



**Stockholm Convention
on Persistent Organic
Pollutants**

Persistent Organic Pollutants Review Committee

Thirteenth meeting

Rome, 17–20 October 2017

**Report of the Persistent Organic Pollutants Review Committee
on the work of its thirteenth meeting**

Addendum

**Risk management evaluation on pentadecafluorooctanoic acid
(CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and
PFOA-related compounds**

At its thirteenth meeting, by its decision POPRC-13/2, the Persistent Organic Pollutants Review Committee adopted a risk management evaluation on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds on the basis of the draft contained in the note by the Secretariat (UNEP/POPS/POPRC.13/3), as revised during the meeting. The text of the risk management evaluation as adopted is set out in the annex to the present addendum. It has not been formally edited.

Annex

**PFOA, ITS SALTS AND PFOA-RELATED
COMPOUNDS**

RISK MANAGEMENT EVALUATION

October 2017

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Executive Summary

1. In June 2015 the European Union (EU) and its member States submitted a proposal to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds¹ in Annexes A, B, and/or C to the Stockholm Convention (UNEP/POPS/POPRC.11/5). At its twelfth meeting in September 2016, the Persistent Organic Pollutants Review Committee (POPRC) concluded that PFOA is persistent, bioaccumulative and toxic to animals including humans. There is widespread occurrence of PFOA and a number of PFOA-related compounds in environmental compartments and in biota and humans. Therefore, PFOA, its salts and PFOA-related compounds that degrade to PFOA are likely, as a result of their long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action is warranted (UNEP/POPS/POPRC.12/11/Add.2).
2. The scope of the chemicals covered is defined in paragraph 21 of the risk management evaluation (UNEP/POPS/POPRC.13/7/Add.2) and a comprehensive list of substances is available in document UNEP/POPS/POPRC.13/INF/6/Add.1.
3. PFOA, its salts and PFOA-related compounds are used in a wide variety of applications and consumer products across many sectors (details see UNEP/POPS/POPRC.12/11/Add.2). PFOA and its salts are, or were, most widely used as processing aids in the production of fluoroelastomers and fluoropolymers, with polytetrafluoroethylene (PTFE) being an important fluoropolymer used in producing, e.g. non-stick kitchen ware. PFOA-related compounds, including side-chain fluorinated polymers, are used as surfactants and surface treatment agents, e.g. in textiles, paper, paints, firefighting foams. Based on the available information in the risk management evaluation, these were the uses with the highest amount of PFOA.
4. Releases occur from past and ongoing production, use and disposal. Direct releases to the environment of PFOA and/or related compounds occur from the production of the raw substances (including PFOA as impurity in the manufacturing of PFOA-related compounds and some alternatives) during the processing, use and disposal of the chemical, from treated articles and from products contaminated with PFOA. Main emission vectors of PFOA and its salts are wastewater and particles/aerosols. Indirect releases of PFOA occur from the biotic and abiotic (photo-) degradation or transformation of precursors. PFOA-related compounds, as defined in para 21, are released to air, water, soil and solid waste, and will, to a greater or lesser degree, degrade to PFOA in the environment and in organisms. Releases of PFOA from degradation contribute a major share to the releases of PFOA in some local environment, e.g. remote inland environments (details see UNEP/POPS/POPRC.12/11/Add.2).
5. The activities of the Strategic Approach to International Chemicals Management (SAICM) at the global level focus on gathering and exchanging information on perfluorinated chemicals and to support the transition to safer alternatives. Voluntary efforts to phase out PFOA and related substances have been implemented, such as the United States Environment Protection Agency (USEPA) PFOA Stewardship Program and work by industry. In 2006, the eight main manufacturers of fluoropolymers and fluorotelomers in the US, Europe and Japan agreed on a phase-out of their production and use of PFOA and related long-chain substances by the end of 2015. A similar program existed with manufacturers in Canada. All Stewardship Program participants were successful at virtually eliminating those chemicals from facility emissions and product content. The voluntary phase out did not include manufacturers using PFOA in countries who were not part of the voluntary efforts, i.e. including those having large manufacturers and/or users of PFOA like China, India and Russia (details see UNEP/POPS/POPRC.12/11/Add.2).
6. Regulatory risk management approaches are implemented or underway in several national legislative control actions i.e. Norway, EU (existing restriction) and in Canada. These actions prohibit manufacture, making available on the market and use of PFOA, its salts and PFOA-related compounds with exemptions (time-limited or not). Based on technical and socio-economic assessments, these risk management approaches are considered technically and economically feasible. In 2016 Canada published legislation which prohibits PFOA, its salts and precursors as well as products containing them, unless present in manufactured items, and with a limited number of exemptions. Norway bans

¹ PFOA-related compounds are differently defined according to the chemical scope in different approaches. In this document, the term “PFOA-related compounds” is used as defined in section 1.1. If quoted from other information sources the original wording of analogue terms, such as “PFOA-related substances” (e.g. used in ECHA 2015a), is maintained.

the use of PFOA in consumer products and textiles since 2014 with certain exemptions. The EU restricts the manufacture, placing on the market and use (including import) of PFOA, its salts and PFOA-related compounds as well as articles containing these substances. The EU risk management approach considers exemptions for certain uses; however, it does not cover the degradation to PFOA from long-chain perfluoroalkyl and polyfluoroalkyl substances (PFASs). In the US a rule proposed in 2015 would require manufacturers of PFOA and PFOA-related chemicals to notify new uses of these chemicals to USEPA in order to allow the evaluation of new uses and, if necessary, take action to prohibit or limit the activity.

7. In the processes of developing the regulatory risk management approaches for PFOA, its salts and

PFOA-related compounds in Canada, the EU and Norway, technical and socio-economic information has been included in the decision-making process to allow for certain exemptions. In general, these risk management approaches are considered technically and economically feasible. Information received from industry stakeholders during these regulatory processes indicates that exemptions with or without time limitation were needed for certain uses where stakeholders asserted and scientific committees concluded that alternatives were not economically and/or technically feasible. A prohibition of PFOA, its salts and PFOA-related compounds with possible specific exemptions for certain uses is also considered to be technically and economically feasible under the Stockholm Convention.

8. The information on the availability of alternatives considering efficacy and efficiency indicates that appropriate alternatives may currently not be available for several uses, namely: (1) equipment used to manufacture semiconductors and related infrastructure; (2) latex printing inks; (3) textiles for the protection of workers from risks to their health and safety; (4) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment; (5) plasma nano-coatings; (6) medical devices; (7) production of implantable medical devices; (8) photographic coatings applied to films, papers or printing plates; (9) photo-lithography processes for semiconductors or in etching processes for compound semiconductors; (10) certain pharmaceutical chemicals; and (11) use of sulfluramid. However, for most of these uses, the development of alternatives is underway. In restricting or banning PFOA, its salts and PFOA-related compounds under the Stockholm Convention, this could be considered with specific exemptions with time limits or acceptable purposes without time limits.

9. Similarly, as expected for the Canadian, Norwegian and the EU approaches, globally restricting or prohibiting PFOA, its salts and PFOA-related compounds will positively impact human health, the environment including biota, and agriculture by decreasing emissions and subsequently exposure. The full magnitude and extent of the risks of PFOA, its salts and PFOA-related compounds cannot be quantified. The risk management of these substances is driven by scientific data and precautionary actions to avoid the potentially severe and irreversible adverse impacts resulting from continued unrestricted emissions. The available alternatives are expected to pose lower health risks than an unrestricted use of PFOA, its salts and PFOA-related compounds.

10. The EU, Norwegian and the Canadian risk management approaches are considered to have moderate cost impacts because the market is already replacing PFOA, its salts and PFOA-related compounds and because the risk management approaches provide exemptions for certain uses with or without time limits. The same can be expected for the combined regulatory and voluntary approaches taken in the US and Australia. Cost competitive alternatives to PFOA, its salts and PFOA-related compounds that do not exhibit persistent organic pollutants (POPs) characteristics have already been implemented in many countries. This indicates partial economic and technical feasibility of alternatives. Substituting these compounds with appropriate alternatives leads to savings of health and environmental costs resulting from decreased exposure. Furthermore, a restriction or prohibition would prevent further contamination of surface water, groundwater and soil and would thus reduce costs for identification and remediation of contaminated sites.

11. PFOA is unintentionally formed from incomplete combustion of fluoropolymers.

12. The Committee recommends, in accordance with paragraph 9 of Article 8 of the Convention, that the Conference of the Parties to the Stockholm Convention consider listing and specifying the related control measures of PFOA, its salts and PFOA-related compounds:

13. Based on the evaluation of uses and the efficiency and efficacy of possible control measures, the Committee recommends to the Conference of the Parties that it consider listing pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annex A or B to the Convention with specific exemptions for the following:

- (a) For five years from the date of entry into force of the amendment in accordance with Article 4:
 - (i) Manufacture of semiconductors or related electronic devices:
 - a. Equipment or fabrication plant related infrastructure containing fluoropolymers and/or fluoroelastomers with PFOA residues;
 - b. Legacy equipment or legacy fabrication plant related infrastructure: maintenance;
 - c. Photo-lithography or etch processes;
 - (ii) Photographic coatings applied to films;
 - (iii) Textiles for oil and water repellency for the protection from dangerous liquids for the protection of workers from risks to their health and safety;
- (b) For ten years from the date of entry into force of the amendment for manufacture of semiconductors or related electronic devices: refurbishment parts containing fluoropolymers and/or fluoroelastomers with PFOA residues for legacy equipment or legacy refurbishment parts;
- (c) For use of perfluorooctane iodide, production of perfluorooctane bromide for the purpose of producing pharmaceutical products with a review of continued need for exemptions. The specific exemption should expire in any case at the latest in 2036.

14. The Committee invites Parties and observers, including the relevant industries, to provide information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds in particular in the following applications:

- (a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment: information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects;
- (b) Transported isolated intermediates in order to enable reprocessing in another site than the production site: information on the quantities used, extent of transport and risks, and use;
- (c) Medical devices: information on specific applications/uses and timelines foreseen as needed for potential related exemptions;
- (d) Implantable medical devices: information on the quantities used, extent of transport and risks, and use;
- (e) Photo imaging sector: information on paper and printing, and information relevant for developing countries;
- (f) Automotive industry: information on spare parts;
- (g) Firefighting foams: information on chemical composition of mixtures and the volumes of pre-installed amount of firefighting foam mixtures.

15. For the applications above, information regarding socio-economic aspects as well as other relevant information is also welcomed.

16. In addition, the Committee will collect and evaluate in the intersessional period additional information in the view of a possible listing of PFOA in Annex C from Parties and observers information that would assist the further evaluation by the Committee of PFOA, its salts and PFOA-related compounds in relation to its unintentional formation and release, in particular from primary aluminum production and from incomplete combustion. In doing so, relevant experts serving under the various technical and scientific processes under the Stockholm and Basel Conventions as indicated in decision SC-8/21 are especially invited to provide input.

1 Introduction

17. In June 2015, the European Union (EU) and its member States submitted a proposal to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annex A, B, and/or C of the Stockholm Convention (UNEP/POPS/POPRC.11/5). This proposal was considered by the Persistent Organic Pollutants Review Committee (POPRC) at its eleventh meeting held in October 2015, where the Committee concluded that PFOA fulfilled the screening criteria in Annex D and that issues related to the inclusion

of PFOA-related compounds that potentially degrade to PFOA and the inclusion of PFOA salts should be addressed in the draft risk profile (see decision POPRC-11/4).

18. The substances covered by the risk profile are PFOA including its isomers, its salts and PFOA-related compounds. At its twelfth meeting held in September 2016, by its decision POPRC-12/2, the Committee adopted the risk profile (UNEP/POPS/POPRC.12/11/Add.2) and decided to establish an intersessional working group to prepare a risk management evaluation that includes an analysis of possible control measures for PFOA, its salts and PFOA-related compounds in accordance with Annex F to the Convention. Further, the Committee invited Parties and observers to submit to the Secretariat the information specified in Annex F before 9 December 2016.

19. Consistent with the risk profile, this risk management evaluation focuses on PFOA including isomers, its salts and PFOA-related compounds. This risk management evaluation is accompanied by a background document (UNEP/POPS/POPRC.13/INF/6), and to assist with the identification of PFOA-related compounds a non-exhaustive list of substances covered or not covered by the risk management evaluation is also provided (UNEP/POPS/POPRC.13/INF/6/Add.1).

1.1 Chemical identity of PFOA, its salts and PFOA-related compounds

20. PFOA, its salts and PFOA-related compounds fall within a family of perfluoroalkyl and polyfluoroalkyl substances (PFASs). Perfluorinated acids, like PFOA, are not degradable in the environment and in biota (including humans). Certain polyfluorinated substances can be degraded to persistent perfluorinated substances like PFOA under environmental conditions and are therefore precursors. Those PFASs that can be degraded to PFOA in the environment and in biota are referred to as PFOA-related compounds.

21. The risk management evaluation covers:

- (a) PFOA (pentadecafluorooctanoic acid, CAS No: 335-67-1, EC No: 206-397-9) including any of its branched isomers;
- (b) Its salts; and
- (c) PFOA-related compounds which, for the purposes of this risk management evaluation, are any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety $(C_7F_{15})C$ as one of the structural elements, for example:
 - (i) Polymers with $\geq C_8$ based perfluoroalkyl side chains;²
 - (ii) 8:2 fluorotelomer compounds;
 - (iii) 10:2 fluorotelomer compounds.

The compounds below do not degrade to PFOA and are therefore not included as PFOA-related compounds:

- (i) $C_8F_{17}-X$, where $X = F, Cl, Br$;
- (ii) Fluoropolymers³ that are covered by $CF_3[CF_2]_n-R'$, where $R' = \text{any group}$, $n > 16$;⁴
- (iii) Perfluoroalkyl carboxylic and phosphonic acids (including their salts, esters, halides and anhydrides) with ≥ 8 perfluorinated carbons;
- (iv) Perfluoroalkane sulfonic acids (including their salts, esters, halides and anhydrides) with ≥ 9 perfluorinated carbons;
- (v) Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) as listed in Annex B to the Stockholm Convention.

² DuPont, 1998. Technical information: Zonyl fluorochemical intermediates.

³ Fluoropolymers have a carbon-only polymer backbone with F directly attached to backbone C atoms.

⁴ Such as PTFE (polytetrafluoroethylene), FEP (fluorinated ethylene propylene polymer) and PFA (perfluoroalkoxy polymer).

22. Data on PFOA are summarized in Table 1 and Table 2.⁵ Tables with data for PFOA salts and PFOA-related compounds are provided in a background document to the risk profile (see section 1.1 of document UNEP/POPS/POPRC.12/INF/5).

Table 1: Information pertaining to the chemical identity of PFOA

CAS number:	335-67-1
CAS name:	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-
IUPAC name:	Pentadecafluorooctanoic acid
EC number:	206-397-9
EC name:	Pentadecafluorooctanoic acid
Molecular Formula	C ₈ HF ₁₅ O ₂
Molecular Weight	414.07 g/mol
Synonyms	Perfluorooctanoic acid; PFOA; pentadecafluoro-1-octanoic acid; perfluorocaprylic acid; perfluoro-n-octanoic acid; pentadecafluoro-n-octanoic acid; pentadecafluorooctanoic acid; n-perfluorooctanoic acid; 1-cctanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro

Table 2: Overview of relevant physiochemical properties of PFOA

Property	Value	Reference/Remark
Physical state at 20°C and 101.3 kPa	Solid	(Kirk, 1995)
Melting/freezing point	54.3°C 44-56.5°C	(Lide, 2003) (Beilstein, 2005) cited in (ECHA, 2013a)
Boiling point	188°C (1013.25 hPa) 189°C (981 hPa)	(Lide, 2003) (Kauck and Diesslin, 1951)
Vapour pressure	4.2 Pa (25°C) for PFO; extrapolated from measured data 2.3 Pa (20°C) for PFO; extrapolated from measured data 128 Pa (59.3°C) for PFO; measured	(Kaiser et al., 2005); (Washburn et al., 2005) (Washburn et al., 2005) (Washburn et al., 2005)
Water solubility	9.5 g/L (25°C) 4.14 g/L (22°C)	(Kauck and Diesslin, 1951) (Prokop et al., 1989)
Dissociation constant	approximately 0.5 <1.6, e.g. 0.5 1.5-2.8	(Johansson et al. 2017) (Vierke et al., 2013) (Kissa, 2001)
pH-value	2.6 (1 g/L at 20°C)	(ECHA, 2015a) (reliability not assignable)

23. Major synthesis routes of fluorotelomer-based substances including side-chain fluorinated polymers as well as an overview of the syntheses routes of major fluoropolymers are illustrated in two figures of supplementary information provided by the Swiss Federal Office for the Environment (FOEN) (see section I of FOEN, 2017). Moreover, specific information regarding the transformation/degradation of fluorotelomers to PFOA is summarized in that document (see section II of FOEN, 2017).

24. There are two manufacturing processes to produce PFOA, its salts and PFOA-related compounds: electrochemical fluorination (ECF) and telomerization. From 1947 until 2002, the ECF process was mainly used to manufacture ammonium perfluorooctanoate (APFO; ammonium salt of PFOA) worldwide (80-90% in 2000) which results in a mixture of branched and linear isomers (78% linear and 22% branched isomers). In the ECF process, octanoyl fluoride is commonly used to make perfluorooctanoyl fluoride that was further reacted to make PFOA and its salts (Buck et al., 2011). In addition, some manufacturers have used the telomerization process to produce linear PFOA and related compounds. In the telomerization process, an initial perfluoroalkyl iodide (telogen) reacts with tetrafluoroethylene (taxogen) to yield a mixture of perfluoroalkyl iodides with different

⁵ UNEP/POPS/POPRC.13/INF/6/Add.1.

perfluoroalkyl chain lengths (Telomer A). Telomer A are reacted further to insert ethylene and create fluorotelomer iodides (Telomer B), which are then used to make a variety of fluorotelomer-based products. Another study suggests that ECF is still used by some manufacturers in China (Jiang et al., 2015). The global production of PFOA using ECF is still ongoing, whereas most of the manufacturers using telomerization have ceased their production of PFOA and related compounds (Wang et al., 2014a).

25. ISO Standard ISO 25101:2009 specifies a method for the determination of the linear isomers of PFOA in unfiltered samples of drinking water, ground water and surface water (fresh water and sea water) using high-performance liquid chromatography-tandem mass spectrometry (HPLC MS/MS). The method is applicable to a concentration range of 10 ng/L to 10 000 ng/L for PFOA. Depending on the matrix, the method may also be applicable to higher concentrations ranging from 100 ng/L to 200 000 ng/L after suitable dilution of the sample or reduction in sample size (ISO 2009). According to a summary of PFOA-methods in ECHA, 2015a, quantification limits vary dependent on the method from 1 ppb to 2000 ppb (further details see ECHA, 2015a,b,c). The unique chemical and physical properties of PFOA prevent it from being measured using conventional analysis. More complex analytical techniques using liquid chromatography and tandem mass spectrometry (LC/MS-MS) have been proven most reliable for analyzing PFOA in biological and environmental samples, and therefore, are the analytical methods of choice (Xu et al., 2013; EFSA, 2008; Loos et al., 2007). This type of analysis has allowed for sensitive determination of many PFASs including PFOA in air, water, and soil (ATSDR, 2015).

1.2 Conclusions of the POPs Review Committee regarding Annex E information

26. At its eleventh meeting (decision POPRC-11/4), the Committee concluded that the proposal by the EU to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds meets the criteria set out in Annex D to the Convention (UNEP/POPS/POPRC.12/11).

27. Based on the draft risk profile for pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in accordance with paragraph 6 of Article 8 of the Convention (UNEP/POPS/POPRC.12/11), the Committee adopted the risk profile for pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds (UNEP/POPS/POPRC.12/11/Add.2) and:

(a) Decided, in accordance with paragraph 7 (a) of Article 8 of the Convention, that pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds are likely as a result of their long-range environmental transport to lead to significant adverse human health and/or environmental effects such that global action is warranted;

(b) Also decided, in accordance with paragraph 7 (a) of Article 8 of the Convention and paragraph 29 of the annex to decision SC-1/7 of the Conference of the Parties, to establish an intersessional working group to prepare a risk management evaluation that includes an analysis of possible control measures for pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in accordance with Annex F to the Convention;

(c) Invited in accordance with paragraph 7 (a) of Article 8 of the Convention, Parties and observers to submit to the Secretariat the information specified in Annex F before 9 December 2016.

