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SYNTHESIS PAPER ON PER- AND POLYFLUORINATED CHEMICALS (PFCS)

Series on Risk Management
No. 27

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OECD Environment, Health and Safety Publications

Series on Risk Management

No. 27

SYNTHESIS PAPER ON PER- AND POLYFLUORINATED CHEMICALS (PFCS)

IOMC
INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS
A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

Environment Directorate
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This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organisations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

This document has been prepared by the OECD/UNEP Global PFC Group with the aim of raising awareness of perfluorinated chemicals in developing countries and underwent several rounds of comments in that framework. The paper, which will be disseminated in the form of a brochure and through a series of webinars, provides a synthetic overview of the key issues, initiatives and information sources on four key topics: PFC uses, scientific evidence, alternatives and regulatory insights. This work supports efforts in the framework of the Strategic Approach to International Chemicals Management (SAICM) and corresponds to a need expressed by developing countries in the framework of the Global PFC Group and at a workshop held in Beijing in September 2011.

ACKNOWLEDGEMENTS

The Global PFC Group is grateful for the initial versions of the chapters of this synthesis paper that were provided by Germany (scientific evidence), Canada (regulatory approaches) and the FluoroCouncil (uses and alternatives) and to the US, Norway, Russia, and Professor Liu Jianguo (Peking University) for their inputs and written comments. The different inputs were ably drawn together and further improved by Zhanyun Wang and Martin Scheringer (Swiss Federal Institute of Technology, Zürich). The work was overseen by Peter Börkey in the OECD Secretariat.

OECD/UNEP Global PFC Group

Draft Synthesis paper on per- and polyfluorinated chemicals (PFCs)

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BACKGROUND, AIM AND SCOPE

Per- and polyfluorinated chemicals (PFCs)[A][B], or more specifically per- and polyfluoroalkyl substances (PFASs), are a large group of chemicals that have been used since the 1950s as ingredients or intermediates of surfactants and surface protectors for assorted industrial and consumer applications. During the last decade, several PFASs have been recognized as highly persistent, potentially bioaccumulative and toxic. In addition, many PFASs have been detected globally in the environment, biota, humans and food items. Initially, most attention was given to perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA), two PFAS chemicals found commonly in the environment, biota and human and most studied with regard to toxicity and ecotoxicity. Lately, more attention has also been given to other PFASs.

Since 2000, there has been an increasing interest in OECD and non-OECD countries in this particular category of chemicals, and there has been a trend towards restricting the use of long-chain PFASs (for a definition of this term, see the *Terminology* section) at the international and national level. While some data is available showing the levels and temporal trends of some PFASs in the environment, there remains a critical need for more information on PFASs on both the technical and policy levels, particularly in developing countries. The objective of this document is to provide an overview of the current understanding of PFASs, particularly long-chain PFASs, regarding their major historical and current uses, scientific information about their relevance for human health and the environment (sources to the environment, human exposure, environmental fate and potential adverse effects on humans), alternatives and regulatory approaches.

This document has been prepared by the OECD/UNEP Global PFC Group, which brings together experts from developed and developing countries in governments, academia, industry and NGOs (information on the Group see box 1 and on the website: http://www.oecd.org/ehs/pfc/). The Group's activities aim to support the implementation of resolutions II/5 and III/ of the International Conference on Chemicals Management. These resolutions encourage the "development, facilitation and promotion in an open, transparent and inclusive manner of national and international stewardship programmes and regulatory approaches to reduce emissions and the content of relevant perfluorinated chemicals (PFCs) of concern in products and to work towards global elimination, where appropriate and technically feasible."

Box 1: The OECD/UNEP Global PFC Group and its major activities

The OECD/UNEP Global PFC Group was established to facilitate the exchange of information on PFCs and to support a global transition towards safer alternatives. The Group is supported jointly by OECD and UNEP and brings together experts from developed and developing countries in academia, governments, industry and NGOs.

The Group distinguishes between long-chain perfluorinated compounds (LC PFCs) and short-chain perfluorinated compounds (SC PFCs), based on the toxicity and bioaccumulation differences between LC PFCs and SC PFCs. For the moment the work of the Group therefore mostly focuses on LC PFCs.

Its key activities are geared towards the exchange of information through webinars and events, a PFC Web Portal (www.oecd.org/ehs/pfc) and the development of regular surveys of releases and use of PFCs.

More information is available from the PFC Web Portal: www.oecd.org/ehs/pfc

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[A] The 2009 OECD PFC survey provides a list of chemicals that are considered under the general term of perfluorinated chemicals. http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono%282011%291&doclanguage=en

[B] Per- and polyfluorinated chemicals (PFCs) refer to organic compounds with all or some hydrogens replaced by fluorine. In this document, we focus on a specific sub-group of PFCs, namely per- and polyfluorinated alkyl substances (PFASs). Detailed terminology is provided in the Terminology section at the beginning of the document.

TERMINOLOGY

PFASs are chemicals that contain one or more perfluoroalkyl moieties, $–C_nF_{2n+1}$. In the past, PFASs were often referred to as “PFCs” (per- and polyfluorinated chemicals), but this term can also be understood as perfluorocarbons; perfluorocarbons contain only carbon and fluorine and have properties and functionalities different from those of PFASs. In this document, we focus only on PFASs and use the terminology proposed by Buck et al.[1], which divides PFASs into two sub-groups: non-polymeric and polymeric PFASs (see Figure 1).

Within the non-polymeric PFAS group, four families are involved: (i) perfluoroalkyl acids (PFAAs) including but not limited to perfluoroalkyl carboxylic acids (PFCAs) and perfluoroalkane sulfonic acids (PFSAs); (ii) compounds derived from perfluoroalkane sulfonyl fluoride (PASF); (iii) fluorotelomer (FT)-based compounds; and (iv) per- and polyfluoroalkyl ether (PFPE)-based compounds.

Among all non-polymeric PFASs, the term “long-chain PFASs” refers to:

(i) PFCAs with 7 and more perfluoroalkyl carbons, such as PFOA (with 8 carbons or C_8 PFCA) and PFNA (with 9 carbons or C_9 PFCA);
(ii) PFSAs with 6 and more perfluoroalkyl carbons, such as PFHxS (with 6 perfluoroalkyl carbons, or C_6 PFSA) and PFOS (with 8 perfluoroalkyl carbons or C_8 PFSA); and
(iii) Substances that have the potential to degrade to long-chain PFCAs or PFSAs, i.e. precursors such as PASF- and fluorotelomer-based compounds.

Within the polymeric PFAS group we differentiate between

(i) Fluoropolymers: fluorinated polymers consisting of carbon-only backbone with fluorines directly attached to this backbone (e.g., polytetrafluoroethylene or PTFE; polyvinylidene fluoride or PVDF; fluorinated ethylene propylene or FEP; perfluoroalkoxyl polymer or PFA; etc.). Fluoropolymers are not made from PFCAs or their potential precursors (except that perfluorobutylethlyene (PFBE) can be used as a comonomer). PFCA homologues are, however, used as processing aids in the polymerization of some fluoropolymers.
(ii) Side-chain fluorinated polymers: fluorinated polymers consisting of variable compositions of non-fluorinated carbon backbones with polyfluoroalkyl (and possibly perfluoroalkyl) side chains. The fluorinated side-chains, including PASF- and fluorotelomer-based derivatives, are potential precursors of PFCAs.
(iii) Perfluoropolyethers: fluorinated polymers consisting of backbones containing carbon and oxygen with fluorines directly attached to carbon. They are not made from PFCAs or their potential precursors; and PFCAs or their potential precursors are not involved in the manufacturing of perfluoropolyethers.

