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

**DRAFT RISK MANAGEMENT EVALUATION**

(Second draft)

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# Executive Summary

1. In June 2015 the European Union 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[[1]](#footnote-1) in Annex A, B, and/or C of 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 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. 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 are used as surfactants and surface treatment agents (e.g. in textiles, paper and paints, firefighting foams) and for the manufacture of side-chain fluorinated polymers (which are the major PFOA-related compounds used as surfactants and in surface treatment). 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).
3. 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. Indirect releases occur from the degradation or transformation of precursors. PFOA-related compounds, as defined in para 16, 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 to the environment (details see UNEP/POPS/POPRC.12/11/Add.2).
4. Voluntary efforts to phase out PFOA and related substances were initiated, such as the United States Environment Protection Agency (US EPA) PFOA Stewardship Program and work by industry. In 2006, the main manufacturers in the US, Europe and Japan agreed on a global phase out of PFOA and related long-chain substances by the end of 2015. A similar program existed in Canada. All Stewardship Program participants were successful at virtually eliminating those chemicals globally from facility emissions and product content. The voluntary phase out does not include manufacturers using PFOA in countries like China, India or Russia. Companies who were not part of the Stewardship Program increased capacities (details see UNEP/POPS/POPRC.12/11/Add.2).
5. Legislative restriction approaches are implemented or underway in several national legislative control actions i.e. in Canada and Norway (existing restrictions) and the European Union (EU), (proposed restriction). These actions aim at prohibiting manufacture, placing on the market and use of PFOA, its salts and related compounds with general or other exemptions (time limited or not). Based on technical and socio-economic assessments these restrictions are considered technically and economically feasible. Canada published legislation which prohibits PFOA, its salts and precursors and products containing them, unless present in manufactured items. Norway published an amendment to the consumer products regulation in 2014, which bans the use of PFOA in consumer products and textiles. It has a transitional period allowing the import and sale of products before 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 exemptions. The EU it is proposed to totally ban 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. That proposal considers exemptions for certain uses. In the U.S.A., manufacturers of PFOA and PFOA-related chemicals are required since 2015 to notify new uses of these chemicals to EPA in order to allow the evaluation of new uses and, if necessary, take action to prohibit or limit the activity.
6. In the processes of developing the restriction approaches for PFOA and related substances in Canada, the EU and Norway, technical and socio-economic information has been included in the decision-making process to allow for certain exemptions. Information received from stakeholders during the restriction processes indicates that exemptions with or without time limitation are required for certain uses where stakeholders asserted that alternatives were not economically and/or technically feasible. The restriction approaches are considered technically and economically feasible. A prohibition of PFOA, its salts and PFOA-related compounds with possible specific exemptions for critical uses is also considered to be technically and economically feasible under the Stockholm Convention.
7. The information on the availability of alternatives considering efficacy and efficiency indicates that no appropriate alternatives are currently 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 and (10) certain pharmaceutical chemicals. 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 or acceptable purposes with or without time limit.
8. Restricting or prohibiting PFOA, its salts and PFOA-related compounds would 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 and PFOA-related compounds as POP substances cannot be quantified but global action is warranted. The risk management of these substances is driven by scientific data and precautionary action in order to avoid the potentially severe and irreversible 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. The Canadian and Norwegian restrictions and the proposed EU restriction is expected to result in a net benefit to society in terms of human health impacts and an improvement in environmental quality from controlling these substances.
9. The EU, Norwegian and the Canadian restriction approaches are considered to have moderate cost impacts because the market is already replacing PFOA, its salts and PFOA-related compounds and because the restriction 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 U.S. and Australia. Cost competitive alternatives to PFOA, its salts and PFOA-related compounds that do not exhibit POPs characteristics have already been implemented in many countries. This indicates partial economic and technical feasibility of alternatives. Substituting these substances with appropriate alternatives leads to savings of health and environmental costs resulting from decreased exposure. Further, a restriction or prohibition would lead to a decrease in contamination of surface water, groundwater and soil and would thus reduce costs for identification and remediation of contaminated sites.
10. [The Committee recommends, in accordance with paragraph 9 of Article 8 of the Convention, the Conference of the Parties to the Stockholm Convention to consider listing and specifying the related control measures of PFOA, its salts and PFOA-related compounds

(a) In Annex A, with or without specific exemptions accompanied with a specific part of Annex A that details actions; or

(b) In Annex B, with acceptable purposes/specific exemptions accompanied with a specific part of Annex B that details actions.

1. Further, the Committee recommends to consider specifying exemptions for the following uses: (1) equipment and related infrastructure used to manufacture semiconductors, (2) photo-lithography processes for semiconductors or in etching processes for compound semiconductors , (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)aqueous film-forming foams used in firefighting application, (6) medical devices, (7) production of implantable medical devices and (8) photographic coatings applied to films, papers or printing plates. ]

# Introduction

1. In June 2015 the European Union 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).
2. 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 POPRC 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.
3. This risk management evaluation is accompanied by a background document (PFOA INF, 2017a) and a non-exhaustive list of substances covered or not covered by the risk management evaluation (PFOA INF, 2017b).

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

1. 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. Certain polyfluorinated substances can be degraded to persistent perfluorinated substances like PFOA under environmental conditions and are therefore precursors. Those PFASs, which can be degraded to PFOA in the environment, are referred to as PFOA-related compounds.
2. The risk management evaluation covers:
3. PFOA (pentadecafluorooctanoic acid, CAS No: 335-67-1, EC No: 206-397-9; including its isomers);
4. Its salts; and
5. 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 (C7F15)C as one of the structural elements, for example:
   1. Polymers with C8 to C16 based fluorinated side chains;[[2]](#footnote-2)
   2. 8:2 fluorotelomer compounds;
   3. 10:2 fluorotelomer compounds.

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

1. C8F17-X, where X= F, Cl, Br;
2. Fluoropolymers[[3]](#footnote-3) that are covered by CF3[CF2]n-R’, where R’=any group, n>16 [[4]](#footnote-4); or
3. Perfluoroalkyl carboxylic and phosphonic acids (including their salts and esters) with ≥ 8 perfluorinated carbons; or
4. Perfluoroalkane sulfonic acids (including their salts and esters) with ≥ 9 perfluorinated carbons; or
5. PFOS, its salts and PFOSF as listed in Annex B to the Stockholm Convention.
6. Data on PFOA are summarized in Table 1 and Table 2. Tables with data for PFOA salts and related PFOA 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 | C8HF15O2 |
| 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-Octanoic 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 | <1.6, e.g. 0.5  1.5-2.8 | (Vierke et al., 2013)  (Kissa, 2001) |
| pH-value | 2.6 (1 g/L at 20 °C) | (ECHA, 2015a) (reliability not assignable) |

1. There has been some uncertainty in regards to the acid dissociation constant (pKa) of PFOA. Some have reported the pKa to be as high as 3.8, while others have suggested it may be < 1 (De Voogt, 2010). The current weight of evidence suggests that PFOA should be considered a strong acid (pKa< 1) in aqueous solution at environmentally relevant concentrations (De Voogt, 2010; Vierke, et al., 2013).
2. 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 which was further reacted to make PFOA and its salts (Buck et al., 2011).The current extent of global ECF manufacturing is unknown; however, most of the manufacturers may be using the telomerization process nowadays, which mainly results in linear compounds (Wang et al., 2014a) [[5]](#footnote-5). Telomerization reacts a perfluoroalkyl iodide (telogen) with tetrafluoroethylene (taxogen) to yield a mixture of perfluoroalkyl iodides (Telomer A) that are reacted further to insert ethylene and create fluorotelomer iodides (Telomer B) that 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).
3. A standardized method for the analysis of presence of PFOA in different matrices is currently not available. The unique chemical and physical properties of PFOA prevent it from being measured using conventional analysis. More complex methodology of liquid chromatography and tandem mass spectrometry (LC/MS-MS) has been proven most reliable for analyzing PFOA in biological and environmental samples and therefore the analytical method of choice (Xu et al., 2013; EFSA, 2008; Loos et al., 2007). This type of analysis has allowed for more sensitive determination of many perfluorinated chemicals (PFCs), including PFOA, in air, water, and soil (ATSDR, 2015).

Conclusions of the Review Committee regarding Annex E information

1. At its eleventh meeting (decision POPRC-11/4) the Committee concluded that the proposal by the European Union to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annexes A, B and/or C to the Stockholm Convention meets the criteria set out in Annex D to the Convention (UNEP/POPS/POPRC.12/11).
2. According to document UNEP/POPS/POPRC.12/11, after having completed the 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, the Committee adopted the risk profile for pentadecafluoroctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds[[6]](#footnote-6) and:
3. 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;
4. 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;
5. 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.

Data sources

Overview of data submitted by Parties and observers

1. This risk management evaluation is primarily based on information that has been provided by Parties to the Convention and observers. Data relating to Annex F were submitted by the following parties:
2. Parties: Australia, Austria, Azerbaijan, Canada, China, Colombia, Denmark, India, Japan, Mauritius, Monaco, Norway, Serbia;
3. 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).

Other key data sources

1. In addition to the above-mentioned references, information has been used from open information sources as well as scientific literature (see list of references). The following key references were used a basis to develop the present document:
2. The risk profile for PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.12/11/Add.2);
3. The regulatory impact analyses statement related to the Canadian restriction approach (Canada 2016c)
4. 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 legislative Proposal for the EU (EUROPEAN COMMISSION, 2017).

Status of the chemical under International Conventions

1. 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).