1.3 Data sources

1.3.1 Overview of data submitted by Parties and observers

28. This risk management evaluation is primarily based on information that has been provided by Parties to the Convention and observers. Information specified in Annex F forms was submitted by the following Parties:

(a) Parties: Australia, Austria, Azerbaijan, Canada, China, Colombia, Denmark, India, Japan, Mauritius, Monaco, Norway, Serbia;

(b) Observers: Bavarian Textile and Apparel Association (VTB) in cooperation with South-western Textile Association (SWT), European Apparel and Textile Confederation (Euratex), Global Industry Council for Fluoro Technology (Fluoro Council), Confederation of the German Textile and Fashion Industry, Imaging and Printing Association Europe (I&P Europe), International POPs Elimination Network (IPEN), Semiconductor Industry Association (SIA).

1.3.2 Other key data sources

29. In addition to the above-mentioned references and comments received from Parties and observers,⁶ information has been used from open information sources as well as scientific literature (see list of references). The following key references were used as a basis to develop the present document:

- (a) The risk profile for PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.12/11/Add.2);
- (b) The regulatory impact analyses statement related to the Canadian risk management approach (Canada 2016c);
- (c) The report for an EU proposal for a restriction for PFOA, PFOA salts and PFOA-related substances (ECHA, 2014a) and related opinions of scientific committees in the EU (ECHA, 2015b, 2015c), the amended version of the report (ECHA, 2015a) and the current EU restriction (European Commission, 2017).

1.4 Status of the chemical under international conventions and frameworks

30. A review of PFOS and PFOA was conducted under the Oslo/Paris Commission for the Protection of Marine Environment of the North East Atlantic (OSPAR) in order to assess the potential impact upon the environment. This resulted in the inclusion of PFOS on the list of chemicals for priority action in 2003, while PFOA was not added to the list at that time (OSPAR, 2006).

31. Perfluorinated chemicals and the transition to safer alternatives is one of the issues of concern recognised by the Strategic Approach to International Chemicals Management (SAICM). Activities by SAICM focus on gathering and exchanging information on perfluorinated chemicals and to support the transition to safer alternatives. This work has been coordinated by the Global Perfluorinated Chemicals Group, which is supported by the Organization for Economic Co-operation and Development (OECD) and UNEP.

1.5 National or regional control actions

32. An overview related to risk reduction approaches for PFASs was provided by OECD (OECD, 2015). The document includes information on existing risk reduction approaches in countries including voluntary risk reduction measures taken by corporations (see pp. 61 to 64 in OECD, 2015). According to the risk profile (UNEP/POPS/POPRC.12/11/Add.2) and Annex F submissions, national and/or regional regulations related to PFOA comprise the following:

- (a) In 2013, the EU identified both PFOA and its ammonium salt (APFO) as Substances of Very High Concern (SVHC) due to their persistent, bioaccumulative and toxic properties, and PFOA and APFO were included into the REACH-Candidate List (ECHA, 2013a, 2013b). On request industry is obliged to inform consumers on the occurrence to the listed substances in consumer articles if the SVHC in those articles is present in a concentration of more than 0.1 % (w/w). PFOA/APFO is restricted as a substance or in a mixture for the supply to consumers according to regulation (EU) 317/2014;
- (b) In 2014, Germany and Norway submitted a joint restriction proposal for the inclusion of PFOA within Annex XVII (restriction) of the REACH regulation within the EU (ECHA, 2014a). The aim of the proposal was a total ban on manufacture, placing on the market and use (including import) of PFOA and its salts, including substances that may degrade to PFOA (PFOA-related compounds). The restriction also covers articles containing these substances. The EU restriction entered into force on 4 July 2017. The restriction applies from 4 July 2020 (European Commission, 2017);
- (c) PFOA was included in Annex VI of the Classification, Labelling and Packaging (CLP) Regulation (Regulation (EC) No 1272/2008), by the Commission Regulation (EU) No 944/2013 of 2 October 2013 (index number: 607-704-00-2). PFOA has been classified as Carc. 2 H351, Repr 1B H360D, Lact H362, STOT RE 1 (liver) H372, Acute tox 4 H332, Acute tox 4 H302 and Eye dam 1 H318;

⁶<http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC12/POPRC12Followup/PFOAInfo/tabid/5453/Default.aspx>.

(d) The Norwegian Environment Agency published an amendment to the consumer products regulation in 2014, banning the use of PFOA in consumer products and textiles. This has a transitional period allowing the import and sale of products manufactured before the phase-out. Since 1 June 2014, it has been prohibited to manufacture, import, export and make available on the market textiles, carpets, other coated consumer products and consumer products that contain PFOA and individual salts and esters of PFOA with specified exemptions (Norway, 2016; more details in section 2.2);

(e) In June 2006, the Government of Canada published a Notice of Action Plan for the assessment and management of perfluorocarboxylic acids and their precursors. The Action Plan included measures to prevent the introduction of new substances into Canada that would contribute to the level of perfluorocarboxylic acids in the environment, and to seek action from industry to address sources of PFCAs already in Canadian commerce. To this end, a voluntary Environmental Performance Agreement was signed on 30 March 2010. Signatories to the Performance Agreement agreed to reduce the amount of PFOA and long-chain perfluorocarboxylic acids in perfluorinated chemicals in Canadian commerce by 95% by 31 December 2010, and to virtually eliminate them by 31 December 2015. Participating companies met the targets under the Agreement and the final report was published on 1 June 2017.⁷ Within Canada following the screening assessment conducted in 2012, PFOA, its salts and precursors were found to meet the criterion of Section 64(a) of the Canadian Environmental Protection Act, 1999 (CEPA) and were added to the List of Toxic Substances in Schedule 1 of the Act. Furthermore, in October 2016, the Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012, were published in Canada. As of 23 December 2016, these amendments prohibit PFOA, its salts and precursors and products containing them, unless present in manufactured items.⁸ Furthermore, the amendments provide time-limited exemptions and ongoing permitted uses for certain applications where the development of alternatives is underway or where there are currently no known alternatives (Canada, 2016c; more details see section 2.2);

(f) In the US, the United States Environment Protection Agency (USEPA) established the PFOA Stewardship Programme in 2006. This is a programme that includes eight major OECD based manufacturers of PFOA, its salts and PFOA-related compounds (Arkema, Asahi, BASF, Clariant, Daikin, 3M/Dyneon, DuPont and Solvay Solexis). The programme was a voluntary initiative to the substantial phase-out the manufacture and use of PFOA, PFOA precursors and related higher homologue substances (USEPA, 2015). It was successfully completed at the end of 2015. On 21 January 2015, the USEPA proposed a Significant New Use Rule under the Toxic Substances Control Act (TSCA) to require manufacturers of PFOA and PFOA-related chemicals, including as part of articles, and processors of these chemicals to notify USEPA at least 90 days before starting or resuming new uses of these chemicals in any products. This notification would allow USEPA the opportunity to evaluate the new use and, if necessary, take action to prohibit or limit the activity.⁹ While in general, eligible polymers are exempted from the full USEPA new chemical premanufacture notice and review process, effective 26 January 2010 the USEPA rescinded the exemption for polymers containing as an integral part of their composition, except as impurities, certain perfluoroalkyl moieties consisting of a CF₃- or longer chain length. This exclusion included polymers that contain any one or more of the following: perfluoroalkyl sulfonates (PFAS), perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule (FR 2010 01-27);

(g) In China several national actions were taken in 2011 to restrict new installations of PFOA production facilities, to eliminate PFOA-containing paints and fluoropolymers that use PFOA in the polymerization and to encourage the development of alternatives to PFOA. In 2013, fluoropolymer coatings for non-stick pans, kitchenware and food processing equipment that use PFOA in the polymerisation were recognized as products with high pollution and high environmental risk in the Comprehensive Catalogue for Environmental Protection. In January 2017, new technical

⁷ <http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=AE06B51E-1>.

⁸ Under the Prohibition of Certain Toxic Substances Regulations a “manufactured item” is a product “formed into a specific physical shape or design during its manufacture and that has, for its final use, a function or functions dependent in whole or in part on its shape or design.” Examples of manufactured items include semiconductors and frying pans, but would exclude products such as firefighting foams, inks, paints, or coatings (Canada Comments on 1st draft RME).

⁹ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/and-polyfluoroalkyl-substances-pfass-under-tsca>.

requirements for textile products came into force, in particular establishing limits of PFOA levels to 0.05 mg/kg in coated infant textile products and to 0.1 mg/kg in all other coated textile products, respectively (see section VI of FOEN, 2017).

2 Summary information relevant to the risk management evaluation

33. PFOA and its salts are, or were, most widely used as processing aids in the production of fluoroelastomers and fluoropolymers, with polytetrafluoroethylene (PTFE) being an important fluoropolymer. PFOA-related compounds, including side-chain fluorinated polymers, are used as surfactants and surface treatment agents (e.g. in textiles, paper and paints, firefighting foams). PFOA, its salts and PFOA-related compounds are used in a wide variety of applications and consumer products across many sectors (UNEP/POPS/POPRC.12/11/Add.2).

34. Releases occur from past and ongoing production and use. Direct releases to the environment occur from the production of the raw substance (including PFOA as impurity in the manufacturing of PFOA-related compounds and some alternatives), during the processing, use and disposal of the chemical, from treated articles and from products contaminated with PFOA. Main emission vectors of PFOA and its salts are water, wastewater and dust particles. Historic releases to the environment from PFOA manufacturing are available from a plant in the US into air and water between 1951 and 2003. Some estimates of releases during the disposal of the chemical are available, particularly from sewage treatment plants, wastewater treatment plants and landfill sites. Indirect releases occur from the degradation or transformation of precursors. PFOA-related compounds are released to air, water, soil and solid waste and will degrade to PFOA in the environment and in organisms. An assessment of sources of PFOA to the Baltic Sea estimated that 30% of the releases were due to transformation of fluorotelomers. Thus, releases of PFOA from degradation of PFOA-related compounds contribute a substantial share to the releases of PFOA to the environment (UNEP/POPS/POPRC.12/11/Add.2). Additional information regarding the transformation/degradation of fluorotelomers to PFOA is summarized in section II of FOEN, 2017. A summary of further risk profile information is given in section 3.1. According to a study from 2008, perfluorocarbons (PFCs) are widely used in aluminium production and emissions of PFCs (possibly including PFOA; not specified in the study) occur during specific electrolysis processes in aluminium manufacturing (see EP 2008).

35. Switzerland provides information on the unintentional formation of PFOA from inadequate incineration of fluoropolymers e.g. from municipal solid waste incineration (MSWI) with inappropriate incineration or open burning facilities at moderate temperatures. Some recent studies qualitatively show that small, but measurable amounts of PFOA and a wide range of other PFCA homologues can be generated during the thermolysis of non-functionalized PTFE (Ellis et al., 2001, 2003; Schlummer, 2015) and functionalized PTFE (Feng et al., 2015) at temperatures between 250°C and 600°C. This may be particularly critical for developing countries and countries with economies in transition, where wastes are often not incinerated to sufficiently high temperatures and without proper treatment of flue gases due to a lack of adequate facilities (see FOEN, 2017).

36. National and regional control actions differ with regard to their chemical scope and exemptions (see Table 3). The chemical scope of the possible measures discussed in the present risk management evaluation has a different scope compared to other regulatory risk management approaches and is based on principles and obligations of the Stockholm Convention. It is noteworthy that PFOA-related compounds for the purposes of this risk management evaluation covers degradation to PFOA from long-chain PFASs with more than eight perfluorinated carbon atoms except for those explicitly excluded in the definition of PFOA-related compounds as they do not degrade to PFOA under natural conditions (see para 21). This goes beyond the EU risk management approach which does not cover the degradation to PFOA from long-chain PFASs. The degradation from long-chain PFASs is also not considered in the Norwegian risk management approach. The Canadian risk management approach also applies to long-chain PFCAs, their salts, and their precursors. However, long-chain PFASs have been included on Norway's priority list of substances whose release to the environment should be eliminated by 2020, and they are included in the US Stewardship Program (IPEN Comments on 2nd draft risk management evaluation (RME)). A general definition of "long-chain PFCAs" ($C_nF_{2n+1}COOH$, $n \geq 7$) is provided by the OECD (OECD, 2017). As a result of the existing production processes, fluorotelomer-based substances have been generally manufactured as mixtures of homologues with a range of perfluoroalkyl chain lengths (for examples, see DuPont, 1998), including those that have more than eight perfluorinated carbon atoms.¹⁰ Therefore, the

¹⁰ Commercial products containing primarily >99% of one individual homologue may exist; this requires additional purification processes.

information provided in the present risk management evaluation covers to a certain extent also those fluorotelomer-based substances with longer chain PFAS (longer than 8:2).

37. Table 3 gives an overview on the regulatory risk management approaches and exemptions in Canada, the EU and Norway. Section 3 in the background document (UNEP/POPS/POPRC.13/INF/6) provides further details on the legislative approaches in these countries.

Table 3: Overview of regulatory risk management approaches, their chemical scope and exemptions for uses related to PFOA, its salts and PFOA-related compounds in Canada, the EU and Norway (for details see Canada, 2016c, European Commission, 2017 and Norway, 2016)

	Canada	EU	Norway
	Prohibit manufacture, use, sale, offer for sale or import of the substances and products containing these substances	Prohibit manufacturing, use or placing on the market (1) as substances, as constituents of other substances and (2) articles or any parts thereof containing one of the substances	Prohibit to manufacture, import, export and make available on the market (1) textiles, carpets and other coated consumer products that contain the substances and (2) consumer products that contain the substances
Chemical scope	<p>PFOA and its salts;</p> <p>Compounds that consist of a perfluorinated alkyl group that has the molecular formula C_nF_{2n+1} in which $n=7$ or 8 and that is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom;</p> <p>Perfluorocarboxylic acids that have the molecular formula $C_nF_{2n+1}CO_2H$ in which $8 \leq n \leq 20$, and their salts;</p> <p>Compounds that consist of a perfluorinated alkyl group that has the molecular formula C_nF_{2n+1} in which $8 \leq n \leq 20$ and that is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom.</p> <p>(see Canada, 2016c)</p>	<p>PFOA and its salts;</p> <p>Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula C_7F_{15}- directly attached to another carbon atom, as one of the structural elements.</p> <p>Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C_8F_{17}- as one of the structural elements.</p> <p>Exclusions: $C_8F_{17}-X$, where $X = F, Cl, Br$; $C_8F_{17}-C(=O)OH$, $C_8F_{17}-C(=O)O-X'$ or $C_8F_{17}-CF_2-X'$ (where X'=any group, including salts).</p> <p>Does not apply to PFOS and its derivatives, which are listed in Part A of Annex I to Commission Regulation (EC) No 850/2004 (see European Commission, 2017)</p> <p>PFOA <25ppb, related compounds <1,000 ppb</p>	<p>PFOA and individual salts and esters of PFOA (CAS No: 335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5) (See Norway, 2016)</p>
Exemptions for photo-imaging	<p>Photo media coatings until 31 December 2016</p> <p>Since then partially captured under exemptions for manufactured items</p>	<p>Photographic coatings applied to films, papers or printing plates</p>	<p>Photographic coatings for film, paper or printing plate until 2016</p>
Exemptions for semiconductor industry	<p>Partially captured under exemptions for manufactured items</p>	<ul style="list-style-type: none"> - Equipment used to manufacture semiconductors (until 4 July 2022); - Photo-lithography processes for semiconductors or in etching processes for compound semiconductors; -semiconductors or compound semiconductors. 	<p>Adhesives, foil or tape in semiconductors until 2016</p>

	Canada	EU	Norway
Exemptions for firefighting	Aqueous film-forming foams used in firefighting applications	- Concentrated firefighting foam mixtures that were placed on the market before 4 July 2020 and are to be used, or are used in the production of other firefighting foam mixtures; - Firefighting foam mixtures which were: a) placed on the market before 4 July 2020; or b) produced in accordance with paragraph 4(e), provided that, where they are used for training purposes, emissions to the environment are minimized and effluents collected are safely disposed of.	Not covered by the restriction
Exemptions for medical uses	Partially captured under exemptions for manufactured items	- Medical devices (until 4 July 2032); - Production of implantable medical devices within the scope of Directive 93/42/EEC.	Medical devices are exempted from restrictions
Exemptions for textiles	Partially captured under exemptions for manufactured items	- Textiles for the protection of workers from risks to their health and safety (until 4 July 2023); - Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment (until 4 July 2023).	Textiles for consumer use are restricted when PFOA concentration is above 1ug/m ² for any part of the product.
Exemptions for inks	Water-based inks until 31 December 2016	Latex printing inks (until 4 July 2022)	
Exemptions for nano-coating	Partially captured under exemptions for manufactured items	Plasma nano-coating (until 4 July 2023)	
Exemptions for food packaging	Partially captured under exemptions for manufactured items		Food packaging, food contact materials are exempted from this regulation

38. Specific information on the long-chain PFASs was not submitted to the Secretariat with the Annex F submissions of Parties and observers. Moreover, the long-chain PFASs are not considered in the socio-economic assessments of the regulatory risk management approaches in the EU and Norway. Accordingly, the information in the present risk management evaluation does not explicitly cover long-chain PFASs so far. At EU level, Germany and Sweden prepared a restriction proposal for the long-chain PFCAs of chain lengths between 9 and 14 carbon atoms and related substances.¹¹ The conclusion of the risk assessment is that, despite that no intentional uses in the EU were identified so far, a restriction on a Union-wide basis is justified to reduce the release of these substances into the environment and to prevent any future manufacturing, placing on the market and use. This EU-wide measure may be the first step for global action.

2.1 Identification of possible control measures

39. The control measure may be achieved in different ways under the Convention:

- (a) PFOA, its salts and PFOA-related compounds may be listed in Annex A, with or without specific exemptions accompanied with a specific part of Annex A that details specific actions; or

¹¹ <https://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance-rev/16121/term>.

(b) PFOA, its salts and PFOA-related compounds may be listed in Annex B, with acceptable purposes/specific exemptions accompanied with a specific part of Annex B that details specific actions; and/or

(c) PFOA may be listed in Annex C as an unintentional persistent organic pollutant to capture potential formation and unintentional release from anthropogenic sources.

40. Possible control measures may include: (1) prohibition of production, use, import and export; (2) restriction of production, use, import and export; (3) control of discharges or emissions; (4) replacement of the chemicals by alternatives; (5) clean-up of contaminated sites; (6) environmentally sound management of obsolete stockpiles; (7) prohibition of reuse and recycling of wastes or stockpiles; (8) establishment of exposure limits in the workplace; and (9) establishment of thresholds or maximum residue limits in water, soil, sediment or food.

41. PFOA occurs as unintentional impurity in manufacturing of fluoro chemicals. However, unintentional generation from manufacturing can be addressed by establishing appropriate concentration limits in the Annex A or B recommendation for PFOA, its salts and PFOA-related compounds in manufacturing of alternatives.

2.2 Efficacy and efficiency of possible control measures in meeting risk reduction goals

42. According to the information submitted by IPEN, the most cost-effective and practicable control measure for PFOA and PFOA-related compounds is the prohibition of all production, use, import and export, which is particularly relevant in developing and transition countries that lack adequate regulatory and enforcement infrastructure. According to the information submitted by IPEN, this would be best accomplished by listing PFOA, its salts and PFOA-related compound in Annex A to the Stockholm Convention with no exemptions. Measures under Article 6 would address the clean-up of contaminated sites such as at or near manufacturing facilities, airports, military bases and other sources, and environmentally sound management of stockpiles and wastes (IPEN Comments on 1st draft risk RME).

43. Information received from stakeholders in the EU regulatory process indicates that exemptions for use where alternatives are not economically and/or technically feasible are required (ECHA, 2014a, 2015a).

44. The ECHA Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) considered that the restriction on PFOA, its salts and PFOA-related substances is the most appropriate EU-wide measure to address the identified risks. The EU restriction was adjusted to the occurrence in concentrations equal to or greater than 25 ppb of PFOA including its salts or 1000 ppb of one or a combination of PFOA-related substances. These limit values reflect the possible presence of unavoidable impurities and unintended contaminants, and take account of the capabilities of analytical methods (see European Commission, 2017). Details on modifications proposed by the scientific committees within the EU are documented in ECHA, 2015c.

45. In the process of developing the regulatory risk management approaches in Canada, Norway and the EU related to PFOA, its salts and PFOA-related compounds, technical and socio-economic information has been considered as a decision basis to allow for general or specific exemptions. As a consequence the exemptions in existing regulatory risk management approaches may give an indication for the identification of uses for which, there may not be accessible chemical and/or non-chemical alternatives in a country, based on technical and socio-economic considerations.

