfluoroalkyl acids in wastewater effluent discharging into the Long Island Sound. *Environmental Pollution*, 23 July.

EMCC, 2018. *European Monitoring Centre on Change*. [Internet] Available at: <https://www.eurofound.europa.eu/observatories/emcc/erm/factsheets/miteni> [Funnet January 2019].

Ericson, I. et al., 2009. Levels of Perfluorinated Chemicals in Municipal Drinking Water from Catalonia, Spain: Public Health Implications. *Archives of Environmental Contamination and Toxicology*, November, p. 631–638.

Ericson, I. et al., 2007. Perfluorinated chemicals in blood of residents in Catalonia (Spain) in relation to age and gender: a pilot study. *Environ Int*, pp. 616-623.

Erikson, U., Haglund, P. & Karrman, A., 2017. Contribution of precursor compounds to the release of per- and polyfluoroalkyl substances (PFASs) from waste water treatment plants (WWTPs). *J Environ Sci*, pp. 80-90.

Eriksson, U., Haglund, P. & Karrman, A., 2017. Contribution of precursor compounds to the release of per- and polyfluoroalkyl substances (PFASs) from waste water treatment plants (WWTPs). *J Environ Sci*, pp. 80-90.

Eschauzier , C., Haftka, J., Stuyfzand , P. & de Voogt, P., 2010. Perfluorinated compounds in infiltrated river rhine water and infiltrated rainwater in coastal dunes.. *Environmental Science and Technology*, pp. 44(19):7450-5.

EU, 2019. *Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants*, s.l.: s.n.

EURATEX, 2018. *EURATEX input to UBA Call for Information on short chain PFASs*, s.l.: s.n.

Eurofeu, 2018. *Firefighting Foam is needed to fight Flammable Liquid Fires in High Risk Applications - a presentation*, s.l.: s.n.

EWG, 2010-2015. *EWG's Tap Water Database*, s.l.: s.n.

Falk, S., Brunn, H. & Stahl, T., 2012. Temporal and spatial trends of perfluoroalkyl substances in liver of roe deer. *Environmental Pollution* , July, pp. 1-8.

FFFC, 2011. *Estimated Inventory of PFOS-based Aqueous Film Forming Foam (AFFF), 2011 update*.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Filipovic, M. & Berger, U., 2015. *re perfluoroalkyl acids in waste water treatment plant effluents the result of primary emissions from the technosphere or of environmental recirculation?* *Chemosphere* 129, 74-80, s.l.: s.n.

Filipovic, M. et al., 2014. Historical usage of aqueous film forming foam: A case study of the widespread distribution of perfluoroalkyl acids from a military airport to groundwater, lakes, soil and fish. *Chemosphere*, 26 September, pp. 39-45.

Food Standards Australia New Zealand, 2016. Occurrence of perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and perfluorohexane sulfonate (PFHxS) in foods and water sampled from contaminated sites.

Fromme, H. et al., 2010. Pre- and postnatal exposure to perfluorinated compounds (PFCs). *Environ Sci Technol*, pp. 7123-9.

Fuertes et al, 2017. Perfluorinated alkyl substances (PFASs) in northern Spain municipal solid waste landfill leachates. *Chemosphere, Volume 168, Pages 399-407*.

Fu, J. et al., 2015. Elevated levels of perfluoroalkyl acids in family members of occupationally exposed workers: the importance of dust transfer.. *Sci. Rep. 5, 9313*.

Fu, J. et al., 2016. Occurrence, temporal trends, and half-lives of perfluoroalkyl acids (PFAAs) in occupational workers in China.. *Sci. Rep. 6, 38039*;

Galatius, G., Bossi, R., Sonne, C. & Dietz, R., 2013. PFAS profiles in three North Sea top predators: metabolic. *Environ Sci Pollut Res*, March, p. 8013-8020.

Gallen et al, 2017. Occurrence and distribution of brominated flame retardants and perfluoroalkyl substances in Australian landfill leachate and biosolids. *J. Hazard. Mater. 312, 55e64*..

Gao, Y. et al., 2015. Differential Accumulation and Elimination Behavior of Perfluoroalkyl acid Isomers in Occupational Workers in a Manufactory in China. *Environmental Science and Technology*, 30 April, pp. 6953-6962.

Gebbink, W. A., Glynn, A., Darnerud, P. O. & Berger, U., 2015. Perfluoroalkyl acids and their precursors in Swedish food: The relative importance of direct and indirect dietary exposure. *Environmental Pollution*, pp. 108-115.

Genualdi, S. et al., 2010. Global pilot study of legacy and emerging persistent organic pollutants using sorbent-impregnated polyurethane foam disk passive air samplers. *Environment International*, pp. 59:183-200.

Gewurtz, S. B. et al., 2013. Perfluoroalkyl acids in the Canadian environment: Multi-media assessment of current status and trend. *Environment International*, 3 July, pp. 183-200.

Global Safety Management Inc., 2016. *Beeswax Safety Data Sheet*. [Internet]
Available at: https://beta-static.fishersci.com/content/dam/fishersci/en_US/documents/programs/education/regulatory-documents/sds/chemicals/chemicals-b/S25192.pdf
[Funnet 25 January 2019].

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Glynn, A. et al., 2012. Perfluorinated alkyl acids in blood serum from primiparous women in Sweden: Serial sampling during pregnancy. *Environmental Science and Technology*, 6 July, p. 9071–9079.

Glynn, A. et al., 2012. Perfluorinated alkyl acids in blood serum from primiparous women in Sweden: serial sampling during pregnancy and nursing, and temporal trends 1996–2010. *Environ Sci Technol.*, pp. 9071-9.

Gomez-Canela et al, 2012. *Occurrence and fate of perfluorinated compounds in sewage sludge from Spain and Germany. Environ Sci Pollut Res Int 19 (9), 4109-4119.*, s.l.: s.n.

Gómez-Canela, C., Barth, J. & Lacorta, J., 2012. Occurrence and fate of perfluorinated compounds in sewage sludge from Spain and Germany. *Environ Sci Pollut Res*, p. 4109–4119.

Gomis, M. et al., 2017. Historical human exposure to perfluoroalkyl acids in the United States and Australia reconstructed from biomonitoring data using population-based pharmacokinetic modelling. *Environ Int.*, pp. 92-102.

Greenpeace, 2013. *Hazardous chemicals in branded textile products on sale in 25 countries/regions during 2013, Greenpeace Research Laboratories Technical Report 06/2013*, s.l.: s.n.

Greenpeace, 2014. *Hazardous chemicals in branded luxury textile products on sale during 2013. Greenpeace Research Laboratories Technical Report 01/2014*, s.l.: s.n.

Greenpeace, 2016. *Per- and poly-fluorinated chemicals in branded waterproof clothing, footwear, hiking and camping equipment, Greenpeace Research Laboratories Technical Report 01-2016*, s.l.: s.n.

Groffen, T., Lopez-Anita, A. & D` Hollander, W., 2017. Perfluoroalkylated acids in the eggs of great tits (*Parus major*) near a fluorochemical plant in Flanders, 228:140-148.. *Belgium. Environ Pollut.*, pp. 140-148.

Gyllenhammar, I. et al., 2015. Influence of contaminated drinking water on perfluoroalkyl acid levels in human serum - A case study from Uppsala, Sweden. *Environmental Research*, pp. 673-83.

Gützkow, K. et al., 2012. Placental transfer of perfluorinated compounds is selective in a Norwegian Mother and Child sub-cohort study. *Int. J. Hyg. Environ. Health*, pp. 216-219.