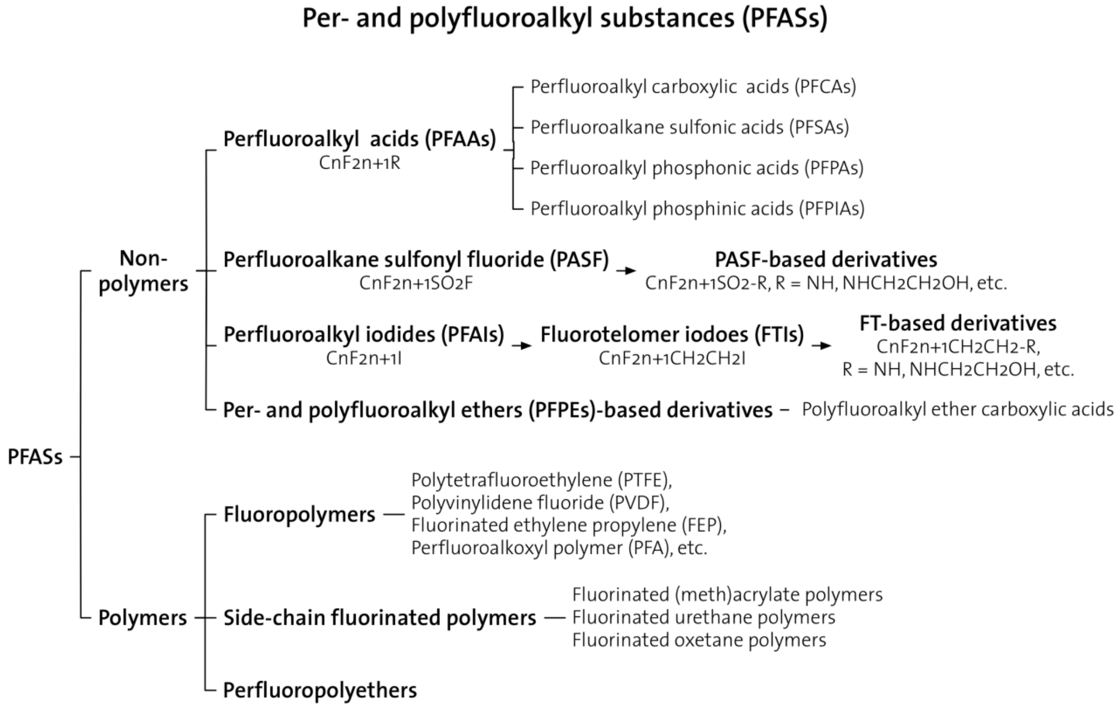

Figure 1: General classification of per- and polyfluoroalkyl substances (PFASs)[1]

In this synthesis paper, we focus mainly on PFCAs and their potential precursors (PASF- and fluorotelomer-based compounds). PFOS and related substances were included in Annex B (restriction of production and use) of the Stockholm Convention in 2009; for these substances, information on their relevance for human health and the environment and on commercial alternatives has been documented by the POP Review Committee of the Stockholm Convention. Therefore, we do not repeat detailed information on PFOS and related substances, but we provide short summaries and refer to the relevant documents on the Stockholm Convention website in each chapter, so that readers can look into more details if needed.

The synthesis paper consists of four major chapters,

(i) Chapter 1 – historical and current major uses of PFASs
(ii) Chapter 2– scientific evidence regarding source, exposure, environmental fate and potential adverse effects of PFASs
(iii) Chapter 3 – recent developments on alternatives to long-chain PFASs
(iv) Chapter 4 – regulatory approaches with respect to PFASs

CHAPTER 1. HISTORICAL AND CURRENT MAJOR USES OF PFASS

PFASs, both polymeric and non-polymeric, have been extensively used in various industries worldwide (see Table 1 and 2), due to their properties such as dielectrical properties, resistance to heat and chemical agents, low surface energy and low friction properties, etc.. The highly stable carbon-fluorine bond and the unique physicochemical properties of PFASs make these substances valuable ingredients for products with high versatility, strength, resilience and durability, which provide benefits to manufacturers and consumers. In this chapter, we provide an overview of historical and current major uses of PFASs, including PFCAs, PFSAs and their potential precursors (PASF- and fluorotelomer-based compounds) as well as relevant fluoropolymers and side-chain fluorinated polymers.

Since 2002, there has been a trend amongst global manufacturers to replace long-chain PFCAs, PFSAs and their potential precursors with chemicals containing shorter perfluoroalkyl chains or with non-perfluoroalkyl products.[2] This trend is driven by the undesired properties of long-chain PFASs concerning human health and the environment, as summarized in Chapter 2. Hence, some of the uses listed here may have been or are going to be replaced by alternatives, which are summarized in Chapter 3.

1.1 Industry branch-specific information on the uses of PFASs

1.1.1 Aviation, aerospace and defence

Fluoropolymers such as PTFE are extensively used in various mechanical components (e.g. semiconductors, wiring, tubing, piping, seals, gaskets, cables, etc). In addition, the salts of PFSAs (primarily PFOS) have been used as additives with a content of about or less than 0.1% in hydraulic fluids to prevent evaporation, fires and corrosion.[3]

1.1.2 Automotive

PFASs, primarily fluoropolymers, are used to improve fuel-delivery systems and to prevent gasoline seepage, for example, by reducing fugitive gas vaporization of hydrocarbons through fuel delivery tubing walls. In addition, these PFASs are used in under-hood wiring and components to make them heat and fluid resistant.

1.1.3 Biocides

Non-polymeric PFASs have been applied in biocides in two ways: (i) as active ingredients, for example, short-chain PFAS-based sulfonamides in some plant growth regulators and herbicides[4] and N-ethyl perfluorooctane sulfonamide (also known as sulfluramid or sulfuramid) in ant baits to control leaf-cutting ants, red imported fire ants and termites;[3] (ii) as inert ingredients (enhancers), e.g. two PFAS-based substances have been approved in pesticide formulations in the United States.[5]

Table 1: Overview of major historical and current uses of non-polymeric per- and polyfluoroalkyl substances (PFASs). It should also be noted that some uses may be obsolete and replaced by (non)fluorinated alternatives, which are discussed in Chapter 3. AFFF = aqueous film-forming foams, FFFPs = film-forming fluoroprotein.

Industry branch	**Non-polymers**		
	PFAAs	PASF-based compounds	Fluorotelomer-based compounds
1. Aviation, aerospace & defense	additives in aviation hydraulic fluids[3]		
2. Biocides		active ingredient in plant growth regulators or ant baits;[3] enhancers in pesticide formulations[5]	
3. Construction products		additives in paints and coatings	additives in paints and coatings
4. Electronics	flame retardants[6]		
5. Energy	as a fuel cell and battery electrolyte[6]		
6. Fire-fighting		film formers in AFFF[7]	film formers in AFFF and FFFP[7]
7. Household products	wetting agent in floor polishes	wetting agent or surfactant in products such as floor polishes and cleaning agents	wetting agent or surfactant in products such as floor polishes and cleaning agents
8. Metal plating	wetting agent, mist suppressing agent[3]	wetting agent, mist suppressing agent[3]	wetting agent, mist suppressing agent[3]
9. Oil and mining production	surfactants in oil well stimulation[3]	surfactants in oil well stimulation[3]	surfactants in oil well stimulation[3]
10. Paper and packaging		oil and grease repellent[4]	oil and grease repellent[3]
11. Polymerization	(emulsion) polymerization processing aids[8]	(co)monomer of side-chain fluorinated polymers[4]	(co)monomer of fluoropolymers & side-chain fluorinated polymers[8,9]
12. Semiconductors	active ingredients in etching processes[3]		

Table 2: Overview of major historical and current uses of polymeric per- and polyfluoroalkyl substances (PFASs). It should also be noted that some uses may be obsolete and replaced by (non)fluorinated alternatives, which are discussed in Chapter 3. AR-AFFF = alcohol-resistant aqueous fire-fighting foams, FFFPs = film-forming fluoroprotein; FP = fluoroprotein foam.