46. Currently, controlled incineration with high temperatures of 850°C or higher is usually carried out in waste incinerators in developed countries. High temperature incineration (e.g., at 1000°C) is effective to destroy PFOA and to prevent the formation of PFOA from the thermolysis of highly fluorinated polymers (see Taylor, 2009, Taylor et al. 2014 and Yamada et al., 2005). It is currently unclear to what extent formation of PFOA may occur in municipal waste incinerators where (1) flue gases may reach temperatures of 850°C or greater and may result in different degradation products (García et al., 2007); (2) other substances coexist and may interfere with the thermolysis of fluoropolymers (e.g., thermolysis of PTFE is inhibited by a hydrogen or chlorine atmosphere in contrast to steam, oxygen or sulfur dioxide, which accelerate decomposition; Simon and Kaminsky, 1998); and (3) technologies such as activated carbon injection (ACI) coupled with baghouse filtration (BF) may be installed to remove dioxin or mercury and may also trap PFCAs (EU Commission, 2006). A recent study found PFOA in the flue gases from the incinerator of Harlingen, the Netherlands. However Taylor et al. 2014 concluded that waste incineration of fluorotelomer-based polymers does not lead to the formation of detectable levels of PFOA under conditions representative of typical municipal waste incineration in the US.

47. PFOA or its salts may be removed from off-gases by scrubbing such gases with aqueous NaOH (Sulzbach et al., 1999) and K₂CO₃ solutions (Sulzbach et al., 2001) and other treatment methods.
48. Although controlled incineration and off-gas cleaning may be utilized in developed countries, it may not be the most cost-effective and accessible option in all countries.
49. For PFOA formed as a by-product in incineration processes, there is a relation to polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/PCDF) and other unintentional persistent organic pollutants (POPs) releases formed by combustion. Best available techniques and best environmental practices (BAT/BEP) relevant to unintentionally produced POPs for various types of incinerators and other thermal sources are described in the Stockholm Convention BAT/BEP guidelines relevant to Article 5 and Annex C, in Sections V.A, VI.A and VI.C, including providing for appropriate incineration conditions, reduction of open burning, and flue gas treatment. BAT/BEP as described in these relevant documents are being applied for other unintentionally produced substances such as hexachlorobenzene (HCB), pentachlorobenzene (PeCB), polychlorinated biphenyls (PCB) and PCDD/PCDF and will be effective to a certain extent for PFOA as well. In other words, the technical measures required to minimise releases of unintentionally produced PFOA from incineration are already required to a certain extent according to existing BAT/BEP for incineration processes. Additional costs for implementation of measures to reduce releases of PFOA, enforcement and supervision are therefore considered low, as the control measures for other unintentional POPs are already applied.
50. Monitoring of PFOA, namely for chemical analysis, will induce additional costs, even if monitoring programmes for other POPs (e.g. PCDD/PCDF, HCB and PCB) are already established. Monitoring capacity for PFOA is needed in developing countries and countries with economies in transition.

Other control measures

51. The USEPA uses a combination of regulatory and voluntary approaches, including Significant New Use Rules and the voluntary PFOA Stewardship Program (OECD, 2015). The USEPA has established health advisory levels for PFOA and PFOS in drinking water at 70 ppt (FR 2016 05-25). In the US State of Vermont, the health advisory level for PFOA in drinking water is 20 ppt.¹² In the US State of New Jersey, the guidance level for PFOA in drinking water is 40 ppt.¹³ In China several actions were taken to restrict PFOA production or PFOA-containing products and to encourage the development of alternatives to PFOA (see para 32 (g)).
52. Australia's approach to risk reduction is a combination of voluntary and regulators actions. The regulatory approach, implemented under the Industrial Chemicals (Notification and Assessment) Act of 1989 requires industry to provide toxicity data for new substances including PFASs or products containing new PFASs being introduced into Australia. Besides, Australia has been monitoring manufacture, import and use of PFASs (including PFOA-related substances) based on information requested of industry, raising awareness of the chemical industry and the general public through the publication of alerts on long-chain PFASs since 2002. Further, additional data requirements are needed for new per- and poly-fluorinated chemicals for assessment prior to introduction into Australia. Assessment recommendations are set out for new PFASs and existing PFASs reassessed. The import of new PFCs that have improved risk profiles but are still persistent, are being managed (Australia, 2016). Australia has also identified 18 high-priority defence sites where groundwater is contaminated with PFAS including PFOA (IPEN Comments on 1st draft RME). For PFOS, PFOA and PFHxS, Australia has implemented health based guidance values, expressed as a tolerable daily intake (TDI), for use when investigating contaminated sites and conducting human health risk assessments (Australia Gov. 2017). In Australia, the TDI for PFOA is 0.16 µg/kg of body weight. The drinking water quality value is 0.56 µg/L for PFOA (AU Health Dep., 2017). A recent report describes remediation options for PFOA and PFOA (CRCCARE, 2017).

¹² See <http://www.healthvermont.gov/response/environmental/pfoa-drinking-water-2016>.

¹³ See http://www.nj.gov/dep/watersupply/dwc_quality_pfoa.html.

53. The German commission on human biomonitoring has derived new HBM-I values¹⁴ for PFOS and PFOA. Based on an assessment of the literature on animal and human epidemiological studies which it discussed during its last meeting in May 2016, and following clarification of a few open details, the HBM Commission has decided to set HBM I values for PFOA and PFOS in blood plasma of 2 ng PFOA/mL and 5 ng PFOS/mL (UBA, 2016).

54. In 2006, Canada launched the “Action Plan for the Assessment and Management of Perfluorinated Carboxylic Acids and their Precursors”. As a result, Canada implemented a combination of regulatory and voluntary actions to reduce the risk of PFOA and certain long-chain PFAS. The first measure implemented as an early risk management action prior to the final risk assessment, was a voluntary Environmental Performance Agreement with manufacturers of PFOA and LC-PFCAs. Signatories to the Agreement agreed to reduce the amount of PFOA and long-chain (C₉-C₂₀) PFCAs in perfluorinated chemicals in commerce by 95% by 31 December 2010, and to eliminate them by 31 December 2015. The 2010 reduction target was met by all signatories and the final report shows that the 2015 target has been met. In 2016, PFOA was prohibited under the Prohibition of Certain Toxic Substances Regulations, with a limited number of exemptions (Canada, 2016c).

55. In 2014, the Danish EPA published a study on groundwater contamination associated with point sources of perfluoroalkyl substances, including PFOA and PFOA-related compounds. Based on the findings of groundwater contamination, a study assessing and proposing health based quality criteria was commissioned. This study led to establishing a sum criterion drinking water limit value for 12 PFASs. The limit value is 0.1 µg/L drinking water and is a sum criterion for the presence of all of the 12 PFASs. The same sum criterion limit value is valid for groundwater and a sum criterion limit value for the same PFASs in soil has been established at 0.4 µg/L (dry soil) (Denmark, 2016). The Danish government has also issued an advisory limit for PFCs in food packaging materials of 0.35 micrograms/cm² of packaging material, in practice acting as a ban.¹⁵

56. Since 2014, the Swedish National Food Agency has health-based guidance values for the sum of commonly occurring PFASs (including PFOA) in drinking water (NFA 2017). Since 2016 a total of 11 PFAS are included in the guidance value. If the sum of PFASs exceeds 90 ng/L actions are recommended to lower the levels as much as possible below this action level. If the sum of PFASs exceed 900 ng/L use of the water for consumption or cooking is not recommended. The Australian Department of Health determined drinking quality values for PFOA and PFOS/PFHxS based on the final health based guidance values. These values will be used in undertaking contaminated site investigations and human health risk assessments across Australia (see AU Health Dep 2017). The USEPA established health advisory levels for PFOA and PFOS in drinking water (see USEPA, 2016). The European Food Safety Authority is currently updating PFOA-related health based guidance values (EFSA, 2017).

57. Norway is conducting ongoing remediation of PFAS contaminated soil due to use of aqueous film forming foams (AFFFs) at airports and fire training areas (Norway, 2016).

58. The Swedish Chemicals Agency has published a strategy for reducing the use of PFASs (Swedish Chemicals Agency, 2016b). PFASs applications which could result in environmental contamination should be minimized and ultimately discontinued. Actions to achieve this aim include prioritizing the implementation of measures for uses that can result in substantial direct releases to the environment and work on the global arena including the Stockholm Convention. PFASs-containing firefighting foams are proposed to be collected and destroyed after being used (with some exemptions) (Sweden Comments on 3rd draft RME).

59. The use of AFFFs may result in leakage into the ground and contaminate soil and groundwater. The Swedish Chemicals Agency, the Swedish Civil Contingencies Agency and the Swedish Environmental Protection Agency have therefore produced a leaflet to the Swedish Rescue Services with recommendations to reduce the use of AFFFs (Swedish Chemicals Agency, 2017). The Swedish Chemicals Agency has also together with the Swedish Civil Contingencies Agency invested in training and information provision for rescue services. Seminars have been held intended to offer the rescue services tools for extinguishing fires in a manner that minimises any impact on the environment (Sweden Comments on 3rd draft RME). The commercial airports in Sweden have

¹⁴ HBM I value represents the concentration of a substance in a body matrix below which, according to the Commission's current assessment, adverse health effects are not expected and therefore, no exposure reduction measures are necessary.

¹⁵ <https://www.foedevarestyrelsen.dk/Leksikon/Sider/Papir-og-pap.aspx>.

replaced PFAS with non-fluorinated alternatives that are degraded to carbon dioxide and water when used (IPEN Comments on 2nd draft RME). The Fire Fighting Foam Coalition has published “Best Practice Guidance for Use of Class B Firefighting Foams” that includes guidance on proper foam selection, containing and eliminating foam discharge, and disposal of foam and firewater (FFFC).¹⁶ Among others, it recommends the use of training foams that do not contain fluorosurfactants for training purposes.

60. Greenpeace’s Detox campaign and the Zero Discharge of Hazardous Chemicals (ZDHC) Programme focus on reducing emissions through wastewater. Voluntary maximum residue limits in water have been already recommended and applied by many companies (e.g. H&M, Adidas, Esprit, etc.) (TM, 2016).

61. The POPRC developed a series of recommendations to deal with the PFOS waste stream that are highly applicable to PFOA, its salts and related compounds as they are used for similar applications. Decision POPRC-6/2 outlines a series of risk reduction measures in short-, medium- and long-term frameworks (for more information, see decision POPRC-6/2 and UNEP, 2017).

62. In 2015, the Swedish Environmental Protection Agency conducted a screening of PFASs (including PFOA) in approximately 500 water samples, including groundwater, surface water, landfill leachate and effluents from sewage treatment plants (Swedish Environmental Protection Agency, 2016). The most significant point sources identified were areas where firefighting foams have been used (airports and firefighting training sites) as well as waste and wastewater treatment facilities. Suggested risk reduction measures include: restriction of the release of PFASs from point sources, limit of the use of PFASs-containing firefighting foams, working internationally to limit the use and emissions of PFASs at industrial sites, and development of remediation techniques for PFASs. In Sweden, a network of all relevant authorities has been established since 2014 to provide support and information to other authorities, counties, municipalities, water producers and others regarding issues around PFASs (including PFOA) such as risk assessment and management (Sweden Comments on 2nd draft RME).

63. It is assumed that the degradation of fluorotelomer-based polymeric products represents a potential indirect source of PFCAs from degradation during use (e.g. sewage treatment plant sludge from laundering textiles) or disposal (e.g. landfill or incineration) (see Prevedouros et al., 2006, Wang et al., 2014a, Wang et al., 2014b).

64. A number of fluoropolymer and fluoroelastomer producers in many parts of the world have developed and implemented various technologies to recover and recycle PFOA and other fluorinated emulsifiers from their production process, including treatment of off-gases, wastewater streams and fluoropolymer dispersions, so as to reduce emissions and exposure to them. These technologies (BAT/BEP) are summarized in section IV of FOEN, 2017. Some of these technologies may also be used to treat waste streams and products of other relevant industries to reduce emissions and exposure of PFOA and related compounds (FOEN, 2017).

65. In 2014, FluoroCouncil published “Guidance for Best Environmental Practices (BEP) for the Global Apparel Industry, including focus on fluorinated repellent products” (FluoroCouncil, 2014). The guidance recommends a set of basic actions in the following schematic areas for BEP of fluorinated durable water repellents: (1) raise environmental awareness with all employees; (2) follow advice of the Safety Data Sheet (SDS) and Technical Data Sheet (TDS) for the product; (3) use the product only if necessary to obtain effects desired; (4) use only what you need: work with the chemical supplier to set the amount; (5) mix only what will be used in the scheduled run; (6) schedule runs to avoid bath changes and wasted liquors; (7) reuse/recycle residual liquors/surplus of liquors if this can be done without jeopardizing quality; (8) maintain all equipment in excellent working condition and conduct periodic operations audits; (9) optimize drying and curing conditions in the stenter frame; (10) dispose of chemicals appropriately; (11) consider additional opportunities to minimize waste and emissions (see FluoroCouncil, 2014).

66. It is indicated by industry stakeholders that most photo-imaging products do not contain PFOA-related compounds. Waste materials, which are associated with the manufacture of a small number of films containing PFOA-related compounds, are typically disposed by high temperature incineration and excess coating formulations may be sent for silver recovery. Thereby, the waste is incinerated at high temperatures (I&P Europe, 2016a). This represents the situation in Europe (IPEN Comments on 1st draft RME).

¹⁶ https://docs.wixstatic.com/ugd/331cad_188bf72c523c46adac082278ac019a7b.pdf.

67. Following the listing of PFOA, its salts and PFOA-related compounds in the Stockholm Convention a concentration level for low POP content would be established in cooperation with the Basel Convention, which also typically will be tasked with determining the methods that constitute environmentally sound disposal. Introducing waste management measures, including measures for products and articles upon becoming waste, in accordance with Article 6 of the Convention, would ensure that wastes containing PFOA, its salts and PFOA-related compounds at concentrations above the low POP content are disposed of in an effective and efficient way such that their POPs content is destroyed or otherwise disposed of in an environmentally sound manner. These measures would also address proper waste handling, collection, transportation and storage and ensure that emissions and related exposures to PFOA, its salts and PFOA-related compounds from waste are minimized. Establishment of the low POP value and the guidelines developed in cooperation with the Basel Convention will help Parties to dispose of waste containing PFOA, its salts and PFOA-related compounds in an environmentally sound manner (see Canada, 2016a).

2.2.1 Evaluation of uses and production of short-chain fluorinated alternatives

68. The evaluation aims to identify uses that are needed by society and for which, there may not be accessible chemical and/or non-chemical alternatives. Exemptions in existing regulatory risk management approaches (see Table 3) give an indication for the identification of such uses based on technical and socio-economic considerations.

A. Uses in semiconductor industry

69. Industry stakeholders have identified use in semiconductor industry as potentially critical. The Semiconductor Industry Association (SIA) surveyed its member companies and found that several companies continue to use PFOA and related chemicals in the photo-lithography process, a key step in the manufacturing process to produce advanced semiconductors (SIA Comments on 1st draft RME). This sector is responsible for a very low share of total emissions of PFOA and PFOA-related compounds. The volume used in the sector is a minor part of the total volumes used in the EU and the substances are reported to be used under strictly controlled conditions. Typical control measures are documented in the OECD Emissions Scenario Document No. 9, Photoresist Uses in Semiconductor Manufacturing (OECD, 2010; SIA, 2016).

70. Information submitted by the sector tends to demonstrate that substitution is currently not possible, and that the timeframes for substitution are long (10 years).

71. The public consultations within the EU confirmed that the costs incurred would be high if this use was not derogated. Because of the low amounts used and the fact that emissions are expected to be low, a time limited derogation (until 4 July 2022) for the equipment used to manufacture semiconductors is given in the EU restriction.

72. Besides, derogation without time limitation is given for photo-lithography processes for semiconductors or etching processes for compound semiconductors and for semiconductors or compound semiconductor under the EU restriction (see ECHA 2015c and European Commission, 2017).

73. In Canada, semiconductors in manufactured items are exempted, whereas in Norway an exemption for adhesives, foil or tape in semiconductors terminated in 2016.

74. SEMI (a global industry association serving the manufacturing supply chain for the micro- and nano-electronics industries) supports the exemption for photo-lithography processes for semiconductor manufacturing and highlights that this exemption should take the form of an “acceptable purpose” (SEMI Comments on 2nd draft RME).

75. Besides, SEMI proposes a number of additional proposals for exemptions and acceptable purposes. In addition to the manufacturing equipment, an exemption without time limit is proposed for their replacement and spare parts. Further, SEMI proposes a five-year exemption for facility-related chemical, gas, and air distribution and control systems for semiconductor manufacturing fabrication facilities as well as a five-year exemption for chemical container systems for the storage, conveyance, and transport of substances or mixtures (SEMI Comments on 2nd draft RME). In addition, SIA requests that suppliers are provided with an acceptable purpose exemption under Annex B for its uses of PFOA and related compounds in manufacturing “tools” and ancillary equipment. The incorporation of small amounts of PFOA and related compounds into the fluoropolymers used in tools and ancillary equipment, including seals, coatings, valves, gaskets, and containers found in these tools, as well as spare parts is needed to achieve critical performance and functional requirements. These complex pieces of equipment are used in fabrication facilities with minimal potential for exposure. In

conclusion, SIA calls for an exemption under Annex B of the Convention for the industry's uses of PFOA and related compounds in its manufacturing processes and the use of these chemicals in advanced manufacturing equipment (SIA Comments on 1st draft RME).

B. Technical textiles¹⁷

76. For non-technical textiles used in outdoor applications (e.g. awnings and outdoor furnishing, camping gear), alternatives are available and an exemption is not justified in the EU.

77. For filter materials for oil and fuel filtration some companies claim that no alternatives are available. However, other companies report the availability of alternatives (short-chain fluorinated chemicals) in high performance areas (ECHA, 2014a, 2015a). Overall, it cannot be fully assessed whether an exemption is justified in the professional sector due to data gaps mainly on volumes, specific uses and substances. It could be agreed to grant a transitional period for the remaining uses in the professional sector as personal protection equipment needs to fulfil specific requirements, which are established in respective standards (e.g. standard EN 13034 for protective clothing).

78. For textiles for the protection of workers from risks to their health and safety a time-limited derogation (until 4 July 2023) is given in the EU. The ECHA SEAC proposes a similar exemption for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment (European Commission, 2017).

79. In Norway, only textiles for consumer use are restricted, while textiles for professional use are not covered. The Canadian approach does not apply to manufactured items, i.e. import, use, sale and offer for sale of textiles containing PFOA, its salts and its precursors are not restricted in Canada.

80. According to the information submitted by the Bavarian Textile and Apparel Association and South-Western Textile Association (VTB SWT), PFOA may occur as an impurity of the production of side-chain fluorinated polymers, which are used as formulations/mixtures for the oil-, water- and chemical-repellent finishing of textiles. Application technique is performed at highest standard and, if at all, only traces of PFOA are transferred by impregnation. As a cross-sectional industry, the professional, technical and protective textile sector of the textile industry has to fulfil many different performance standards in particular medical, chemical, environmental protection as well as fuel-repellency safety standards for the automotive and aircraft industries. Almost all of these textiles have to be certified in long procedures, which could take years and several textiles are regulated by various other EU- and national laws. These are complemented by standards and regulations of separate enterprises, called in Germany "TL" which could be translated i.e. Technical Performance profile. The German textile industry staff is adequately trained, the occupational health and safety is strictly fulfilled and monitored (VTB SWT, 2016). Technical standards such as those used in Germany could be elaborated as examples of good practice (Netherlands Comments on 2nd draft RME). However, the PFOA amounts and manufacturing process and conditions in other countries and regions are not known and could be substantial; resulting in human exposure and environmental releases (IPEN Comments on 1st draft RME).

81. Side chain fluorinated polymers based on PFOA related substances (e.g. 8:2 Fluorotelomer acrylates) used for textile treatment contain 2% unbound residues of PFOA related substances (Russel et al., 2008). These unbound residues can be released to the environment via air and water during the use and waste phase of the treated textile. PFOA related substances can moreover be used in impregnation agents (ECHA 2015a). The European Apparel and Textile Confederation (EURATEX) consider the inclusion of exemption for water-, oil- and chemical-repellence crucial for occupational safety. The transitional period of 6 years would enable ongoing and new projects to deliver results for better performing and environmentally friendlier fluorinated and non-fluorinated polymer alternatives within the European REACH process (Euratex, 2016).

82. According to Textile+Mode association, a lot can be done to meet the risk reduction goals. A common practice is the containment technology. It allows the recycling of PFOA and reuse during polymerization and the retention from contaminated air and process wastewater. During the textile refinement, the minimization of emissions is a common practice. The use of best environmental practice (BEP) in production is a major key to avoid emissions and/or to bring them down to a very low level. In the EU technical textiles are produced respecting the BEP. The treatment with fluorinated products has the aim to minimize the influence of the environment by durable oil- and water

¹⁷ Technical textiles with high performance requirements means textiles such as textiles for the protection of workers from risks to their health and safety or textile membranes intended for use in medical textiles, filtration in water treatment or production processes and effluent treatment.

repellency. The properties have been developed and optimized within the last decades to reach and keep up this high level of protection. Therefore, an exemption for professional, technical and protective textiles, which must meet durable repellency performance standards, is considered indispensable (TM, 2016).