National or regional control actions taken

1. An overview related to risk reduction approaches for PFASs was provided by the Organization for Economic Co-operation and Development (OECD) (OECD, 2015). The document includes information on voluntary risk reduction measures taken by corporations[[7]](#footnote-7). 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:
2. In 2013, the EU identified both PFOA and 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). Inclusion upon this list means the substances can be subject to further review and ultimately phased out under the Authorization process. Moreover, 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;
3. In 2014, Germany and Norway lodged a joint 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 also including substances that may degrade to PFOA (PFOA-related compounds). The proposed restriction also covers articles containing these substances. After submission of the proposal to the European Chemicals Agency (ECHA) stakeholders delivered new information during the public consultation. Subsequently, the EU restriction proposal was updated including several proposals for derogation. These are further introduced in chapter 2.2.The updated EU restriction proposal is available in ( EUROPEAN COMMISSION, 2017);
4. PFOA was included under 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;
5. 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 before 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)
6. 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 (CEPA) and were added to the List of Toxic Substances in Schedule 1 of the Act. 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 PFCAs (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 March 30, 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 December 31, 2010, and to virtually eliminate them by December 31, 2015. Furthermore, in October 2016, the *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012,* were published in Canada. As of December 23, 2016, these amendments prohibit PFOA, its salts and precursors and products containing them, unless present in manufactured items. 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);
7. In the United States of America, the US EPA established the PFOA Stewardship Programme in 2006. This is a programme that includes eight major 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 (US EPA, 2015). It was successfully completed at the end of 2015. On January 21, 2015, the US EPA 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 EPA at least 90 days before starting or resuming new uses of these chemicals in any products. This notification would allow EPA the opportunity to evaluate the new use and, if necessary, take action to prohibit or limit the activity;[[8]](#footnote-8)
8. Russia regulates APFO in occupational air. A number of short- and middle chain PFASs are regulated in occupational air and water (OECD, 2013).

# Summary information relevant to the risk management evaluation

1. A summary of risk profile information is given in section 3.1.
2. Several legislative restriction approaches for PFOA and related compounds exist or are underway. It is important to note that these approaches 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 restriction approaches. It is noteworthy, that PFOA-related compounds for the purposes of this risk management evaluation covers degradation to PFOA from long chain PFCs[[9]](#footnote-9) except those explicitly excluded in the definition of PFOA-related compounds as they do not degrade to PFOA under natural conditions (see para 16). This goes beyond the EU restriction approach which does not cover degradation to PFOA from longer chain PFCs. The degradation from longer chain PFCs are also not considered in the Norwegian restriction approach. The Canadian restriction also applies to long-chain perfluorocarboxylic acids, their salts, and their precursors.
3. Specific information on the longer chain PFCs was not submitted to the Secretariat with the Annex F submissions of Parties and observers. Moreover, the longer chain PFCs are not considered in the socio-economic assessments of the restriction approaches in the EU and Norway. Accordingly the information in the present draft risk management evaluation does not explicitly cover longer chain PFCs so far. At EU level, Germany and Sweden are preparing a restriction proposal for the long-chain perfluorinated carboxylic alkyl acids of chain lengths between 9 and 14 carbon atoms and related substances. As far as possible, information generated in the process of elaborating this restriction proposal will be considered for the draft risk management evaluation.

Identification of possible control measures

1. The objective of the Stockholm Convention is to protect human health and the environment from persistent organic pollutants. When assessing control measures under the Convention, consideration must also be given to the potential for PFOA-related compounds to degrade to PFOA and thus contribute to the total environmental load. When assessing whether exemptions would be appropriate, the considerations as identified in Annex F to the Convention and the POPRC General guidance on considerations related to alternatives and substitutes for listed persistent organic pollutants and candidate chemicals[[10]](#footnote-10) should be taken into account.
2. Possible control measures may include (1) prohibition or restriction of production, use, import and export, (2) control of discharges or emissions, (3) replacement of the chemicals by alternatives, (4) clean-up of contaminated sites, (5) environmentally sound management of obsolete stockpiles, (6) prohibition of reuse and recycling of wastes or stockpiles (7) establishment of exposure limits in the workplace and (8) establishment of maximum residue limits in water, soil, sediment or food.
3. The control measure “prohibition or restriction of production, use, import and export” may be achieved in different ways under the Convention:
4. 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
5. 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
6. PFOA may be listed in Annex C as an unintentional POP to capture PFOA as unintentional impurity in the manufacturing of PFOA-related compounds and some alternatives.
7. Similar to the risk management evaluation on short-chain chlorinated paraffins it is concluded that listing PFOA in Annex C is not required. SCCP are present as an impurity in articles produced with MCCPs (UNEP/POPS/POPRC.12/11/Add.3). This is because SCCPs occur as impurity in manufacturing of MCCPs, which are commonly used as alternatives for SCCPs. This is analogue to the unavoidable fraction of PFOA and PFOA-related substances which is created when manufacturing short chain fluorinated alternatives. Accordingly the POPRC decided to recommend that SCCPs should be listed in Annex A or B and not in Annex C (Decision POPRC-12/3). Therefore, listing of PFOA, its salts and PFOA-related compounds in Annex C is not recommended. Concerns with respect to unintentional generation can be addressed by establishing appropriate concentration limits for PFOA and PFOA-related compounds in manufacturing.

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

1. According to IPEN In order to reduce and eliminate emissions of PFOA and PFOA-related compounds, control measures at all life cycle stages need to be in place. The most cost effective and practicable control measure for PFOA and PFOA-related compounds is the prohibition of all production, use, import and export. This is particularly relevant in developing and transition countries that lack adequate regulatory and enforcement infrastructure. This would be best accomplished by listing PFOA, its salts and PFOA-related compound in Annex A of the Stockholm Convention. 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 (comment IPEN 2017).
2. Information received from stakeholders in the EU restriction process indicates that exemptions for use where alternatives are not economically and/or technically feasible are required (ECHA, 2014a, 2015a).
3. The EU Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC), consider that the proposed restriction on PFOA, its salts and PFOA-related substances is the most appropriate EU-wide measure to address the identified risks, provided that the scope and conditions are modified notably raising the 2 ppb threshold to 25 ppb/1000 ppb. Based on this consideration as well as other stakeholder contributions the initial restriction proposal was modified. Details on the modifications by proposed by the scientific committees within the EU are documented in (ECHA, 2015c).
4. As a result a new EU restriction proposal[[11]](#footnote-11) was elaborated as follows (EUROPEAN COMMISSION, 2017):

PFOA, its salts and PFOA-related substances:

1. Shall not be manufactured, or placed on the market as substances on their own from (date -3 years after date of entry into force of the Regulation);
2. Shall not (date -3 years after date of entry into force of the Regulation), be used in the production of, or placed on the market in a) another substances, as a constituent; b) a mixture; c) an article in a concentration equal to or above 25ppb of PFOA including its salts or 1000ppb of one or a combination of PFOA-related substances;
3. Paragraph 1 and 2 shall apply from a) (date – 5 years after entry into force of the Regulation) to: i) equipment used to manufacture semiconductors; ii) latex printing inks. b) (date – 6 years after entry into force of the Regulation) to: i) textiles for the protection of workers from risks to their health and safety; ii) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment; iii) plasma nano-coating. c) (date – 15 years after entry into force of the Regulation) to medical devices other than implantable medical devices within the scope of Directive 93/42/EEC;
4. By way of derogation,[[12]](#footnote-12) paragraph 1 and 2 shall not apply to any of the following: a) perfluorooctane sulfonic acid and its derivatives, which are listed in Part A of Annex I to Regulation (EC) No 850/2004; b) the manufacture of a substance where this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 6 atoms; c) a substance that is to be used, or is used as a transported isolated intermediate provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met; d) a substance, constituent of another substance or mixture that is to be used, or is used: i) in the production of implantable medical devices within the scope of Directive 93/42/EEC; ii) in photographic coatings applied to films, papers or printing plates; iii) in photo-lithography processes for semiconductors or in etching processes for compound semiconductors; e) concentrated fire-fighting foam mixtures that were placed on the market before (date – 3 years after date of entry into force of this Regulation) and are to be used, or are used in the production of other fire-fighting foam mixtures;
5. Paragraph 2(b) shall not apply to fire-fighting foam mixtures which were: a) placed on the market before (date – 3 years after entry into force of this Regulation); 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;
6. Paragraph 2(c) shall not apply to a) articles placed on the market before (date – 3 years after date of entry into force of this Regulation); b) implantable medical devices produced in accordance with point (i) of paragraph 4(d); c) articles coated with the photographic coatings referred to in point (ii) of paragraph 4(d); d) semiconductors or compound semiconductors referred to in point (iii) or paragraph 4(d).
7. In Canada, the *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012,* came into force on December 23, 2016 and prohibit PFOA, its salts and precursors and products containing them, unless present in manufactured items. The amendments prohibit the manufacture, use, sale, offer for sale or import of PFOA and LC-PFCAs and products containing these substances with a limited number of exemptions to the prohibitions. In this Canadian Regulation the following terminology is used: “Perfluorooctanoic acid, its salts, and its precursors (collectively referred to as PFOA); long-chain perfluorocarboxylic acids, their salts, and their precursors (collectively referred to as LC-PFCAs)”. Time-limited exemptions and ongoing permitted uses are available for certain applications where the development of alternatives is underway or in case of no known alternatives. The amendments allow (1) the use, sale, offer for sale or import of manufactured items containing PFOA or LC-PFCAs; (2) the use, sale, offer for sale and import of these substances in aqueous film-forming foams used in firefighting applications; (3) the manufacture, use, sale, offer for sale or import of water-based inks and photo media coatings containing PFOA and LC-PFCAs, until December 31, 2016; (4) the use, sale or offer for sale of PFOA and LC-PFCAs and products containing these substances that were either manufactured or imported before the coming into force of the amendments or the end of the temporary exemption period, as applicable; and (5) the use or import of products containing PFOA and LC-PFCAs if intended for personal use. Further, manufacturers and importers of PFOA and LC-PFCAs and products containing these substances are allowed to apply for a permit to continue their activities after the coming into force of the amendments or after expiry of a temporary exemption. Permits are valid for one year and can potentially be renewed twice (Canada, 2016c).
8. The amendments protect the Canadian environment by preventing the reintroduction of PFOA and LC-PFCAs as industry is already working towards phasing out these substances. The amendments are expected to have a low cost impact on industry. The substances are not currently manufactured in Canada and are only known to be imported. Furthermore, industry sectors have already completed the transition to alternatives, or are expected to do so prior to the coming into force of the amendments. Development of alternatives in water-based inks and photo media coatings is underway, and companies expect to eliminate their use by the end of 2016, when the temporary exemption would expire. For aqueous film-forming foams, which would be allowed under the amendments, the development of alternatives has begun and will be monitored (Canada, 2016c).
9. The Norwegian consumer products regulation amended in 2014 bans the use of PFOA in consumer products and textiles with a transitional period allowing the import and sale of products before phase out. The following applies:
10. From 1 June 2014, it is prohibited to manufacture, import, export and make available on the market textiles, carpets and other coated consumer products that contain PFOA and individual salts and esters of PFOA, when the content of the substance in the product's individual parts is greater than or equal to 1 μg/m2. Individual parts comprise the materials of which the product is manufactured, and the product's individual components;
11. From 1 June 2014, it is prohibited to manufacture, import, export and make available on the market consumer products that contain PFOA and individual salts and esters of PFOA, when the content of the substance in the product's individual parts is greater than or equal to 0.1%. The prohibitions on manufacture and export will not apply until 1 January 2016 to: (a) adhesives, foil or tape in semiconductors, (b) photographic coatings for film, paper or printing plate;

The prohibitions on import and sale will not apply until 1 January 2018 to products for which it can be documented that the manufacture took place prior to the prohibitions in paragraphs 1 to 2, cf. paragraph 3 came into force. The prohibitions do not apply to food packaging, food contact materials and medical devices and shall not apply to spare parts for consumer products made available for sale prior to 1 June 2014 (Norway, 2016).