Industry branch	**Polymers**		
	Fluoropolymers	Side-chain fluorinated polymers	Perfluoropolyethers
1. Automotive	raw materials for components such as low-friction bearings & seals[9]		lubricants[8]
2. Aviation, aerospace & defense	insulators;[10] “solder sleeves”;[10]		
3. Cable & wiring	coating for weathering, flame and soil resistance[9]		
4. Construction products	coating of architectural materials (fabrics, metals, stone, tiles, etc.);[8] additives in paints	additives in paints and coatings	surface-treatment agent for conserving landmarks[8]
5. Electronics	insulators;[9] “solder sleeves”;[10]		vapor-phase soldering media[8]
6. Energy	film to cover solar collectors due to weatherability[8]		
7. Fire-fighting	raw materials for fire-fighting equipment, including protective clothing	fuel repellents for FP & foam stabilizers in AR-AFFF and FFFP;[7] coating for fire-fighting equipment	
8. Food processing	fabrication materials[9]		
9. Household products	nonstick coating[9]		
10. Medical articles	surgical patches cardiovascular grafts;[9] raw materials for implants in the human body[10]	stain- and water-repellents for surgical drapes and gowns	
11. Paper and packaging		oil and grease repellent[4]	oil and grease repellent
12. Semiconductors	raw materials for equipment[8,10]		working fluids in mechanical vacuum pumps[8]
13. Textiles, leather and Apparel	raw materials for highly porous fabrics[10]	oil and water repellent and stain release[4]	oil and water repellents

1.1.4 Cable and wiring

Due to their dielectric properties, low flammability or other mechanical properties, fluoropolymers such as PTFE or PVDF are widely used for cables and wires that are used in communication facilities (as insulators for high frequency electronics), low-frequency plenum cables, computer networks, automotive (heat resistance, engine oil, transmission fluid and brake fluid resistant), aerospace applications, and other demanding areas.[8]

1.1.5 Construction products

Fluoropolymers, such as PTFE and PVDF, are largely used as fire- or weather-resistant coating for materials (such as glass fabrics, tiles, flagstones, concrete or metals) in various construction-related applications.[8] In addition, PFASs such as fluoropolymers, side-chain fluorinated polymers, PASF- and fluorotelomer-based compounds can be used as additives (as leveling agents, dispersion agents, and for improving gloss and antistatic properties) blended in paints (e.g. low and no-VOC water-borne latex paints) where very low surface tension is needed.

1.1.6 Electronics

Fluoropolymers, due to the properties such as dielectric and water-repellent, are used in applications such as printed circuit boards, which are laminates of copper on a fiber-reinforced fluoropolymer layer.[8] In addition, due to the piezoelectric and pyroelectric properties, PVDF films are used in applications such as speakers and transducers, in order to provide an electrical signal in response to mechanical or thermal signals, or inversely, mechanical motion or a change in heat content in response to an applied electrical field.[8] The potassium salt of PFBS (CAS No. 29420-49-3) is marketed as flame retardants for polycarbonate resins.[6,11]

1.1.7 Energy

Fluoropolymers (e.g. FEP films) are applied to cover solar collectors, in order to enhance their weatherability.[8] Besides, the lithium salt of PFAAs such as trifluoromethanesulfonic acid has been investigated as a fuel cell and battery electrolyte.[4]

1.1.8 Fire-fighting

PFASs are used in (i) fire-fighting foams and (ii) fire-fighting equipment. Fire-fighting foams such as aqueous film-forming foams (AFFF), alcohol-resistant aqueous film-forming foams (AR-AFFF), fluoroprotein foam (FP) and film forming fluoroprotein (FFFP) are used to extinguish fires of petroleum and other flammable liquids. Various PFCA-, PASF- and fluorotelomer-based derivatives (polymeric or non-polymeric) have been developed as active ingredients (film formers, fuel repellents or foam stabilizers) used in small amounts in these fire-fighting foams. According to the Fire Fight Foam Coalition (http://www.fffc.org/), AFFF agents are mainly used in military, aircraft rescue fire fight (ARFF), municipal (e.g. fire departments), petro-chemical industry and oil platforms as well as merchant ships.[12] Fire-fighting equipment, including protective clothing for firefighters, can be either surface treated with side-chain fluorinated polymers or made from fluoropolymers such as woven, porous PTFE and its copolymers.

1.1.9 Household products

PFASs have been applied in many household applications. Fluoropolymers are used to coat the surfaces of cookware to impart non-stick properties.[8] Certain PFASs are used as emulsifiers, surfactants or wetting agents in applications such as cleaning agents, floor polishes and latex paints.[5,8] In addition, some PFASs are added in after-market products (such as water repellent sprays for apparel and footwear) that are applied to treat textiles, upholsteries, carpets, and leather, in order to impart water, oil, soil and stain resistance.[8] Typically these PFASs are PFAA-derivatives as well as PASF- and FT-based side-chain fluorinated polymers and non-polymeric compounds.[10]

1.1.10 Medical articles

The inert and non-adhesive character of fluoropolymers makes them suitable materials for implants and other articles.[8] In addition, there is still a substantial film use [x-rays] in medicine that require PFAS substances as surfactants in the making of the film. Medical fabrics, such as woven or nonwoven surgical drapes and gowns are treated with side-chain fluorinated polymers (such as PASF- or fluorotelomer-based (meth)acrylate polymers and polyurethanes) to modify the surfaces, in order to impart water-, oil- and stain-resistance.

1.1.11 Metal plating (hard metal plating and decorative plating):

Non-polymeric PFASs (such as the potassium, lithium, diethanolamine and ammonium salts of PFOS or 6:2 fluorotelomer sulfonate) have been used as surfactants, wetting agents and mist suppressing agents for both decorative chrome plating and hard chrome plating processes. Recent technology development on using chromium (III) instead of chromium (VI) has made PFOS use in decorative chrome plating obsolete. For hard plating, chromium (III) does not work,[5] and PFOS is still used for this application.

1.1.12 Oil and mining production

Non-polymeric PFASs such as PASF-based compounds, fluorotelomer-based compounds, and the salts of PFOS have been used as surfactants in the oil and mining industry to improve the performance of extraction fluids and thereby increase the efficiency of oil and gas extraction, as evaporation inhibitors for gasoline, as hydrocarbon solvents, and to increase the extraction efficiency in copper and gold mining.[5]

1.1.13 Paper and packaging

Three major types of PFASs have been applied in the paper and packaging industry: (i) side-chain fluorinated polymers in which the PASF- or fluorotelomer-based alcohols, their acrylate or methacrylate esters are attached on side chains; (ii) phosphate ester salts made through the esterification of PASF- or fluorotelomer-based alcohols with phosphoric acid;[4] (iii) perfluoropolyethers. The surface treatment with these PFASs imparts oil- and water-repellent properties to paper, paperboard and molded pulp products, including those that are in direct contact with food.

1.1.14 Polymer manufacturing

The ammonium salts (in some cases also the sodium salts) of long-chain PFCAs such as PFOA and PFNA have been applied as processing aids (emulsifiers) at low concentrations (around 0.5 wt%) in the polymerization of certain fluoropolymers (i.e. PTFE, FEP, PFA and PVDF) and fluoroelastomers.[4,13] After 2006, many fluoropolymer manufacturers in China, Japan, Western Europe and the United States started to replace the salts of long-chain PFCAs with the salts of short-chain PFCAs (such as PFHxA)[14,15] or other non-perfluoroalkyl alternatives (such as polyfluoroalkyl ether carboxylic acids) for fluoropolymer manufacturing.[1]

1.1.15 Semiconductors

Fluoropolymers such as PFA are used to manufacture components (such as complex molded wafer baskets) that are used to handle corrosive liquids and gases in the semiconductor industry, where requirements for very pure materials are paramount.[8] Small amount of PFOS are used in photolithography applications in manufacturing semiconductor chips (i.e. in liquid etchant in the photo mask rending process).[5]

1.1.16 Textiles, leather, carpets, apparel and upholstery

PFASs are involved in this field in two ways: (i) Highly porous fabrics (e.g., Gore-Tex®) are prepared by a process based on the fibrillation of high-molecular-mass PTFE. These types of fabrics are widely used in outdoors wear and camping accessories, due to their high permeability for water vapour, but none for liquid water.[10] (ii) Side-chain fluorinated polymers (such as PASF- or fluorotelomer-based (meth)acrylate polymers and polyurethanes) are used as finishes to modify the surfaces of targeted materials (such as textiles, carpets, leather, etc.), in order to impart water-, oil-, soil- and staining resistance. The finishes/treatments are applied to materials in mills/tanneries and as after-market applications by professionals or do-it-yourself as aqueous dispersions. In some after-market applications, they are applied as solutions in hydrocarbon-based or halogenated solvents.[8]