C. *Certain printing inks*

83. Comments from the industry submitted during the EU public consultation indicate that PFOA and related compounds are present in latex inks used in professional printers. This use only continues in printers that are no longer manufactured, and therefore a phase-out is already underway. There seems to be a clear decreasing trend in the amounts used and related emissions. The company that has manufactured the printers and inks in question claims that in absence of a transitional period of 5 years, there would be a need for premature replacement of the printers in use, and the costs would be high because there would be a loss in image quality. The scientific committee of the EU concluded that it is justified to accept a transitional period of 5 years for latex printing (ECHA, 2015c) so that a time limited derogation (until 4 July 2022) is given in the EU (European Commission, 2017). For water-based inks a time limited exemption (until 31 December 2016) was in place in Canada (Canada Comments on 1st draft RME). The Norwegian risk management approach, however, only applies to consumer products and does not restrict PFOA use in inks for professional use/printers.

D. *Production of short-chain fluorinated alternatives*

84. According to FluoroCouncil, industry may perform reprocessing of an unavoidable fraction of PFOA and PFOA related substances as isolated intermediates to produce C₆ fluorotelomer alternatives in another site than the production site and therefore an exemption for transported isolated intermediates is needed (FluoroCouncil Comments on 2nd draft RME). An exemption for transported isolated intermediates without time limit is given in the EU restriction according to its paragraph 4(c) provided that the conditions in points (a) to (f) of Article 18(4) of the EU Regulation (EC) No 1907/2006 are met (European Commission, 2017). An exemption should also be considered under the Stockholm Convention for transported isolated intermediates in order to enable reprocessing in another site than the production site. The conditions could be similar to what is established under the EU risk management approach, i.e. that the synthesis of (an)other substance(s) from an intermediate takes place on other sites under the following strictly controlled conditions: (1) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage; (2) procedural and control technologies shall be used that minimise emission and any resulting exposure; (3) only properly trained and authorised personnel handle the substance; (4) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered; (5) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures; (6) substance-handling procedures are well documented and strictly supervised by the site operator.

E. *Photo-imaging*

85. According to the Imaging and Printing Association Europe (I&P Europe), the primary control measure adopted voluntarily has been to pursue the development of alternatives. Since 2000, the industry has reformulated/ discontinued a large number of products, resulting in a world-wide reduction in the use of PFOA-related compounds of more than 95%. Although replacements do not currently exist for the remaining few applications, further reduction in use of these substances is anticipated as the transition continues towards digital imaging. I&P Europe believes that additional control measures for ongoing uses are not necessary (I&P Europe, 2016a).

86. According to I&P Europe, the non-availability of PFOA-related compounds for the manufacture of the remaining relevant imaging products will also adversely affect involved customer groups such as healthcare and military. In view of the healthcare sector for example, it could be financially challenging for hospitals and doctor's offices with tight budget restraints to invest in new technologies necessitated by discontinuation of current conventional photographic products. It can be expected that such impact is larger in developing countries and in certain EU countries in the medical area such as Italy, Spain, Portugal, Greece and a number of Eastern European countries (I&P Europe, 2016a).

87. Within the EU risk management approach, an exemption is given for photographic coatings applied to films, papers or printing plates (European Commission, 2017). The specific exemptions for this use in Norway and Canada expired in 2016. However, the Norwegian risk management approach

only applies to consumer products and the Canadian approach does not apply to manufactured items. Hence, the import, use, sale and offer for sale of photo media coatings applied to film, papers or printing plates are not restricted in Canada.

F. Nano-coating

88. During the EU public consultation on the restriction dossier, only one company applying coating for smartphone manufacturers requested a derogation for 3 years for pulsed plasma nano-coating in order to be able to move to an alternative C₆ chemical. (ECHA, 2015c). For plasma nano-coating a time-limited exemption (until 4 July 2023) is given in the EU (European Commission, 2017). The Canadian approach does not apply to manufactured items. Hence, the import, use, sale and offer for sale of coatings applied to smartphones (or other electronic equipment) are not restricted in Canada.

G. Spare parts

89. EU industry stakeholders requested an exemption for spare parts of various types (aviation, telecommunication, semiconductors, information and communications technology industry). The concern relates to the possibility to place on the market and use in the EU spare parts already manufactured at the date of entry into force. According to their comments, in the absence of derogation, those spare parts would have to be destroyed, which would represent an economic loss for EU manufacturers. The ECHA RAC and SEAC found that the derogation for spare parts in stock before the entry into force of the restriction was justified for all applications, including the cases mentioned above as well as other cases, given the costs of their elimination and low emissions associated with their prolonged life (ECHA, 2015c). In the EU restriction, there is no exemption for spare parts (European Commission, 2017).

90. Further, the Canadian Vehicle Manufacturers' Association (CVMA) requests specific exemptions for automotive service and replacement parts. According to CVMA, the industry has been proactively phasing out PFOA use for some time. However, service and replacement parts might still contain PFOA. These parts represent a small percentage of PFOA use and will decrease naturally over time as the vehicle fleet turns-over. Automotive manufacturers need to ensure the availability of original equipment and spare parts in order to satisfy customer demand (CVMA 2017). According to the information submitted by IPEN, an exemption would also result in ongoing PFOA releases to humans and the environment from production and use.

91. According to SEMI, regarding manufacturing equipment and related infrastructure in the semiconductor industry, a transitional period would be required also for maintenance, spare, replacement, or refurbished parts for legacy equipment or legacy fabrication plant infrastructure (comment SEMI, 2017 on first draft RME).

H. Firefighting foams

92. AFFF is a generic term for firefighting and/or vapor suppression products used globally to extinguish fires. AFFFs were designed to be especially effective in extinguishing Class B (flammable liquids) fires. AFFFs may contain PFOA or PFOA-related substances. Not every situation will necessarily require the use of firefighting foams. Only a careful consideration of the specific situation at hand (emergency incident or design of fire/property protection system) and review of local building codes and other regulations can determine the proper product selection. Over the past decade, AFFF manufacturers have been replacing PFOS-based products with fluorotelomer-based fluorosurfactants. Today most firefighting foams are manufactured with fluorochemicals/telomers based on a perfluorohexane (C₆) chain (further details see UNEP/POPS/POPRC.12/INF/15/Rev.1), but there are fluorine-free foam or other methods of extinguishment alternatives available fulfilling the requirements of efficiency for many areas of use in Class B fires (Swedish Chemicals Agency, 2016a). For firefighting foams containing PFOA-related substances a number of alternatives exist (see paras 155 to 162).

93. To be consistent with the exemption for foams already in use, and to avoid the need for early replacement of exempted foams, SEAC proposed to derogate these mixtures from the EU restriction for 20 years. This is the normal lifetime for firefighting foams, and this time period is supported by comments from the public consultations (ECHA, 2015c). In the European process, despite concerns raised by some firefighters and foam manufacturers that, in high risk chemical plants and large storage areas, fluorine containing foams with a PFOA and related substances content of up to 1,000 ppb would be needed for another 10 years, the European Commission received ample information from two different sources, demonstrating the availability and effectiveness of entirely fluorine free foams. In addition, short chain fluorine based foams already exist. Here, impurities of PFOA and PFOA related substances seem to be a problem, rather than their presence being essential to technical performance.

The Commission considered that the general deferral of three years should be a reasonable timeframe for the firefighting foam manufacturing industry to adapt their formulations to the restriction.

94. According to the information submitted by IPEN, the normal lifetime of firefighting foam varies considerably with temperature and storage conditions. 20 years is an inappropriate length of time for continued dispersive use of POPs, a use which has led to massive contamination of groundwater in many countries. Germany, supported by Austria, proposes to include a short transitional period for the use of foams already placed on the market, since the firefighting foams are very stable and may be stored for very long time until used in the case of fire. To avoid continued emissions to the environment from this source, existing foams should be replaced with sustainable/suitable alternatives (Germany Comments on 1st draft RME; Austria Comments on 2nd draft RME).

95. Regarding the placing on the market of new AFFFs for professional use, SEAC notes that during the EU public consultations, some stakeholders (firefighting services, foam manufacturers) have requested higher concentration limits for PFOA-related substances and PFOA, or total exemption of firefighting foams. Overall, given the information provided, SEAC proposed to adopt a higher limit value of 1 000 ppb per substance, for both PFOA or for each PFOA-related substance when used in firefighting foam concentrates, and to reconsider this concentration limit with an aim to lower it in the proposed review of the restriction 5 years after entry into force (ECHA, 2015c).

96. Within the EU restriction according to its paragraph 4 (e), an exemption is given for concentrated firefighting foam mixtures that were placed on the market before 4 July 2020 and are to be used, or are used in the production of other firefighting foam mixtures. An exemption is given for firefighting foam mixtures (1) placed on the market before 4 July 2020 or (2) produced in accordance with paragraph 4(e), provided that, where they are used for training purposes, emissions to the environment are minimized and effluents collected are safely disposed of (European Commission, 2017). In Canada, a not-time-limited exemption is given to AFFFs used in firefighting applications (Canada 2016c). There are no exemptions in place for firefighting foams in Norway, however, the risk management approach does not apply since it concerns consumer products and AFFFs are for professional use only. The Canadian Fuels Association (CFA) supports the exemption of AFFFs as proposed in the RME (CFA Comments on 2nd draft RME).

I. Medical devices

97. In the EU public consultation, stakeholders have indicated that substitution is ongoing but is a lengthy process given the complexity of the supply chains and the certification processes. General transitional period of a minimum of 5 years was requested, but for some devices this transitional period could be too short. In the specific case of implantable medical devices, a manufacturer requested a transitional period of 15 years (ECHA, 2015c).

98. Within the EU restriction, time-limited exemption (until 4 July 2032) is given for medical devices other than implantable medical devices within the scope of Directive 93/42/EEC. In addition, an exemption without time limitation is given for the production of certain implantable devices (European Commission, 2017). Norway has an exemption in place for medical devices (no time limit).

J. Transported intermediate use in the production of pharmaceutical products

99. According to chemical industry, alternatives have not been developed for all pharmaceutical and some other highly specialized chemicals which use PFOA-related chemicals as their raw material and/or processing media and which have socio-economic benefit in particular performance standards (FluoroCouncil, 2016a). There is no information specifying “other highly specialized chemicals”. In the SAICM context environmentally persistent pharmaceutical pollutants are adopted as a global emerging policy issue, while recognizing that pharmaceuticals have major benefits for human health and animal welfare. Perfluorooctyl bromide (PFOB) is produced from perfluorooctyl iodide (PFOI). PFOI is produced at one single site in Japan during the production of 6:2 fluorotelomer-based substances (telomerisation, separation and distillation in closed system), and then transported as isolated intermediate to another site in Japan to produce PFOB. All the wastes generated from this production of PFOI are collected in closed system and are incinerated. A minor amount of emission to the air can be expected and is estimated to be less than 1 kg per year. Afterwards, PFOB is transported to two sites in the US and Sweden to produce relevant pharmaceutical products (Daikin Comments on 2nd RME and information from IFPMA at POPRC-13).

100. PFOB is used as a processing aid in the manufacture of “microporous” particles for pharmaceutical applications. PFOB is not a PFOA related compound. PFOB does, however, contain unintended trace levels of PFOI, a PFOA related compound. The residual PFOB in the finished “microporous” pharmaceutical products is typically 0.1%, which translates to residual PFOI at levels

of 0.1 ppm. The detection limit for PFOB in the porous particles is 0.1%. The PFOI residual in all currently produced pharmaceutical products totals to less than 2g per year. Emission of PFOI to the environment from pharmaceutical production is currently less than 30g total per year. PFOB in process waste is captured in serial carbon beds, which is the best available technology and it controls emissions to less than 1% and typically to less than 0.1% (Information from IFPMA at POPRC-13).

101. The “microporous” particles enable the combination of more than two active pharmaceutical ingredients into one pharmaceutical with desirable ratios to maximize the effect. The microporous particle technology also enables delivery efficiency and targeted delivery in the lungs. The manufactured pharmaceutical products currently marketed are for the treatment of patients with chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF). Research on additional pharmaceutical applications is ongoing in early and late stage development (Information from IFPMA at POPRC-13).

102. Extensive efforts have been made to identify alternative agents, with at least 15 agents screened, but PFOB was found to be the only one suitable for manufacture of the “microporous” pharmaceutical products and to have a suitable toxicological profile that is safe for administration in humans (NDA 020-091 FDA approval of Imagent®). Given these efforts, it is improbable that an alternative agent can be identified without compromising the properties of the “microporous” particles. If an alternative agent was found, this would still require repeat clinical trials and re-registration of the products which total period will be in excess of 10 years. For this type of pharmaceutical products, there is need to secure continuous delivery to patients, hence further consideration on the appropriate way to address this application is required (Information from IFPMA at POPRC-13).

K. Use of sulfluramid

103. *N*-Ethyl perfluorooctane sulfonamide (known as sulfluramid; EtFOSA; CAS No: 4151-50-2) has been used as an active ingredient in ant baits to control leaf-cutting ants from *Atta* spp. and *Acromyrmex* spp. in many countries in South America as well as for control of red imported fire ants, and termites (UNEP/POPS/POPRC.6/13/Add.3/Rev.1). Fluorosurfactants may also be used as “inert” surfactants (enhancers used in pesticide formulations but not constituting active ingredients) in pesticide products (UNEP/POPS/POPRC.12/INF/15/Rev.1).

104. Sulfluramid is used in baits for the control of leaf-cutting ants, according to the delegation from Brazil the use of sulfluramid in Brazil prevents damage corresponding to losses of up to 14.5 % of trees per hectare. Other agricultural products likely to suffer costly losses are soybean and maize. Also, the per-hectare capacity to support livestock is likely to decrease if forage for grazing is reduced by ants (UNEP/POPS/POPRC.12/INF/15/Rev.1).¹⁸

105. Insect baits for control of leaf-cutting ants from *Atta* spp. and *Acromyrmex* spp. are listed as acceptable purpose for the production and use of PFOS, its salts and PFOSF in Annex B (UNEP/POPS/POPRC.12/INF/15/Rev.1).

2.2.2 Costs and benefits of implementing control measures

106. In a HELCOM report, cost-effective management options to reduce discharges, emissions, and losses of hazardous substances including PFOA have been assessed. Besides measures at industrial sources, measures at urban sources can also reduce emission of PFOS/PFOA, such as advanced treatment of municipal waste water by activated carbon (further details also in other options see HELCOM, 2013).

107. PFOA has already been phased out widely in many uses, indicating that the costs of alternatives have not inhibited the PFOA substitution. Important points to consider when evaluating the costs of alternatives for any product include the following. Alternatives with a higher initial purchase cost may actually be cheaper over the whole life span of the product when durability and other factors are taken into account. Mass-production of alternatives can significantly lower their costs. The costs of initiatives to protect health and the environment are frequently overestimated in advance and later decline rapidly after the regulation is implemented. Finally, costs of environmentally sound disposal of end-of-life products are also an important factor to take into account (Ackermann and Massey, 2006).

¹⁸ Oficio DFIA/SDA/MAPA n° 123/2008 from Ministry of Agriculture, Livestock and Food Supply, Animal and Plant Protection Secretariat Agriculture Inputs Inspection Department.

108. For the EU restriction, the substitution costs according to the EU proposal for a restriction have been estimated related to: (1) fluoropolymers import and use of PTFE mixtures; (2) textiles use in the EU; (3) textiles import in article; (4) firefighting foams; (5) paper; and (6) paints and inks. The estimation was made by the industry for the current uses (worst case scenario) and for the time period after the restriction will enter into force (more realistic case). Due to the lack of data, estimation associated with the import of PFOA in articles, photographic applications and semiconductors was not made. The estimated substitution costs for the EU range from 1.39 to 158.44 million euros with a 34.7 million euros central estimate for the more realistic case for the EU (see ECHA, 2015a, Table F.2-6).

109. The EU public consultation with industry has shown that the main fluoropolymer manufacturers have already developed several alternatives to replace PFOA. These alternatives are often exclusively manufactured and used by each company. As a consequence, there are usually no market prices available (yet). However, there are some indications on the increase in operating costs, which can be used to assess the costs of the proposed restriction to fluoropolymer manufacturers. Accordingly, it is assumed that the use of alternatives induces a low to moderate increase in production costs (0-20%). This increase arises from the higher costs and/or the higher amounts of alternatives that will be used. Industry stated that there is no change in the quality of the PTFE manufactured with the alternatives (ECHA, 2015a).

110. Regarding the investment costs, mainly (former) manufacturers of PFOA and PFOA-related substances industry, stated during the preparation of the EU restriction, that industry has already invested considerable resources to develop short-chain PFASs in terms of R&D efforts and capital (over 500 million euros have been reported, which was also confirmed in the EU public consultation). For downstream users, substantial costs can be expected to switch to short-chain alternatives due to reformulation of products, adapting production processes and testing. In this respect, up to 1 million euros per company have been reported, depending on the specific conditions of the case at hand (ECHA, 2015a).

111. According to I&P Europe, the primary barrier to completely eliminate the use of PFOA-related compounds at this time remains to be technical. However, the costs of research and development are also relevant for consideration, since such investment may represent a significant financial burden during the time when imagining industry is focused on the creation of innovative new digital imagining technologies. The economic costs associated with the substitution of PFOA-related compounds in the few remaining relevant photographic uses have in most cases become prohibitive. The small remaining relevant uses are niche products in markets that IP Europe members anticipate to further decline (I&P Europe, 2016b).

112. For the EU, it has been shown that there are considerable costs to society connected with hypercholesterolemia, developmental toxicity and cancer. These costs will manifest through direct costs such as medical treatment and indirect costs such as loss of life quality for affected individuals. It has not been possible to estimate the share of the overall disease burden that can be attributed to PFOA and PFOA-related substances. However, the large risk characterization ratios imply that there will be significant benefits to human health from restricting PFOA and "PFOA-related substances" (ECHA, 2015a). According to the information from Norway, the socio-economic assessment in the EU emphasized mostly on the persistent, bioaccumulative and toxic (PBT) properties of PFOA for the reason of reducing the emissions. Newer studies have also shown correlations between exposure to PFOA and reduced effects of vaccines and PFOA is presumed to be an immune hazard to humans (see e.g. UNEP/POPS/POPRC.12/11/Add.2. or NTP, 2016).

113. The EU restriction is not expected to lead to wider economic impacts within Europe because the market is already developing towards replacing PFOA and PFOA-related substances. This is reflected by the estimated moderate compliance costs. Furthermore, the restriction is not expected to trigger effects with regard to the competitiveness of the EU and global industry because both will have to substitute PFOA and "PFOA-related substances" to comply with the restriction. The restriction is not expected to have major effects on employment in the EU (ECHA, 2015a).

114. The cost of removing and destroying PFOS that is present in existing products, such as firefighting systems, is generally estimated to be well below 1,000 euros per kilogram, although it can be much higher in individual cases. An example is the Barendrecht railway tunnel in the Netherlands, where at least 3,500 euros per kilogram was spent on removing PFOS from the firefighting system. This operation did not achieve complete removal, which would require a second round of flushing or replacement of the main pipe, costing at least another 400,000 euros per kilogram of the remaining PFOS. The railway operator was not required to do this, which could be interpreted as an indication

that the cost was considered disproportionate, although this reason was not put forward explicitly (Oosterhuis et al., 2017).

115. A regulatory initiative has been developed as part of Canada's Chemical Management Plan (CMP) with the objective to protect the environment from risks associated with the manufacture, use, sale, offer for sale or import of (among other substances) PFOA and long-chain PFCAs. In the Canadian risk management process, scientific evidence has demonstrated that PFOA and long-chain PFCAs are persistent, that they accumulate and biomagnify in terrestrial and marine animals, and that they are toxic to the environment under the Canadian Environmental Protection Act, 1999 (CEPA). Although no quantitative analysis of benefits of the initiative has been conducted, the regulatory controls for PFOA and long-chain PFCAs in Canada will protect the environment. An improvement in environmental quality is expected from controlling these substances.

116. Norway states that control measures will have positive impacts on human health, since we are still exposed to PFAS in our everyday environment (Norway, 2016). The number of consumer products containing PFOA has decreased, and the levels in all-weather clothing have decreased after the introduction of a national regulation of PFOA in consumer products in 2013 (Norway Comments on 2nd draft RME).

