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

**Addendum to the adopted RISK MANAGEMENT EVALUATION**

(UNEP/POPS/POPRC.13/7/Add.2 from 16 November 2017)

**Draft for comment**

February 2018

**Contents**

[Executive Summary 4](#_Toc507148932)

[1 Introduction 7](#_Toc507148933)

[1.1 Overview of actions to date 7](#_Toc507148934)

[1.2 Structure of this document 8](#_Toc507148935)

[1.3 Data sources 8](#_Toc507148937)

[2 Chemical identity of PFOA, its salts and PFOA-related compounds 9](#_Toc507148938)

[2.1 Chemical identity according to the RME 9](#_Toc507148939)

[2.2 Possible exclusion of sulfluramid from the scope of the RME 9](#_Toc507148940)

[2.3 Possible exclusion of 1-H-PFO from the scope of the RME 11](#_Toc507148941)

[2.4 Inclusion of 8:2 fluorotelomer methacrylate, polymer with methyl methacrylate in the scope of the RME 12](#_Toc507148942)

[3 Information on unintentional formation and release 13](#_Toc507148943)

[3.1 Unintentional formation and release from incomplete combustion 13](#_Toc507148944)

[3.2 Unintentional formation and release from primary aluminium production 13](#_Toc507148945)

[3.3 Summary and conclusion related to unintentional formation and release 14](#_Toc507148946)

[4 Uses of PFOA, salts and PFOA-related compounds where further exemptions may be needed 15](#_Toc507148947)

[4.1 Introduction 15](#_Toc507148948)

[4.2 (a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment 15](#_Toc507148949)

[4.2.1 Introduction 15](#_Toc507148950)

[4.2.2 Efficacy and efficiency of possible control measures 15](#_Toc507148951)

[4.2.3 Information on alternatives 16](#_Toc507148952)

[Short-chain fluorinated alternatives 16](#_Toc507148953)

[Non-fluorine-containing alternatives 16](#_Toc507148954)

[Non-chemical alternatives 17](#_Toc507148955)

[4.2.4 Information on impacts on society 17](#_Toc507148956)

[4.2.5 Synthesis of Information 18](#_Toc507148957)

[4.2.6 Conclusion 18](#_Toc507148958)

[4.3 (b) Use of PFOI (perfluorooctane iodide) as intermediate to enable reprocessing at another site than the production site to TFE (tetrafluoroethylene) and HFP (hexafluoropropylene) 18](#_Toc507148959)

[4.3.1 Efficacy and efficiency of possible control measures 18](#_Toc507148960)

[4.3.2 Information on alternatives 21](#_Toc507148961)

[4.3.3 Information on impacts on society 21](#_Toc507148962)

[4.3.4 Synthesis of information 21](#_Toc507148963)

[4.3.5 Conclusion 21](#_Toc507148964)

[4.4 (c) Medical devices other than implantable devices 21](#_Toc507148965)

[4.4.1 Introduction 21](#_Toc507148966)

[4.4.2 Efficacy and efficiency of possible control measures 22](#_Toc507148967)

[Identification of uses for PFOA and PFOA-related compounds in medical devices 22](#_Toc507148968)

[Timescales foreseen for potential exemptions 23](#_Toc507148969)

[4.4.3 Information on alternatives 23](#_Toc507148970)

[4.4.4 Information on impacts on society 24](#_Toc507148971)

[4.4.5 Other considerations 24](#_Toc507148972)

[4.4.6 Syntheses of information 24](#_Toc507148973)

[4.4.7 Conclusion 25](#_Toc507148974)

[4.5 (d) Implantable medical devices 25](#_Toc507148975)

[4.5.1 Efficacy and efficiency of possible control measures 25](#_Toc507148976)

[4.5.2 Information on alternatives 25](#_Toc507148977)

[4.5.3 Information on impacts on society 26](#_Toc507148978)

[4.5.4 Syntheses of information 26](#_Toc507148979)

[4.5.5 Conclusion 26](#_Toc507148980)

[4.6 (e) Photo-imaging sector 27](#_Toc507148981)

[4.6.1 Introduction 27](#_Toc507148982)

[4.6.2 Efficacy and efficiency of possible control measures 27](#_Toc507148983)

[Paper and printing sector 27](#_Toc507148984)

[Use in developing countries 27](#_Toc507148985)

[Control measures 28](#_Toc507148986)

[4.6.3 Information on alternatives 28](#_Toc507148987)

[4.6.4 Information on impacts on society 28](#_Toc507148988)

[4.6.5 Syntheses of information 28](#_Toc507148989)

[4.6.6 Conclusion 29](#_Toc507148990)

[4.7 (f) Automotive industry 29](#_Toc507148991)

[4.7.1 Introduction 29](#_Toc507148992)

[4.7.2 Efficacy and efficiency of possible control measures 29](#_Toc507148993)

[4.7.3 Information on alternatives 31](#_Toc507148994)

[4.7.4 Information on impacts on society 31](#_Toc507148995)

[4.7.5 Syntheses of information 32](#_Toc507148996)

[4.7.6 Conclusion 32](#_Toc507148997)

[4.8 (g) Fire-fighting foams 32](#_Toc507148998)

[4.8.1 Introduction 32](#_Toc507148999)