Hamid et al, 2018. Review of the fate and transformation of per- and polyfluoroalkyl substances (PFASs) in landfills. *Environmental Pollution, Volume 235, Pages 74-84.*

Hansen, K. J., Clemen, L., Ellefson, M. & Johnson, H., 2001. Compound-specific, quantitative characterization of organic fluorochemicals in biological matrices. *Environ Sci Technol*, pp. 766-770.

Hansen, S. et al., 2016. Exposure to per- and polyfluoroalkyl substances through the consumption of fish from lakes affected by aqueous film-forming foam emissions — A

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

combined epidemiological and exposure modeling approach. The SAMINOR 2 Clinical Study. *Environment International*, pp. 272-282.

Hanssen, L. et al., 2013. Partition of perfluoroalkyl substances (PFASs) in whole blood and plasma, assessed in maternal and umbilical cord samples from inhabitants of arctic Russia and Uzbekistan. *Science of the Total Environment*, pp. 430-437.

Haug, L., Huber, S., Becher, G. & Thomsen, C., 2011. Characterisation of human exposure pathways to perfluorinated compounds - comparing exposure estimates with biomarkers of exposure. *Environ Int.*, pp. 687-693.

Haug, L., Thomsen, C. & Becher, G., 2009. A sensitive method for determination of a broad range of perfluorinated compounds in serum suitable for large-scale human biomonitoring. *Journal of Chromatography A*, pp. 385-393.

Hekster, F., de Voogt, P., Pijnenburg, A. & Laane, R., 2002. *Perfluoroalkylated substances: Aquatic environmental assessment, Report RIKZ/2002.043.*, s.l.: Government of the Netherlands Ministry of Infrastructure and the Environment of the Netherlands Ministry of Infrastructure and the Environment, Amsterdam, The Netherlands..

Hengxin, 2015. *Chromium fog inhibitor tetraethyl ammonium perfluorohexanesulfonate and its preparation method*. China, Patentnr. CN106411733.

Hengxin, 2018. *Hubei Hengxin Chemical Co. Products (HX-601, HX-168)*, s.l.: s.n.

Hengxin, 2019. *Products (HX-601, HX-168)*. [Internett]
Available at: http://www.fluoride-cn.com/product_en.html

Herzke, D., Nygård, T. & Heimstad, E. S., 2016. *Environmental pollutants in the terrestrial and urban environment 2015*, Trondheim: Norwegian Environmental Agency.

Herzke, D., Nygård, T. & Heimstad, E. S., 2017. *Environmental pollutants in the terrestrial and urban environment 2016*, Trondheim: Norwegian Environmental Agency.

Herzke, D. et al., 2014. *Environmental pollutants in the terrestrial urban environment 2013*, Trondheim: Norwegian Environmental Agency.

Herzke, D., Nygård, T., Heimstad, E. S. & Uggerud, H. T., 2015. *Environmental pollutants in the terrestrial and urban environment 2014*, Trondheim: Norwegian Environmental Agency.

Herzke, D., Olsson, E. & Posner, S., 2012. Perfluoroalkyl and polyfluoroalkyl substances (PFASs) in consumer products in Norway - a pilot study. *Chemosphere*, Issue 8, pp. 980-987.

Herzke, D., Olsson, E. & Posner, S., 2012. Perfluoroalkyl and polyfluoroalkyl substances (PFASs) in consumer products in Norway - A pilot study. *CHEMOSPHERE*, August.

Higgins, C. P. & Luthy, R. G., 2006. Sorption of perfluorinated surfactants on sediments. *Environmental Science and Technology*, pp. 40(23), 7251-7256.

Hill, P., Taylor, M., Goswami, P. & Blackburn, R., 2017. Substitution of PFAS chemistry in outdoor apparel and the impact on repellency performance. *Chemosphere*, pp. 500-507.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Hoke, R., Bouchelle, L., Ferrell, B. & Buck, R., 2012. Comparative acute freshwater hazard assessment and preliminary PNEC development for eight fluorinated acids. *Chemosphere*, pp. 725-733.

Holmstrom, K. et al., 2010. Temporal trends of perfluorinated surfactants in Swedish peregrine falcon eggs (*Falco peregrinus*),. *Environmental Science and Technology*, pp. 1;44 (11):4083-8..

Houtz, E. F., Higgins , C. P., Field , J. A. & Sedlak, D. L., 2013. Persistence of Perfluoroalkyl Acid Precursors in AFFF-Impacted Groundwater and Soil. *Environmental Science & Technology*, 25 Juli, pp. 8187-8195.

Houtz, E., Wang, M. & Park, J.-S., 2018. Identification and Fate of Aqueous Film Forming Foam Derived Per- and Polyfluoroalkyl Substances in a Wastewater Treatment Plant. *Environ. Sci. Technol.*, 19 October.

Huang et al, 2010. Electro fluorination and its fine-fluorine production branches. *Chemical Production and Technology* 17(4):1-7.

Huang et al, 2015. *PFOS in China: production, application & alternatives*, s.l.: s.n.

Huang J et al, ND. *Preliminary study on the environmental friendliness of PFOS substitutes for key applications in China; and Presentation: PFOS in China: Production, Application & Alternatives.*, s.l.: s.n.

Huber, S. et al., 2012. Temporal trends and spatial differences of perfluoroalkylated substances in livers of harbor porpoise (*Phocoena phocoena*) populations from Northern Europe, 1991-2008.. *Science of the Total Environment*, pp. 419:216-24..

Huber, S., Haug, L. S. & Schlabach, M., 2011. Per- and polyfluorinated compounds in house dust and indoor air from northern Norway - a pilot study.. *Chemosphere*, pp. 1686-1693.

Huber, S., Warner, N. A. & Nygård, T., 2015. A BROAD COCKTAIL OF ENVIRONMENTAL POLLUTANTS FOUND IN EGGS OF THREE SEABIRD SPECIES FROM REMOTE COLONIES IN NORWAY. *Environmental Toxicology and Chemistry*, pp. 1296-1308.

Hundley, S., Sarrif, A. & Kennedy, G., 2006. Absorption, Distribution, and Excretion of Ammonium Perfluorooctanoate (APFO) After Oral Administration to Various Species. *Drug Chem. Toxicol*, pp. 29:137-145.

Hurley, S. et al., 2018. Time Trends in Per- and Polyfluoroalkyl Substances (PFASs) in California Women: Declining Serum Levels, 2011-2015. *Environ. Sci. Technol.*, p. 277-287.

Huset et al, 2008. Occurrence and Mass Flows of Fluorochemicals in the Glatt Valley Watershed, Switzerland. *Environmental Science & Technology* 42 (17).

Huset, C., Chiaia, A., Barofsky, D. & Jonkers,, N., 2008. Occurrence and mass flows of fluorochemicals in the Glatt Valley Watershed, Switzerland. *Environ. Sci. Technol.*, pp. 6369-6377.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Hu, X. C. et al., 2016. Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants. *Environmental Science and Technology Letters*, 9 August, pp. 344-350.

Hu, X. C. et al., 2016. Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants. *Environmental Science and Technology Letters*, 9 August, pp. 344-350.

Hu, X. et al., 2018. Can profiles of poly- and Perfluoroalkyl substances (PFASs) in human serum provide information on major exposure sources?. *Environ Health*, p. 11.

Hölzer, J. et al., 2008. Biomonitoring of Perfluorinated Compounds in Children and Adults Exposed to Perfluorooctanoate-Contaminated Drinking Water. *Environmental Health Perspectives*, June, pp. 651-657.