1.2 Specific information on uses of PFOS

Perfluorooctane sulfonic acid (PFOS, CAS No. 1763-23-1), its salts and perfluorooctane sulfonyl fluoride (POSF, CAS No. 307-35-7) have been listed under Annex B of the Stockholm Convention since 2009, and hence, their production and use is restricted. The Convention recognizes production and uses for acceptable purposes and specific exemptions, such as metal plating, insect baits for control of leaf-cutting ants, chemically driven oil production, aviation hydraulic fluids, photo-imaging, certain medical devices, coatings and coating additives, electric and electronic parts of colour printers, among others. A full list of acceptable purposes and specific exemptions is provided in Annex B of the Stockholm Convention (http://chm.pops.int). To support implementation of the Convention, the Conference of the Parties has instructed the development of several documents that describe the uses:

(i) 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.
    a. (http://chm.pops.int/Implementation/NIPs/Guidance/GuidanceonBATBEPfortheuseofPFOS/tabid/3170/Default.aspx)
(ii) Guidance for the inventory of perfluorooctane sulfonic acid (PFOS) and related chemicals listed under the Stockholm Convention on POPs
    a. (http://chm.pops.int/Implementation/NIPs/Guidance/GuidancefortheinventoryofPFOS/tabid/3169/Default.aspx)

CHAPTER 2. SCIENTIFIC EVIDENCE ON SOURCES TO THE ENVIRONMENT, HUMAN EXPOSURE, ENVIRONMENTAL FATE AND POTENTIAL ADVERSE EFFECTS ON HUMANS OF PFASS

In this chapter, we provide an overview of the current understanding of the health and environmental profiles (sources to the environment, human exposure, environmental fate and potential adverse effects on humans) of PFASs with a focus on long-chain PFAAs such as PFCAs and PFSAs and their potential precursors. For in-depth information on a specific PFAS chemical or topic, we recommend readers to consult the literature cited below. For example, a detailed profile of PFOS and its salts regarding their relevance for human health and the environment has been adopted and published by the Stockholm Convention (UNEP/POPS/POPRC.2/17/Add.5).

2.1 Sources and exposure routes of PFAAs and their potential precursors

2.1.1 Sources to the environment

PFAAs can be emitted into the environment from both direct and indirect sources.[1,13] "Direct" sources refer to PFAA emissions from the life cycle (manufacture, use and disposal) of products that contain PFAAs or their derivatives as ingredients, as unreacted raw materials (residuals) or as unintended by-products (impurities); "indirect" sources refer to formation of PFAAs from degradation of precursors such as some PASF- and fluorotelomer-based compounds, abiotically[16] or biotically.[17]

Depending on physicochemical properties, manufacturing procedures, and use and disposal patterns, PFAAs and their potential precursors may enter the environment via various exposure routes (Figure 2):

(i) through fugitive releases or through waste streams (exhaust gases, wastewater, sludge, solid wastes) from manufacturing sites;[13,18-20]
(ii) through volatilization along the supply chain from manufacturers to downstream industrial users or end consumers;
(iii) through fugitive releases or through waste streams (exhaust gases, wastewater, sludge, solid wastes) from downstream industrial user sites (e.g., fluoropolymer manufacturing sites, paper and textile factories), where products containing PFAAs and their potential precursors are applied, further processed or incorporated into industrial/consumer products;[13,21,22]
(iv) through volatilization,[23-26] wash off or direct use in the environment[3,27-30] during use phase of products containing PFAAs and their potential precursors;
(v) through inappropriate treatments of wastes containing PFAAs and their potential precursors, including use of sewage sludge as fertilizer,[31,32] untreated outgassing from landfills[33] or insufficient wastewater treatments,[33-35] etc.

Here, we provide an overview of each stage in the product life cycle, however, for specific products such as those mentioned in Chapter 1, exposure routes of relevant substances to the environment should be assessed individually along the product life cycle.

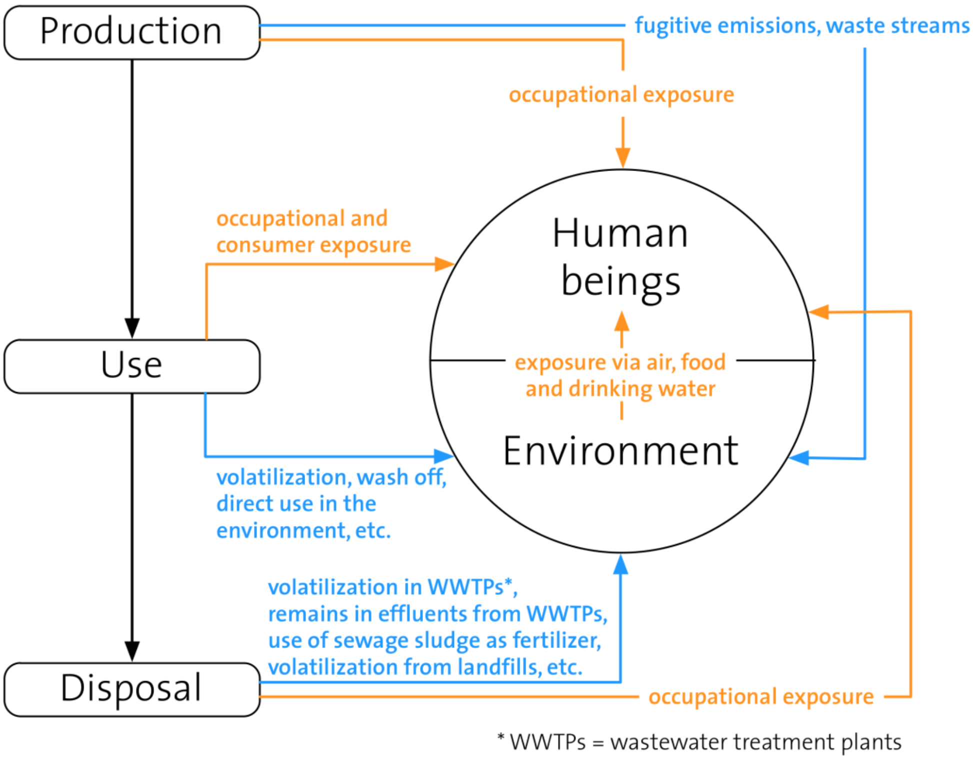

Figure 2: Exposure routes of PFAAs and their potential precursors to the environment and human beings during the life cycle of PFAS-containing products

2.1.2 Human exposure

In general, human exposure to PFAAs and their potential precursors can be divided into three major types: occupational exposure, general human exposure, and exposure from mother to foetus or infants.

Occupational exposure occurs during the performance of job duties. For example, high PFAA levels were found in workers at PFAS-related production sites,[36] and professional ski waxers,[37-40] which is higher than the PFAA levels detected in general population.