117. In Australia, societal impacts of PFOA have recently come to the fore with the identification of a number of sites contaminated by the historic use of AFFFs at airports and firefighting training facilities to fight liquid fuel fires. Firefighting foams containing PFOA, PFOS and PFHxS have been phased out in a range of uses. It is noted that legacy use of AFFFs has contaminated some defense and civil airport sites, with contamination migrating off-site in some instances through surface and groundwater. The migration of PFOA from the point of use has resulted in the contamination of ground and surface water in adjoining areas that, in some instances, were used for human consumption and agricultural purposes. In sites where drinking water has been contaminated, an alternative source of drinking water has been provided. Some agricultural activities have been affected, for example, market gardens and small scale poultry and egg production, where PFOA has contaminated water previously used for these purposes. The stigma of being in a contaminated environment has led to decreasing property and business values and the loss of income for some land and business owners. This in turn has led to a level of stress and anxiety in the affected communities which is further compounded by the uncertainty of the health impacts of the residents. While the impact on Australia is largely from the legacy use of PFOA-containing AFFFs, the implementation of control measures will provide some assurance to Australian communities that the potential for ongoing or future contamination is being minimized (Australia, 2016). In April 2017, two major spills of PFOA (22,000 and 5,000 litres) containing AFFFs occurred at Brisbane airport and resulted in government warnings to avoid consuming fish from the area's waterways (IPEN Comments on 2nd draft RME). The Australian federal government is developing a whole-of-government response and also working in collaboration with Australian States and Territories to manage and respond to PFAS contamination (Australia Comments on 2nd draft RME).

118. Continued use of PFOA in firefighting foams would result in the ongoing contamination of groundwater and soil surrounding military sites and airports across the world, with all its associated remediation, compensation and legal costs in addition to harms to human health and the environment (Wang et al., 2017; LaSalle, 2016; The Senate Foreign Affairs, Defence and Trade, 2016; Air Services Australia, 2016; Filipovic et al., 2015; Houtz et al., 2016). Recent calculations of the total costs for cleaning up groundwater polluted by PFAS around firefighting areas in Norway show that 3.5-5.5 million euros is required per training site. These numbers include investment and operation of groundwater cleaning systems necessary in some Norwegian airports polluted by PFAS from firefighting foams. Chemical analysis show that PFOA migrates into the ground water to a higher extent than PFOS (Norway Comments on 3rd draft RME).

119. In 2005 PFAS containing firefighting foam has been used at the German Airport Düsseldorf because of a plane crash and firefighting trainings. PFAS (also PFOA), contaminated soil and leached into groundwater. The PFAS containing groundwater polluted two lakes nearby which are now closed for the public, the consumption of fish is prohibited. In 2007 the local environment authority of Düsseldorf found elevated PFAS levels in the north of Düsseldorf. In the next years the airport Düsseldorf was found to be the main PFAS-source. The remediation of the groundwater will take years or even decades. Further, about 3000 tonnes of soil polluted with PFAS were excavated and disposed of.¹⁹ Other airports in Germany have similar PFC contaminated areas resulting from the use of AFFFs for training purposes in the past (i.e. Nürnberg airport). The costs of such remediation actions are discussed in ECHA, 2015a (Germany Comments on 3rd draft RME).

120. In Germany, there is one prominent case showing the consequences of (illegal) disposal of waste/sludge on agricultural fields. Because of the disposal of industrial sludge PFOA leached into the surrounding surface water and a drinking water reservoir, Lake Möhne, was polluted (see Skutlarek et al. 2006, Wilhelm et al. 2009, Wilhelm et al. 2010, Hölzer et al. 2008, Hölzer et al. 2009). The drinking water thus contained elevated levels of PFOA. Thus, human biomonitoring studies showed higher PFOA levels in blood from people living in Arnsberg compared to inhabitants of a nearby area which received drinking water from a different source. According to information from the media the purification costs for the groundwater of about 2.5 million euros have been incurring since 2006. The purification plant will be operated during the next years and operating costs are about 100,000 euros per year (Germany Comments on 3rd draft RME).²⁰

121. High levels of PFAS in drinking water, in the µg/L range, have been detected since 2011 in a number of municipalities in Sweden. The costs for addressing PFAS contamination of drinking water for some municipalities are provided such as charcoal filtering of water in Uppsala (annual cost 1 million euros) and new water supply in Ronne by (3 million euros) (Swedish Environmental Protection Agency, 2016). Firefighting training sites have been shown to be the main sources of this pollution, which in some cases have resulted in water supplies being closed. The municipalities have released information that wild fish caught from lakes downstream pollution area should not be eaten too often (Swedish Chemicals Agency, 2013). For PFAS-containing water derived from a cavern near an old airfield, a carbon filter system has been installed to clean 150-200 m³ of water from the caverns before it flows out into receiving waterways (Defoort et al. 2012). PFAS have also contaminated drinking water for 15 million inhabitants and several sites in USA. However, carbon filter systems may not work for all PFAS (Wang et al., 2017).

122. Regarding professional, technical and protective textiles, the sales of German manufacturers in 2013 amounted up to 6 billion euros (see VTB SWT, 2016 and TM, 2016).

123. Due to accessibility or costs of alternative technologies, some of alternative technologies for PFOA in developing countries may be available a few years later

2.3 Information on alternatives (products and processes)

2.3.1 Overview of alternatives

124. Due to concerns about the impact of long-chain perfluoroalkyl acids (PFAAs) on humans and the environment these PFAAs and their precursors are being substituted in many applications by other substances, including fluorinated alternatives which are structurally similar to the substances they replace. These fluorinated alternatives comprise particularly short-chain PFAAs and functionalized perfluoropolyethers (PFPEs), in particular per- and polyfluoroether carboxylic acids and (PFECAs) and per- and polyfluoroethersulfonic acids (PFESAs) having an acidic functional group attached to a per- or polyfluoroether chain instead of a perfluoroalkyl chain (Wang et al., 2015). An overview of some known fluorinated and non-fluorinated alternatives for different industry branches is given in the reference documents (ECHA, 2015a, Table C.1-1; see UNEP/POPS/POPRC.13/INF/6; Section 3 and UNEP, 2017).

¹⁹ See <https://www.dus.com/de-de/konzern/unternehmen/verantwortung/umweltschutz/gew%C3%A4sserschutz/grundwassersanierung>.

²⁰ The costs have to be borne by the community according to the results of a court case (<https://www.wp.de/staedte/altkreis-brilon/ruhrverband-klagt-im-pft-umweltskandal-auf-schadenersatz-id9731569.html>).

2.3.2 Sector specific aspects

125. The following paragraphs discuss sector specific aspects related to alternatives. Nevertheless, several aspects related in particular to risks of the alternatives (e.g. short-chain fluorinated substances) cannot be assigned to a single sector, but apply to all of those sectors where the respective alternatives are relevant.

A. *Manufacture of fluoropolymers*

Functionalized perfluoropolyethers (PFPEs)

126. According to FluoroCouncil, there are various alternative polymerization processing aids (PPA) used for replacing PFOA in the manufacture of fluoropolymers (FluoroCouncil, 2016a).

127. Fluoropolymer producers used ammonium or sodium perfluorooctanoate (APFO and NaPFO) as processing aids in the (emulsion) polymerization of polytetrafluoroethylene, perfluorinated ethylene-propylene copolymer, perfluoroalkoxy polymer and certain fluoroelastomers. In addition, ammonium perfluorononanoate (APFN) was applied in the emulsion polymerization of polyvinylidene fluoride (Prevedouros et al., 2006). Most producers have developed their own alternatives. Commercialized fluorinated alternatives are functionalized PFPEs including amongst others ADONA from 3M/Dyneon ($\text{CF}_3\text{OCF}_2\text{CF}_2\text{CF}_2\text{OCHF}_2\text{COO-NH}_4^+$; CAS No: 958445-44-8; Gordon, 2011), GenX from DuPont or C_3 Dimer salt²¹($\text{CF}_3\text{CF}_2\text{CF}_2\text{OCF}(\text{CF}_3)\text{COO-NH}_4^+$; CAS No: 62037-80-3; Du Pont, 2010), cyclic or polymeric functionalized PFPEs from Solvay (Marchionni et al., 2010; Pieri et al., 2011; Spada and Kent, 2011) as well as EEA-NH₄ from Asahi ($\text{C}_2\text{F}_5\text{OC}_2\text{F}_4\text{OCF}_2\text{COO-NH}_4^+$; CAS No: 908020-52-0; EFSA, 2011a). Additional information on alternatives to PFOA in fluoropolymer production with emphasis on the manufacture of fluoropolymers in China and fluorinated emulsifier-free aqueous emulsion polymerization processes is compiled in section V of FOEN, 2017.

128. Three PFOA-alternatives with ether moieties (GenX, ADONA and EEA-NH₄) that are generally shorter and/or less fluorinated were assessed in the EU restriction process (ECHA, 2015a, section C3). C_3 Dimer salt, ADONA and EEA-NH₄ are applied as alternatives for the use of PFOA as polymerization processing agent where it is applied as emulsifying agent enabling reactants from the aqueous phase and reactants from the hydrophobic phase to get into contact in an emulsion and react with each other (ECHA, 2015a). According to ECHA most of the stakeholders stated that there are no technical differences between fluoropolymers produced with the alternatives and fluoropolymers produced with PFOA (or stakeholders do not know whether there are any differences) (ECHA, 2015a). Fluoropolymer manufacturers stated during the EU public consultation that the production costs varied from none to 20% increase when applying the alternatives (ECHA, 2015a). The increase is a result of higher costs of the alternatives as well as higher amounts of the alternatives needed to manufacture one unit of fluoropolymer. Some downstream users mentioned that no cost effects occurred after substitution from PFOA to alternatives.

129. Toxicokinetic data of C_3 Dimer salt indicate little or no metabolism, but rapid excretion. It is presumably cleared non-metabolized within 2-7 days (mouse), 10-11 h (monkey) and 4-48 h (rat). C_3 Dimer salt is classified as skin irritating and eye damaging. Moreover, repeated administration resulted in liver enlargement and hepatocyte hypertrophy as well as liver cell necrosis at 0.5 mg/kg/day in male mice. With respect to carcinogenicity, a two-year rat study gave tumors at higher doses (≥ 50 mg/kg/day). With regards to environmental risks (data were taken from the registration dossier) related to C_3 Dimer salt, it was concluded that the substance is probably not acutely toxic ($\text{LC}/\text{EC}_{50} > 100$ mg/L) or chronically toxic ($\text{NOEC} > 1$ mg/L) to aquatic organisms. Regarding all available information a full PBT assessment including assessment of the criteria persistence, bioaccumulation and toxicity according to the EU chemicals legislation (for guidance see ECHA, 2017a) cannot be performed. However, the registrant acknowledges in the chemical safety report (CSR) that the C_3 Dimer salt fulfils the P and the T criterion based on specific target organ toxicity after repeated exposure (STOT RE 2). The C_3 Dimer salt is likely to fulfil the PBT criteria of the European chemicals legislation, see REACH Annex XIII (ECHA, 2015a).

130. With respect to ADONA, it turned out that the substance is persistent. No data related to carcinogenicity were available. Concerning environmental risks (data were taken from the registration dossier under the REACH regulation) related to ADONA it was concluded that the substance is probably not acutely toxic ($\text{LC}/\text{EC}_{50} > 100$ mg/L) or chronically toxic ($\text{NOEC} > 1$ mg/L) to aquatic

²¹ IUPAC name: Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoate; CAS No: 62037-80-3.

organisms. Regarding all available information a full PBT assessment cannot be performed. The substance will most probably fulfil the P criterion of REACH Annex XIII. Based on the data for environmental toxicity, the substance does not fulfil the T criterion. The registration dossier lacks toxicological information relevant to humans. Thus the data are not sufficient to conclude or to refute on the PBT-properties of the substance (ECHA, 2015a). Based on a document from the European Food Safety Authority from 2011, 3M reported that the elimination half-life of ADONA was between 12 and 34 days from the bodies of three workers, while it takes about four years in humans to clear half of the PFOA (see The Intercept, 2016 and EFSA 2011b).

131. In another study (Gordon, 2011) the toxicity of ADONA was evaluated in acute and repeated-dose studies of up to 90 days, in eye and skin irritation, dermal sensitization, genotoxicity, and developmental toxicity studies. The substance was evaluated as a peroxisome proliferator-activated receptor alpha (PPAR α) agonist in rats, moderately toxic orally and practically non-toxic dermally in acute rat studies. In rabbits ADONA turned out to be a mild skin irritant and a moderate to severe eye irritant as well as a weak dermal sensitizer in local lymph node assays in mice. Based on the weight of evidence from five assays, ADONA was not considered genotoxic. No developmental toxicity was observed except at maternally toxic doses. Regarding ADONA as a PPAR α agonist the liver was the primary target organ in male rats and the kidney in female rats. It was concluded by the author that the toxicity profile for ADONA is acceptable for its intended use as PPA and is superior to the one of APFO.

132. EEA-NH₄ is considered persistent. Provided data is not sufficient to conclude on not bioaccumulating (B). Regarding environmental risks (data were taken from the registration dossier) related to EEA-NH₄ no acute toxicity (LC/EC₅₀>100 mg/L) to aquatic organisms was determined. On the basis of all available information a full PBT assessment with consideration of the knowledge from the PFOA-PBT assessment cannot be performed. The substance will most probably fulfil the P criterion of REACH Annex XIII. Based on the data for environmental toxicity, the substance does not fulfil the T criterion. Toxicity data on human health were provided in the registration. The registrant points out that the substance is classified as toxic for reproduction category 2. Thus the substance fulfils the T-criterion of Annex XIII and it remains a PBT suspect. (ECHA, 2015a).

133. Serum elimination half-lives of the two PFECAs, GenX (in rats and mice) and ADONA (in rats and humans), were reported (ECHA, 2014b; EFSA, 2011b). Provided elimination half-lives were shorter compared to the one for PFOA, but it was considered impossible to draw a conclusion on the bioaccumulation potential of PFECAs and PFESAs due to the fact that no quantitative serum elimination half-life threshold is defined in regulations as a criterion for bioaccumulation, the interspecies variation has not been elucidated and the studies were often conducted with different dosing methods (e.g. oral vs. intravenous, single vs. repeated dose). As a consequence reported serum elimination half-lives between substances cannot be directly compared (Wang et al., 2015).

B. Textile and carpet sector

134. The properties, performance and associated hazards of fluorinated and non-fluorinated durable water repellent (DWR) chemistry for textile finishing have recently been reviewed (Holmquist et al., 2016); the following sub-sections present an overview of individual chemistry.

Short-chain fluorinated alternatives

135. Short-chain fluorotelomer-based substances replacing their long-chain equivalents have been identified as alternatives for a variety of uses including, amongst others, textile and carpet uses (USEPA, 2012).

136. Side-chain fluorinated polymers comprising non-fluorinated carbon backbones and side chains containing a mixture of 6:2-14:2 fluorotelomer moieties or moieties derived from PFOSF were used in surface treatment products to give water- and oil-resistance to textile, leather and carpets (Buck et al., 2011). A trend to use shorter-chain homologues to replace long-chain fluorotelomer- or PFOSF-based derivatives on side-chains can be observed (Ritter, 2010). Several surface treatment products containing C₄ side-chain fluorinated polymers derived from perfluorobutane sulfonyl fluoride (PBSF) have been commercialized (Renner, 2006). In addition, products mostly based on highly purified fluorotelomer raw materials (mostly 6:2), including copolymers derived from 6:2 fluorotelomers and organosiloxane (Dow Corning, 2007), have been developed by fluorotelomer manufacturers (Ritter, 2010). Short-chain polyfluoroalkyl alcohols such as 3:1 and 5:1 fluorotelomer alcohols (FTOHs) have been commercialized and can be used as building blocks for side-chain fluorinated polymers (Wang et al., 2013).

137. Chemical alternatives to PFOA-related compounds used for stain- and water-repellency are available and include textile and carpet surface treatment applications based on acrylate, methacrylate

adipate and urethane polymers. With regard to short-chain PFASs, PBSF-based and 6:2 fluorotelomer-based substances, including polymers, have been applied. According to a variety of scientific studies, and the Madrid Statement (Madrid Statement, 2015), an international scientific consensus statement, these compounds have raised concerns with regards to persistency and bioaccumulation and should not be regarded as acceptable alternatives considering criteria outlined in the POPRC Alternatives Guidance document (see UNEP/POPS/POPRC.13/INF/6; Section 3).

138. Compounds based on $\leq C_6$ -based fluorotelomer chemistry are used to manufacture fluorotelomer-based products indicating the technical feasibility of this alternative. Higher volumes must be applied to achieve the same technical performance and costs of $\leq C_6$ -based fluorotelomer products are higher (ECHA, 2015a).

139. For fluorotelomer products based on 8:2 fluorotelomer alcohol (8:2 FTOH), the short-chain 6:2 FTOH is used as an alternative. This substance will not degrade to PFOA, but rather to other acids, such as perfluorobutanoic acid (PFBA), perfluoropentanoic acid (PFPeA), perfluorohexanoic acid (PFHxA), and 2H,2H,3H,3H-undecafluoro octanoic acid (5:3 fluorotelomer acid) (ECHA, 2015a). According to another study (Ellis et al., 2004) perfluoroheptanoic acid (PFHpA) is formed as well upon the atmospheric degradation of 6:2 FTOH, and it is stated that PFHpA and PFHxA are the most abundantly formed PFCAs upon the atmospheric oxidation of 6:2 FTOH. In soil-bound residues, 5:3 acid may not be available for further biodegradation (Liu et al., 2010a; Liu et al., 2010b). In activated sludge, 6:2 FTOH also undergoes rapid primary biotransformation, and more than 97 % of 6:2 FTOH may be converted to at least 9 transformation products within 3 days. Major biotransformation products include 5:3 acid, PFHxA, and PFPeA (Zhao et al., 2013b). Similar biotransformation products were also found in a study using an aerobic river sediment system (Zhao et al., 2013a). More information regarding the transformation/degradation of 6:2 fluorotelomers can be found in section II of FOEN, (2017).

140. According to a study sponsored by FluoroCouncil considering data from published and unpublished scientific studies, the fluorinated chemical alternatives to PFOA (6:2 FTOH, PFHxA/PFHx, 6:2 methacrylate and 6:2 acrylate) do not meet the overall Stockholm Convention POPs criteria. The study concludes that 6:2 FTOH meets one of the POP criteria of the Stockholm Convention (meets criteria based on atmospheric transport, but additional information is necessary to determine if concentrations in remote environments are of potential concern according to Annex D paragraph 1 (d) (i). persistence, bioaccumulation, ecotoxicity and toxicity to humans not fulfilled). PFHxA and its anion PFHx meet the criteria of persistence, because they are likely to be environmentally persistent even though data on the degradation half-life of PFHxA in soil, sediment and water are not available. The criteria of bioaccumulation, long-range environmental transport, ecotoxicity and toxicity to humans are not fulfilled (FluoroCouncil, 2014a). A more recent report based on the previous assessment considered newly published studies and supports the initial conclusion that none of the analyzed short-chain PFASs (6:2 FTOH, PFHxA/PFHx, 6:2 methacrylate and 6:2 acrylate) meet the Stockholm Convention POP criteria (FluoroCouncil, 2016b). Nevertheless, the alternatives and alternative mixtures may still exhibit hazardous characteristics that should be assessed before considering such substances to be suitable alternatives.

141. Risks related to short-chain chemistry are described in detail in sections C.2.2 (human health risks) and C.2.3 (environmental risks) of (ECHA, 2015a). Main findings related to 6:2 FTOH based on several studies (Lindeman et al., 2012; Maras et al., 2006; Martin et al., 2009; Mukerji et al., 2015; Oda et al., 2007; Ishibashi et al., 2007; Vanparys et al., 2006; all cited by ECHA, 2015a) are outlined in the background document of this risk management evaluation (UNEP/POPS/POPRC.13/INF/6; Section 4). Further available studies on short-chain PFASs have been compiled by FluoroCouncil.²²

142. 6:2 FTOH will undergo biotransformation, resulting in PFCAs containing 3 to 5 fluorinated carbon atoms. These PFCAs are structurally similar to PFOA, only differing in the number of fluorinated carbon atoms. These short-chain PFCAs are equally persistent in the environment and cannot be further degraded under biotic or abiotic conditions (ECHA, 2015a). However, the bioaccumulation potential of PFCAs with <7 fluorinated carbons is expected to be lower than that of PFOA (Conder et al., 2008).

143. Metabolites of 6:2 FTOH are expected to be persistent, to have a lower bioaccumulation potential in wildlife and humans and a lower toxicity to aquatic organisms compared to PFOA (ECHA 2015a). However, short-chain PFCAs are more mobile than PFOA in an aqueous

²² See <https://fluorocouncil.com/Resources/Research>.

environment, and can potentially contaminate drinking water (Eschauzier et al., 2013; Gellrich et al., 2012). Also, they may accumulate more in vegetables, which can be a different route of exposure (Krippner et al. 2015; Blaine et al. 2014). Results of another study indicate that fluorotelomer carboxylic acids are more acutely toxic to aquatic invertebrate and plant species compared to their corresponding PFCAs (Mitchell et al., 2011). However, it should be considered that environmental concentration may change over time, especially if used in higher amounts due to a phase out of PFOA, its salts and PFOA-related substances.