Ingelido, A. M. et al., 2018. Biomonitoring of perfluorinated compounds in adults exposed to contaminated drinking water in the Veneto Region, Italy. *Environment International*, pp. 149-159.

IPEN, 2018. *Fluorine-free firefighting foams (3F) viable alternatives to fluorinated aqueous film-forming foams. Stockholm Convention POPRC-14, September 2018, Rome.*
https://ipen.org/sites/default/files/documents/IPEN_F3_Position_Paper_POPRC-14_12September2018d.pdf, s.l.: s.n.

Jain, R. B., 2018. Contribution of diet and other factors to the observed levels of selected perfluoroalkyl acids in serum among US children aged 3-11 years. *Environmental Research*, pp. 268-275.

Jakobsson, K. et al., 2014. *Exponering för perfluorerade ämnen (PFAS) i dricksvatten i Ronneby kommun. Rapport 8/2014.* (In, s.l.: s.n.

Jiang et al, 2015. Perfluoroalkyl acids (PFAAs) with isomer analysis in the commercial PFOS and PFOA products in China. *Chemosphere*, 127, 180–187.

Ji, K. et al., 2012. Serum concentrations of major perfluorinated compounds among the general population in Korea: dietary sources and potential impact on thyroid hormones. *Environ Int*, pp. 78-85.

Johansson, J. H., Shi, Y., Salter, M. & Cousins, I. T., 2018. Spatial variation in the atmospheric deposition of perfluoroalkyl acids: source elucidation through analysis of isomer patterns. *Environmental Science Processes and Impacts*, 4 May.

Jones, P. D. et al., 2003. Binding of perfluorinated fatty acids to serum proteins. *Environmental Toxicology and Chemistry*, pp. 22(11): 2639-49.

JRC, 2012. *EU Wide Monitoring Survey on Waste Water Treatment Plant Effluents*, s.l.: s.n.

Jönsson, B., Axmon, A., Axelsson, J. & Lindh, C., 2009. *Retrospektiva studier av halterna av perfluorerade ämnen i plasma hos kvinnor mellan 1987 och 2007. Rapport till Naturvårdsverket - 2009-03-31.* (In Swedish), s.l.: s.n.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Jönsson, B., Axmon, A. & Lindh, C., 2014. *Tidstrender för och halter av perfluorerade alkylsyror (PFAAs) i serum samt ftalatmetaboliter och alkylfenoler i urin hos unga svenska män och kvinnor - Resultat från den fjärde uppföljningsundersökningen år 2013*, s.l.: s.n.

Jönsson, B. et al., 2010. *Tidstrender för och halter av persistenta fluorerade, klorerade och bromerade organiska miljögifter i serum samt ftalater i urin hos unga svenska män - Resultat från den tredje uppföljningsundersökningen år 2009-2010*, s.l.: s.n.

Kaboré, H. A. et al., 2018. Worldwide drinking water occurrence and levels of newly-identified perfluoroalkyl and polyfluoroalkyl substances. *Science of the Total Environment*, pp. 1089-1100.

Kallenborn R, Berger, U. & Järnberg, U., 2004. *Perfluorinated alkylated substances (PFAS) in the Nordic environment*, Copenhagen: Nordic Council of Ministers.

Kannan, K. et al., 2004. Perfluorooctanesulfonate and related fluorochemicals in human blood from several countries. *Environ Sci Technol*, pp. 4489-4495.

Kaufland, (undated). *Substituting PFC*. [Internett]

Available at:

https://media.kaufland.com/images/PPIM/AP_MarketingDocument/bul/21/94/Asset_169219_4.pdf

[Funnet 19 December 2018].

Kemi, 2015b. *Chemical Analysis of Selected Fire-fighting foams on the Swedish Market 2014*, s.l.: s.n.

KEMI, 2015. *Occurrence and use of highly fluorinated substances and alternatives*, s.l.: s.n.

KEMI, 2015. *Occurrence and use of highly fluorinated substances and alternatives..*

[Internett]

Available at: <https://www.kemi.se/global/rapporter/2015/report-7-15-occurrence-and-use-of-highly-fluorinated-substances-and-alternatives.pdf>

[Funnet 18 December 2018].

Kemi, 2017. *Proposal for the Identification of a Substance of Very High Concern on the Basis of the Criteria Set out in REACH Article 57, Perfluorohexane-1-sulphonic acid and its salts, Annex XV dossier, March 2017*, s.l.: s.n.

Kemi, 2017. *Proposal for the Identification of a Substance of Very High Concern on the Basis of the Criteria Set out in REACH Article 57, Perfluorohexane-1-sulphonic acid and its salts, Annex XV dossier, March 2017*, s.l.: s.n.

Keutel, K. & Koch, M., 2016. *Untersuchung fluortensidfreier Löschmittel und geeigneter Lösungsverfahren zur Bekämpfung von Bränden häufig verwendeter polarer (d. h. schaumzerstörender) Flüssigkeiten*. 187, s.l.: Institut für Brand- und Katastrophenschutz Heyrothsberge, Abteilung Forschung - Institut der Feuerwehr -. Arbeitsgemeinschaft der Innenministerien der Bundesländer A.V.A.F., Katastrophenschutz und zivile Verteidigung.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Kim, S. et al., 2011. Distribution of perfluorochemicals between sera and milk from the same mothers and implications for prenatal and postnatal exposures. *Environ Pollut*, pp. 169-74.

Kim, S.-J., Shin, H., Lee, Y.-B. & Cho, H.-Y., 2017. Sex-specific risk assessment of PFHxS using a physiologically based pharmacokinetic model. *Archives of Toxicology*, p. 92:1113-1131 .

Kingsley, S. et al., 2018. Variability and predictors of serum perfluoroalkyl substance concentrations during pregnancy and early childhood. *Environ Res*, Issue 165, pp. 247-257.

Kissa, E., 2001. *Fluorinated surfactants and repellents*. Second edition red. New York: CRC Press.

Klenow, S. et al., 2013. Dietary exposure to selected perfluoroalkyl acids (PFAAs) in four European regions. *Food Additives & Contaminants: Part A*, pp. 2141-2151.

Konieczny, R. M. et al., 2016. *Screening programme 2016: Suspected PBT-compounds*, Trondheim: Norwegian Environment Agency.

Kottoff et al, 2015. Perfluoroalkyl and polyfluoroalkyl substances in consumer products. *Environ Sci Pollut Res (2015) 22:14546-14559*.

Kowalczyk, J. et al., 2013. Absorption, Distribution, and Milk Secretion of the Perfluoroalkyl Acids PFBS, PFHxS, PFOS, and PFOA by Dairy Cows Fed Naturally Contaminated Feed. *J. Agric. Food Chem.*, pp. 61 (12), pp 2903-2912.

Kowalczyk, J. et al., 2015. Can perfluoroalkyl acids biodegrade in the rumen simulation technique (RUSITEC)?. *Environ Sci Eur.*, p. 27(1):30.

Kubwabo, C., Stewart, B., Zhu, J. & Marro, L., 2005. Occurrence of perfluorosulfonates and other perfluorochemicals in dust from selected homes in the city of Ottawa, Canada. *Journal of Environmental Monitoring*, pp. 7 (11), 1074-1078.

Kwok, K. Y. et al., 2013. Transport of Perfluoroalkyl substances (PFAS) from an arctic glacier to downstream locations: Implications for sources. *Science of The Total Environment*, 23 March, pp. 46-55.

Kärrman, A. et al., 2007. Exposure of perfluorinated chemicals through lactation: levels of matched human milk and serum and a temporal trend, 1996-2004, in Sweden.. *Environ Health Perspect*, pp. 226-230.