General human exposure to PFAAs and their potential precursors occurs via (i) indoor and outdoor air and aerosols, (ii) drinking water, (iii) dust, and (iv) food.[36,41-45] Sources of PFAAs and their potential precursors in various food items are contaminated air, water and soil as well as food packaging materials.[45-52] Dust might be a minor exposure pathway for adults in comparison to dietary intake,[53] however, it may be a significant pathway for infants and toddlers.[36,54]

Of particular concern is exposure of the foetus and of infants to PFASs. This exposure occurs in two ways: (i) PFCAs and PFSAs present in maternal blood may pass through the placenta, and are thus delivered to the foetus.[55] (ii) Lactating mothers likely transfer PFAAs to their infants through breast-feeding. Two studies show that PFOA levels in maternal blood decreased to 54% after six months and to 7% after 12 months of breast-feeding compared to their blood levels at child birth,[56] whereas PFOA levels in the serum of six-month-old infants were 4.6 times higher than maternal blood levels at birth.[57] Another Norwegian study estimated that breast-fed infants around 6 months of age take up 4.1 ng PFOA per kg body weight, which is 15 times higher than the uptake of adults.[58]

2.2 Environmental fate of PFAAs and their potential precursors

2.2.1 Persistence, fate, and transport in the environment

PFAAs are highly persistent in the environment, whereas their potential precursors such as fluorotelomer alcohol (FTOHs) and perfluorooctane sulfonamido ethanols (*x*FOSEs) are transformed into PFCAs and/or PFSAs, abiotically[16] or biotically.[17] PFAAs and their potential precursors are ubiquitous in the environment, even in remote regions.[59,60] Short-chain PFAAs are generally more mobile than their long-chain homologues; they are not retarded in soil and have already been detected in groundwater.[61] Among all environmental media, open ocean water is likely the largest global reservoir of PFAAs such as PFOA, PFNA and likely the other PFCA homologues;[62] water currents transport these PFAAs into remote areas, such as the Arctic.[63] In contrast, many PFAA precursors such as FTOHs and xFOSEs are semivolatile, have been frequently detected in air, and are transported via air currents and washed out by precipitation. There are probably no real environmental sinks of PFAAs; the long-term fate of these substances is transport to deep ocean water and/or sediment burial.[13]

For PFOA, its higher homologues and PFOS, the global fate and, in particular, their transport pathways to remote areas such as the Arctic have been studied by using global multi-media environmental fate models.[64-69] The modeling studies on PFOA and its higher homologues were recently reviewed[62] and were generally found to support the conclusion that direct uses of PFOA- and PFNA-based products were the dominant global sources for these two PFCAs.[13] Freshwater that is not affected by direct manufacturing sources may be affected by PFCA-laden municipal and industrial wastewater and from PFCA-laden runoff from precipitation.[70-74] Remote inland environments (such as alpine lakes, remote streams, remote soils, the High Arctic) are primarily affected by precipitation, but the ultimate origin of the PFCAs in the precipitation is uncertain; it could be from direct sources (manufacturing, use and disposal), indirect sources (precursor transformation) or a combination of both.[62,67,68,75]

2.2.2 Bioaccumulation in biota and humans

PFAAs have been detected worldwide in organisms, especially in fish, polar bears and seals.[60,76] Long-chain PFCAs are bioaccumulative[77] and can biomagnify along terrestrial food chains.[78-80] It should be noted that aquatic organisms take up PFASs from both water and contaminated food, whereas terrestrial organisms take up PFASs through food and air.[78-80] Various PFSAs and PFCAs are present in the blood of the general human population,[36,81,82] of which PFOA and PFOS are the most frequently detected species. PFOA and PFOS both have long residence times in human blood of more than 1000 days. Besides blood, these two PFAAs are enriched in the lung, liver and kidneys. In comparison to PFOA and PFOS, perfluorobutanoic acid (PFBA), perfluorobutane sulfonic acid (PFBS) and perfluorohexanoic acid (PFHxA) are likely eliminated by various species within shorter periods of time, whereas perfluorohexane sulfonic acid (PFHxS) has even longer elimination half-lives (see Table 3).

Table 3: Elimination half-life ($t_{1/2}$, days) of perfluorobutanoic acid (PFBA), perfluorobutane sulfonic acid (PFBS), perfluorohexanoic acid (PFHxA), perfluorohexane sulfonic acid (PFHxS), perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in serum in rat, monkey and human. Figures are derived from the Refs. 15,83-94

$t_{1/2}$, days	PFBA	PFBS	PFHxA	PFHxS	PFOA	PFOS
Rat	0.3	0.2	0.05–0.2	7	5	25
Monkey	2	4	1	100	21	45
Human	3–4	26	< 28	3000	1000	1500

2.3 Potential adverse effects of PFAAs in humans

High levels of PFOS and PFOA are toxic for reproduction and development of the fetus (such as reducing birth weight[95] and lowering semen quality[96]) and are potentially carcinogenic in animal tests.[94,97-99] In addition, 8:2 fluorotelomer phosphate diesters (8:2 PAPs), 8:2 FTOH, and PFOA show endocrine effects in different in vitro and in vivo tests.[100-102] Furthermore, a study with 656 children has demonstrated that elevated exposures to PFOA and PFOS are associated with reduced humoral immune response to routine childhood immunizations in children aged five and seven years.[103]

In addition to toxicity studies, a large epidemiological study of 69,000 persons – the C8-science panel[C] – found probable links between elevated PFOA blood levels and the following diseases: high cholesterol (hypercholesteremia), ulcerative colitis, thyroid diseases, testicular cancer, kidney cancer, preeclampsia, and elevated blood pressure during pregnancy.[104-113] The reason for this study was to determine whether a probable link exists between PFOA and any human disease as part of a class action settlement of a lawsuit involving releases of the chemical known as PFOA from DuPont's Washington Works in Wood County, West Virginia. Inhabitants of the surrounding area showed 500-times elevated PFOA-concentrations in blood compared to the general population.

[C] http://www.c8sciencepanel.org/index.html

CHAPTER 3. RECENT DEVELOPMENTS ON ALTERNATIVES TO LONG-CHAIN PFASS

Since 2002, there has been a trend amongst global manufacturers and downstream users to replace long-chain PFASs, in particular PFOS and PFOA, with alternative chemicals or non-chemical techniques. This chapter aims to give an overview of this on-going transition process. Due to a lack of information in the public domain, it is not possible to cover all major industry branches that are listed in Chapter 1, nor can details including chemical structure, transition time plans, and environmental and toxicological profiles of all alternatives be provided. However, it should be noted that two documents have been published under the Stockholm Convention where readers can find detailed information on alternatives to PFOS and related chemicals:

(i) Draft guidance on alternatives to perfluorooctane sulfonic acid and its derivatives (UNEP/POPS/POPRC.6/13/Add.3/Rev.1); [5]
(ii) Technical paper on the identification and assessment of alternatives to the use of perfluorooctane sulfonic acid in open applications (UNEP/POPS/POPRC.8/INF/17).[3]

3.1 Commercially available alternatives to long-chain PFASs

Three types of alternatives are available:

(i) substances with shorter per- or polyfluorinated carbon chains;

(ii) non-fluorine-containing substances; and (iii) non-chemical techniques.

3.1.1 Substances with shorter per- or polyfluorinated carbon chains

Various substances with shorter per- or polyfluorinated carbon chain have been developed that may be used for replacement of many uses of long-chain PFASs.[114] Major substance groups include:

(i) 6:2 fluorotelomer-based chemicals as replacements of their higher homologues;[1]
(ii) perfluorobutane sulfonyl fluoride (PBSF)-based derivatives as replacements of chemicals based on perfluorooctane sulfonyl fluoride (POSF) in surface treatment and coatings;[1]
(iii) mono- and polyfluorinated-ether-functionality compounds (e.g., polyfluoroalkyl ether carboxylic acids are alternative processing aids for fluoropolymer manufacturing[1]);
(iv) fluorinated oxetanes;
(v) other fluorinated polymers.

It should be noted that some PFAS-manufacturers in China and Italy have initiated the production of perfluorohexane sulfonyl fluoride (PHxSF) and its derivatives as replacements of POSF-based chemicals (e.g., in textile finishing agents).[115,116] However, these substances are not suitable as alternatives, since they are potential precursors of PFHxS that is also defined as a long-chain PFSA.

3.1.2 Non-fluorine-containing substances

Non-fluorine containing substances are available for some applications, but may not work as well as long-chain PFASs, particularly in situations where extremely low surface tension and/or durable oil- and water-repellence is needed.[114] Major substance groups include:

(i) propylated naphthalenes or biphenyls (as water repelling agents for rust protection systems, marine paints, coatings, etc.);
(ii) fatty alcohol polyglycol ether sulphate (as levelling and wetting agents);

(iii) sulfosuccinates (for surface coating, paint and varnish);
(iv) hydrocarbon surfactants (for photographic industry);
(v) naphthalene derivatives,
(vi) siloxanes and silicone polymers (for impregnation of textiles, leather and carpets or for surface coating, paint and varnish);
(vii) stearamidomethyl pyridine chloride (for impregnation of textiles, leather and carpets);
(viii) polypropylene glycol ether, amines, and sulphates.