144. POPs characteristics raise concerns about the suitability of a number of fluorinated chemical alternatives to PFOA including PFHxS, PFHpA, PFHxA, PFBS, PFBA, 4:2 FTOH, 6:2 FTOH, 6:2 fluorotelomer acid (6:2 FTA) and 6:2 fluorotelomer sulfonate (6:2 FTS). Due to its very persistent and very bioaccumulative (vPvB) properties, PFHxS was recently unanimously added by the EU member states to the REACH list of substances of very high concern (SVHC) (ECHA, 2017b). In addition, Norway recently nominated PFHxS for addition to the Stockholm Convention. These characteristics raise concerns regarding implementation of Article 3 paragraphs 3 and 4. Specific information and corresponding references related to adverse effects of these alternatives are available (UNEP/POPS/POPRC.13/INF/6; Section 5).

Non-fluorine containing alternatives

145. According to representatives of the textile industry (VTB SWT, 2016), non-fluorine containing alternatives including paraffins, alpha olefin modified siloxanes, fatty-acid modified melamine resins and fatty-acid modified polyurethanes exist for standard- and outdoor clothing with low-level of repellency (VTB SWT, 2016). In some cases, when applying fluorine-free alternatives, quality requirements of professional, technical and protective textiles cannot be fulfilled due to, for example, a lack of chemical-, oil- and/or dirt-repellent properties, inadequate abrasion and/or wash resistance especially in industrial and chemical cleaning applications, poor dry soil-repellency, a lack of weather resistance and UV-stability, blocking of breathable membranes (e.g. in protective clothing after short wash-cycles) or limited options related to further processing (VTB SWT, 2016).

146. A range of fluorocarbon-free, water-repellent finishing agents for textiles include commercial products such as BIONIC-FINISH®ECO and RUCO-DRY® ECO marketed by Rudolf Chemie Ltd., Geretsried/Germany; Purtex® WR, Purtex® WA, Purtex® AP marketed by the Freudenberg Group, Weinheim/Germany; and ecorepel® marketed by Schoeller Technologies AG, Sevelen/Switzerland (Stockholm Convention, 2014).

147. Concerning water-repellant properties, there are several substances that can be applied instead of highly fluorinated substances, whereas alternatives for grease- and dirt-repellent agents are rare. Most prominent

water-repellent alternatives are silicone-based agents. These include high molecular weight polydimethylsiloxanes (PDMS), mixtures of silicones and stearamidomethylpyriden chloride (sometimes in combination with carbamide (urea) and melamine resins), waxes and paraffins (usually consisting of modified melamine-based resins) and dendrimers that are being developed to imitate the ability of the lotus blossom to repel water (Swedish Chemicals Agency, 2015).

148. Paraffin repellents are liquid emulsions that should not be classified as hazardous to health according to the producers. However, some of the identified ingredients seem to be harmful. The main ingredient in most products is paraffin oil/wax (mixtures of long chain alkanes), which is considered harmless in pure form. Some products also contain isocyanates, dipropylene glycol, metal salts or other unknown substances, which may be harmful. Most components are readily biodegradable and do not bioconcentrate or accumulate in organisms and food chains, and the toxicity to aquatic and terrestrial organisms is insignificant, even when regarding concentrations above the water solubility (Danish EPA, 2015b).

149. Most silicones applied in textile impregnation agents are based on PDMS which are inert and have in general no adverse effects. Various siloxanes, especially the cyclic siloxanes known as D4, D5 and D6 and specific linear siloxanes are intermediates for the synthesis of silicone polymers used for textile impregnation. Siloxanes are persistent and widespread in the environment. Mostly, they are detected in urban areas and in the aquatic environment. High levels have been found in livers of fish, which were caught close to outlets of sewage treatment plants. Siloxanes are generally removed from the aqueous phase by sedimentation, and exhibit a long half-life in sediments. In soils, siloxanes are transformed depending on the conditions into hydroxylated forms, which still may be persistent (Danish EPA, 2015b; further information see also P05, 2012 and Davies, 2014). In Canada, it is concluded that D4 is entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

150. With regards to dendrimer-based repellents there are no data on health properties of the active substances and other components, but producers of commercial products have provided health data in the MSDSs and made some proposals for classification of the product. According to information from producers these products should not be classified as harmful for the environment, but it is not possible to evaluate these statements on the basis of available information (Danish EPA, 2015b) The compositions of the products were not specified sufficiently for an assessment, but some of the products include unknown siloxanes, cationic polymers, isocyanates, or irritating organic acids. In summary, the health assessment information for this group of chemicals is insufficient for an assessment of the possible health effects of the impregnation agents (further information see also P05, 2012 and Davies, 2014).

151. A recent study noted that non-fluorinated chemical alternatives can meet water repellency requirements for outdoor apparel. The authors propose that the use of PFAS chemistry for outdoor apparel is over-engineering and that significant environmental and toxicological benefits could be achieved by switching outdoor apparel to non-fluorinated chemistry (IPEN Comments on 2nd draft RME referring to Hill et al., 2017).

Non-chemical alternatives

152. With regards to textiles, tightly woven fabric is one of the alternative non-chemical technologies. Another technology is the so-called reverse osmosis membrane comprising extremely thin films made of polymer materials and constructed in a way that it is highly impermeable to water in liquid form, but permeable to water vapor, which leads to a breathable fabric. An alternative to PTFE is a composite of a hydrophobic polyester and a hydrophilic polymer forming a microstructure, which allows the fabric to breathe (Swedish Chemicals Agency, 2015).

153. The Swedish Chemicals Agency presents one example of an international initiative to find fluorine-free alternatives (Swedish Chemicals Agency, 2015). Huntsman Textile Effects, which is a global supplier of dyes and other chemicals for the textile industry, has started to collaborate with DuPont with the aim to develop a new product with water-repellent properties. Based on information provided by the companies, this is the sector's first water-repellent treatment agent consisting totally of renewable material, 63% of which is obtained from plant-based raw materials (Ecotextile News, 2015; cited by Swedish Chemicals Agency, 2015). According to the manufacturer, the finish is up to three times more durable than existing non-fluorinated repellents, maintains fabric breathability for maximum comfort, is compatible with common finishing auxiliaries (including resins and cross-linking agents) and is not made with genetically modified organisms (Chemours, 2017).

154. The company Pyua has developed a technology (CLIMALOOPTM), which is fluorocarbon-free and promises highest performance with respect to impermeability, breathability and wind impermeability. The technology is based on recycled material and developed for long lasting outdoor applications. Moreover, each Pyua product is completely recyclable and produced in an ecologically and socially sustainable manner (Pyua, 2017).

C. *Firefighting foams*

Short-chain fluorinated alternatives

155. During the last several years, manufacturers of fluorotelomer-based AFFFs have been replacing long-chain fluorinated surfactants with short-chain fluorinated surfactants (UNEP, 2017). AFFFs based on pure 6:2 fluorotelomers were developed to replace early products based on a mixture of mainly 6:2 and 8:2 fluorotelomers (Klein, 2012; Kleiner and Jho, 2009). DuPont, for example, commercialized two AFFFs based on 6:2 fluorotelomer sulfonamidealkylbetaine (6:2 FTAB) or 6:2 fluorotelomer sulfonamideaminoxide (Wang et al., 2013). Suppliers offering a portfolio of short-chain fluorotelomer-based surfactants include Chemguard, Chemours and Dynax (UNEP, 2017).

156. Chemical alternatives include C₆-fluorotelomers such as 6:2 fluorotelomer sulfonyl betaine, sometimes combined with hydrocarbons and the 3M product dodecafluoro-2-methylpentan-3-one. The direct release of substances to the environment and the detection of C₆ compounds in the environment including the Arctic, human and wildlife make this use of fluorinated alternatives undesirable (see UNEP/POPS/POPRC.13/INF/6) (IPEN, 2016).

Non-fluorine containing alternatives

157. A variety of fluorine-free Class B foams are on the Swedish market indicating the technical feasibility of this alternative. The firefighting foam Moussoll-FF 3/6 was introduced at a Swedish airport and is degraded to carbon dioxide and water in the environment. It is considered effective in fire suppression required at airports where high safety standards have to be fulfilled. Swedavia, which

owns ten Swedish airports, including Arlanda and Landvetter, had previously used fluorine-based firefighting foams but in June 2011 switched to a fluorine-free alternative. The Swedish Armed Forces began phasing out the use of perfluorinated substances in firefighting foam in Sweden in 2011. Nowadays the Swedish Armed Forces use a fluorotelomer-based firefighting foam, i.e. the substance that is broken down to perfluorinated substances (further details see Swedish Chemicals Agency, 2015). Norwegian airports, military properties and several offshore companies have also introduced fluorine-free foams (Norway Comments on 3rd draft RME).

158. With respect to firefighting foams, it is estimated in a study (RPA, 2004) that the cost for fluorine-free alternatives is approximately 5-10% higher than the one for fluorosurfactant foams. Based on information provided by a manufacturer of the fluorine-free alternatives, the cost would fall in case of an increased market size (Poulsen et al., 2005). This study does not consider the internalized costs of continued reliance on fluorosurfactant foams, including the costs of groundwater remediation, contamination of aquatic environments, subsistence and commercial fishers, and environmental and public health (IPEN Comments on 2nd draft RME). Lifetime costs for using AFFF, fluoroprotein (FP), or film forming fluoroproteins (FFFP) far outweigh those of fluorine-free foams just because of legal and financial liabilities of using a fluorochemical based foam (see Queensland Gov., 2016a and 2016b) as indicated above which include infringement of operating license conditions, reputational and brand image damage (see Klein 2013). Increasing evidence suggests that fluorochemical contamination of groundwater is an ongoing serious issue impacting agriculture, fisheries, property prices, with considerable political and public concern fallout resulting in hugely expensive and damaging and legal challenges. Remediation costs are still substantial, especially off-site, compounded by high analytical and consultancy costs in the case of environmental contamination with fluorinated breakdown products from an AFFF, FP or FFFP (see e.g. Klein 2013).

159. The BAT/BEP Guidance for use of PFOS and related chemicals under the Stockholm Convention on POPs (UNEP, 2017) confirms that non-fluorinated foams exist and are in use. According to a review undertaken by the Queensland Government in Australia, many fluorine-free foams are acknowledged as meeting the toughest amongst the firefighting standards and exceeding film-forming fluorinated foam performance in various circumstances and that fluorine-free foams are widely used by airports and other facilities including oil and gas platforms (see Queensland Gov., 2016b). According to the Swedish Armed Forces it is difficult to find fluorine-free alternatives which meet specific safety requirements (see Swedish Chemicals Agency, 2016).

160. Manufacturers and some users mention that fluorine-free firefighting foams do not have comparable extinguishing effects as foams with fluorosurfactants. Compared to fluorine-based firefighting foams approximately twice as much water and foam concentrate are needed when extinguishing liquid fires. According to some fluoro surfactants foam manufacturers, some analysis confirmed that fluorine-free firefighting foams may offer less protection against re-ignition, which makes it impossible to apply this alternative for some operations (Swedish Chemicals Agency, 2015). According to the Fire Fighting Foam Coalition (FFFC) AFFF agents containing fluorotelomer-based fluorosurfactants are the most effective foam agents currently available to fight flammable liquid fires in military, industrial, aviation and municipal applications. Test data provided by the United States Naval Research Laboratories (NRL) (NRL, 2016) showed that, in pool fire tests, an AFFF agent achieved extinguishment in 18 seconds compared to 40 seconds of the fluorine-free foam. In foam degradation tests, fluorine-free foam degraded after 1-2 minutes, while the AFFF lasted 35 minutes before it has been degraded. The FFFC does not support the opinion that AFFF agents are no longer needed and recommends the use of AFFF only in specific circumstances where a significant flammable liquid hazard occurs and that all available measures to minimize emissions to the lowest possible level should be implemented when using AFFF agents (FFFC, 2017). However, blockage factors (i.e. vapour suppression) were indistinguishable between a fluorine-free-foam and two AFFFs tested (Williams et al. 2011). Airports and offshore companies around the world have introduced fluorine-free foam and are satisfied by the performance.

161. A Spanish foam manufacturer presented results from a series of new fire tests (Wilson, 2016) run on five commercially available short-chain (C₆) AFFF agents and five commercially available fluorine-free foams (tests were run with the four different fuels gasoline, heptane, jet A1 and diesel). It was shown that the short-chain AFFF foams performed significantly better compared with fluorine-free foams on all fuels except diesel. None of the fluorine-free foams managed to extinguish the jet A1 fire (the fuel used in the International Civil Aviation Organization (ICAO) fire tests that determine the acceptability of foams for airport use in many countries) (FFFC, 2017). However, fluorine-free foams certified to different ICAO levels (required for use at civilian airports) are available on the market (see FFFP, 2017) and are already introduced at airports in practice (see above).

162. The institute for fire and disaster control Heyrothsberge in Germany tested six fluorine free alcohol resistant firefighting foams and one PFAS containing foam for their ability to extinguish fires of five different polar liquids. The authors conclude that there are fluorine-free foams available which show a similar performance compared with PFAS containing foams (see Keutel and Koch, 2016).

D. Paper and food packaging

Short-chain fluorinated alternatives

163. Products based on 6:2 fluorotelomers have been developed by fluorotelomer manufacturers with the aim to replace earlier products such as side-chain fluorinated polymers and phosphate diesters that were based on longer-chain fluorotelomer derivatives (Loi et al., 2013). For example, several 6:2 fluorotelomer-based side chain fluorinated polymers have been registered in the Inventory of Effective Food Contact Substance (FCS) Notifications of the United States Food and Drug Administration including e.g. products from Asahi or Daikin (Wang et al., 2013). However, according to the information submitted by IPEN, there is a lack of publicly available information on toxicity and POPs properties.

164. A global manufacturer in specialty chemicals, received in 2015 US Food and Drug Administration (FDA) food contact approval for an oil- and grease-resistance additive, which is PFOA-free and provides high levels of oil-, grease- and water-resistance to paper and board. The additive is also compliant with the recommendations or use as a surface refining and coating agent in paper and board, which is intended for food contact applications. The additive is based on a cationic 6:2 fluorotelomer-based side-chain fluorinated polymer and provides a strong and long lasting barrier to both grease and water. According to the manufacturer, due to its performance properties and environmental profile the additive is considered particularly suitable for the use in both size press and wet-end applications to produce fast food boxes and wrappers, soup cube boxes, butter wrap and oil bottle labels. It can as well be used in the production of molded pulp plates and cups and in pet food packaging (AMR, 2015).

165. FDA currently does not allow long-chain fluorinated substances in food packaging applications. FDA removed the last legacy long-chain PFOA-related substances from 21 CFR 176.170 in 2016 (see 81 Fed. Reg. 5–8). Any 2015 FDA approvals for a resistance coating applied to paper and board would have been for a short-chain alternative, and would have been done through the Food Contact Notification (FCN) process.

Non-fluorine containing alternatives

166. At least one manufacturer from Norway has developed a fluorine-free alternative using a high-density paper, which prevents the passage of grease (Swedish Chemicals Agency, 2015). The Norwegian paper producer Nordic Paper is using mechanical processes to produce, without using any persistent chemical, extra-dense paper that inhibits leakage of grease through the paper.²³

167. More information is available in Norden 2013, SFT 2007 and Nordic Ecolabelling 2014. Nordic Ecolabelling 2014 indicates that for impregnation and coating paper can be surface treated using starch, alginates, CMC (carboxymethylcellulose), chromium compounds, fluoride chemicals or silicone. Organotin compounds are used as catalysts in the silicone coating of grease-proof paper and may migrate into food in contact with paper. Butyltin is specifically mentioned as catalyst in the paper. The Ecolabel contains requirements to prevent the presence of chromium, fluoride compounds, whereas solvent-based painting/coating agents, D4 and D5 and organotin catalysts may not be used in the silicone treatment. These substances may still be used elsewhere and thus be imported into Europe.

168. The German BfR (Bundesinstitut für Risikobewertung) maintains a database concerning recommendations on Food Contact Materials including fluorinated and non-fluorinated substances.²⁴

2.3.3 Uses where no alternatives are currently identified for all uses

A. Technical textiles with high performance requirements

169. Industry associations noted that especially in the field of professional, technical and protective textiles and other advanced textiles (e.g. for fuel cell separators for e-mobility innovations), no alternatives meeting the high demand by legal requirements and by customers are currently available.

²³ Information from Norwegian Pollution Control Authority (former Statens Forurensningstilsyn), 2009.

²⁴ https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp.

However, it is admitted that those textile products that must only fulfil low-performance requirements (e.g. standard clothing, standard outdoor textiles), which were formerly treated with PFOA-related compounds, may be treated by C₆-products or even fluorine-free alternatives (VTB SWT, 2016; Euratex, 2016).

170. Stakeholders state that protective textiles finished with the C₆-chemistry need large amounts of C₆-products for the initial finishing and repeated professional re-impregnation with further C₆-products after each washing step in order to meet high safety standards; this will result in additional emissions of PFASs due to the larger amounts of used chemicals compared to the C₈-chemistry (VTB SWT, 2016). In this context, it was mentioned that over the life-cycle technical textiles treated with 6:2 fluorotelomer-based finishes often exhibit 4-8 times more PFAS total emissions compared to the observed emissions using the C₈-chemistry (Euratex, 2016).

171. The textile industry reported that the C₈-chemistry is able to fulfill the high requirements related to repellency of dangerous liquids and dusts while having a minor detrimental effect on flame retardations. This preferable combination of the two effects cannot be obtained by C₆-based products. Moreover, it was stated that technical protective textiles protect workers from being contaminated by liquids or dangerous substances (e.g. infectious liquids). Thus, serious health issues might occur in case of neglected re-impregnation, which is required due to a decrease in protection performance over time (VTB SWT, 2016), (TM, 2016).

B. *Imaging and printing industry*

172. According to I&P Europe, PFOA-related compounds were successfully replaced by non-perfluorinated chemicals, chemicals with short (C₃-C₄) perfluorinated chains, telomers, and reformulations. However, a small number of relevant uses remain. PFOA-related compounds are considered necessary for the application of coating layers during manufacture of some remaining conventional photographic products (i.e. products in which the image formation is based on silver halide technology). They serve as surfactants, static control agents (important for preventing employee injury, operating equipment and product damage and fire and explosion hazards (I&P Europe, 2016b), dirt repellents during coating operations, friction control agents and provide adhesion control for coated layers and are considered unique, as they combine all these properties in one molecule without showing adverse effects on photographic performance (I&P Europe, 2016a).

173. An estimation of costs with regards to the replacement of the remaining relevant uses of PFOA-related substances in the photo and printing industry cannot be estimated. The formulas of imaging coatings are proprietary and differ from company to company and from product to product. Thus, each company will identify different costs when changing formulation compositions, which may take several years of effort with respect to research and development (not only the performance of substances is evaluated when developing alternatives, but also environmental, health and safety issues). Economic costs associated with substitution of PFOA-related substances concerning few remaining critical relevant uses in the imaging and photographic sector are considered prohibitive by the industry. The remaining critical uses are described as niche products in markets that I&P Europe members plan to diminish (I&P Europe, 2016a).

C. *Semiconductor industry*

174. Non-PFOA-based alternatives appear to be available in the semiconductor industry for some applications, such as the uses as surfactants. However, some uses with respect to PFOA-related substances as a constituent material in process, chemical formulations for very specialized application steps (e.g. for the photo-lithographic applications) remain. In a study from 2010, it was found that for those companies using PFOA within their photo-lithographic applications derogations will be necessary in order to be able to continue production (van der Putte et al., 2010). According to representatives of the semiconductor industry, alternatives for some applications may not be available, and the industry requires a significant amount of time to identify, test, and qualify substitutes before they are introduced into commercial production. A specific time frame needed for transition is not indicated (see SIA, 2017). A time limited exemption could provide the time needed to enable to continue the transition to appropriate alternatives in semiconductor manufacturing processes. SEMI further states, that this exemption should take the form of an acceptable purpose (see SEMI, 2017).

D. *Use of sulfluramide*

175. Currently, the active ingredients registered in Brazil for producing bait to control leaf-cutting ants are sulfluramid, fipronil and chlorpyrifos. Chlorpyrifos as insect baits is no longer used in Brazil for control leaf cutting ants (UNEP/POPS/POPRC.12/INF/15/Rev.1). The effectiveness of these substances has been questioned; thus new alternatives are being studied in Brazil. According to the Brazilian Annex F information, sulfluramid cannot currently be efficiently replaced in Brazil by any

other registered products commercialized for the same purpose (UNEP/POPS/POPRC.12/INF/15/Rev.1, UNEP/POPS/COP.7/INF/21).

176. According to Brazil, fenoxycarb, pyriproxyfen, diflubenzuron, teflubenzuron, silaneafone, thidiazuron, tefluron, prodron, abamectin, methoprene, hydramethylnon, boric acid, some insecticides from the group of neonicotinoids, pyrethroids, Spinosyns, etc., had been tested for leaf-cutting ants, but they were not effective (UNEP/POPS/POPRC.12/INF/15/Rev.1).