Kärrman, A. & Kallenborn, R., 2018. *Screening of PFAS and total organic fluorine (TOF) in Nordic Countries*, s.l.: Nordisk Screeninggruppe.

Kärrman, A. et al., 2006. Perfluorinated chemicals in relation to other persistent organic pollutants in human blood. *Chemosphere*, pp. 1582-1591.

Kärrman, A., Wang, T., Kallenborn, R. & Langseter, A. M., 2019. *PFASs in the Nordic environment: Screening of Poly- and Perfluoroalkyl Substances (PFASs) and Extractable Organic Fluorine (EOF) in the Nordic Environment*, Copenhagen: Nordic Council of Ministers.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Labadie, P. & Chevreuil, M., 2011 a. Partitioning behaviour of perfluorinated alkyl contaminants between water, sediment and fish in the Orge River (nearby Paris, France). *Environmental Pollution*, pp. 391-397.

Labadie, P. & M, C., 2011 b. Biogeochemical dynamics of perfluorinated alkyl acids and sulfonates in the River Seine (Paris, France) under contrasting hydrological conditions. *Environmental Pollution* , pp. 3634-3639.

Lam, J., Kwok, K. & Lam , P., 2015. Perfluoroalkyl Substances (PFASs) in Marine Mammals from the South China Sea and Their Temporal Changes 2002-2014: Concern for Alternatives of PFOS?. *Environmental Science and Technology*, pp. 50(13):6728-36.

Land, M. et al., 2018. Temporal trends of perfluoroalkyl acids in humans and in the environment. Summary of Systematic Review SR5. *EviEM, Stockholm. Additional information on trend can be accessed here:*
http://www.eviem.se/Documents/projekt/2017/SR5%20Additional%20files/Additional%20file%207_Re-analysed%20time%20trends.pdf.

Land, M. et al., 2018. *Temporal trends of perfluoroalkyl acids in humans and in the environment. Summary of Systematic Review SR5*, Stockholm: EviEM.

Lanza, H. A. et al., 2016. Temporal monitoring of perfluorooctane sulfonate accumulation in aquatic biota downstream of historical aqueous film forming foam use areas. *Environmental Toxicology and Chemistry*, 28 December, p. 2022–2029.

LASTFIRE, 2016. *International Oil and Petrochemical Forum: Developing best industry practice in Storage Tank Fire Hazard Management*.
<http://www.lastfire.co.uk/uploads/WHAT%20IS%20LASTFIRE%202016%20Update.pdf> (last accessed 18.12.2018), s.l.: s.n.

Lastfire, 2018. *Testing Press Release*. s.l.:s.n.

Letcher, R., Chu, S. & McKinney, M., 2014. Comparative hepatic in vitro depletion and metabolite formation of major perfluorooctane sulfonate precursors in arctic polar bear, beluga whale, and ringed seal. *Chemosphere* 225–231, p. 225–231.

Li , Y. et al., 2017. Analysis of a broad range of perfluoroalkyl acids in accipiter feathers: method optimization and their occurrence in Nam Co Basin, Tibetan Plateau. *Environ Geochem Health*.. (Epub ahead of print) *PubMed PMID: 28357613*.

Lin, A., Panchangam, S. & Ciou, P., 2010. High levels of perfluorochemicals in Taiwan's wastewater treatment plants and downstream rivers pose great risk to local aquatic ecosystems. *Chemosphere*, Volum 80(10), pp. 1167-74.

Lin, A. Y., Panchangam , S. & Lo, C. C., 2009. The impact of semiconductor, electronics and optoelectronic industries on downstream perfluorinated chemical contamination in Taiwanese rivers. *Environmetal Pollution*, Volum 2009, pp. 1365-1372.

Lin, C., Chen, P., Lin, Y. & Lin, L., 2009. Association among serum perfluoroalkyl chemicals, glucose homeostasis, and metabolic syndrome in adolescents and adults. *Diabetes Care*, pp. 702-707.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Liu et al, 2010. *Aerobic biodegradation of [14C] 6:2 fluorotelomer alcohol in a flow-through soil incubation system. Chemosphere 80 (7), 716-723. DOI: 10.1016/j.chemosphere.2010.05.027, s.l.: s.n.*

Liu et al, 2010b. 6- 2 Fluorotelomer alcohol aerobic biodegradation in soil and mixed bacterial culture. *Chemosphere 78 (4), 437-444.*

Liu, J. & Avendaño, S. M., 2013. Microbial degradation of polyfluoroalkyl chemicals in the environment: A review. *Environment International, 61, 98-114.. Environment International, pp. 98-114.*

Liu, J., Zhong, G., Li, W. & Avendaño, S., 2019. Isomer-specific biotransformation of perfluoroalkyl sulfonamide compounds in aerobic soil. 651, .. *Science of the Total Environment,, pp. 766-774.*

Li, Y. et al., 2018. Half-lives of PFOS, PFHxS and PFOA after end of exposure to contaminated drinking water. *Occup Environ Med, pp. 46-51.*

Li, Y. et al., 2018. Half-lives of PFOS, PFHxS and PFOA after end of exposure to contaminated drinking water. *Occup Environ Med , p. 46-51.*

Ma et al, 2018. Riverine inputs and source tracing of perfluoroalkyl substances (PFASs) in Taihu Lake, China. *Sci Total Environ. 15; 612:18-25.*

Ma, X., Shan, G., Chen, M. & Zha, J., 2018. Riverine inputs and source tracing of perfluoroalkyl substances (PFASs) in Taihu Lake, China. *Science of the Total Environment, 1 September , pp. 18-25.*

MacInnis, J. J. et al., 2017. Emerging investigator series: a 14-year depositional ice record of perfluoroalkyl substances in the High Arctic.. *Environmental Science Processes & Impacts, 10 January.*

Maisonet, M. et al., 2012. Maternal concentrations of polyfluoroalkyl compounds during pregnancy and fetal and postnatal growth in British girls. *Environ Health Perspect, pp. 1432-1437.*

Mak, Y. L. et al., 2009. Perfluorinated Compounds in Tap Water from China and Several Other Countries. *Environmental Science and Technology, 29 May, p. 4824-4829.*

Ma, R. & Shih, K., 2010. Perfluorochemicals in wastewater treatment plants and sediments in Hong Kong. *Environ. Pollut., pp. 1354-1362.*

Martin, J. et al., 2010. PFOS or PreFOS? Are perfluorooctane sulfonate precursors (PreFOS) important determinants of human and environmental perfluorooctane sulfonate (PFOS) exposure?. *Journal of Environmental Monitoring, pp. 1979-2004.*

Martin, J. W., Ellis, D. A. & MAbury, S. A., 2006. Atmospheric Chemistry of Perfluoroalkanesulfonamides: Kinetic and Product Studies of the OH Radical and Cl Atom Initiated Oxidation of N-Ethyl Perfluorobutanesulfonamide. *Environ. Sci. Technol., pp. 864-872.*

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Martin, J. W. et al., 2006. Kinetic and Product Studies of the OH Radical and Cl Atom Initiated Oxidation of N-Ethyl Perfluorobutanesulfonamide.. *Environmental Science & Technology*, pp. 864-872.

Martin, J. W., Mabury, S. A., Solomon, K. R. & Muir, D. C., 2003a. Bioconcentration and tissue distribution of perfluorinated acids in rainbow trout (*Oncorhynchus mykiss*).. *Environmental Toxicology and Chemistry*, pp. 22(1), 196-204.

Massachusetts Toxics Use Reduction Act Science Advisory Board, 2017. *Updated EHS Summary of Perfluorohexane sulfonic acid for the MA TURA Science Advisory Board Meeting – March 29, 2017*, s.l.: s.n.