For example, a new technology in decorative chrome plating based on chromium (III) instead of chromium (VI) has enabled the use of hydrocarbon surfactants and thus made the use of PFOS obsolete.[3]

3.1.3 Non-chemical techniques

In some cases, it is possible to use non-chemical techniques to replace long-chain PFASs. For example, various biological, physical or natural control methods have been developed to control leaf cutter ants.[3] In addition, foam blankets and other barrier materials are used for mist suppression in electrochemical metal plating as non-chemical alternatives to the PFOS-based fluorinated surfactant mist suppression.[117]. Depending on the needed properties of the material, other techniques not considered here may also be available. These are, however, beyond the scope of this paper.

3.2 Health-related and environmental profiles of some alternatives

Alternatives to long-chain PFASs undergo regulatory review in some countries, where companies are required to submit specific information which may include information on the health and environmental profiles (such as bioaccumulation potential, (eco)toxicity, biodegradability, etc.) of alternatives. For example, the U.S. Environmental Protection Agency (US EPA) has reviewed over 150 alternatives (http://www.epa.gov/oppt/pfoa/pubs/altnewchems.html). Due to confidentiality and trade secret concerns, many of these data have not been published or made publically available. In addition, in other countries with lower regulatory requirements, it is unclear whether the health and environmental profiles of alternatives would be fully tested before they are commercialized. Furthermore, information on actual releases and exposures of alternatives is largely missing.

Here, we provide a list of publications on the health-related and environmental profiles of some alternatives that are publicly available (see Box 2). Most of this information concentrates on PFBA, PFBS and PFHxA as they occur as ingredients or undesired impurities in products or degradation products of some alternatives. Since the industrial transition from long-chain PFASs to alternatives is an ongoing process and more information on alternatives will become available, we recommend readers to consult the website of the OECD/UNEP Global PFC Group, where information regarding commercial alternatives of long-chain PFASs and the health-related and environmental profiles of these alternatives is regularly updated (http://www.oecd.org/ehs/pfc/informationonshort-chainpfcsandotheralternatives.htm).

Box 2: Publicly available information on the health and environmental profiles of some alternatives

(i) NICNAS, Department of Health and Ageing, Australian Government (2005) Existing chemical hazard assessment report: potassium perfluorobutane sulfonate. http://www.nicnas.gov.au/Publications/CAR/Other/Potassium_Perfluorobutane_Sulfonate_PDF.pdf

(ii) Poulsen et al. (2005) More environmentally friendly alternatives to PFOS-compounds and PFOA. Environmental Project No.1013, Danish Ministry of the Environment. http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/udgiv/publications/2005/87-7614-668-5/html/helepubl_eng.htm

(iii) Sonneveld et al. (2007). Perfluoroalkyl acids have no endocrine disrupting activities via human steroid hormone receptors as determined by a panel of CALUX bioassays. *Organohalogen Compounds* 69, 674/1.

(iv) Chengelis et al. (2009) A 90-day repeated dose oral (gavage) toxicity study of perfluorohexanoic acid (PFHxA) in rats (with functional observational battery and motor activity determinations). *Reprod Toxicol* 27(3–4), 342.

(v) Chengelis et al. (2009) Comparison of the toxicokinetic behavior of perfluorohexanoic acid (PFHxA) and nonafluorobutane-1-sulfonic acid (PFBS) in cynomolgus monkeys and rats. *Reprod Toxicol* 27(3–4), 400–406.

(vi) Loveless et al. (2009) Toxicological evaluation of sodium perfluorohexanoate. *Toxicology* 264(1–2), 32–44.

(vii) D'eon et al. (2010). Determining the molecular interactions of perfluorinated carboxylic acids with human sera and isolated human serum albumin using nuclear magnetic resonance spectroscopy. *Environ Toxicol Chem*, 29(8), 1678–1688.

(viii) Eriksen et al (2010): Genotoxic potential of the perfluorinated chemicals PFOA, PFOS, PFBS, PFNA and PFHxA in human HepG2 cells. *Mutat Res-Envir Muta* 700(1–2), 39–43.

(ix) Iwai et al. (2010) Ecotox and Pk findings for ammonium perfluorohexanoate (APFHx). Poster # P2, in PFAA Days III, June 8–10, 2010, U.S. EPA Research Triangle Park Campus.

(x) Himmelstein et al. (2008) Sodium perfluorohexanoate pharmacokinetics in rats during & after 90-day oral gavage administration. Poster #956, in 47th Society of Toxicology Annual Meeting, March 16–20, Seattle, USA

(xi) Iwai (2011) Toxicokinetics of ammonium perfluorohexanoate. *Drug Chem Toxicol* 34(4), 341–346.

(xii) Iwai et al. (2011) A 24-month oral combined chronic toxicity/carcinogenicity study of perfluorohexanoic acid (PFHxA) in rats, Poster #54, in STP Annual Symposium, June 19–23, 2011, Denver, USA

(xiii) Gannon et al. (2011) Absorption, distribution, metabolism, and excretion of [1-^{14}C]-perfluorohexanoate ([^{14}C]-PFHx) in rats and mice. *Toxicology* 283(1), 55–62.

(xiv) Gordon (2011) Toxicological evaluation of ammonium 4,8-dioxa-3H-perfluorononanoate, a new emulsifier to replace ammonium perfluorooctanoate in fluoropolymer manufacturing. *Regul Toxicol Pharmacol* 59(1), 64.

(xv) Iwai et al. (2012) Combined developmental and perinatal/postnatal reproduction oral toxicity study of ammonium perfluorohexanoate in mice. Poster # 2372, in 51st Society of Toxicology Annual Meeting, 2012, March 11–15, 2012, San Francisco, USA

(xvi) Cassone et al. (2012) In ovo effects of perfluorohexane sulfonate and perfluorohexanoate on pipping success, development, mRNA expression, and thyroid hormone levels in chicken embryos. *Toxicol Sci* 127(1), 216–224

(xvii) The Stockholm Convention secretariat (2012) Technical paper on the identification and assessment of alternatives to the use of perfluorooctane sulfonic acid in open applications. (UNEP/POPS/POPRC.8/INF/17)

More and regularly updated information can be found on the PFC Web Portal: www.oecd.org/ehs/pfc

CHAPTER 4 – REGULATORY APPROACHES WITH RESPECT TO PFASS

This chapter provides an overview of regulatory approaches taken by countries and international bodies with respect to PFASs, mainly long-chain PFCAs (C_8 and greater). A regulatory overview for PFOS and its related chemicals is not provided here. As a result that they have been listed under Annex B (restriction of production and use) of the Stockholm Convention since 2009, parties that have ratified the Convention are required to implement domestic control measures of PFOS and its related chemicals.

4.1 An overview of regulatory approaches for long-chain PFCAs

Risk management is a process that sets out control conditions for chemical substances that may cause harm, such as uses of a chemical substance, the way it is made, and/or the amount or concentration that is released to the environment. A number of different tools exist for managing substances of concern, including regulations, rules for use, and voluntary controls.

In the case of long-chain PFCAs, risk management tools may be used to control any aspect of the life cycle from the design and development stage to the manufacture, use, handling/storage, import, export, release and ultimate disposal of the chemicals. Proposed regulatory or risk management controls for long-chain PFCAs in North America and Europe are moving towards restrictions and bans on use and production, in addition to controls for handling and releases. These restrictions and bans are currently proposed to capture both long-chain PFCAs and their potential precursors. Restrictions and bans on long-chain PFCAs will also further contribute to reduction, or elimination, of product content of long-chain PFCAs, and the availability of these substances of being recycled into new products. In Table 4, we provide an overview of regulatory approaches being undertaken by different countries as well as international bodies. More country-specific details can be found in the later sub-sections.