177. According to the decision SC-6/7, Brazil undertake studies to obtain peer-reviewed information on the feasibility of using alternatives to PFOS, its salts, PFOSF and their related chemicals within an integrated pest management approach and to submitted to Secretariat. This study conclude that, based on technical feasibility, humans and environment effects, cost/effectiveness, availability and viability, that there are no alternatives to replace sulfluramid to control leaf-cutting ants (Information from Brazil, 2016).²⁵

178. Information on volumes is contained in UNEP/POPS/POPRC.12/INF/15/Rev.1. It was noted that there are some reports indicating that sulfluramid may degrade to PFOA and is in the list of precursors of PFOA (UNEP/POPS/POPRC.13/INF/6/Add.1).

2.3.4 Summary of alternatives

179. The following paragraphs summarize information on alternatives from sections 2.3.1 to 2.3.3.

Summary of risks related to short-chain fluorinated alternatives

180. There is an increasing concern among authorities in Europe regarding risks for health and the environment exhibited by short-chain PFASs. These concerns are due to their persistence, high mobility in water and soil and potential toxic properties of these substances. Although some of the short-chain PFAS may not formally fulfil the current PBT-criteria under Europe's REACH legislation, they are extremely persistent, very mobile in aquatic systems and in soil, and their increasing use may lead to a continuous exposure that could be of equal concern as bioaccumulation (Norway Comments on 2nd draft RME). Already now short-chain PFAS are ubiquitously present in the environment, even in the remote areas (see e.g. Zhao et al., 2012).

181. The higher solubility in water compared to long-chain PFASs with more hydrophobic alkyl chains also contributes to the fact that some short-chain PFASs, in particular short-chain PFCAs and PFSAAs, do enter drinking water reservoirs faster and certain tend to accumulate in water-rich edible plant tissues like leaves and fruits. The presence in groundwater and drinking water might lead to a continuous exposure of organisms to certain short-chain PFASs, currently still at a relatively low level, but given the high persistence and the increasing use of these substances a temporal increase in environmental concentrations may be expected. This is even more valid as removal of short-chain PFASs from water cannot be performed effectively, not even with modern expensive technologies (e.g. using granular activated carbon or nano-filtration), due to their low adsorption potential (see German Environment Agency, 2016b).

182. It should be noted, that Germany is proposing to identify substances having such properties related to mobility and persistency as substances of very high concern under REACH in a similar manner as substances being very persistent and very bioaccumulative (see German Environment Agency, 2017). As described in chapter 2.3.2 these substances are considered alternatives to PFOA for several applications (e.g. textile sector, firefighting foams, paper and food packaging). Often, these short-chain alternatives are less effective and higher quantities are required. This data suggests that the replacement of PFOA, its salts and related compounds by short-chain fluorinated substances may be identified as a regrettable substitution.

183. In this context it should be noted that that pollution with short-chain PFAS is a heavy burden for the community/society. In Germany more than 450 ha of agricultural fields were polluted with PFAS most probably by intermixing paper sludge with compost. PFAS have been found in elevated concentrations in soil and groundwater. Short-chain PFAS are the main contaminants in this area. As a consequence, two drinking water wells were closed. Because short-chain PFAS can be taken up in the edible part of the plants and crops have been shown elevated levels of short-chain PFAS, before harvesting PFAS levels in crops need to be analysed in this area. Only crops not enriching PFAS can be cultivated and harvests showing elevated levels of short-chain PFAS cannot be consumed by humans or used as feed. A solution to purify the soil or to stop short-chain PFAS reaching the

²⁵ <http://chm.pops.int/tabid/4814/Default.aspx>.

groundwater has not been found yet. Because of the large polluted area, excavation does not seem to be appropriate. The overall consequences for the inhabitants, the public and the farmers are immense. The costs for remediation and water purification and the supply for clean drinking water are high.²⁶ The local water supply company has invested three million euros during the last two years for the supply of clean drinking water in the region. This investment is going to rise to 8 million euros until 2018 because a new purification plant based on activated carbon is being built and because operating costs will increase. Due to the properties of short-chain PFAS, the activated carbon has to be exchanged frequently, to avoid breakthrough of the chemicals. As a consequence the price for drinking water increased by 13.4% in this area in 2017. A further increase of the costs is possible (Germany Comments on 3rd draft RME).²⁷

Summary of the availability of appropriate alternatives for specific sectors and uses

184. Based on the analysis of alternatives, the following table summarizes for which sectors and specific uses alternatives to the use of PFOA, its salts and PFOA-related compounds are available or not.

Table 4: Availability of alternatives to the use of PFOA, its salts and PFOA-related compounds for specific sectors and uses

Sector	Use	Appropriate alternative available	Type of alternative
Textile sector	Standard performance requirements (e.g. standard clothing)	Yes	Non-fluorine containing products (e.g. paraffins); Non-chemical alternatives Short-chain fluorinated products (e.g. C ₆ -based)
	High performance requirements (e.g. protective textiles for professional use)	No	
Polymer manufacturing	Polymerization processing aid	Yes	Substances with ether linkage(s) between perfluoroalkyl moieties (e.g. ADONA)
Firefighting foams	Fighting against liquid fires	Yes	Protein-based or detergent-based firefighting foams Short-chain fluorinated products (e.g. C ₆ -based)
Paper and food packaging	Food packaging	Yes	Non-fluorine containing products (e.g. high-density paper) Short-chain fluorinated products (e.g. C ₆ -based)
Imaging and printing industry	Manufacture of small number of remaining conventional photographic products	No	
Semiconductor industry	Constituent material in process chemical formulations for very specialised application steps (e.g. for photo-lithographic applications)	No	

²⁶ To date there is no scientific paper available, but some information is provided by the local authorities (in German see <http://www.landkreis-rastatt.de/Lde/PFC.html> and <http://www.baden-baden.de/stadtportrait/aktuelles/themen/pfc-problematik/>).

²⁷ <http://www.star-energiewerke.de/de/Kopfnavigation/News/Pressearchiv-2017/PFC-Folge-In-Rastatt-steigt-der-Preis-fuer-Trinkwasser.html>.

2.4 Summary of information on impacts on society of implementing possible control measures

2.4.1 Health, including public, environmental and occupational health

185. There is widespread occurrence of PFOA and a number of PFOA-related compounds in environmental compartments and in biota and humans. PFOA, its salts and related compounds that degrade to PFOA are likely, as a result of their long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action is warranted (UNEP/POPS/POPRC.12/11/Add.2). Therefore, prohibiting or restricting PFOA, its salts and related compounds would positively impact human health and the environment by decreasing emissions and subsequently human and environmental exposure (see e.g. Norway, 2016; ECHA, 2015a, 2015c).

186. When assessing the human health and the environmental impacts of restricting PFOA and PFOA-related substances, it is crucial to take into account the specific concerns of these substances as PBT substances. These concerns are particularly related to the potential of PFOA to persist in the environment, which means that it is not (or only to a small extent) removed from the environment. Even if the emissions of PFOA and PFOA-related substances will cease, it will not result in an immediate reduction of environmental concentrations. In addition to its persistence, PFOA is mobile in the environment and has the potential to be distributed over long distances, e.g. via long range atmospheric transport. As a consequence, PFOA is present in the environment on a global scale, also in remote areas where PFOA emissions are negligible. Continuous use and emissions may lead to rising concentrations in the environment and to long-term, large-scale environmental and human exposure to PFOA. In combination with the potential of PFOA to accumulate in living organisms as well as its toxicological properties, continuous use and emissions of PFOA and PFOA-related substances may lead to adverse effects on human health and the environment arising from long-term exposure. These effects will be very difficult to reverse, once they have occurred. The magnitude and extent of the risks of PFOA and PFOA-related substances as POPs remain uncertain. Therefore, the risk management of these substances is driven by scientific data and precautionary action to avoid potentially severe and irreversible impacts resulting from continued emissions. This is evident even though the full physical impacts on human health and the environment of reducing the emissions of PFOA and PFOA-related substances cannot be quantified (ECHA, 2015a).

187. The EU restriction of PFOA and PFOA-related substances will require industry to phase out respective compounds in nearly all applications and sectors, eliminating all significant emission sources (apart from releases originating from the existing stock and exempted uses of PFOA and PFOA-related substances) (ECHA, 2015a). In the background document to the EU proposal for a restriction it is stated that there are considerably less data available on the toxicological properties of the most suitable alternatives than there are on PFOA. However, based on the analysis of alternatives they are expected to pose lower health risks than PFOA and PFOA-related substances. The restriction is therefore expected to result in a net benefit to society in terms of human health impacts (ECHA, 2015a).

188. Canada prohibits PFOA and long-chain PFCAs with certain exemptions to allow on-going and time-limited uses of these substances where technically or economically feasible alternatives do not exist or to allow sufficient time for the transition to alternatives to occur (see Canada, 2016c). While no quantitative analysis of benefits has been conducted, the amendments will protect the environment by prohibiting the manufacture, use, sale, offer for sale or import of PFOA and long-chain PFCAs. An improvement in environmental quality is expected from controlling these substances (Canada, 2016c).

189. Australia expects positive impacts from control measures related to avoided contamination of surface water, groundwater and drinking water and subsequently reducing the potential for human exposure (Australia, 2016).

190. Regarding professional, technical and protective textiles which must meet durable repellency performance standards, representatives from the textile industry state that, in view of the already made big progress of avoiding emissions, further restriction would seriously endanger the public health, environmental and occupational health by a ban of professional, technical and protective textiles (see VTB SWT, 2016 and TM, 2016).

191. According to representatives of the European photo industry, control measures implemented by the photo-imaging industry, including reformulation and product discontinuance, have reduced the use of PFOA-related compounds worldwide by more than 95%. The emissions from the small number of ongoing uses by the photo-imaging industry have been assessed by a number of competent authorities in the EU, including ECHA, and determined not to pose a relevant risk to the environment

or human health (I&P Europe, 2016a). PFOA emissions from photographic applications and from the semiconductor industry appear to be less than 100 kg/year for the whole EU (and therefore lower risks in relative terms) (ECHA 2015c).

192. According to SIA, the total amount of PFOA and its related substances in semiconductor photolithography formulations sold in North America in 2015 was 720 kg. According to information provided by SEMI, the fluoropolymers incorporated into all semiconductor manufacturing equipment produced over the course of the last five years (2011-2015 data) at global level remain a marginal source of PFOA, estimated to be no more than 120 kg/year. Also, the fluoropolymer materials incorporated into facilities-related chemical, gas, and air distribution and control systems for semiconductor manufacturing (related infrastructure) are a marginal source of PFOA, estimated to be no more than 25 kg/year (SEMI Comments on 1st draft RME).

2.4.2 Agriculture, aquaculture and forestry

193. PFOA is present in sewage sludge that is applied to agricultural land in certain countries depending on national legislation. Several agricultural crops showed species-dependent adverse effects (e.g. root growth and necrosis) mediated by PFOA (see UNEP/POPS/POPRC.12/11/Add.2 referring to Li, 2009 and Stahl et al., 2009). Crops grown in sewage treatment plant solid-amended soil take up PFOA alternatives such as PFBA and PFPeA (Blaine et al., 2013). PFBA, PFHxA, PFHpA, PFOA, and perfluorononanoic acid (PFNA) are translocated into plants (Bizkarguenaga et al., 2016; Krippner et al., 2014). PFOA and PFBA are also found in pine needles along ski tracks (Chropenova et al., 2016). In Australia, the legacy use of PFOA-containing AFFFs has affected some agricultural activities (see section 2.2.3). The use of sludge from any waste water treatment plant contaminates agricultural fields with PFASs, among them PFOA and related substances (Germany Comments on 1st draft RME). In Germany, the (illegal) disposal of waste/sludge to agricultural fields has caused contamination of soil, ground and drinking water, agricultural crops and human exposure with severe consequences including loss of income for farmers (see section 2.2.2). Therefore, restricting PFOA, its salts and PFOA-related compounds would have benefits for agriculture.

2.4.3 Biota (biodiversity)

194. There is widespread occurrence of PFOA and a number of PFOA-related compounds in environmental compartments and in biota and humans. PFOA, its salts and related compounds that degrade to PFOA are likely, as a result of their long-range environmental transport, to lead to significant adverse human health and/or environmental effects (UNEP/POPS/POPRC.12/11/Add.2). Restricting PFOA, its salts and PFOA-related compounds would positively impact on biota by decreasing emissions and subsequently exposure of biota. This would have a flow on benefit for indigenous communities highly reliant on native species in their diet (IPEN Comments on 2nd draft RME).

2.4.4 Economic aspects

195. Cost competitive alternatives to PFOA that do not exhibit POPs characteristics, such as fluorine-free alternatives used in firefighting foams or paper and food packaging, have already been implemented in many countries. This indicates economic feasibility of several alternatives. The economic aspects of substituting alternatives for PFOA include the savings made on health and environmental costs resulting from exposure to PFOA (IPEN, 2016).

196. In the EU, the use of PFOA and PFOA-related substances has contributed to the contamination of (drinking) water and soil with corresponding high costs of remediation. Most of the contamination has been caused by the use of PFAS (including PFOA and PFOA-related substances) in firefighting foams in fire events and training exercises. The remediation costs are mainly related to the treatment of ground/drinking water and the excavation and disposal of contaminated soil. The severity and extent of the damage caused and the related costs entailed difference between the cases reported. In some cases the total remediation cost is not known yet or not reported. Where costs are reported, they are very case specific often covering other PFAS as well, which makes it very difficult to derive a robust general estimate of remediation cost per kg PFOA and PFOA-related substances. However, the data available indicate that there are considerable costs related to the remediation of PFAS including PFOA and PFOA-related substances (ECHA, 2015a; specific cost figures see Table A.F.1-1 in ECHA, 2015a).

197. Environmental contamination with PFOA and PFOA-related compounds is also related to industrial activities according to examples such as from the US and the Netherlands (Norway Comments on 1st draft RME). Norway refers to ongoing remediation of PFAS contaminated soil due to use of AFFFs at airports and fire training areas (Norway, 2016). In Australia, the stigma of being in a contaminated environment due to the legacy use of PFOA-containing AFFFs has led to decreasing property and business values and the loss of income for some land and business owners (see section 2.2.2). PFAS compounds are found in Danish groundwater at several locations in Denmark. PFAS are present near specific industries or activities, primarily fire drill sites. At some fire drill sites the PFOA concentration was exceeding the German limit value for drinking water for PFOA by approximately a factor of 10 and initiated the work establishing the Danish sum criterion drinking water limit value for 12 perfluorinated substances. It should also be noted that other PFAS compounds were also found at these sites (Danish EPA, 2014). High levels of PFAS (including PFOS and PFOA) have been found in groundwater in Sweden, especially in connection with the firefighting training sites and in areas where fires have been extinguished. In some cases, the concentrations of PFASs have been exceeded the action level of the National Food Agency in Sweden. As a consequence, wells and water utilities have had to introduce new treatment steps or switch to a non-contaminated water source (Swedish Chemicals Agency, 2016a). Identification and management of contaminated sites and groundwater can cause significant costs which will be reduced in the future if PFOA and PFOA-related compounds will be restricted. Finally, it should also be noted that these examples all come from developed countries with high capacity for prevention and remediation. In developing countries or countries in transition such actions would either need external funding and expertise or would not be conducted at all, leading to unacceptable harm to health and the environment (IPEN Comments on 2nd draft RME).

198. A benchmark study using cost-effectiveness analysis to assess the proportionality of measures to control PFOA (and other substances) looks at the cost-effectiveness estimates for regulatory measures that have been applied or considered for PFOA. Although the search and assessment presented in the study has an explicit global scope and all available studies, reports, and publications that could be found online were included, there may be a slight European oversampling “bias” due to the authors’ domicile and language coverage. The available evidence suggests that measures costing less than 1,000 €/kg substance use or emission reduction will usually not be rejected for reasons of disproportionate costs, whereas for measures with costs above 50,000 €/kg substance such a rejection is likely. The mean estimated unit costs for substitution, emission control and remediation costs for PFOA are 1,580 €/kg (range 28 to 3,281) (see Oosterhuis et al., 2017).

199. The regulatory PFOA risk management approaches in Canada, the EU and Norway are not expected to lead to wider economic impacts, because the market is already replacing PFOA and PFOA-related substances. This is reflected by the estimated moderate compliance cost (ECHA, 2015a; Canada 2016c).

200. A technical and economic assessment has not been made to establish whether countries such as those in Latin America and the Caribbean or in Africa have the capacity to comply with obligations arising from including PFOA, its salts and PFOA-related compounds in any of the Annexes to the Convention, as well as the financial resources to develop inventories, carry out monitoring, and eliminate the substances or wastes containing them.

201. PFOA, its salts and PFOA-related compounds are used in some semiconductor production processes. Although replacement of the chemical by alternatives is ongoing, the functions of the alternatives are still inadequate and it is uncertain that the replacement would be finished by 2019. If they fail in replacement, semiconductor supply would decrease, and that may cast a large negative impact to IT development in the world (Japan, 2016). According to representatives of the semiconductor industry, without an exemption, the cost-effectiveness of the restriction would be disproportionate for the semiconductor manufacturing equipment industry (SEMI Comments on 1st draft RME).

202. Norway states that the continued use of PFOA and PFOA-related compounds in textiles causes high socio-economic costs due to the PBT properties of the substances. Norway’s experience is that fewer textiles for consumers contain PFOA, and in the remaining textiles, the PFOA concentration has decreased (Norway Comments on 1st draft RME).

203. The photo-imaging industry has been very successful at developing alternatives for most uses of PFOA-related compounds, eliminating more than 95% of the worldwide use since 2000. However, the industry claims that the surfactant and static control properties of PFOA-related compounds are important for the application of coating layers during manufacture of some remaining traditional film products (i.e. products in which the image formation is based on silver halide technology). The industry cannot estimate the cost of replacing this use of PFOA-related compounds, but notes that

these are niche products in markets that will diminish (I&P Europe, 2016a). It is clear that digital imaging will replace the need for PFOA in this use and the transition is occurring rapidly.

204. FluoroCouncil member companies have invested significantly into the development of alternative polymerization aids and short-chain products and emission control technologies. Another cost to be recognized is the economic and human health cost of completely ceasing production of certain PFOA-related chemicals used in pharmaceuticals and other highly specialized applications. It should be noted that the environmental releases for these applications can be well controlled (FluoroCouncil, 2016a).

2.4.5 Movement towards sustainable development

205. Elimination of PFOA is consistent with sustainable development plans that seek to reduce emissions of toxic chemicals and several of the in 2015 globally adopted sustainable development goals. The SAICM makes the essential link between chemical safety and sustainable development. The Overarching Policy Strategy of SAICM aims to promote, by 2020, that chemicals or chemical uses that pose an unreasonable and otherwise unmanageable risk to human health and the environment based on a science-based risk assessment and taking into account the costs and benefits as well as the availability of safer substitutes and their efficacy, are no longer produced or used for such uses.²⁸ The Global Plan of Action of SAICM contains guidance on measures to support risk reduction that include prioritizing safe and effective alternatives for persistent, bioaccumulative, and toxic substances. In order to globally collaborate in gathering and exchanging information on perfluorinated chemicals and to support the transition to safer alternatives, a Global PFC group and a web-portal has been developed within SAICM.²⁹

206. Industry representatives of the professional, technical and protective textile sector invite other Parties to join R&D projects in the technical textile sector on appropriate alternatives (more details see VTB SWT, 2016 and TM, 2016).

2.4.6 Social costs

207. IPEN considers that social costs associated with the elimination of PFOA are far outweighed by the health and environmental benefits (IPEN, 2016).

208. The restriction in the EU is not expected to have major effects on employment because, for the vast majority of uses, alternatives that are implementable with a reasonable cost are available. In addition, as imported articles and mixtures will also be covered by the restriction, relocation of production facilities to outside the EU is not a likely response by the industry concerned. Hence, it is not expected that there will be a significant loss (or gain) in employment in the EU due to the closing down and/or relocation of business activities (ECHA, 2015a).

209. Regarding the professional, technical and protective textile sector, industry considers that a total production ban by listing the substance under Annex A would result in negative effects on employment in the professional, technical and protective textile industry in Europe (see VTB SWT, 2016 and EURATEX, 2016).

2.5 Other considerations

2.5.1 Access to information and public education

210. Several Parties and observers have submitted information on the access to information and public education:

(a) Monitoring Network in the Alpine Region for Persistent and other Organic Pollutants: <http://www.monarpop.at/>;

(b) Environmental Agency Austria: http://www.umweltbundesamt.at/ummuki_symposium/;

(c) Information related to initiatives under the Canadian Environmental protection Act, 1999: [http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=1FE509F3-1](http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=1FE509F3-1;);

²⁸ <http://www.saicm.org/Home/tabid/5410/language/en-US/Default.aspx>.

²⁹ <http://www.oecd.org/ehs/pfc/>.