Ma, X., Shan, G. & Chen, M., 2018. Riverine inputs and source tracing of perfluoroalkyl substances (PFASs) in Taihu Lake, China. *Science of the Total Environment*, pp. 18-25.

McMurdo, C. J. et al., 2008. Aerosol Enrichment of the Surfactant PFO and Mediation of the Water–Air Transport of Gaseous PFOA. *Environmental Science & Technology*, 23 April, pp. 3969-3974.

Meyer, T., De Silva, A., Spencer, C. & Wania, F., 2011. Fate of perfluorinated carboxylates and sulfonates during snowmelt within an urban watershed. *Environmental Science and Technology*, pp. 1; 45(19):8113-9.

Midwor, 2018. *Mitigation of environmental impact caused by DWOR textile finishing chemicals studying their nontoxic alternatives*, s.l.: s.n.

Miljeteig, C. et al., 2009. High levels of contaminants in ivory gull *Pagophila eburnea* eggs from the Russian and Norwegian Arctic.. *Environmental Science and Technology*, 15 July, pp. 43(14):5521-8.

Mogensen, U. et al., 2015. Breastfeeding as an Exposure Pathway for Perfluorinated Alkylates. *Environ Sci Technol*, pp. 10466-73.

Munoz, G., Giraudel, J.-L., Botta, F. & Labadie, P., 2015. Spatial distribution and partitioning behavior of selected poly- and perfluoroalkyl substances in freshwater ecosystems: A French nationwide survey. *Science of the Total Environment*, pp. 48-56.

Möller, A., Ahrens, L., Sturm, R. & de Voogt, P., 2010. Distribution and sources of polyfluoroalkyl substances (PFAS). *Environmental Pollution*, pp. 3243-3250.

Nelson, J., Hatch, E. & Webster, T., 2010. Exposure to polyfluoroalkyl chemicals and cholesterol, body weight, and insulin resistance in the general U.S. population. *Environ Health Perspect*, pp. 197-202.

Neumann, P., 2013. Europäische Union: 71.000 kommunale Kläranlagen. *wwt - Das Praxismagazin für das Trink- und Abwassermanagement*.

Ng, C. A. & Hungerbühler, K., 2014. Bioaccumulation of Perfluorinated Alkyl Acids: Observations and Models. *Environmental Science and Technology*, pp. 48, 4637–4648.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Nguyen, M. A. et al., 2017. Spatial distribution and source tracing of per- and polyfluoroalkyl substances (PFASs) in surface water in Northern Europe. *Environmental Pollution*, January , pp. 1438-1446.

NICNAS, 2018. *Perfluoroheptanoic acid (PFHpA) and its direct precursors: Environment tier II assessment*. [Internett]
Available at: https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environment-assessments/perfluoroheptanoic-acid-pfhpa-and-its-direct-precursors#_ENREF_25
[Funnet 17 December 2018].

Nielsen, C. J., 2017. *M 792: Potential PFBS and PFHxS Precursors*, s.l.: Norwegian Environment Agency.

Noorlander, C. W. et al., 2011. Levels of Perfluorinated Compounds in Food and Dietary Intake of PFOS and PFOA in The Netherlands. *Journal of Agricultural and Food Chemistry*, pp. 7496-7505.

Nordic Risk Assessment Group, 2014. *Analysis of per- and polyfluorinated substances in articles*. Norden, Nordic Council of Ministers, s.l.: s.n.

Nordic Screening Report, 2018. s.l.: s.n.

Norin, H. & Schulze, P., 2007. *Fluorerade miljögifter i impregneringsmedel (in Swedish)*, s.l.: Swedish Society for Nature Conservation.

Norwegian Environment Agency, 2016. *Screening programme 2016: Suspected PBT-compounds*, s.l.: Norwegian Environment Agency.

Norwegian Environment Agency, 2017b. Monitoring of environmental contaminants in air and precipitation. Report M-757/2017.
<http://www.miljodirektoratet.no/no/Publikasjoner/2017/September-2017/Monitoring-of-environmental-contaminants-in-air-and-precipitation/>.

Norwegian Environment Agency, 2017. *Screening program 2016. Selected PBT compounds.*, s.l.: s.n.

Norwegian Environment Agency, 2017. *Screening programme 2016 - Suspected PBT compounds*, s.l.: s.n.

Norwegian Pollution Control Authority, 2006. *Kartlegging av perfluoralkylstoffer (PFAS) i utvalgte tekstiler (in Norwegian)*, s.l.: s.n.

Numata, J. et al., 2014. Toxicokinetics of Seven Perfluoroalkyl Sulfonic and Carboxylic Acids in Pigs Fed a Contaminated Diet. *J. Agric. Food Chem.*, p. 6861–6870.

Nyberg, E. et al., 2017. *Monitoring of POPs in human milk from Stockholm and Gothenburg, 1972-2015. Updated version – 2017-09-01.* , s.l.: s.n.

Nøst, T. et al., 2014. Repeated measurements of per- and polyfluoroalkyl substances (PFASs) from 1979 to 2007 in males from Northern Norway: Assessing time trends, compound correlations and relations to age/birth cohort. *Environment International*.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

OECD , 2013. *OECD/UNEP Global PFC Group, Synthesis paper on per-and polyfluorinated Chemicals (PFCs)*. [Internett]

Available at: https://www.oecd.org/env/ehs/risk-management/PFC_FINAL-Web.pdf
[Funnet 19 December 2018].

OECD, 2012. *Portal on Per and Poly Fluorinated Compounds*, s.l.: s.n.

Olsen, G. et al., 2012. Temporal trends of perfluoroalkyl concentrations in American Red Cross adult blood donors, 2000–2010. *Environ. Sci. Technol.*, p. 6330–6338.

Olsen, G. et al., 2003. An occupational exposure assessment of a perfluorooctanesulfonyl fluoride production site: biomonitoring. *AIHA Journal*, Sep-Oct, pp. 651-9.

Olsen, G. W. et al., 2007. Half-Life of Serum Elimination of Perfluorooctanesulfonate, Perfluorohexanesulfonate, and Perfluorooctanoate in Retired Fluorochemical Production Workers. *Environmental Health Perspectives*, September, pp. 1298-1305.

Oxford Dictionary, Accessed 29 March 2019. *Definition of generation in English*, s.l.: s.n.

Pan, Y. et al., 2018. Worldwide Distribution of Novel Perfluoroether Carboxylic and Sulfonic Acids in Surface Water.. *Environ Sci Technol.*, Issue 14, pp. 7621-7629.

Pan, Y. et al., 2017. Novel Chlorinated Polyfluorinated Ether Sulfonates and Legacy Per-/Polyfluoroalkyl Substances: Placental Transfer and Relationship with Serum Albumin and Glomerular Filtration Rate. *Environ Sci Technol*, Volum 3, pp. 634-644.

Papadopoulou, E., Haug, L., Sabaredzovic, A. & Eggesbø, M., 2015. Reliability of perfluoroalkyl substances in plasma of 100 women in two consecutive pregnancies. *Environmental Research*, p. 421–429.

Parsons, J., Sáez, M., Dolfing, J. & de Voogt, P., 2008. Biodegradation of Perfluorinated Compounds. *Reviews of Environmental Contamination and Toxicology*, pp. 53-71.

Pereira, H. C., Ullberg, M., Kleja, D. B. & Gustafsson, J. P., 2018. Sorption of perfluoroalkyl substances (PFASs) to an organic soil horizon–Effect of cation composition and pH. *Chemosphere*, 4 May, pp. 183-191.