1. The following table gives an overview on the above described restriction approaches and exemptions in Canada, the EU and Norway.

Table 3: Overview of restriction 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** |
| --- | --- | --- | --- |
| Restriction | 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 | PFOA and its salts;  Compounds that consist of a perfluorinated alkyl group that has the molecular formula CnF2n+1 in which n = 7 or 8 and that is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom;  Perfluorocarboxylic acids that have the molecular formula CnF2n+1CO2H in which 8 ≤ n ≤ 20, and their salts;  Compounds that consist of a perfluorinated alkyl group that has the molecular formula CnF2n+1 in which 8 ≤ n ≤ 20 and that is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom.  (see Canada, 2016c) | PFOA and its salts;  Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula C7F15- directly attached to another carbon atom, as one of the structural elements.  Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C8F17- as one of the structural elements.  Exclusions:  C8F17-X, where X= F, Cl, Br;  C8F17-C(=O)OH, C8F17-C(=O)O-X' or C8F17-CF2-X' (where X'=any group, including salts).  Does not apply to PFOS and its derivatives, which are listed in Part A of Annex I to Regulation (EC) No 850/2004  (see EUROPEAN COMMISSION, 2017)  PFOA<25ppb, related compounds <1,000 ppb | PFOA and individual salts and esters of PFOA (CAS number. 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) |
| Exemptions for photo-imaging | Photo media coatings until December 31, 2016  Since then partially captured under exemptions for manufactured items | Photographic coatings applied to films, papers or printing plates | Photographic coatings for film, paper or printing plate until 2016 |
| Exemptions for semiconductor industry | Partially captured under exemptions for manufactured items | - Equipment used to manufacture semiconductors (date – 5 years after entry into force of the Regulation);  - Photo-lithography processes for semiconductors or in etching processes for compound semiconductors; | Adhesives, foil or tape in semiconductors until 2016 |
| Exemptions for firefighting | Aqueous film-forming foams used in firefighting applications | - Concentrated fire-fighting foam mixtures that were placed on the market before (date – 3 years after date of entry into force of this Regulation) and are to be used, or are used in the production of other fire-fighting foam mixtures  - Fire-fighting foam mixtures which were: a) placed on the market before (date – 3 years after entry into force of this Regulation); 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. | Note: not relevant for this specific regulation in Norway since it concerns consumer products (and aqueous film-foaming firefighting foams are for professional use only) |
| Medical uses | Partially captured under exemptions for manufactured items | - Medical devices (date – 15 years after entry into force of the Regulation)  - Production of implantable medical devices within the scope of Directive 93/42/EEC | Medical devices are exempted from restrictions |
| Textiles | Partially captured under exemptions for manufactured items | - Textiles for the protection of workers from risks to their health and safety (date – 6 years after entry into force of the Regulation)  - Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment (date – 6 years after entry into force of the Regulation) | Textiles for consumer use are restricted when PFOA concentration is above 1ug/m2 for any part of the product. |
| Inks | Water-based inks until December 31, 2016 | Latex printing inks (date – 5 years after entry into force of the Regulation) |  |
| Nano coating | Partially captured under exemptions for manufactured items | Plasma nano coating (date – 6 years after entry into force of the Regulation) |  |
| Food packaging | Partially captured under exemptions for manufactured items |  | Food packaging, food contact materials |

1. In the process of developing the above described restrictions 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 from the restrictions. As a consequence the exemptions proposed or implemented give an indication for the identification of critical uses based on technical and socio-economic considerations.

*Other control measures*

1. The U.S. Environmental Protection Agency uses a combination of regulatory and voluntary approaches, including Significant New Use Rules and the voluntary PFOA Stewardship Program (OECD, 2015). For further information on the Stewardship Program see Section 1.5.
2. 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), 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 PFCs and existing PFCs 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 defense sites where groundwater is contaminated with PFAS including PFOA (comment IPEN 2017).
3. The German commission on human biomonitoring has derived new HBM-I values[[13]](#footnote-13) 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.[[14]](#footnote-14)
4. Canada has implemented a combination of regulatory and voluntary actions to reduce the risk of certain long-chain PFASs. In 2006, Canada launched the “Action Plan for the Assessment and Management of Perfluorinated Carboxylic Acids and their Precursors”. One of the measures identified in the Action Plan was a voluntary Environmental Performance Agreement with manufacturers of PFCAs. Signatories to the Agreement agreed to reduce the amount of PFOA its salts and related substances and LC-PFCAs in perfluorinated chemicals in commerce by 95% by December 31, 2010, and to eliminate them by December 31, 2015. The 2010 reduction target was met by all signatories and annual progress reports show that the 2015 target should also be met. The Agreement was implemented as an early risk management action while the Department of Health in Canada pursued further assessment to guide future risk management conditions (Canada, 2016c).
5. In 2014, the Danish EPA published a study on groundwater contamination associated with point sources of perfluoralkyl 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 leads to establishing a sum criterion drinking water limit value for 12 perfluorinated substances. The limit value is 0.1 µg/l drinking water and is a sum criterion for the presence of all of the 12 PFCs. The same sum criterion limit value is valid for groundwater and a sum criterion limit value for the same PFCs in soil has been established at 0.4 µg/l (dry soil) (Denmark, 2016).
6. 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 exceed 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.
7. Norway is conducting ongoing remediation of PFAS contaminated soil due to use of AFFF at airports and fire training areas (Norway, 2016).
8. The use of foam may involve toxic firefighting water leak into the ground and contaminate soil and groundwater. In all firefighting applications it is now a requirement to collect water, which means one should strive for as little firefighting water as possible during operation (comment Sweden, 2017). Chemicals Inspectorate, the Swedish Civil Contingencies Agency (MSB) and the Environmental Protection Agency has produced a leaflet to the Swedish Rescue Services with recommendations to reduce the use of firefighting foam (Swedish Chemicals Agency, 2017).
9. In Germany, Greenpeace with its Detox campaign and the Zero Discharge of Hazardous Chemicals (ZDHC) Programme, focus on the wastewater and emissions. Maximum residue limits in water are already recommended and applied by many companies (e.g. H&M, Adidas, Esprit, etc.) (TM, 2016).
10. The POPRC developed a series of recommendations to deal with the PFOS waste stream that are highly applicable to PFOA. Decision POPRC-6/2 outlines a series of risk reduction measures in a short-term, medium-term and long-term framework. The POPRC recommends within the short-term to use best available techniques and best environmental practice destruction technologies for wastes. There should be no permission of landfilling these wastes, unless leachate is properly treated. In case destruction technologies are not available, safe storage has to be ensured. In addition, investigations related to landfills where waste from producers/industrial users are disposed should be launched and drinking water from reservoirs and wells in the vicinity of landfills and around production/user areas should be monitored. Within the medium-term, the POPRC recommends to carry out remediation activities in accordance with the “polluter-pays principle” with the aim to reduce risk (for more information seed Decision POPRC-6/2).
11. The Government of Canada is undertaking research, evaluating findings from new studies, collecting information and investigating potential releases of toxic substances from waste management (e.g. landfills) and recycling facilities in Canada. PFOA and long-chain PFCAs would continue to be included in any monitoring from the waste sector, if needed. Based on the findings, the Government of Canada will implement further risk management activities if warranted (Canada, 2012a).
12. 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 (Naturvårdsverket 2016). The most significant point-sources identified were areas where fire-fighting foams have been used (airports and fire-fighting training sites) as well as waste- and waste water treatment facilities. Suggested risk reducing measures included: restrict the release of PFASs from point sources, limit the use of PFASs-containing firefighting foams, work internationally to limit the use in and emissions of PFASs from industrial activities and develop techniques for PFASs remediation. In Sweden a network consisting of all relevant authorities has been running since 2014 with the aim to provide support and information to other authorities, counties, municipalities, water producers etc. related to issues around PFASs (including PFOA) such as risk assessment and management.
13. The Swedish Chemicals Agency has in a governmental assignment proposed that PFASs-containing fire-fighting foams must be collected and destroyed after being used (with some derogations) (Swedish Chemicals Agency (2016a). The Swedish Chemicals Agency has also provided training for fire-fighters as well as a brochure with recommendations for a reduced use of PFASs-containing fire-fighting foams.
14. The Swedish Chemicals Agency has published a strategy for reducing the use of PFASs (Swedish Chemicals Agency (2016b). Because of the potential negative effects of PFASs on the environment it is stated that 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.
15. Concerning stockpiles of PFOA, an appropriate storage of PFOA wastes until the proper capacity is available for destruction is required to limit environmental impacts (Canada, 2016a). 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), (Prevedouros et al., 2006).
16. It is indicated by industry stakeholders that most photo imaging products do not contain PFOA-related substances. Waste materials, which are associated with the manufacture of a small number of films containing PFOA-related substances, 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). According to IPEN, this rather represents the situation in Europe (comment IPEN 2017).
17. IPEN recommends within the short-term to use best available techniques and best environmental practice destruction technologies for wastes containing PFOA. There should be no permission of landfilling these wastes, unless leachate containing PFOA is properly treated. In case destruction technologies are not available, safe storage has to be ensured. In addition, investigations related to landfills where wastes from PFOA producers/industrial users are disposed should be launched and drinking water from reservoirs and wells in the vicinity of landfills and around PFOA production/user areas should be monitored. Practices related to the management of sludge should be assessed and rivers, lakes, and in particular the fish in the lakes and rivers close to the landfills and production/industrial use areas should be monitored. It is furthermore recommended that occupational exposure at production/industrial use facilities is monitored and that appropriate occupational health and safety measures are implemented. Within the medium-term, if contamination has occurred, IPEN recommends to carry out remediation activities in accordance with the “polluter-pays” principle with the aim to reduce risk (IPEN, 2016a).
18. Following a listing of PFOA, its salts and PFOA-related compounds in the Stockholm Convention a concentration level for low POP content would typically 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 by 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).