Table 4: Overview of regulatory approaches / risk management actions for PFCAs in different countries as well as by international bodies

Country	Action	Proposed Date	Effective Date	Contact Information
Canada	• Voluntary *Environmental performance agreement respecting PFCAs and their precursors in perfluorochemical products sold in Canada.* • http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=AE06B51E-1	March 30, 2010	December 31, 2015	GR-RM@ec.gc.ca
	• Proposed Risk Management Approach for *Perfluorooctanoic acid (PFOA), its salts, and its precursors and long-chain (C_9–C_{20}) perfluorocarboxylic acids (PFCAs), their salts, and their precursors.* http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=F68CBFF1-1	August, 2012	Pending	GR-RM@ec.gc.ca
U.S.	• 2010/15 PFOA Stewardship Program http://www.epa.gov/oppt/pfoa/pubs/stewardship/index.html	January, 2006	December 31, 2015	
	• Significant New Use Rules (SNUR): *Perfluoroalkyl sulfonates and long-chain perfluoroalkyl carboxylate chemical substances* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2012-0268-0001	August 15, 2012	Pending	
Russia	Ammonium perfluorononanoate (APFO, CAS No. 4149-60-4) is regulated in occupational air with a tentative safe exposure level of 0.05 mg/m3 (Hygiene Norm 2.2.5.2308-07). A number of short- and middle chain PFASs are regulated in occupational air and water, and are generally referred to as low hazardous substances.			
Norway	Adopted regulations to restrict the production, import, export or sale of consumer products that contain PFOA in consumer products if they exceed certain limit values. http://alert.scc.ca/wto_e/TBT-NOR-17-07Rev_1.html	December 20, 2011	Pending	postmottak@klif.no
Germany	Proposed quality standards and reduction targets applicable to water bodies, wastewater, and soils to be introduced with respect to PFASs. http://www.umweltdaten.de/publikationen/fpdf-l/3818.pdf	July, 2007 (first draft); revised in July, 2009	Pending	info@umweltbundesamt.de
European Union	C_{11}–C_{14} PFCAs listed as vPvB-substances on the REACH candidate list (Substances of Very High Concern); proposal to list PFOA as well		December, 2012 June, 2013	chemicals@uba.de postmottak@klif.no

4.2 Country-specific information

4.2.1 Canada

In June 2006, the Government of Canada published its Action Plan for the Assessment and Management of Perfluorinated Carboxylic Acids and their Precursors.[118] This Action Plan addresses the assessment and management of the broad class of PFCAs and PFCA precursors as well as identifies the following three major actions related to control measures:

1) **Preventing the introduction into Canada of new substances that would contribute to the observed load of long-chain PFCAs in the environment.**

   On October 13, 2010, the *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (Four New Fluorotelomer-based Substances)* were published in the *Canada Gazette*, Part II;[119] they prohibit, the manufacture, use, sale, offer for sale and import of four fluorotelomer-based substances, found to be precursors to long-chain PFCAs, unless these substances are present in certain manufactured items.

2) **Seeking action from industry to address confirmed sources of PFCAs from substances already in Canadian commerce.**

   A voluntary *Environmental Performance Agreement Respecting PFCAs and their Precursors in Perfluorochemical Products Sold in Canada* was signed on March 30, 2010.[120] The Performance Agreement was identified as an early risk management action, while Environment Canada and Health Canada pursued further assessment to guide further risk management actions. The agreement includes action to reduce PFOA, long-chain PFCAs and their precursors, which are present in the form of residuals or impurities in products currently in commerce in Canada, by 95% by December 31, 2010, and to eliminate them by December 31, 2015.

   Companies participating in this agreement have submitted baseline and annual reporting data. The data received from companies indicates that significant progress is being made in reaching the targets set out in the Performance Agreement, and companies are reducing residual PFCAs in products sold in Canada (http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=AE06B51E-1).

3) **Pursuing further assessment of PFCAs and PFCA precursors already in Canadian commerce.**

   On August 25, 2012, the Government of Canada published two final screening assessment reports on (i) PFOA (C_8), its salts and precursors[121] and (ii) long-chain (C_9–C_{20}) PFCAs, their salts and precursors.[122] These final screening assessment reports conclude that:

   (i) PFOA and long-chain PFCAs are entering or may be entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

   (ii) PFOA and long-chain PFCAs are extremely persistent and meet the criteria for persistence, but do not meet the criteria for bioaccumulation as set out in the Persistence and Bioaccumulation Regulations.123 Nevertheless, the weight of evidence is sufficient to conclude that both PFOA and long-chain PFCAs and their salts accumulate and biomagnify in terrestrial and marine mammals; and

   (iii) PFOA is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

As a result of the outcome of the final screening assessments, the Government of Canada published a Risk Management Approach document for a 60-day public comment period. The Risk Management Approach document proposes the prohibition of PFOA and long-chain PFCAs through regulation. A prohibition regulation would prohibit the manufacture, use, sale, offer for sale, import and export of PFOA and long-chain PFCAs and products containing PFOA and long-chain PFCAs. Further information on the final screening assessment reports and the risk management approach for PFOA and long-chain PFCAs, including their salts and precursors, can be found at: http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=F68CBFF1-1

4.2.2 United States of America

In January 2006, the United States Environmental Protection Agency (US EPA) introduced the voluntary 2010/2015 PFOA Stewardship Program to reduce and eliminate facility emissions and product content for PFOA, precursor chemicals that can break down to PFOA, and related higher homologue chemicals.[124] Participating companies agreed to decrease emissions from the production and product contents of PFOA and PFOA-related compounds by 95% by 2010, and to work toward eliminating them completely by the year 2015. The 2010 progress report shows significant progress has been made in reaching the targets (http://www.epa.gov/oppt/pfoa/pubs/stewardship/preports5.html) and companies reported that they're on track to meet the 2015 goal.[125]

Of note, as outlined in the US EPA's *Long-Chain Perfluorinated Chemicals (PFCs) Action Plan*, 2009, the US EPA intends to consider initiating rulemaking under the Toxic Substances Control Act (TSCA) section 6 to manage long-chain PFASs. If the US EPA can make certain findings with respect to these chemicals, TSCA section 6 provides authority for the US EPA to ban or restrict the manufacture (including import), processing, and use of these chemicals. EPA will also consider additional approaches if assessments of theses chemicals indicate that a different approach to risk management is more appropriate,

On August 15, 2012, the US EPA proposed a Significant New Use Rule (SNUR, see Annex III for definition) under the TSCA to amend a SNUR for perfluoroalkyl sulfonate (PFAS) chemical substances to add PFAS chemical substances that have completed the TSCA new chemical review process but have not yet commenced production or import, and to designate (for all listed PFAS chemical substances) processing as a significant new use. EPA also proposed a SNUR for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances that would designate manufacturing, importing, or processing for use as part of carpets or for treating carpet (e.g., for use in the carpet aftercare market) as a significant new use. Persons subject to these SNURs would be required to notify EPA at least 90 days before commencing any significant new use. The required notifications would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs (http://www.epa.gov/oppt/pfoa/pubs/pfas.html#proposed)

4.2.3 Russia

Regulations regarding PFASs in Russia are implemented in accordance with international conventions and agreements including the Baltic Marine Environment Protection Commission (HELCOM, Recommendation 31E/1), the Stockholm Convention on POPs (Annexes A and B), the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemical and Pesticides in International Trade, the Strategic Approach to International Chemicals Management, SAICM, and the current OECD program on the management of PFASs and transition to safer alternatives. At the same time, in accordance with the Russian legislation, chemicals can only be placed on the Russian market after (i) their hazard is investigated, (ii) relevant hygiene norms in occupational air and other media of human beings are established, and (iii) an adequate authorization document (state registration certificate) is available.