Perez, F. et al., 2013. Accumulation of perfluoroalkyl substances in human tissues. *Environ Int*, pp. 354-362.

Pickard, H. M. et al., 2018. Continuous non-marine inputs of per- and polyfluoroalkyl substances to the High Arctic: a multi-decadal temporal record. *Atmospheric Chemistry and Physics*, April, pp. 5045-5058.

Polisello, S. & Valsecchi, S., 2013. *Rischio associato alla presenza di sostanze perfluoroalchiliche (PFAS) nelle acque potabili e nei corpi idrici recettori di aree industriali nella Provincia di Vicenza e aree limitrofe.*, s.l.: s.n.

POPRC, 2018b. *Decision: POPRC-14/1: Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds*. s.l., UNEP.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

POPs Review Committee, 2017. *Thirteenth meeting: Proposal to list perfluorohexane sulfonic acid (CAS No: 355-46-4, PFHxS), its salts and PFHxS-related compounds in Annexes A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants*, s.l.: s.n.

POPs Review Committee, 2018. *Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds - Draft Risk Profile, April 2018*, s.l.: s.n.

POPs Review Committee, 2018. *Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds - Risk Profile, September 2018*, s.l.: s.n.

Potrykus, A., 2017. *Investigation of sources to PFHxS in the environment*, s.l.: BiPRO GmbH.

Quinete, N. et al., 2010. Degradation Studies of New Substitutes for Perfluorinated Surfactants. *Arch Environ Contam Toxicol*, Issue 59: 20.

RAC/SEAC, 2015b. *Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals*. Helsinki: ECHA.

Rauert, C. et al., 2018b. Atmospheric concentrations of new POPs and emerging chemicals of concern in the Group of Latin America and Caribbean (GRULAC) region. *Environmental Science and Technology*, p. [Epub ahead of print].

Rauert, C. et al., 2018a. Atmospheric concentrations and trends of poly- and perfluoroalkyl substances (PFAS) and volatile methyl siloxanes (VMS) over 7 years of sampling in the Global Atmospheric Passive Sampling (GAPS) network. *Environmental Pollution*, pp. 238:94-102.

Regione del Veneto, 2014. *Annex A to Decree no.59 of 30/07/2014*, s.l.: s.n.

Regione del Veneto, 2016. *Area Sanità e Sociale (2016) –Relazione in tema di sostanze perfluoroalchiliche prodotte dalla ditta MITENI SpA di Trissino (VI)*, s.l.: s.n.

Ren, 2016. *China - Reduction and Phase-out of Perfluorooctane Sulfonic Acid (PFOS) in Priority Sectors Project: environmental assessment*, s.l.: Environmental auditing report for Hubei Hengxin Chemical Co., Ltd (English).

Reth, M. et al., 2011. Water-to-air transfer of perfluorinated carboxylates and sulfonates in a sea spray simulator. *Environmental Chemistry*, 19 August, pp. 381-388.

Rhoads, K. R., Janssen, E. M.-L., Luthy, R. G. & Criddle, C. S., 2008. *Aerobic Biotransformation and Fate of N-Ethyl Perfluorooctane Sulfonamidoethanol (N-EtFOSE) in Activated Sludge*, s.l.: Environ. Sci. Technol..

Roos, A., Berger, U., Järnberg, U. & Bigner, A., 2013. Increasing Concentrations of Perfluoroalkyl Acids in Scandinavian Otters (*Lutra lutra*) between 1972 and 2011: A New Threat to the Otter Population?. *Environmental Science & Technology*, September, pp. 11757-11765.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Roos, A. et al., 2013. Increasing concentrations of perfluoroalkyl acids in Scandinavian otters (*Lutra lutra*) between 1972 and 2011: a new threat to the otter population?. *Environmental Science*, pp. 15; 47(20):11757-65.

Rotander, A., Kärrmann, A. & Bavel, B., 2012. Increasing levels of long-chain perfluorocarboxylic acids (PFCAs) in Arctic and North Atlantic marine mammals, 1984–2009. *Chemosphere*, pp. 278-285.

Rotander, A. et al., 2015. Elevated levels of PFOS and PFHxS in firefighters exposed to aqueous film forming foam (AFFF). *Environment International*, p. 82: 28–34.

Routti, H. et al., 2017. Emission Changes Dwarf the Influence of Feeding Habits on Temporal Trends of Per- and Polyfluoroalkyl Substances in Two Arctic Top Predators. *Environmental Science & Technology*, 18 September, p. 11996–12006.

RPA, 2004. *Perfluorooctane Sulphonate Risk Reduction Strategy and Analysis of Advantages and Drawbacks*, s.l.: s.n.

Rudolf Group, 2016. *RUCO-DRY ECO PLUS Safety Data Sheet*. [Internett]
Available at: https://www.subsport.eu/wp-content/uploads/sites/2/2016/06/ECO-PLUS_Sicherheitsdatenblatt_e.pdf
[Funnet 25 January 2019].

Schellenberger et al, 2018. Facing the rain after the phase out: Performance evaluation of alternative. *Chemosphere*, Volum 193, pp. 675-684.

Schlabach, M. et al., 2018. *Screening Programme 2017 – AMAP Assessment Compounds*, Trondheim: Norwegian Environment Agency.

Schultes, L. et al., 2019. Temporal Trends (1981-2013) of per- and polyfluoroalkyl substances and total fluorine in Baltic cod (*Gadus morhua*). *Environmental Toxicology and Chemistry*, 14 October.

Schultz et al, 2006. Fluorochemical Mass Flows in a Municipal Wastewater Treatment Facility. *Environmental Science & Technology* 40 (23), 7350-7357.

SEAC, 2016. *Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC*, s.l.: s.n.

Siebenaler, R. et al., 2017. Serum perfluoroalkyl acids (PFAAs) and associations with behavioral attributes. *Chemosphere*, pp. 687-693.

Sigma Aldrich, 2017. *Poly(dimethylsiloxane) Safety Data Sheet*. [Internett]
Available at:
<https://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=GB&language=en&productNumber=81153&brand=SIAL&PageToGoToURL=https%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fsearch%3Fterm%3D63148-62-9%26interface%3DCAS%2520No.%26N%3D0%26mode%3Dmatch%2520pa>
[Funnet 25 January 2019].

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Slinde, G. A. & Høisæter, Å., 2017. *Source tracing of PFAS to Tyrifjorden – Final report*, Oslo: Norwegian Environment Agency.

Solberg, 2013. *RE-HEALING foam RF6 Safety Data Sheet*. [Internett]
Available at: http://www.wormald.co.nz/_data/assets/pdf_file/0019/404434/REHEALING-FOAM-RF6-SDS.pdf
[Funnet 8 November 2018].

Solberg, 2015. *RE-HEALING foam RF 3 3% Safety Data Sheet*, s.l.: s.n.

Solberg, 2018. *RE-HEALING foam RF 3 3% Safety Data Sheet*. [Internett]
Available at: <https://www.pacfire.com.au/product/solberg-re-healing-foam-rf3-20-litre-pail/?add-to-cart=1373>
[Funnet 8 November 2018].

Spliethoff, H. et al., 2008. Use of newborn screening program blood spots for exposure assessment: declining levels of perfluorinated compounds in New York State infants. *Environ Sci Technol.*, 15 Jul, pp. 5361-7.

Stasinakis et al, 2013. Contribution of primary and secondary treatment on the removal of benzothiazoles, benzotriazoles, endocrine disruptors, pharmaceuticals and perfluorinated compounds in a sewage treatment plant. *Science of The Total Environment, Volumes 463–464, Pages 1067-1075*.