Identification of critical uses

*Uses in semiconductor industry*

1. In former studies, use in semiconductor industry was identified as potentially critical. SIA surveyed its member companies and found that several companies continue to use PFOA and related chemicals in the photolithography process, a key step in the manufacturing process to produce advanced semiconductors (comment SIA 2017). This sector is responsible for a very low share of total emission of PFOA and PFOA-related substances. The volume used in the sector is a minor part of the total volume used in the EU and the substance is reported to be used under strictly controlled conditions. Typical control measures are documented in the OECD Emissions Scenario Document (SIA, 2016). Information submitted by the sector tends to demonstrate that substitution is currently not possible, and that timeframes for substitution are long (10 years). 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 (5 years after entry into force of the Regulation) for the equipment used to manufacture semiconductors is proposed in the EU restriction proposal. Besides, a derogation without time limitation is proposed in photo-lithography processes for semiconductors or in etching processes for compound semiconductors (EUROPEAN COMMISSION, 2017). In Canada, semiconductors in manufactured items are exempted, whereas in Norway an exemption for adhesives, foil or tape in semiconductors terminated by 2016.
2. The information provided indicates that a complete elimination is possible. A specific time frame is not indicated. According to a statement provided by SEMI (see comments SEMI, 2017) a time frame of 10 years for transition could be appropriate for manufacturing equipment and related infrastructure. In addition, SIA also 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 (comment SIA 2017).

*Technical textiles*

1. 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 a derogation is justified in the professional sector due to data gaps mainly on volumes, specific uses and substances. It could be agreed to grant a longer transitional period for the remaining uses in the professional sector as personal protection equipment needs to fulfill specific requirements, which are established in respective standards (e.g. standard EN 13034 for protective clothing). However, for textiles used in outdoor applications (e.g. awnings and outdoor furnishing, camping gear) alternatives are available and a derogation is not proportionate. For textiles for the protection of workers from risks to their health and safety a time limited derogation (6 years after entry into force of the Regulation) is proposed in the EU. Besides, the same applies also to membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment (EUROPEAN COMMISSION, 2017). 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 and its precursors are not restricted in Canada.
2. 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 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. The textile industry as a cross-sectional industry has to fulfill in the segment of professional, technical, protective textiles many different, performance standards. Almost all of these textiles have to be certified in long procedures which could take years and a lot of are regulated by various others EU- and national laws. These are complemented by standards and regulations of separate enterprises, dealing even more detailed with requirements for parts of cars, machines, apparel 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). However, according to IPEN, 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 (comment IPEN 2017).
3. The European Apparel and Textile Confederation (EURATEX) considers inclusion of derogation for water, oil and chemicals 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. According to EURATEX, continuation of applying C8 chemistry on textile products would maintain the competitiveness of the European technical textile production (Euratex, 2016).
4. According to Textile+Mode, 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. As the technical textiles are produced in the EU, respecting the BEP, the amounts of emissions are close to zero. There are nearly no emissions, this also includes emission paths after production like domestic washing. Within their life cycle technical textiles are rarely washed nor are they in environmental contact under conditions that elute PFOA or related substances into the environment, having in mind, that the treatment with fluorinated products has the aim to minimize the influence of the environment by durable oil- and water 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 durable repellency performance standards is considered indispensable (TM, 2016).

*Certain printing inks (for printing on low surface energy nonporous substrates)*

1. Comments from the industry submitted during the EU stakeholder consultation indicate that C8 perfluorinated chemicals 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 manufacturing 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 longer transitional period of 5 years for this use (ECHA, 2015c). For latex printing inks a time limited derogation (5 years after entry into force of the Regulation) has been proposed in the EU (EUROPEAN COMMISSION, 2017). For water-based inks a time limited exemption (until December 31, 2016) was in place in Canada (comment Canada 2017). According to IPEN, companies in Canada and Norway do not require an exemption for this use anymore (comment IPEN 2017). The Norwegian restriction, however, only applies to consumer products and does not restrict PFOA use in inks for professional use/printers.

*Production of short chain fluorinated alternatives*

1. One company illustrated that an unavoidable fraction of PFOA and PFOA-related substances is created when manufacturing short chain fluorinated alternatives. Industry is planning to reprocess the fraction of PFOA and PFOA-related substances back into C6-chemistry. In that case it has to be ensured that PFOA and PFOA-related substances are on-site isolated intermediate and handled under strictly controlled emissions. Transport of the substance would not be in line with the aim of the restriction, e.g. might lead to transport outside of the EU, and is therefore restricted. Closed system site-limited isolated intermediates are not covered by restrictions under the Stockholm Convention, therefore no exemption is needed to allow this reprocessing (see para 185). The proposed set of thresholds within the EU takes the currently unavoidable fraction of PFOA and PFOA-related substances during production of short-chain alternatives into account. With that set of thresholds it is possible to manufacture short-chain alternatives (ECHA, 2015a). Neither Norway nor Canada have specific exemptions in place. Nevertheless, there is an increasing concern about the short-chained PFASs in Europe (comment Norway 2017).

*Production of pharmaceutical chemicals*

1. Alternatives have been developed and are available for almost all applications currently using PFOA, its salts and PFOA related compounds. 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 social-economic benefit in particular performance standards (FluoroConcil, 2016a). There is no information specifying “other highly specialized chemicals”. According to IPEN, more than 100 countries agreed that environmentally persistent pharmaceutical pollutants are a global emerging policy issue in the SAICM process and this issue should be closely examined before considering exemptions (comment IPEN 2017).

*Photo imaging*

1. 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 reduction in the use of PFOA-related substances of more than 95% worldwide since 2000. Although replacements do not currently exist for the remaining few critical 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 critical uses are not necessary (I&P Europe, 2016a).
2. I&P Europe states, that non availability of PFOA-related substances for the manufacture of the remaining critical imaging products will also adversely affect involved customer groups including 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 or east European countries (I&P Europe, 2016a).
3. Within the EU restriction proposal a derogation is proposed 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 restriction 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.

*Nano coating*

1. For plasma nano coating a time limited derogation is proposed within the EU. Only one company applying coating for smartphone manufacturers requested during the public EU stakeholder consultation on the restriction dossier a derogation for 3 years for pulsed plasma nano coating was requested in order to be able to move to an alternative C6 chemical. During the Public Consultation on the SEAC draft opinion this stakeholder announced that the transition would take longer than initially foreseen, and an extension of the transitional period to 6 years was requested. Only one company provided a confidential SEA that suggests significant economic impacts in case sufficient time is not allowed to switch to alternatives (ECHA, 2015c). On this basis, for plasma nano coating a time limited derogation (6 years after entry into force of the Regulation) is proposed 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.

*Spare parts*

1. During the public EU stakeholder consultation, industry stakeholders requested extending the exemption for spare parts for automobiles included in the draft opinion of the EU scientific committee to other kinds of spare parts (aviation, telecommunication, semiconductors, ICT 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 scientific committee finds derogation for spare parts in stock before the entry into force of the restriction 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 proposal there is no exemption for spare parts (EUROPEAN COMMISSION, 2017). According to SEMI, regarding manufacturing equipment and related infrastructure in the semiconductor industry a transitional period would be required also for spare parts for manufacturing equipment (comment SEMI, 2017).

*Firefighting foams*

1. In order to be consistent with the exemption for foams already in use, and in order to avoid the need for early replacement of exempted foams, SEAC proposes to derogate these mixtures from the proposed 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).
2. Regarding the placing on the market of new firefighting foams, SEAC notes that during the Public Consultations, some stakeholders (firefighting services, foams manufacturers) have requested higher concentration limits for PFOA-related substances and PFOA, or total exemption of firefighting foams. Overall, given the information provided, SEAC proposes 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).
3. Within the EU restriction proposal a derogation is proposed for concentrated fire-fighting foam mixtures that were placed on the market (3 years after date of entry into force of the Regulation) and are to be used, or are used in the production of other fire-fighting foam mixtures. Besides, a derogation is proposed for fire-fighting foam mixtures a) placed on the market before (3 years after entry into force of the Regulation) 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 (EUROPEAN COMMISSION, 2017). In Canada, a specific exemption is given to aqueous film-foaming foams used in firefighting applications (Canada 2016c). There are no exemptions in place for firefighting foams in Norway, however, the restriction does not apply since it concerns consumer products and AFFF are for professional use only. Germany proposes to include a transitional period for the use of the “old” foams, since the firefighting foams are very stable and may be stored for very long time until used in case of fire. Thus, the effect of reducing emissions is rather low in this case (comment Germany 2017).
4. 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 (comment IPEN 2017).

*Medical devices*

1. In the EU consultation process, stakeholders have indicated that substitution is ongoing but is a lengthy process given the complexity of supply chains and the certification processes. General transitional period of a minimum of 5 years is requested, but for some devices this transitional period could be too short. In the specific case of implantable medical devices, a manufacturer requests a transitional period of 15 years (ECHA, 2015c).
2. Within the EU restriction proposal a time limited derogation (15 years after entry into force of the Regulation) is proposed for medical devices other than implantable medical devices within the scope of Directive 93/42/EEC. Besides, a derogation without time limitation is proposed in the production of certain implantable devices (EUROPEAN COMMISSION, 2017). Norway has an exemption in place for medical devices.