- (d) Information on the assessment and management of substances in Canada: <http://www.ec.gc.ca/toxiques-toxics/default.asp?lang=En&n=97324D33-1>;
- (e) Additional information on PFOA, its salts and its precursors is available from the Environment and Climate Change Canada website: <http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=en&n=F68CBFF1-1> and concerning regulatory controls <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=3E603995-1>;
- (f) Norwegian Environment Agency: <http://www.environment.no/>;
- (g) Access to data generated by FluoroCouncil members: <https://fluorocouncil.com/Resources/Research>;
- (h) German Environment Agency: <https://www.umweltbundesamt.de/>. The German Environment Agency has published a leaflet on the environmentally responsible use of fluorinated firefighting foams (German Environment Agency, 2013);
- (i) Federal Institute for Occupational Safety and Health: <http://www.baua.de/de/Startseite.html>;
- (j) Swedish Chemicals Agency: www.kemi.se. Since PFAS contamination concerns many different stakeholders in the society and many authorities are involved in taking and developing various measures, a web based guide has been developed (in Swedish).

2.5.2 Status of control and monitoring capacity

211. PFOA has been measured in various media e.g. human blood and breast milk and in water, soil, sediment and biota including fish. Monitoring data from the database of the Environment Agency Austria (EAA) were provided (more details see Austria, 2016a).

212. In Canada, monitoring in environmental media and biota is used to evaluate the effectiveness of risk management controls and to measure progress towards eliminating PFOA in the Canadian environment. In addition, monitoring of PFOA is carried out as part of the Northern Contaminants Program which was established in 1991 in response to concerns about human exposure to elevated levels of contaminants in wildlife species that are important to the traditional diets of northern Indigenous people (NCP 2013).³⁰ Over the period of 2007-2015, mean PFAS concentrations (wet weight) in liver were consistently comprised mostly of PFOS and ΣPFCAs (low levels of PFOA but mostly C₉, C₁₀ and C₁₁ PFCAs). PFOS was consistently higher than ΣPFCAs, and it was consistently at ppm levels but at greater levels in southern Hudson Bay bears versus western Hudson Bay bears. There was no obvious increasing or decreasing trends for ΣPFCAs and PFOS for both.³¹

213. PFASs including PFOA are part of the Danish monitoring of the aquatic environment. In the period from 2008-2013 PFASs have been included in monitoring of point sources as well as streams, lakes and marine areas. PFOS and PFOA are the most frequently detected PFASs in streams and one of the most frequently detected compounds in wastewater treatment plant effluents. Both in streams and effluents, they are detected in highest concentrations. (Denmark, 2016).

214. PFASs, including PFOA, are included in the Swedish Environmental Surveillance Program³² and the Swedish health related monitoring program³³ (Sweden Comments on 2nd draft RME). PFOA and other perfluorinated compounds are also monitored in humans in Canada, for example under the Northern Contaminants Program, Canadian Health Measures Survey and Canadian Maternal-Infant Research on Environmental Chemicals.

³⁰ Synopsis reports are published on an annual basis and the most recent report is available at <http://pubs.aina.ucalgary.ca/ncp/Synopsis20152016.pdf>.

³¹ Additional information on the program is available at <http://www.science.gc.ca/ncp> .

³² <http://www.naturvardsverket.se/Miljoarbete-i-samhallet/Miljoarbete-i-Sverige/Miljoovervakning/Miljoovervakning/Miljogiftsamordning/>.

³³ <http://ki.se/en/imm/health-related-environmental-monitoring-hami>.

215. PFAS including PFOA are monitored in human blood samples and urine from children and young adults. In the German Environmental Survey (GerES V) data are generated for the period from 2014-2017, PFAS is only one part of the study. The study also examines sources of pollutants such as indoor air and drinking water.³⁴

216. Many countries do not have the capacity to determine the products and wastes containing PFOA, its salts and PFOA-related compounds, as well as to identify their presence in different environmental matrices. This needs to be considered regarding the compliance with the obligations established by the Convention because such lack of capacity prevents to establish inventories, to identify relevant wastes and to carry out the respective monitoring. For this reason it is recommended to carry out pilot projects that allow demonstrating which measures should be taken to achieve effective compliance (Colombia Comments on 2nd draft RME).

217. According to the Annex F submission of IPEN many countries do not have the required infrastructure to adequately monitor production and use of PFOA (IPEN, 2016).

3 Synthesis of information

3.1 Summary of risk profile information

218. PFOA is persistent, bioaccumulative and toxic to animals, including humans. There is widespread occurrence of PFOA and a number of PFOA-related compounds in environmental compartments and in biota and humans. Therefore, it is concluded that PFOA, its salts and related compounds that degrade to PFOA are likely, as a result of their long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action is warranted (UNEP/POPS/POPRC.12/11/Add.2).

219. It is difficult to predict confidently which specific uses and related releases contribute most to the risk, especially as there is such a diverse range of potential sources, and detailed information about most of them is lacking. Important potential sources of PFOA are considered to be the use of side-chain fluorinated polymers in general, and specifically their use in the textile sector, and in manufacturing of fluoropolymers. Other important sources appear to be coatings and firefighting foam. Based on the available information, it is not possible to definitively identify specific uses of PFOA-related substances that will not contribute to PFOA emissions.

220. Annex E related submissions are compiled in a background document to the risk management evaluation (see UNEP/POPS/POPRC.13/INF/6). Other available data on production, uses and releases are compiled in the risk profile (UNEP/POPS/POPRC.12/11/Add.2).

3.2 Summary of risk management evaluation information

221. Restricting or prohibiting PFOA, its salts and PFOA-related compounds would positively impact human health and the environment by decreasing emissions and subsequently human and environmental exposures.

Summary of efficacy, efficiency and availability of appropriate alternatives

222. Several exemptions have been included in the risk management approach in the EU. Canada and Norway also include in their risk management approaches several exemptions, where some of the exemptions terminated at the end of 2016 (see Table 3).

223. According to the information available for the analysis of alternatives, no technical and/or economically feasible alternatives currently exist for some specific uses in the semiconductor industry, but the industry indicates that alternatives will become available within the next years. Because of the low amounts used and the fact that emissions are expected to be low, a time limited exemption (until 4 July 2022) for the equipment used to manufacture semiconductors is given in the EU. Further, in the EU, an exemption without time limitation is given for photo-lithography processes for semiconductors or in etching processes for compound semiconductors. In Canada, semiconductors in manufactured items are exempted. In Norway an exemption for adhesives, foil or tape in semiconductors terminated by 2016. Based on industry information (see SEMI 2017), time limited or non-time limited exemptions should be considered for: (1) equipment containing PFOA residues in

³⁴ <https://www.umweltbundesamt.de/en/topics/health/assessing-environmentally-related-health-risks/german-environmental-surveys/german-environmental-survey-2014-2017-geres-v#textpart-1>.

fluoropolymers and fluoroelastomers used to manufacture semiconductors, their replacement and spare parts and related infrastructure (i.e. facilities-related chemical, gas, and air distribution and control systems and chemical container systems for storage, conveyance, and transport of substances or mixtures); as well as for: (2) photo-lithography processes for semiconductors or in etching processes for compound semiconductors.

224. According to the information available for the analysis of alternatives for textiles, used for instance in the outdoor sector, alternatives are available, but, no technical and/or economically feasible alternatives exist for technical textiles with high performance requirements. This concerns use in textiles for the protection of workers from risks to their health and safety for which a time limited exemption (until 4 July 2023) is given in the EU. This is also the case for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. In Norway only textiles for consumer use are restricted, while textiles for professional use are not covered. The Canadian approach does not apply to manufactured items. Hence, import, use, sale and offer for sale of textiles containing PFOA, its salts or PFOA-related compounds are not restricted in Canada. Time limited exemptions should be considered under the Stockholm Convention for technical textiles with high performance requirements in particular for: (1) textiles for oil and water repellency or in application for the protection from dangerous liquids for the protection of workers from risks to their health and safety; and could be considered for: (2) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. For the latter, additional information to clarify the scope of the applications, used amounts, availability of alternatives and socio-economic aspects is needed to allow for an exemption.

225. The printing inks industry announced the need to use the substances until 2020 because these inks are especially designed for certain professional printers. This use only continues in printers that are no longer manufactured, and therefore a phase-out is already underway. For latex printing inks a time limited exemption (until 4 July 2022) is given in the EU. Canada had an exemption for water-based inks until 2016. The Norwegian risk management approach applies only to consumer products and does not restrict PFOA use in inks for professional printers. Depending on when obligations under the Stockholm Convention for PFOA, its salts and related compounds would possibly enter into force, an exemption may not be necessary for latex printing inks.

226. Production of short-chain fluorinated alternatives includes production of an unavoidable fraction of PFOA and PFOA-related substances that can be addressed by establishing appropriate concentration limits in manufacturing. The set of thresholds in the EU restriction is based on information from industry and takes into account the currently unavoidable fraction of PFOA and PFOA-related substances during production of C₆ fluorotelomer alternatives. One option is for these substances to be re-processed as closed system site-limited isolated intermediates into production of short-chain fluorinated substances. The Stockholm Convention states that “Given that no significant quantities of the chemical are expected to reach humans and the environment during the production and use of a closed-system site-limited intermediate, a Party, upon notification to the Secretariat, may allow the production and use of quantities of a chemical listed in this Annex as a closed-system site-limited intermediate that is chemically transformed in the manufacture of other chemicals that, taking into consideration the criteria in paragraph 1 of Annex D, do not exhibit the characteristics of persistent organic pollutants.”³⁵ Neither Norway nor Canada or the EU has specific exemptions on the production of short-chain fluorinated alternatives in place. Therefore, an exemption for closed-system site-limited intermediates is not needed for substances listed under Annex A or B to the Stockholm Convention to allow such re-processing. For transported isolated intermediates an exemption without time limit is foreseen in the EU restriction according to its paragraph 4(c) provided that specific conditions are met (European Commission, 2017). An exemption could be considered under the Stockholm Convention for transported isolated intermediates in order to enable reprocessing in another site than the production site. The conditions could be similar to what is established under the EU restriction (see para 84). Additional information to clarify the quantities, extent of transport and risks, use is needed to allow for an exemption.

227. No alternative to PFOB as a processing aid has been found for pharmaceutical product manufacturing. PFOB is produced from PFOI which results from the production of 6:2 fluorotelomer-based substances. The production of PFOI takes place at one single site in Japan and is then transported to another site in Japan for use as intermediate in the production of PFOB. Afterwards, PFOB is transported to two sites in the US and Sweden to produce relevant pharmaceutical products. No related exemptions are proposed in the EU, Norway or Canada at the

³⁵ Note (iii) of Part I of Annexes A and B to the Stockholm Convention.

moment. In the SAICM context, environmentally persistent pharmaceutical pollutants have been adopted as an emerging policy issue, while recognizing that pharmaceuticals have major benefits for human health and animal welfare.³⁶ According to information provided, the current production process starting from PFOI is considered the only reasonable way to produce PFOB. Furthermore, if an alternative to PFOB was to be found, the development process to incorporate it into the pharmaceutical products typically would require ten years to complete the three phases of human trials and the regulatory review process.

228. Digital imaging will replace the need for PFOA in photo-imaging and the transition is occurring rapidly. PFOA use in photo-imaging has been reduced by more than 95% worldwide since 2000 (I&P Europe). Further reduction in use of these substances is anticipated as the transition continues towards digital imaging. According to the analysis of alternatives, a small number of relevant uses remain in the photo-imaging sector. Within the EU restriction an exemption is given for photographic coatings applied to films, papers or printing plates without time limitation. The specific exemptions for this use in Norway and Canada expired in 2016, however, the Norwegian risk management approach only applies to consumer products and in Canada the import, use, sale and offer for sale of photo media coatings applied to films, papers or printing plates containing PFOA, its salts or PFOA-related compounds are not restricted. A time limited exemption should be considered under the Stockholm Convention for photographic coatings applied to films. At POPRC-13, industry provided information that time limited exemptions for paper and printing are no longer needed. It was also noted that for developing countries, such information was lacking.

229. One company applying coating for smartphone manufacturers requested, during the public EU consultation, an exemption of 3 years for pulsed plasma nano-coating for the transition to an alternative C₆ chemical. For plasma nano-coating a time limited exemption (until 4 July 2023) is given in the EU. Norway and Canada have no specific exemptions on nano-coating in place. In Canada, the import, use, sale and offer for sale of coatings applied smartphones (or electronic equipment) containing PFOA, its salts or PFOA-related compounds are not restricted. Only one company asked for an exemption for a short period of time.

230. PFOA use in firefighting foams raises concerns because it is a dispersive, direct release to the environment. Alternatives to all uses of PFOA in firefighting foams exist and include fluorine-free solutions as well as fluorosurfactants with C₆-fluorotelomers. Within the EU restriction, a limited exemption is given in order to provide an exemption for foams already placed on market. In addition, Canada provides exemptions for PFOA containing AFFFs used in firefighting application. The risk management approach in Norway does not apply, since it concerns consumer products and AFFFs are for professional use only. A time limited exemption for foams that already installed or placed on the market (as implemented for PFOS in the EU POPs Regulation) are covered under note (ii) and can be continued used in accordance with that provision. Use of existing foams should be avoided and existing foams should be replaced by sustainable alternatives in a short time frame to prevent further pollution. For training purposes, foams containing PFAS, including their fluorinated alternatives, must not be used. Suitable alternatives exist for training purposes.

231. Norway has an exemption in place for medical devices (no time limit). Within the EU restriction, a time limited exemption (until 7 July 2032) is given for medical devices other than for certain implantable medical devices within the scope of Directive 93/42/EEC. For the production of implantable medical devices an exemption without time limitation is given. The import, use, sale and offer for sale of medical devices containing PFOA, its salts or PFOA-related compounds are not restricted in Canada. According to the information submitted by IPEN, possible exemptions for these uses could be considered but consultation with health professionals using these medical devices should be considered. An exemption (with or without time limit) for: (1) use for medical devices; and (2) production of implantable medical devices under the Stockholm Convention, should therefore be considered.

232. Information on alternatives for the treatment of paper and cardboard used in food packaging indicates that appropriate alternatives are available. In the Norwegian risk management approach, food packaging and food contact materials are exempted. The import, use, sale and offer for sale of food packaging containing PFOA, its salts or PFOA-related compounds are not restricted in Canada. In the EU restriction, there are no exemptions for food packaging materials in place. Since appropriate alternatives are available, an exemption under the Stockholm Convention is not considered necessary.

³⁶ http://old.saicm.org/index.php?option=com_content&view=article&id=566&Itemid=775.

233. According to the Canadian automotive industry, information automotive service and replacement parts might still contain PFOA. These parts are needed to ensure availability of original equipment and spare parts to satisfy customer demand. Therefore, specific exemptions are proposed by industry for automotive service and replacement parts. These parts represent a small percentage of PFOA use and will decrease naturally over time as the vehicle fleet turns-over. In Canada, the PFOA-related risk management measures do not impact the use of automotive service and replacement parts as all manufactured items containing PFOA are currently addressed for the sector (see CVMA 2017). No related exemptions are given in the EU. In Norway the prohibitions shall not apply to spare parts for consumer products made available for sale prior to 1 June 2014. An exemption for automotive service and replacement parts could be considered under the Stockholm Convention; however, specification on relevant automotive service and replacement parts as well as sound justification why an exemption would be required, though in existing risk management approaches such an exemption was not considered necessary.

234. Due to increasing concerns about risks related to short-chain fluorinated alternatives (see paras 179 to 181), it remains unclear whether the replacement of PFOA, its salts and related compounds by short-chain fluorinated substances may cause adverse effects possibly comparable to those of the replaced substances. Hence, it remains unclear whether the replacement of PFOA, its salts and related compounds by short-chain fluorinated substances will not be identified as a regrettable substitution. Scientists have warned against the replacement with other fluorinated alternatives in order to avoid long-term harm to human health and the environment (POPRC Alternatives Guidance, Blum et al., 2015).

Summary of information on impacts on society

235. Restricting or prohibiting PFOA, its salts and related compounds would positively impact human health and the environment including biota by decreasing emissions and subsequently reducing human and environmental exposure. Further, restricting or prohibiting PFOA would provide benefits for agriculture by decreasing emissions and subsequently adverse effects on agricultural crops.

236. When assessing the human health and the environmental impacts of restricting PFOA and PFOA-related compounds, it is crucial to take into account the specific concerns of PFOA as a POP substance. The magnitude and extent of the risks of PFOA and PFOA-related compounds cannot be quantified, but global action is warranted. Therefore, the risk management of these substances is driven by scientific data and precautionary action to avoid further potentially severe and irreversible impacts resulting from continued emissions.

237. Based on the analysis of their characteristics, some of the available alternatives are expected to pose lower health risks than PFOA and PFOA-related compounds. The EU restriction is expected to result in a net benefit to society in terms of human health impacts. While no quantitative analysis of benefits has been conducted in the Canadian regulatory risk management process, an improvement in environmental quality is expected from controlling these substances. The EU and the Canadian risk management approaches are considered to have moderate cost impacts because the market is already replacing PFOA and PFOA-related substances and because the risk management approaches provide time-limited exemptions and ongoing permitted uses for certain applications where the development of alternatives is underway or where there are currently no known alternatives. The same can be expected for the Norwegian risk management approach. A global restriction or prohibition under the Stockholm Convention is therefore expected to result in a net benefit to society in terms of human health impacts.

238. Cost competitive alternatives to PFOA that do not exhibit POPs characteristics have already been implemented in many countries. This indicates economic and technical feasibility of the alternatives. The economic aspects of substituting alternatives for PFOA include the (non-quantifiable) savings made on health and environmental costs resulting from decreased exposure.

239. Restricting or prohibiting PFOA, its salts and PFOA-related compounds would reduce costs by decreasing contamination of surface water, groundwater and soil, and would thus reduce costs for the identification and remediation of contaminated sites. The remediation costs are mainly related to the treatment of ground/drinking water and the excavation and disposal of contaminated soil. The data available indicate that there are considerable costs related to the remediation of PFAS including PFOA and PFOA-related compounds.

240. Decision POPRC-6/2 on PFOS outlines a series of risk reduction measures in a short-term, medium-term and long-term framework. The POPRC reaffirms the Stockholm Convention's need to use best available techniques and best environmental practice destruction technologies for wastes. In cases where destruction technologies are not available, safe storage has to be ensured.

3.3 Suggested risk management measures

241. The Committee recommends time limited specific exemptions for uses of PFOA, its salts and PFOA-related compounds where sufficient information was provided as indicated in the concluding statement section.

4 Concluding statement

242. The Committee decides, in accordance with paragraph 9 of Article 8 of the Convention, to recommend to the Conference of the Parties that it consider listing pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annex A or B to the Convention with specific exemptions for the following:

- (a) For five years from the date of entry into force of the amendment in accordance with Article 4:
 - (i) Manufacture of semiconductors or related electronic devices:
 - a. Equipment or fabrication plant related infrastructure containing fluoropolymers and/or fluoroelastomers with PFOA residues;
 - b. Legacy equipment or legacy fabrication plant related infrastructure: maintenance;
 - c. Photo-lithography or etch processes;
 - (ii) Photographic coatings applied to films;
 - (iii) Textiles for oil and water repellency for the protection from dangerous liquids for the protection of workers from risks to their health and safety;
- (b) For ten years from the date of entry into force of the amendment for manufacture of semiconductors or related electronic devices: refurbishment parts containing fluoropolymers and/or fluoroelastomers with PFOA residues for legacy equipment or legacy refurbishment parts;
- (c) For use of perfluorooctane iodide, production of perfluorooctane bromide for the purpose of producing pharmaceutical products with a review of continued need for exemptions. The specific exemption should expire in any case at the latest in 2036.

243. Parties and observers, including the relevant industries, are invited to provide, information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds in particular in the following applications:

- (a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment: information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects;
- (b) Transported isolated intermediates in order to enable reprocessing in another site than the production site: information on the quantities used, extent of transport and risks, and use;
- (c) Medical devices: information on specific applications/uses and timelines foreseen as needed for potential related exemptions;
- (d) Implantable medical devices: information on the quantities used, extent of transport and risks, and use;
- (e) Photo imaging sector: information on paper and printing, and information relevant for developing countries;
- (f) Automotive industry: information on spare parts;
- (g) Firefighting foams: information on chemical composition of mixtures and the volumes of pre-installed amount of firefighting foam mixtures.

For the applications above, information regarding socio-economic aspects as well as other relevant information is also welcomed.

244. Furthermore, Parties and observers are invited to provide information that would assist the further evaluation by the Committee of pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in relation to its unintentional formation and release, in particular from primary aluminum production and from incomplete combustion.

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Please note: Information request submission and comments related to the risk management evaluation are available at the Stockholm Convention website at <http://chm.pops.int/tabid/5339/Default.aspx>.

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