Stefanie Klenow, G. H. B. D. H. &, u.d.

Stein, C. & Savitz, D., 2011. Serum perfluorinated compound concentration and attention deficit/hyperactivity disorder in children 5-18 years of age. *Environ Health Perspect*, pp. 1466-1471.

Stock, N., Furdui, V., Muir, D. & Mabury, S., 2007. Perfluoroalkyl contaminants in the Canadian Arctic: evidence of atmospheric transport and local contamination. *Environmental Science and Technology*, pp. 41(10):3529-36.

Stock, N., Furdui, V., Muir, D. & Mabury, S., 2007. Perfluoroalkyl contaminants in the Canadian Arctic: evidence of atmospheric transport and local contamination. *Environmental Science and Technology*, pp. 41(10):3529-36.

Strynar, M. J. & Lindstrom, A. B., 2008. Perfluorinated Compounds in House Dust from Ohio and North Carolina, USA. *Environmental Science and Technology*, pp. 42(10), 3751-3756.

Subsport, 2012. *A new water repellent surface treatment which contains no fluorocarbons or isocyanates, to be used on textiles and other fibre-based materials*. [Internett]
Available at: <https://www.subsport.eu/case-stories/184-en>
[Funnet 19 December 2018].

Subsport, 2013. *A new fluorine-free (PFC-free) water-repellent for textiles*. [Internett]
Available at: <https://www.subsport.eu/case-stories/374-en>
[Funnet 19 December 2018].

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Subsport, 2015. *PFC-free alternatives for water repellent textile fibres*. [Internet] Available at: <https://www.subsport.eu/case-stories/408-en> [Funnet 19 December 2018].

Sundström, M. et al., 2012. Comparative pharmacokinetics of perfluorohexanesulfonate (PFHxS) in rats, mice and monkeys. *Reproductive Toxicology*, pp. 441-451.

Sundström, M. et al., 2011. A temporal trend study (1972-2008) of perfluorooctanesulfonate, perfluorohexanesulfonate, and perfluorooctanoate in pooled human milk samples from Stockholm, Sweden. *Environ Int.*, pp. 178-183.

Synquest_Laboratories, 2018. *Synquest Laboratories*. [Internet] Available at: <http://synquestlabs.com/product/id/71976.html> [Funnet 11 09 2018].

Taniyasu, S., Yamashita, N., Yamazaki, E. & Petrick, 2013. *The environmental photolysis of perfluorooctanesulfonate, perfluorooctanoate, and related fluorochemicals*. s.l.:Chemosphere, 90(5), 1686-1692. doi:10.1016/j.chemosphere.2012.09.065.

Taniyasu, S. Y. N. Y. E. P. G. & K. K., 2013. *The environmental photolysis of perfluorooctanesulfonate, perfluorooctanoate, and related fluorochemicals*. s.l.:Chemosphere, 90(5), 1686-1692. doi:10.1016/j.chemosphere.2012.09.065.

Tao, L. et al., 2008. Perfluorinated compounds in human breast milk from several Asian countries, and in infant formulas and diary milk from the United States. *Environ Sci Technol*, pp. 8597-8602.

Theobald, N., Gerwinski, W., Caliebe, C. & Haarich, M., 2007. Development and validation of a method for the determination of polyfluorinated organic substances in sea water, sediments and biota. Occurrence of these compounds in the North and Baltic Seas.. *Umweltforschungsplan des Bundesministeriums für Umwelt, Naturschutz, und Reaktorsicherheit, Forschungsbericht*, pp. 202 22 213, UBA-FB 00 001409. 133 pp. (in German, with English abstract).

Toft, G. et al., 2012. Exposure to perfluorinated compounds and human semen quality in Arctic and European populations. *Hum Reprod*, pp. 2532-2540.

Toms, L. et al., 2014. Decline in perfluorooctane sulfonate and perfluorooctanoate serum concentrations in an Australian population from 2002 to 2011. *Environ Int.*, pp. 74-80.

Tomy, G. T. et al., 2004. *Biotransformation of N-Ethyl Perfluorooctanesulfonamide by Rainbow Trout (Onchorhynchus mykiss) Liver Microsomes*, s.l.: Environ. Sci. Technol.,.

Tonnelier, A., Coecke, S. & Zaldívar, J.-M., 2012. Screening of chemicals for human bioaccumulative potential with a physiologically based toxicokinetic model. *Arch Toxicol*, p. 86:393-403.

TÜV SÜD, 2017. *EU – 17th Public Consultation on REACH Candidate List*, s.l.: s.n.

UK Environment Agency, 2019a. Data submitted during public consultation of PFHxS restriction proposal. *Comment no 2886*, 19 December.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

UK Environment Agency, 2019b. Data submitted during public consultation of PFHxS restriction proposal. *Comment no. 2787*, 19 December.

Ullah, S., Huber, S., Bignert, A. & Berger, U., 2014. Temporal trends of perfluoroalkane sulfonic acids and their sulfonamide-based precursors in herring from the Swedish west coast 1991-2011 including isomer-specific considerations.. *Environment International*, pp. 65:63-72..

Ulrich et al, 2016. Getting on with persistent pollutants: Decreasing trends of perfluoroalkyl acids (PFAAs) in sewage sludge. *Chemosphere* 161, 527-535.

UNEP/POPS/POPRC.14/2, 2018. *Draft risk profile: Perfluorohexane sulfonic acid (CAS No 365-46-4. PFHxS) its salts and PFHxS-related compounds*, s.l.: POPs secretariat.

UNEP/POPS/POPRC.14/6, 2018. Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting. 4 October.

UNEP, 2006. Report of the Persistent Organic Pollutants Review Committee on the work of its second meeting. Addendum: Risk profile on perfluorooctane sulfonate..

UNEP, 2008. *Acceptable Purposes: PFOS, its salts and PFOSF*, s.l.: s.n.

UNEP, 2013. *Guidance on alternatives to perfluorooctane sulfonic acid, its salts, perfluorooctane sulfonyl fluoride and their related chemicals*, s.l.: Stockholm Convention on Persistent Organic Pollutants.

UNEP, 2015. Report prepared by the Secretariat pursuant to paragraph 2 (d) of Article 20 on the information provided in the reports submitted by parties pursuant to Article 15 of the Convention.

UNEP, 2017. *Proposal to list perfluorohexane sulfonic acid (CAS No: 355-46-4, PFHxS), its salts and PFHxS-related compounds in Annexes A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants*, s.l.: UNEP/POPS/POPRC.13/4.

UNEP, 2018. *Evaluation of perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) pursuant to paragraphs 5 and 6 of part III of Annex B to the Stockholm Convention*, s.l.: POPRC-14/3.

UNEP, 2019a. *UNEP/POPS/COP.9/INF/12; Report on the evaluation of information on perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride*, s.l.: s.n.

UNEP, 2019b. *Draft risk management evaluation on Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds*. [Internett]

Available at:

<http://www.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC15/Overview/tabid/8052/Default.aspx>

[Funnet 2019].

UNEP, 2019c. UNEP/POPS/POPRC.15/7; Report of the Persistent Organic Pollutants Review Committee on the work of its fifteenth meeting.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

UNEP, 2019. *Report on the evaluation of information on perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride*, s.l.: s.n.

UNEP-POPs, 2016. *Consolidated guidance on alternatives to perfluorooctane sulfonic acid and its related chemicals*, s.l.: s.n.