Costs and benefits of implementing control measures

1. PFOA is already being phased out widely in many uses, indicating that the costs of alternatives have not inhibited PFOA substitution. Important points to consider when evaluating the costs of alternatives for any product include: Alternatives with a higher initial purchase cost may actually be cheaper over the life 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.
2. For the EU restriction proposal, 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, (6) paints and inks. The estimation was made by the industry for current use (worst case scenario) and for the time after 2015 (i.e. when the proposed restriction will enter into force; more realistic case). Due to the lack of data an estimation for import of PFOA in articles, photographic applications and semiconductors was not made. The estimated substitution costs range from 1.39 to 158.44 million € with a 34.7 million € (central estimate; range from 1.39 to 158.44 million €) for the more realistic case (see ECHA, 2015a, Table F.2-6).
3. The EU consultation with industry has shown that the main fluoropolymer manufacturers have already developed several alternatives to replace the use of 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 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 quality of the PTFE manufactured with the alternatives (ECHA, 2015a).
4. Regarding investment costs, industry stated during the preparation of the proposal, mainly and users of PFOA and PFOA-related substances, that industry has already invested considerable resources to develop short-chain PFAS in R&D efforts as well as in capital (over 500 million € 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 € per company have been reported, depending on the specific conditions of the case at hand (ECHA, 2015a).
5. 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 like loss of life quality for the affected individuals. It has not been possible to estimate the share of the overall disease burden, which 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 of restricting PFOA and PFOA-related substances (ECHA, 2015a). According to information from Norway, the socio-economic assessment in EU emphasized mostly on the PBT properties of PFOA for the reason of reducing the emissions. Newer studies do also show correlation with reduced effects of vaccines[[15]](#footnote-15) (comment Norway 2017).
6. The proposed EU restriction is not expected to lead to wider economic impacts, because of the reasonable threshold the market is already developing towards replacing PFOA and PFOA-related substances. This is reflected by the estimated moderate compliance cost. Furthermore, the proposed restriction is not expected to trigger effects with regard to the competiveness of EU and global industry, because both will have to substitute PFOA and PFOA-related substances to comply with the restriction. The proposed restriction is not expected to have major effects on employment, because for the vast majority of uses there are alternatives available that are implementable with a reasonable cost. Also, as imported articles and mixtures will also be covered by the restriction relocation of production facilities to outside the EU are 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).
7. 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 LC-PFCAs . The scientific evidence has demonstrated that these substances are persistent and that they accumulate and biomagnify in terrestrial and marine animals. The ongoing release of PFOA and LC-PFCAs may result in harm to the Canadian environment. CMP is a Government of Canada initiative aimed at reducing the risks posed by certain chemicals to Canadians and their environment. The CMP builds on previous initiatives by assessing chemicals used in Canada and by taking action on chemicals found to be harmful. Final screening assessments conducted in 2012 by the Department of the Environment concluded PFOA and LC-PFCAs are toxic to the environment under the Canadian Environmental Protection Act, 1999 (CEPA). Recent amendments to the *Prohibition of Certain Toxic Substances Regulations* prohibit the manufacture, use, sale, offer for sale or import of PFOA and LC-PFCAs and products containing these substances, unless present in manufactured items. The amendments prohibit PFOA and LC-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). The on-going use, sale, offer for sale, and import of these substances in AFFF used in fire protection applications would be allowed. A temporary permitted use would be allowed for these substances in water-based inks and photo media coatings until the end of 2016[[16]](#footnote-16).While no quantitative analysis of benefits has been conducted, the amendments will protect the environment. An improvement in environmental quality is expected from controlling these substances. A voluntary agreement was made as an early risk management action to encourage manufacturers to work towards eliminating these substances from the Canadian marketplace16.
8. 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). Inspection activity in Norway on consumer products, indicate that the number of consumer products with PFOA has decreased as well as the concentration of PFOA after introduction of the PFOA regulations (comment Norway 2017).
9. 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, as well as PFOS and perfluorohexane sulfonate (PFHxS) been phased out in a range of uses. It is noted that legacy use 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. One of the public health issues has been stress and anxiety in affected communities being driven by the uncertainty around the potential for the levels of exposure to PFOA to cause adverse health effects. In addition, 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, which has compounded concerns. 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).
10. In Germany there are two very prominent cases showing the consequences of (illegal) disposal of waste/sludge on agricultural fields(disposal of sludge from paper industry: see Skutlarek et al. 2006, Wilhelm et al. 2009, Wilhelm et al. 2010, Hölzer et al. 2008, Hölzer et al. 2009; and a wide spread contamination of agricultural fields from sludge from paper industry into compost where soil, groundwater and drinking water were contaminated with PFAS and crops showed elevated levels of PFAS and cannot be consumed anymore. Two drinking water wells were closed) The consequences for the public and the farmers are immense[[17]](#footnote-17) (Comment Germany 2017).
11. High levels of PFAS in drinking water have been detected since 2011 in a number of municipalities in Sweden. Fire exercise sites have been shown to be the main source of this pollution, which in some cases have resulted in water supplies being closed. The municipalities have released information that wild caught fish from lakes downstream pollution area should not be eaten too often. (Swedish Chemicals Agency, 2013). For PFAS derived from a cavern near an old air field a carbon filter system has been installed to clean 150-200 m3 of water from the caverns before it flows out into recipients, (Defoort et al. 2012).
12. The monitoring of time trends of PFAS in the blood of women from Uppsala showed increasing PFHxS- levels while the corresponding measurements for women in Stockholm showed downward trends. After that elevated levels of PFOS and PFHxS. were detected in drinking water in Uppsala, Hydrological studies could trace the source of contamination to an old Military Airport (Swedish Chemicals Agency, 2013). The most contaminated water wells have been closed. These cases show that PFAS contamination of water is a costly threat to drinking water supplies and to fish as food.
13. Regarding professional, technical protective textiles, the sales of German manufacturers of technical textiles in 2013 amounted up to EUR 6 billion. According to German industry representatives, a ban on fluorinated products leads to a substantial decline in economic and innovation power, which means that German textile companies lose their competitiveness and livelihood irreversibly because of their specialization in the production of highly developed niche products with highest requirements (see VTB SWT, 2016 and TM, 2016).
14. According to I&P Europe, the primary barrier to complete elimination of the use of PFOA-related substances at this time remains technical. However, the cost of research and development is also a relevant consideration, since this investment represents a significant financial burden during a time when imagining industry is focused on the creation of innovative new digital imagining technologies. As a matter of fact the economic cost associated with substitution of PFOA-related substances in the few remaining critical photographic uses has in most cases become prohibitive, the small remaining critical uses being niche products in markets that IP Europe members anticipate to further decline (I&P Europe, 2016b).
15. FluoroCouncil member companies have invested over €500 million of R&D and capital expenditures into the development of alternative polymerization aids and short-chain products and emission control technologies. This figure does not include the transition and qualification costs for downstream users to replace PFOA and its related substances, which varied significantly up to over €1,000,000 per use per company, depending on the application. 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 (FluoroConcil, 2016a). Further, reasonable thresholds are required, as are reasonable work-arounds/implementation patterns when there is a final chemical substance that is not considered a precursor but that is manufactured with the use of intermediates that are considered precursors (comment Daikin 2017).
16. IPEN states, that the phase-out of PFOA that has already occurred indicates that costs of alternatives have not inhibited PFOA substitution. Important points to consider when evaluating the costs of alternatives for any product include: Alternatives with a higher initial purchase cost may actually be cheaper over the life 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 (IPEN, 2016).

Information on alternatives (products and processes)

Overview of alternatives

1. For most uses of PFOA and PFOA-related substances alternatives exist. These alternatives are mostly short-chain per- and polyfluorinated substances (with less than seven fully fluorinated C-atoms).(ECHA, 2015a). An overview of some fluorinated and non-fluorinated alternatives for different industry branches is given in (ECHA, 2015a, Table C.1-1; see PFOA INF, 2017a; Section 3.
2. The fact that there are neither fluorine-free alternatives nor alternative methods for some applications can be explained by the unique properties of highly fluorinated substances, which are therefore regarded as “irreplaceable” in some applications (Swedish Chemicals Agency, 2015).

Sector specific aspects

1. 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 sectors, where the respective alternative is relevant.

*Textile and carpet sector*

*Short-chain fluorinated alternatives*

1. Shorter-chain length perfluorinated telomeric substances replacing their long-chain equivalents have been identified as alternatives for a variety of uses including, amongst others, textile and carpet uses (US EPA, 2012).
2. It is stated by IPEN that 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 and adipate. With regards to perfluorinated compounds with shorter alkyl chain length compounds based on PFBS and fluorotelomer-based substances, including polymers, have been applied. According to IPEN (2016), these compounds raise concern and should not be regarded as acceptable alternatives (see PFOA INF, 2017a; Section 3).
3. It is mentioned that ≤ C6-based fluorotelomer chemistry is used to manufacture fluorotelomer-based products indicating the technical feasibility of this alternative, even if ≤ C6-based fluorotelomer chemistry is more expensive compared to C8-based products, i.e. higher volumes must be applied to achieve the same technical performance and costs of ≤ C6-based fluorotelomer products are higher (ECHA, 2015a).
4. For fluorotelomer products based on 8:2 fluorotelomer alcohol (8:2 FTOH), the shorter-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). Other short-chain fluorinated alternatives for PFOA-related substances are degraded to these acids as well (ECHA, 2015a). According to another study (Ellis et al., 2004; cited by ECHA, 2015d) perfluoroheptanoic acid (PFHpA) is formed as well upon atmospheric degradation of 6:2 FTOH and it is stated that PFHpA and PFHxA are the most abundantly formed PFCAs upon oxidation of 6:2 FTOH.
5. Due to microbial degradation and volatilization, 6:2 FTOH in soil can be aerobically biodegraded to transformation products such as 5:3 acid and other PFCAs (mainly PFPeA and PFHxA). 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 with more than 97 mol% is 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).
6. Risks related to fluorotelomer-based 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 summarized in the background document of this risk management evaluation (PFOA INF, 2017a; Section 4).
7. 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 shorter-chain PFCAs are equally persistent in the environment and cannot be further degraded under biotic or abiotic conditions (ECHA, 2015a). However, bioaccumulation potential of PFCAs with <7 fluorinated carbons is expected to be lower than that of PFOA (Conder et al., 2008).
8. In summary, metabolites of 6:2 FTOH are expected to be persistent, to have a lower bioaccumulation potential and a lower toxicity to aquatic organisms compared to PFOA. However, short-chain PFCAs are more mobile than PFOA, particularly in an aqueous 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. It is however admitted that toxicity thresholds are well above environmental concentrations and that they likely pose negligible risk to aquatic invertebrates (Mitchell et al., 2011).
9. According to IPEN 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). These characteristics raise concerns about compliance with Article 3 are not consistent with criteria for a safer alternative to PFOA. IPEN provided specific information and corresponding references related to adverse effects of the short-chain PFOA alternatives 6:2 FTOH, 6:2 FTA, 6:2 FTS, PFHxS, PFHxA, PFBS, PFBA and 4:2 FTOH (see PFOA INF, 2017a; Section 4).
10. According to a study provided by FluoroCouncil the fluorinated chemical alternatives to PFOA (6:2 FTOH and PFHxA/PFHx) do not meet the overall POP criteria according to the Stockholm Convention. 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 1 (d) (i).; persistence, bioaccumulation, ecotoxicity and toxicity to humans not fulfilled). PFHxA and its anion PFHx solely 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 bioaccumulation, long-range environmental transport, ecotoxicity and toxicity to humans are not fulfilled (FluoroCouncil, 2014). 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 PFAS (6:2 FTOH and PFHxA/PFHx) meet the Stockholm Convention POP criteria (FluoroCouncil, 2016b).
11. Industry associations noted that especially in the field of professional, technical 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. However, it is admitted that certain textile products formerly treated with PFOA-related substances, which only must fulfill low-performance requirements (e.g. standard clothing, standard outdoor textiles), may be treated by C6-products or even fluorine-free alternatives (VTB SWT, 2016) (Euratex, 2016).
12. It was mentioned by several stakeholders that protective textiles finished with C6-chemistry need high amounts of C6-products for the initial finishing and repeated professional reimpregnation with further C6-products after each washing step in order to meet high safety standards, which will result in additional emissions of PFCs due to the higher amount of used chemicals compared to C8-chemistry (VTB SWT, 2016). In this context, it was mentioned that over the life-cycle technical textiles treated with telomer-based C6-chemicals often exhibit 4-8 times more PFC total emissions compared to observed emissions using C8-chemistry (Euratex, 2016).
13. The textile industry reported that 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. infective liquids). Thus, serious health issues might occur in case of neglected reimpregnation, which is required due to a decrease in protection performance over time (VTB SWT, 2016) (TM, 2016).