PFASs that are subject to regulations by the international conventions and agreements mentioned above (i.e. PFOS and its related chemicals) are not produced in Russia, which is confirmed by the fact that they are not listed in the Federal Register of Potentially Hazardous Chemical and Biological Substances

(FBEPH, http://www.rpohv.ru/lang/en/) under jurisdiction of the Federal Service on Consumers' Rights Protection and Human Well-being Surveillance (http://rospotrebnadzor.ru/en/web/en/). Neither are they listed in open domestic databases on products produced on the Russian territory. But they are imported to Russia for use as ingredients of foam-forming agents. It should be noted that the accompanying safety data sheet (SDS) for PFASs imported to Russia frequently identify them as surfactants without denoting the nature of the chemical. In addition, regulatory documents of the Customs Union (Belarus, Kazakhstan and Russia) do not foresee bans or restrictions on those PFASs that are subject to regulations by international conventions and agreements.

Among PFASs that are under consideration and listed in the OECD document ENV/JM/MONO(2011)1, in ammonium perfluorononanoate (APFO, CAS No. 41349-60-4) is regulated in Russia in occupational air with a tentative safe exposure level of 0.05 mg/m^3 (Hygiene Norm 2.2.5.2308-07). A number of short- and middle-chain PFASs are regulated in occupational air and water, and are generally referred to low hazardous substances.

4.2.4 Germany

In July 2007, the German Federal Environment Agency (UBA) and the Drinking Water Commission proposed quality standards and reduction targets applicable to water bodies, wastewater and soils with respect to PFASs. The majority of the German Federal States consider limit values for PFASs in sewage sludge and soil as well as wastewater, surface water and groundwater.

A background document *Do without per- and polyfluorinated chemicals and prevent their discharge into the environment* was developed by the UBA further outlining the impacts of PFASs and their releases into the environment (German Federal Environment Agency in 2007, and revised in 2009, http://www.umweltdaten.de/publikationen/fpdf-l/3818.pdf).

4.2.5 Norway

PFOA and PFOS are included in the Norwegian List of Priority Substances, and considered as high-priority hazardous substances that are persistent, bioaccumulative and/or toxic.

In May 2007, the Norwegian Pollution Control Authority (SFT) established a proposal to introduce regulations limiting the levels of 10 substances, including PFOA, in consumer products. The proposed regulations cover production, imports, exports and trade of consumer products that contain one or more of the ten substances when the substance content in the product exceeds or is equal to established limit values. This initiative is on hold pending the results of a separate process under the European Union that proposes to control a number of substances in the proposed Norwegian regulations, not including PFOA.

On June 12th, 2013, Norway adopted a regulation to restrict the production, import, export, or sale of consumer products containing PFOA in levels that exceed certain limit values (http://alert.scc.ca/wto_e/TBT-NOR-17-07Rev_1.html). It is noted that the regulation does not apply to food products, food packaging, fertilizer, tobacco, medicine, means of transport, permanently mounted equipment for means of transport and tires and similar accessories for means of transport.

4.2.6 European Union

1) Harmonized classification and labeling

In 2010, Norway submitted a harmonized classification and labeling proposal according to the CLP-regulation (EC) No. 1272/2008 for PFOA and its ammonium salt (APFO). The Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) adopted two opinions on the proposal and published them in December 2011 (http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance/813/search/+/del/20/col/OPINIONDATERAC/type/desc/pre/3/view and http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance/305/search/+/term). The recent RAC opinions on PFOA and APFO conclude that the substances fulfil among others the criteria for classification as Repr. 1B (H360D; ”May damage the unborn child”) according to the CLP Regulation (Regulation (EC) 1272/2008). The corresponding classification according to Council Directive 67/548/EEC is “toxic for reproduction”, Repr. Cat. 2 (R61; “May cause harm to the unborn child”). On the basis of this opinion the European Commission will decide on the harmonized classification and labelling at the next Adoption to Technical progress (ATP). Subsequently PFOA will be included in Annex VI of the CLP-regulation.

Furthermore, a proposal for the harmonized classification and labelling for perfluorononanoic acid and perfluorodecanoic acid (PFNA and PFDA) is being prepared by Sweden according to the reprotoxic properties of these substances.

2) Identification as Substances of Very High Concern (SVHC)

Germany submitted a proposal to identify long-chain perfluoroalkyl carboxylic acids with 11 to 14 carbon atoms (C_{11}–C_{14} PFCAs) as substances of very high concern according to Art. 57e) of the European Chemicals Regulation (REACH EC 1907/2006).[D] In December 2012, the Member State Committee identified these substances as being very persistent and very bioaccumulative (vPvB). Subsequently the compounds have been added to the Candidate List of Substances of Very High Concern (SVHC). (http://echa.europa.eu/web/guest/regulations/reach/authorisation/the-candidate-list). Inclusion of substances on this list creates legal obligations to companies that are manufacturing, importing or using such chemicals.

In addition, Germany and Norway submitted to the European Chemicals Agency a proposal for the identification of the SVHC properties of PFOA and APFO[126]. Due to its intrinsic properties, Germany and Norway assessed PFOA as a persistent, bioaccumulative and toxic substance (PBT).[126] In June 2013 the Member State Committee agreed unanimously with this assessment. PFOA and APFO are also listed on the REACH Candidate List.[E]

3) Restrictions

[D] http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance/1509/search/+/del/20/col/PROPOSINGREASONAXVR/type/desc/pre/1/view

http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance/1510/search/+/del/20/col/PROPOSINGREASONAXVR/type/desc/pre/1/view

http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance/1513/search/+/del/20/col/PROPOSINGREASONAXVR/type/desc/pre/1/view

http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance/1514/search/+/del/20/col/PROPOSINGREASONAXVR/type/desc/pre/1/view

[E] http://echa.europa.eu/web/guest/candidate-list-table

Germany and Norway are preparing a restriction dossier to restrict the use, the manufacturing and the import of PFOA including relevant precursors, and articles containing PFOA.

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ANNEX I: ACRONYMS

AFFF	aqueous film-forming foams
CAS	Chemical Abstracts Service
ECHA	European Chemicals Agency
FEP	fluorinated ethylene propylene copolymer
FFFP	film-forming fluoroprotein
FP	fluoroprotein foam
FT	fluorotelomer
OECD	Organisation for Economic Co-operation and Development
PASF	perfluoroalkane sulfonyl fluoride
PBSF	perfluorobutane sulfonyl fluoride
PBT	persistent, bioaccumulative, toxic
PFA	perfluoroalkoxyl polymer
PFAAs	perfluoroalkyl acids
PFASs	per- and polyfluoroalkyl substances
PFBA	perfluorobutanoic acid
PFBS	perfluorobutane sulfonic acid
PFCAs	perfluoroalkyl carboxylic acids
PFHxA	perfluorohexanoic acid
PFHxS	perfluorohexane sulfonic acid
PFOA	perfluorooctanoic acid

PFOS	perfluorooctane sulfonic acid
PFNA	perfluorononanoic acid
PFPEs	per- and polyfluoroalkyl ethers
PFSAs	perfluoroalkane sulfonic acids
PHxSF	perfluorohexane sulfonyl fluoride
POSF	perfluorooctane sulfonyl fluoride
PTFE	polytetrafluoroethylene
PVDF	polyvinylidene fluoride
SNUR	Significant New Use Rule
US EPA	United States Environmental Protection Agency
vPvB	very persistent, very bioaccumulative
*x*FOSE	N-methyl and N-ethyl perfluorooctane sulfonamido ethanols

ANNEX II: SIGNIFICANT NEW USE RULE (SNUR), UNITED STATES

Section 5(a) of the Toxic Substances Control Act (TSCA) authorizes EPA to determine if a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2):

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of humans or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of humans or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use.

This provides EPA with an opportunity to review and evaluate the data before the submitter begins manufacturing, importing, or processing for the significant new use. EPA may then regulate the manufacture, import, or processing of that chemical substance before the initiation of the significant new use, if regulation is warranted.

EPA also uses significant new use rules (SNURs) in appropriate circumstances to ensure that, once a chemical has been phased out or taken off the market for certain uses, no company will be able to resume manufacturing or processing the chemical for that use without prior notice to the Agency. These are sometimes referred to as "dead chemical SNURs." This action can prevent older chemical substances that we now know to be dangerous from returning to the market after responsible companies have replaced them with safer substances.

Further Information: http://www.ec.gc.ca/toxiques-toxics/default.asp?lang=en&n=F64D6E3B-1