UNEP-POPS, 2017. *Guidance on best available techniques and best environmental practices for the use of perfluorooctane sulfonic acid (PFOS) and related chemicals listed under the Stockholm Convention on Persistent Organic Pollutants*, s.l.: United Nations and Stockholm Secretariat.

US EPA, 2013. *Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances; Final Significant New Use Rule. Published on 22 October 2013.*, s.l.: s.n.

US EPA, 2015. *Significant New Use Rules: Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances.*, s.l.: s.n.

US EPA, 2018. *Drinking Water Health Advisories for PFOA and PFOS*, s.l.: s.n.

USA), 3. (. M. a. M. C., 1981. *Mist suppressant*. USA, Patentnr. GB 2077765.

Valsecci, S., Rusconi, M., Mazzoni, M. & Polsello, S., 2015. Occurrence and sources of perfluoroalkyl acids in Italian river basins. *Chemosphere*, 126-134 June.

Vestergren, R., Berger, U., Glynn, A. & Cousins, I., 2012. Dietary exposure to perfluoroalkyl acids for the Swedish population in 1999, 2005 and 2010. *Environ Int.* , pp. 120-127.

Vorkamp, K., Falk, K. & Møller, S., 2018. Perfluoroalkyl substances (PFAS) and polychlorinated naphthalenes (PCN) add to the chemical cocktail in peregrine falcon eggs. *Science of Total Environment*, pp. 894-901.

Wang et al, 2011. 6:2 fluorotelomer sulfonate aerobic biotransformation in activated sludge of waste water treatment plants. *Chemosphere*, 82(6), 853-858.

Wang et al, 2013. Fluorinated alternatives to long-chain perfluoroalkyl carboxylic acids, perfluoroalkane sulfonic acids (PFASs) and their potential precursors. *Environment International* 60, 242-248.

Wang et al, 2015. Influence of cations on the partition behavior of perfluoroheptanoate (PFHpA) and perfluorohexanesulfonate (PFHxS) on wastewater sludge. *Chemosphere* 131, 178-183.

Wang , Z., Cousins , I., Scheringer, M. & Hungerbühler, K., 2013. Fluorinated alternatives to long-chain perfluoroalkyl carboxylic acids (PFCAs), perfluoroalkane sulfonic acids (PFASs) and their potential precursors. Review. *Environ Int.*, pp. 242-8.

Wang, F., Shih, K., Ma, R. & Li, X., 2015. Influence of cations on the partition behavior of perfluoroheptanoate (PFHpA) and perfluorohexanesulfonate (PFHxS) on wastewater sludge.. *Chemosphere*, July, pp. 178-183.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Wang, Y. et al., 2010. Distribution of Perfluorooctane Sulfonate and other Perfluorochemicals in the ambient environment around a manufacturing facility in China. *Environ. Sci. Technol.*, pp. 8062-8067.

Wang, Z. et al., 2017. Toward a Comprehensive Global Emission Inventory of C(4)-C(10) Perfluoroalkanesulfonic Acids (PFASs) and Related Precursors: Focus on the Life Cycle of C(8)-Based Products and Ongoing Industrial Transition.. *Environmental Science and Technology*, Issue 8, pp. 4482-4493.

Weber, R., 2016. *Challenges of per- and polyfluorinated alkylated substances (PFAS) and their application in the textile value chain*. [Internet]
Available at: http://www.global-chemicals-waste-platform.net/fileadmin/files/Summer_School_2016/Presentations_Tuesday
[Funnet 19 December 2018].

Weber, R., 2016. *Some lessons learned from PFOS/PFAS management in Germany*, *Science and Policy of Organohalogenes*. Firenze, Italy, pre-Dioxin Symposium 28 August 2016.

Webster, E. & Ellis, D., 2010. Potential role of sea spray generation in the atmospheric transport of perfluorocarboxylic acids.. *Environmental Toxicology and Chemistry*, 13 March, p. 1703-1708.

Wei, O. et al., 2012. Perfluorinated compounds in the vicinity of a fire training area-human biomonitoring among 10 persons. *International Journal of Hygiene and Environmental Health*, Vol. 215, p. 212- 215.

WeylChem Group, 2018. *WeylChem Group Homepage*. [Internet]
Available at: <https://www.weylchem.com/home-en.html>

WHO, 2017. *Keeping our water clean: the case of water contamination in the Veneto Region, Italy*. , s.l.: s.n.

WHO, 2017. *Keeping our water clean: the case of water contamination in the Veneto Region, Italy*. (<http://www.euro.who.int/en/publications/abstracts/keeping-our-water-clean-the-case-of-water-contamination-in-the-veneto-region,-italy-2017>);, s.l.: s.n.

Wilhelm, M. et al., 2009. Preliminary observations on perfluorinated compounds in plasma samples (1977-2004) of young German adults from an area with perfluorooctanoate contaminated drinking water. *Int. J. Hyg. Environ. Health*, p. 142-145.

Winkens, K., Vestergren, R., Berger, U. & Cousins, I., 2017. Early life exposure to per- and polyfluoroalkyl substances (PFASs): A critical review. *Emerging Contaminants*, pp. 55-68.

Wong, F. et al., 2018. Assessing temporal trends and source regions of per- and polyfluoroalkyl substances (PFASs) in air under the Arctic Monitoring and Assessment Programme (AMAP). *Atmospheric Environment*, p. 172 (2018) 65-73.

Yeung, L., Robinson, S., Koschorreck, J. & Mabury, S., 2013. . Part II. A Temporal Study of PFOS and Its precursors in Human Plasma from Two German Cities in 1982-2009. *Environmental Sci Technol.*, pp. 3875-3882.

Draft BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON PFHxS, ITS SALTS AND PFHxS-RELATED SUBSTANCES

Ye, X. et al., 2018. Per- and polyfluoroalkyl substances in sera from children 3 to 11 years of age participating in the National Health and Nutrition Examination Survey 2013–2014. *International Journal of Hygiene and Environmental Health*, pp. 9-16.

Yi, L. et al., 2016. Isolation, identification, and degradation performance of a PFOA-degrading strain. *Genetics and Molecular Research*, Issue 15, pp. 1-12.

Zafeiraki, E. et al., 2015. Determination of perfluoroalkylated substances (PFASs) in drinking water from the Netherlands and Greece. *Food Additives & Contaminants: Part A*, pp. 32:12, 2048-2057.

ZDHC, 2012. *Durable Water and Soil Repellent Chemistry in the Textile Industry- A Research Report*, s.l.: s.n.

Zhang, C. et al., 2013. Sorption of short- and long-chain perfluoroalkyl surfactants on sewage sludges. *Journal of Hazardous Materials*, 15 September, pp. 689-699.

Zhang, C., Yan, H., Li, F. & Zhou, Q., 2015. Occurrence and fate of perfluorinated acids in two wastewater treatment plants in Shanghai, China. *Environmental Science and Pollution Research*, February.

Zhang, Y., Beesoon, S., Zhu, L. & Martin, J. W., 2013. Biomonitoring of Perfluoroalkyl Acids in Human Urine and Estimates of Biological Half-Life. *Environmental Science and Technology*, p. 10619–10627.

Zhao, S., Wang, B. & Zhu, L., 2018. Uptake, elimination and biotransformation of N-ethyl perfluorooctanesulfonamide (N-EtFOSA) by the earthworms (*Eisenia fetida*) after in vivo and in vitro exposure. *Environmental Pollution*, pp. 19-25.

Zhao, Z., Xie, Z., Möller, A. & Ebinghaus, R., 2012. Distribution and long-range transport of polyfluoroalkyl substances in the Arctic. *Environmental Pollution*, June, pp. 71-77.