*Non-fluorine containing alternatives*

1. 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 repellency (VTB SWT, 2016). In some cases, when applying fluorine-free alternatives, quality requirements of professional technical, protective textiles cannot be fulfilled due to e.g. 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). In addition, according to a statement from the Confederation of the German Textile and Fashion Industry, many fluorine-free alternatives are not sufficiently investigated with regards to toxicology, environmental impact or are affected by other or future substance restrictions (TM, 2016).
2. 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 Techologies AG, Sevelen/Switzerland (Stockholm Convention, 2014).
3. 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 (e.g. high molecular weight polydimethylsiloxanes (PDMS)), mixtures of silicones and stearamidomethyl pryriden chloride (sometimes in combination with carbamide (urea) and melamine resins), waxes and paraffins (usually consisting of modified melamine-based resins) and dendrimers being developed to imitate the ability of the lotus blossom to repel water (Swedish Chemicals Agency, 2015).
4. 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 consist of isocyanates, dipropylene glycol, metal salts or other unknown substances, which might 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).
5. Most silicones applied in textile impregnation agents are based on PDMS. They are inert and feature in general no adverse effects. Siloxanes are persistent and are 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).
6. 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 the information provided by the producers, these products should not be classified as harmful. 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. 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).

*Non-chemical alternatives*

1. The Danish EPA refers amongst others to a technology enabling the production of carpets with dirt- and water-repellant qualities applying properties that can be “incorporated” into the synthetic fibres (polypropylene) (Poulsen et al., 2005). As a result, the use of impregnation agents containing PFOA-related compounds is unnecessary (IPEN, 2016). However, it is admitted that this technology does not seem to be applied yet (Statens Forureningstilsyn, 2004; cited by Poulsen et al., 2005).
2. With regards to textiles tightly woven fabrics is one alternative non-chemical technology. Another technology is the so-called reverse osmosis membrane comprising extremely thin films manufactured out 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).
3. 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, 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 consisting totally of renewable material, 63% of which is obtained from plant-based, non-GMO raw materials (Ecotextile News, 2015; cited by Swedish Chemicals Agency, 2015).
4. 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).
5. With respect to textile finishes the company Chemours has developed the so-called Teflon EcoEliteTM finish, which is the first renewably sourced, non-fluorinated fabric treatment for durable water repellency and is manufactured with 60% renewably sourced raw materials. 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).

*Polymerization processing aid*

1. According to FluoroCouncil there are various alternative polymerization processing aids (PPA) used for replacing PFOA in the manufacture of fluoropolymers (FluoroCouncil, 2016a).
2. Three potential PFOA-alternatives with ether functionality (ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate (C3 Dimer salt), ammonium salt of 2,2,3-trifluoro-3-[1,1,2,2,3,3-hexafluoro-3-(trifluoromethoxy)propoxy]-propanoic acid (ADONA), and ammonium salt of perfluoro[(2-ethyloxy-ethoxy)acetic acid] (EEA-NH4)) that are generally shorter and/or less fluorinated are assessed (ECHA, 2015a, section C3). C3 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 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.
3. Toxicokinetic data of C3 Dimer salt indicate little or no metabolism, but rapid excretion. It is presumably not bioaccumulating and cleared unmetabolized within 2-7 days (mouse), 10-11 h (monkey) and 4-48 h (rat). C3 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 C3 Dimer salt it was concluded that the substance is probably not acutely toxic (LC/EC50 > 100 mg/L) or chronically toxic (NOEC > 1 mg/L) to aquatic organisms. Regarding all available information a full PBT assessment[[18]](#footnote-18) with consideration of the knowledge from the PFOA-PBT assessment cannot be performed. However, the registrant acknowledges in the CSR that the substance fulfils the P and the T criterion based on STOT RE 2. A high to very high mobility to ground water may lead to a lesser bioaccumulation potential than for PFOA. On the other side, PFOA is as well very water soluble and log Koc values are also in the range of 1 to 2.1. To conclude, the substance is likely to fulfil the PBT criteria of REACH Annex XIII as well (ECHA, 2015a).
4. With respect to ADONA it turned out that the substance is persistent, but not bioaccumulating. No data related to carcinogenicity were available. Concerning environmental risks (data were taken from the registration dossier) related to ADONA it was concluded that the substance is probably not acutely toxic (LC/EC50 > 100 mg/L) or chronically toxic (NOEC > 1 mg/L) to aquatic organisms. Regarding 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. 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 half-life of ADONA was between 12 and 34 days in the bodies of three workers, while it takes about four years in humans to clear half of the PFOA (The Intercept, 2016).
5. EEA-NH4 is considered persistent but not bioaccumulating. 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. Thus, the substance remains a PBT suspect. Provided data are not sufficient to conclude on not B (ECHA, 2015a).
6. An alternative PPA replacing APFO in the manufacturing of fluoropolymers exists. The alternative lies within the range of branched fluoro-ethers, which can be used for all products. The new PPA offers the same or enhanced performance and its manufacturing process will use low emission technology. Moreover, it is stated that the alternative is already registered and approved by authorities exhibiting a rapid bioelimination of 12-24 hours in various different animals and an improved toxicological profile compared to APFO (Van der Putte, 2010).

*Firefighting foams*

*Short-chain fluorinated alternatives*

1. IPEN highlighted that alternatives to the use of PFOA in firefighting foams exist. Chemical alternatives include fluorosurfactants with shorter chain length and C6-fluorotelomers, such as perfluorhexane ethyl 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 PFOA INF, 2017a) (IPEN, 2016).

*Non-fluorine containing alternatives*

1. A variety of fluorine-free Class B foams (e.g. protein-based or detergent-based firefighting 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 the sort of fire suppression, which is required at airports where high safety standards have to be fulfilled (Swedish Chemicals Agency, 2015).
2. With respect to firefighting foams it is estimated in a study (RPA, 2004) that the price 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 price would fall in case of an increased market size (Poulsen et al., 2005).
3. Manufacturers and 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. Some analysis confirmed that fluorine-free firefighting foams may offer less protection against re-ignition, which makes it a not acceptable alternative for some operations (Swedish Chemicals Agency, 2015). According to the Fire Fighting Film 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. To conclude, the FFFC does not support the opinion that AFFF agents are no longer needed and admits that AFFF should only be used 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).
4. 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 ICAO fire tests that determine the acceptability of foams for airport use in many countries (FFFC, 2017).

*Paper and food packaging*

*Short-chain fluorinated alternatives*

1. It was noted that alternative treatments of paper and cardboard used in packaging including short-chain telomer-based compounds have been identified, but no further information was provided (IPEN, 2016).
2. Archroma, a global leader in specialty chemicals, received FDA (US Food and Drug Administration) food contact approval for a new oil and grease resistance additive (Cartaguard KST), 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 new additive is based on a cationic C6-fluoropolymer and provides a strong and long lasting barrier to both grease and water. 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 (Archroma, 2015).

*Non-fluorine containing alternatives*

1. It was mentioned that at least one manufacturer (from Norway) has developed a fluorine-free alternative using a high-density paper, which prevents the passage of grease through it (Swedish Chemicals Agency, 2015). A survey conducted by the Norwegian Food Safety Authority in 2006 concluded that no fluorinated substances were used in fast-food packaging in Norway. 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 (IPEN 2016).

No alternative

*Imaging and printing industry*

1. According to I&P Europe PFOA-related substances were successfully replaced by non-perfluorinated chemicals, chemicals with short (C3-C4) perfluorinated chains, telomers, and reformulations. However, a small number of critical uses remains. PFOA-related substances are considered essential 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).
2. Based on information provided by stakeholders alternatives for PFOA-related substances have to provide an equivalent combination of surface-active properties that have not been found yet for a single class of chemicals (I&P Europe, 2016a). PFOA-related substances exhibit a lack of photoactivity (and thus do not interfere with the imaging process), promote uniformity of photo processing results (by controlling surface wetting properties), control splicing tape adhesion properties, are compatible with photo-retouching materials, improve camera, projector, and printer transport (to eliminate unwanted photographic effects) and prevent the formation of particles (that can clog magnetic strip readers) (I&P Europe, 2016a).
3. An estimation of costs with regards to the replacement of the remaining critical 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 uses in the imaging and photographic sector are considered prohibitive. In addition, the remaining critical uses are described as niche products in markets that I&P Europe members plan to diminish (I&P Europe, 2016a).

*Semiconductor industry*

1. Non PFOA-based alternatives appear to be available in the semiconductor industry for some non-critical applications, such as the uses as surfactants. However, some critical uses with respect to PFOA-related substances as a constituent material in process chemical formulations for very specialized application steps (e.g. for the photolithographic applications) remain. For those companies using PFOA within their critical photolithographic 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. (see SEMI, 2017).

Summary of alternatives

1. 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*

1. There is an increasing concern about risks related to short-chained PFASs in Europe (comment Norway 2017). These concerns are discussed due to the persistence, bioaccumulation and toxicity properties of these substances. As described in chapter 2.3.2 these substances are considered alternatives to PFOA for several applications (e.g. textile sector, fire-fighting foams, paper and food packaging). Often, these short-chain alternatives are less effective and higher quantities are required. 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.

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Sector** | **Use** | **Appropriate alternative available** | **Type of alternative** |
| Textile sector | Standard performance requirements (e.g. standard clothing) | Yes | Short-chain fluorinated products (e.g. C6-based); Non-fluorine containing products (e.g. paraffins); Non-chemical alternatives |
| High performance requirements (e.g. protective textiles) | No |  |
| Polymer manufacturing | Polymerization processing aid | Yes | Substances with ether linkage(s) between perfluoroalkyl moieties (e.g. ADONA) |
| Fire-fighting foams | Fighting against liquid fires | Yes | Short-chain fluorinated products (e.g. C6-based) |
| Paper and food packaging | Food packaging | Yes | Short-chain fluorinated products (e.g. C6-based); Non-fluorine containing products (e.g. high-density paper) |
| Imaging and printing industry | Manufacture of conventional photographic products | No |  |
| Semiconductor industry | Constituent in process chemical formulations (e.g. for photolithographic applications) | No |  |

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

Health, including public, environmental and occupational health

1. 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 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, restricting or prohibiting 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).
2. When assessing the human health and the environmental impacts of restricting PFOA, its salts and PFOA related compounds it is crucial to take the specific concerns of these substances as PBT substances into account. 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 exposure of humans and the environment 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 PBT substances remain uncertain. Therefore, the risk management of these substances is driven by scientific data and precautionary action in order to avoid the potentially severe and irreversible impacts resulting from continued emissions. It is evident that 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).
3. The EU proposal for a 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 proposed restriction is therefore expected to result in a net benefit to society in terms of human health impacts (ECHA, 2015a).
4. Canada prohibits PFOA and LC-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 LC-PFCAs. An improvement in environmental quality is expected from controlling these substances (Canada, 2016c).
5. Australia expects positive impacts from control measures related to avoided contamination of surface water, groundwater and drinking water and positive impact on public health (Australia, 2016; see also section 2.2.3).
6. According to European textile industry representatives, if the production in the EU and the import of essential protective textiles would be prohibited, many legal requirements and industry standards could no longer be met with the loss of these professional, technical protective textiles and result in risks for human health and the environment. Regarding professional, technical 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 protective textiles (see VTB SWT, 2016 and TM, 2016).
7. 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 substances 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 the ECHA, and determined not to pose a relevant risk to the environment or human health (I&P Europe, 2016a). Further restrictions on the ongoing uses in the photo imaging sector, would not have relevant health or environmental benefits.
8. According to FluoroCouncil, the development of alternative chemicals focused on finding substitutes with an improved product stewardship profile. Furthermore, exposure to and emissions of alternative chemicals can be reduced to their minimum levels by adopting stringent BEP and BAT throughout the entire value chain. FluoroCouncil member companies have invested in state-of-art emission control equipment to minimize any potential impact on workers and the environment, and have produced educational materials and programs to institute BAT/BEP downstream (FluoroCouncil, 2016a).

Agriculture, aquaculture and forestry

1. PFOA is present in sewage sludge which is sometimes applied to agricultural land. 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 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 PFAS, among them PFOA and related substances (Comment Germany 2017); 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 2.2.3). Therefore, restricting PFOA, its salts and related compounds would cause benefits for agriculture.

Biota (biodiversity)

1. 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 related compounds would positively impact on biota by decreasing emissions and subsequently exposure of biota.

Economic aspects

1. Cost competitive alternatives to PFOA that do not exhibit POPs characteristics have already been implemented in many countries. This indicates economic feasibility of 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).
2. 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 differ 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 also other PFAS, 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). Environmental contamination with PFOA and PFOA-related substances is also related to industrial activities according to examples e.g. from the U.S. and the Netherlands (Comment Norway, 2017). Norway refers to ongoing remediation of PFAS contaminated soil due to use of AFFF 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 2.2.3). PFAS compounds are found in Danish groundwater at several locations in Denmark. PFAS are present near specific industries / 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 approx. 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 fluorine surfactants (including PFOS and PFOA) have been found in groundwater in Sweden, especially in connection with the fire drill sites and in areas where fires have been extinguished. In some cases, the concentrations of fluorine surfactants have been so high that they have exceeded the action level of the National Food Agency in Sweden. As a consequence, wells and water utilities had to introduce new processing steps or had to stop operation (Swedish Chemicals Agency, 2017). Identification and management of contaminated sites and groundwater can cause significant costs which will be reduced in the future if PFOA and related substances will be restricted.
3. The regulatory proposals for PFOA restrictions 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).
4. PFOA, its salts and PFOA-related compounds are used in some semi-conductor 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, semi-conductor 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 proposed restriction would be disproportionate for the semiconductor manufacturing equipment industry (see comments SEMI, 2017).
5. According to industry representatives, a ban on fluorinated products leads to a substantial decline in economic and innovation power, which means that European textile companies lose their competitiveness (see VTB SWT, 2016; TM, 2016; Euratex, 2016). Norway states that the continued use of PFOA and PFOA-related substances 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 (Comment Norway 2017).
6. The photo imaging industry has been very successful at developing alternatives for most uses of PFOA-related substances, eliminating more than 95% of the worldwide use since 2000. However, the industry claims that the surfactant and static control properties of PFOA-related substances 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 substances, 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.
7. 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).

Movement towards sustainable development

1. Elimination of PFOA is consistent with sustainable development plans that seek to reduce emissions of toxic chemicals. The Strategic Approach to International Chemicals Management (SAICM) makes the essential link between chemical safety and sustainable development. The Global Plan of Action of SAICM contains measures to support risk reduction that include prioritizing safe and effective alternatives for persistent, bioaccumulative, and toxic substances. The Overarching Policy Strategy of SAICM aims to ensure, 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.
2. Industry representatives of the professional, technical 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).

Social costs (employment etc.)

1. IPEN considers that social costs associated with the elimination of PFOA are far outweighed by the health and environmental benefits (IPEN, 2016).
2. The proposal for a restriction in the EU is not expected to have major effects on employment, because for the vast majority of uses there are alternatives available that are implementable with a reasonable cost. In addition, as imported articles and mixtures will also be covered by the restriction relocation of production facilities to outside the EU are 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).
3. Regarding the professional, technical 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 protective technical textile industry in Europe (see VTB SWT, 2016 and EURATEX, 2016).

Other considerations

Access to information and public education

1. Several parties and observers have submitted information on the access to information and public education:
2. Monitoring Network in the Alpine Region for Persistent and other Organic Pollutants: http://www.monarpop.at/;
3. Environmental Agency Austria: http://www.umweltbundesamt.at/ummuki\_symposium/;
4. 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;
5. Information on the assessment and management of substances in Canada: http://www.ec.gc.ca/toxiques-toxics/default.asp?lang=En&n=97324D33-1;
6. 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;
7. Norwegian Environment Agency: http://www.environment.no/;
8. Access to data generated by FluoroCouncil members: https://fluorocouncil.com/Resources/Research;
9. German Federal Environment Agency: https://www.umweltbundesamt.de/;
10. Federal Institute for Occupational Safety and Health: <http://www.baua.de/de/Startseite.html>.
11. Swedish Chemicals Agency: Since PFAS contamination concerns many different stakeholder in the society and since many authorities are involved in taking and developing various measures, a web based guide has been developed. [www.kemi.se](http://www.kemi.se) (in Swedish).

Status of control and monitoring capacity

1. PFOA has been measured in various media e.g human blood and breast milk and in water, soil, sediment biota (fish). Monitoring data from the database of the Environment Agency Austria (EAA) were provided (more details see Austria, 2016a).
2. Perfluorinated substances including PFOA are part of the Danish monitoring of the aquatic environment. In the period from 2008-2012/13 PFASs have been included in monitoring of point sources and streams, lakes as well as marine areas. PFOS and PFOA are the most frequently detected perfluorinated compounds 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. In Denmark, PFOA is not routinely monitored in maternal milk or human blood. However, several Danish surveys have monitored PFASs including PFOA (Denmark, 2016).
3. PFOA and precursors were measured in indoor dust in Norwegian homes (Norway, 2016; referring to Bohlin-Nizzetto et al., 2015).
4. According to the Annex F submission of IPEN listing of PFOA in Annex A with no exemptions would be the most effective way since many countries do not have the required infrastructure to adequately monitor production and uses of PFOA (IPEN, 2016).

# Synthesis of information

## Summary of risk profile information

1. At its twelfth meeting the POPRC adopted the risk profile (UNEP/POPS/POPRC.12/11/Add.2) and decided that PFOA, 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. PFASs, which can be degraded to PFOA in the environment, are referred to as PFOA-related compounds.
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. PFOA-related compounds are used as surfactants and surface treatment agents (e.g. in textiles, paper and paints, firefighting foams) and for the manufacture of side-chain fluorinated polymers. 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).
3. 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 U.S. 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 contribute a major share to the releases of PFOA to the environment (UNEP/POPS/POPRC.12/11/Add.2).
4. 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).
5. 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. Other important sources appear to be coatings and firefighting foam. Based on the available information, it is not possible to definitively identify specific uses or PFOA-related substances that will not contribute to PFOA emissions, but 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 risk in relative terms) (ECHA 2015c). According to information provided by representatives of the semiconductor industry, 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 per 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 per year (see comments SEMI 2017).
6. Several parties and observers (Australia, Austria, Canada, Denmark, Monaco, Norway, India, Japan, Bavarian Textile and Apparel Association in cooperation with South-western Textile Association, Confederation of the German Textile and Fashion Industry, FluoroCouncil, Imaging and Printing Association Europe, International POPs Elimination Network, Semiconductor Industry Association) submitted additional information to Annex E related to production, use or releases. Annex E related submissions are compiled in a background document to the draft risk management evaluation (see PFOA INF, 2017a). Other available data on production, uses and releases are compiled in the risk profile (UNEP/POPS/POPRC.12/11/Add.2).”

## Summary of risk management evaluation information

1. Restricting or prohibiting PFOA, its salts and related compounds would positively impact human health and the environment by decreasing emissions and subsequently human and environmental exposure.
2. The control measure “Prohibition or restriction of production, use, import and export” may be achieved under the Convention by listing in Annex A or B. Listing under Annex A or B can be with or without exemptions and/or acceptable purposes.

*Summary of efficacy, efficiency and availability of appropriate alternatives*

1. Several exemptions have been included in the restriction proposal in the EU. Besides, Canada and Norway also include in their restrictions several exemptions. Some of the exemptions terminated at the end of 2016.
2. According to the information available for the analysis of alternatives, no technical and/or economically feasible alternatives exist for 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 (5 years after entry into force of the Regulation) for the equipment used to manufacture semiconductors is proposed in the EU. Further, in the EU an exemption without time limitation is proposed in 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. Time limited exemptions could be considered for equipment and related infrastructure used to manufacture semiconductors as well as for photo-lithography processes for semiconductors or in etching processes for compound semiconductors.
3. According to the information available for the analysis of alternatives for textiles, used for instance in the outdoor sector, alternatives are available.
4. According to the information available for the analysis of alternatives, no technical and/or economically feasible alternatives exist for technical textiles with high performance requirements. There are questions about PFOA use in textiles for the protection of workers from risks to their health and safety for which a time limited exemption (6 years after entry into force of the Regulation) is proposed in the EU. There are also questions related to 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 could be considered under the Stockholm Convention for technical textiles with high performance requirements in particular for (1) textiles for the protection of workers from risks to their health and safety and for (2) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment.
5. 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. Currently, for latex printing inks a time limited exemption (5 years after entry into force of the Regulation) is proposed in the EU. Canada had an exemption for water-based inks until 2016. The Norwegian restriction applies only to consumer products and does not restrict PFOA use in inks for professional printers. Depending on when restrictions 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.
6. Production of short chain fluorinated alternatives includes production of an unavoidable fraction of PFOA. The set of thresholds in the EU restriction proposal is based on information from industry and takes the currently unavoidable fraction of PFOA and PFOA-related substances during production of short-chain alternatives already into account. One option is for these substances to be re-processed as closed system site-limited isolated intermediates into production of shorter-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.”[[19]](#footnote-19) Therefore, an exemption for closed-system site-limited intermediates is not needed for substances listed under Annex A or B of the Stockholm Convention to allow such re-processing. Neither Norway nor Canada or the EU have specific exemptions on the production of short chain fluorinated alternatives in place. An exemption under the Stockholm Convention is not considered appropriate.
7. According to industry information, alternatives have not been developed for all pharmaceutical and some other highly specialized chemicals which use PFOA related chemicals as their raw material. However, there is no information specifying the term “other highly specialized chemicals”. No related exemptions are proposed in the EU, Norway or Canada at the moment. In addition, more than 100 countries agreed that environmentally persistent pharmaceutical pollutants are a global emerging policy issue in the SAICM context.[[20]](#footnote-20) An exemption for certain pharmaceutical chemicals and other highly specialized chemicals could be considered under the Stockholm Convention, however, more information on specific substances and sound justification would be required.
8. 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 critical uses remain in the photo imaging sector. Within the EU restriction proposal an exemption is proposed 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 restriction 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. An exemption could be considered under the Stockholm Convention for photographic coatings applied to films, papers or printing plates.
9. One company applying coating for smartphone manufacturers requested during the public EU stakeholder consultation an exemption for 3 years for pulsed plasma nano-coating in order to be able to move to an alternative C6 chemical. For plasma nano-coating a time limited exemption (6 years after entry into force of the Regulation) is proposed 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. Since only one EU company asked for an exemption for a short period of time, this use should be further evaluated before granting an exemption under the Stockholm Convention.
10. PFOA use in firefighting foams raises concerns because it is a dispersive, direct release to the environment. Alternatives to the use of PFOA in firefighting foams exist and include fluorosurfactants with shorter chain length and C6-fluorotelomers as well as fluorine-free solutions. Within the EU restriction proposal a limited exemption is proposed in order to provide an exemption for foams already in use. A transitional period for the use of foams already placed on the market is under discussion. In addition, Canada provides exemptions for PFOA containing aqueous film-forming foams used in firefighting application. The restriction in Norway does not apply since it concerns consumer products and AFFF are for professional use only. A time limited exemption for the use of PFOA in aqueous film-forming foams used in firefighting application under the Stockholm Convention should be considered and a time limited exemption for foams already placed on the market could be discussed in a global context.
11. Norway has an exemption in place for medical devices (no time limit). Within the EU restriction proposal a time limited exemption (15 years after entry into force of the Regulation) is proposed 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 proposed. The import, use, sale and offer for sale of medical devices containing PFOA, its salts or PFOA-related compounds are not restricted in Canada. An exemption (with or without time limit) for (1) the use for medical devices and (2) for production of implantable medical devices under the Stockholm Convention should therefore be considered.
12. Information on alternatives for the treatment of paper and cardboard used in food packaging indicates that appropriate alternatives are available. In the Norwegian restriction, 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 proposal 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.
13. Due to increasing concerns about risks related to short-chain alternatives (see para 143) 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.

*Summary of information on impacts on society*

1. Restricting or prohibiting PFOA, its salts and related compounds would positively impact human health and the environment including biota by decreasing emissions and subsequently human and environmental exposure. Further, restricting or prohibiting would provide benefits for agriculture by decreasing emissions and subsequently adverse effects on agricultural crops.
2. When assessing the human health and the environmental impacts of restricting PFOA, its salts and PFOA related compounds it is crucial to take the specific concerns of these substances as POP substances into account. The magnitude and extent of the risks of PFOA and PFOA-related substances as POP substances cannot be quantified, but global action is warranted. Therefore, the risk management of these substances is driven by scientific data and precautionary action in order to avoid the potentially severe and irreversible impacts resulting from continued emissions.
3. Based on the analysis of their characteristics, some of the available alternatives are expected to pose lower health risks than PFOA and PFOA-related substances. 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 restriction process, an improvement in environmental quality is expected from controlling these substances. The EU and the Canadian restriction approaches are considered to have moderate cost impacts because the market is already replacing PFOA and PFOA-related substances and because the restriction 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 restriction. 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.
4. 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.
5. Restricting or prohibiting PFOA, its salts and related compounds would reduce costs by decreasing contamination of surface water groundwater and soil and would thus reduce costs for 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 substances.
6. The 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 for instance recommends to use best available techniques and best environmental practice destruction technologies for wastes. In case destruction technologies are not available, safe storage has to be ensured. Within the medium-term, the POPRC recommends to carry out remediation activities in accordance with the “polluter-pays principle” with the aim to reduce risk.

## Suggested risk management measures

1. The control measure “Prohibition or restriction of production, use, import and export” may be achieved under the Convention by listing in Annex A or B as described in the concluding statement.

# Concluding statement

1. Having decided 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;
2. Having prepared a risk management evaluation and considering the management options and noting the information on the availability of alternatives;
3. **[**The Persistent Organic Pollutants Review Committee recommends, in accordance with paragraph 9 of Article 8 of the Convention, the Conference of the Parties to the Stockholm Convention to consider listing and specifying the related control measures of pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds
4. In Annex A with specific exemptions accompanied with a specific part of Annex A that details actions; or
5. In Annex B with acceptable purposes/specific exemptions accompanied with a specific part of Annex B that details actions. ]
6. **[**The Committee recommends to consider specifying exemptions for the following uses:
7. Equipment and related infrastructure used to manufacture semiconductors (time limited (Annex A));
8. Photo-lithography processes for semiconductors or in etching processes for compound semiconductors (time limited (Annex A));
9. Textiles for the protection of workers from risks to their health and safety (time limited (Annex A));
10. Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment (time limited (Annex A));
11. Aqueous film-forming foams used in firefighting application (time limited (Annex A)
12. Medical devices (time limited or not (Annex A/B));
13. Production of implantable medical devices (time limited or not (Annex A/B);
14. Photographic coatings applied to films, papers or printing plates (time limited or not (Annex A/B).

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1. In this document, the term “PFOA-related compounds” is used. 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. [↑](#footnote-ref-1)
2. DuPont, 1998. Technical information: Zonyl fluorochemical intermediates. [↑](#footnote-ref-2)
3. Fluoropolymers are carbon-only polymer backbone with F directly attached to backbone C atoms. [↑](#footnote-ref-3)
4. Such as PTFE (polytetrafluoroethylene), FEP (fluorinated ethylene propylene polymer) and PFA (perfluoroalkoxy polymer). [↑](#footnote-ref-4)
5. This statement may need to be updated. Most manufacturers using telomerization have stopped producing PFOA and related chemicals, e.g., DuPont, Dyneon (Comment Switzerland, 2017). [↑](#footnote-ref-5)
6. UNEP/POPS/POPRC.12/11/Add.2. [↑](#footnote-ref-6)
7. Details see p. 61 to 64 in (OECD, 2015). [↑](#footnote-ref-7)
8. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/and-polyfluoroalkyl-substances-pfass-under-tsca [↑](#footnote-ref-8)
9. The term “long-chain PFCs” means perfluorinated chemicals with more than eight perfluorinated carbon atoms. [↑](#footnote-ref-9)
10. UNEP/POPS/POPRC.5/10/Add.1. [↑](#footnote-ref-10)
11. The adopted restriction will be published in April or May 2017 in the Official Journal of the European Union. In the final version of the risk management evaluation a reference to the Official Journal will be provided. [↑](#footnote-ref-11)
12. The term “derogation” is used in EU chemicals legislation. It can be considered equivalent to the term “exemption” in the context of the Stockholm Convention. [↑](#footnote-ref-12)
13. 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. [↑](#footnote-ref-13)
14. see https://www.umweltbundesamt.de/sites/default/files/medien/355/dokumente/hbm\_i\_values\_for\_pfoa\_and\_pfos.pdf. [↑](#footnote-ref-14)
15. e.g. <https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf>. [↑](#footnote-ref-15)
16. http://www.ec.gc.ca/toxiques-toxics/default.asp?lang=En&n=E68CF568-1. [↑](#footnote-ref-16)
17. 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/>. [↑](#footnote-ref-17)
18. Assessment of the criteria persistence, bioaccumulation and toxicity according to the EU chemicals legislation (guidance see <https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf>). [↑](#footnote-ref-18)
19. See Stockholm Convention text, note (iii) of Part I of Annexes A and B. [↑](#footnote-ref-19)
20. See http://www.saicm.org/Meetings/ICCM4/tabid/5464/language/en-US/Default.aspx. [↑](#footnote-ref-20)