[4.8.2 Efficacy and efficiency of possible control measures 33](#_Toc507149000)

[Stockpiles already placed to market 33](#_Toc507149001)

[Control measures for in-use stockpiles of PFOA fire-fighting foam 34](#_Toc507149002)

[4.8.3 Information on alternatives 35](#_Toc507149003)

[Short-chained fluorinated alternatives 35](#_Toc507149004)

[Non-fluorine containing alternatives 35](#_Toc507149005)

[4.8.4 Information on impacts on society 36](#_Toc507149006)

[4.8.5 Other considerations 37](#_Toc507149007)

[4.8.6 Syntheses of information 37](#_Toc507149008)

[4.8.7 Conclusion 38](#_Toc507149009)

[5 Synthesis of information 38](#_Toc507149010)

[5.1 Summary of information and concluding statement for uses 38](#_Toc507149011)

[5.2 Discussion on listing in Annex A/B 44](#_Toc507149012)

# Executive Summary

1. In June 2015 the European Union (EU) and its member States submitted a proposal to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and   
   PFOA-related compounds[[1]](#footnote-2) in Annexes A, B, and/or C to the Stockholm Convention (UNEP/POPS/POPRC.11/5). At its twelfth meeting in September 2016, the Persistent Organic Pollutants Review Committee (POPRC) concluded that PFOA is persistent, bioaccumulative and toxic to animals including humans. There is widespread occurrence of PFOA and a number of PFOA-related compounds in environmental compartments and in biota and humans. Therefore, PFOA, its salts and PFOA-related compounds that degrade to PFOA are likely, as a result of their long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action is warranted (UNEP/POPS/POPRC.12/11/Add.2).
2. At its thirteenth meeting in October 2017, the POPRC adopted the risk management evaluation (RME) on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2) and recommended to the COP that it consider listing the chemicals in Annex A or B to the Convention with specific exemptions specified in decision POPRC-13/2 (also in UNEP/POPS/POPRC.13/7/Add.2 para 13). However, the members of the POPRC were unable to reach conclusions on whether exemptions may be needed for specific uses. Furthermore, additional work was needed to consider the possibility of unintentional releases and specific issues related to substance identity.
3. The Committee also invited Parties and observers to provide information that would assist the Committee to further evaluate the chemical identity of PFOA-related compounds chemical list and the possible exclusion of sulfluramid and 1-H-PFO from the scope of the RME. Sulfluramid is manufactured by using PFOSF as an intermediate. From a structural point of view, sulfluramid is related to PFOS. In the environment it degrades in significant yields to PFOS based on experimental evidence. However abiotic transformation to PFOA may occur. Therefore, sulfluramid should be covered under the listing of PFOS, its salts and PFOSF of the Stockholm Convention rather than under the listing of PFOA. Based on the further information submitted, 1-H-PFO should not be excluded from the scope of PFOA related substances since studies with a structural similar substance suggest that a transformation to PFOA is possible.
4. The RME identified that PFOA could potentially be unintentionally formed from incomplete combustion and primary aluminium production but that further information was needed on this topic. Information on unintentional formation and release of PFOA, its salts and PFOA was only provided by two observers to the Convention (IPEN and ACAT). However, the information provided substantiated information detailed in the RME for releases of PFOA from incomplete combustion sources. Additional information and preferably also measurements / quantitative data from other incinerators would be desirable to justify a possible listing of PFOA, its salts and PFOA-related compounds in Annex C based on more specific evidence. No new information on unintentional releases of PFOA linked to aluminium production were provided. Most of the information identified in literature and detailed in the RME relates to emissions of CF4 and C2F6, which are unrelated to PFOA. From the currently available information it is not possible to conclude that aluminium production represents a relevant source of PFOA releases to the environment.
5. According to the RME, time limited exemptions could be considered for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. Specific information on membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment has been provided by Canada, IPEN and ACAT. Furthermore, relevant information has been identified in the submissions from HCWH Europe (Health Care Without Harm) and MedTech Europe related to medical devices. However, specific information on the scope of the applications, used amounts, non-availability of alternatives and socio-economic aspects is still lacking and the information reviewed does not substantially help to enable the Committee to evaluate whether there is a specific need for an exemption. Based on the evaluation of available information a time limited exemption could be considered for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. This, however, depends on whether additional information will be made available by the industry.
6. For transported isolated intermediates, an exemption without time limit is foreseen in the EU restriction according to its paragraph 4(c), provided that specific conditions are met. Therefore, the need for an exemption should be assessed under the Stockholm Convention to enable reprocessing in another site than the production site. The Committee requested information related to the quantities used, extent of transport and possible risks, and use. Additional information was submitted by IPEN and ACAT and Archroma (a member of FluoroCouncil), where Archroma provided relevant information about the processing. IPEN and ACAT suggest that the POPRC should not recommend an exemption for non-site-limited isolated intermediates on the basis that this would undermine the Stockholm Convention text. This specifically allows exemptions for on-site isolated intermediates only. Based on the evaluation of available information a time limited exemption could be considered for PFOI as an isolated intermediate to enable reprocessing at another site than the production site for the production of TFE and HFP, if additional relevant information about the specific volumes of the PFOI-containing fraction, release quantities and possible risks and risk management measures are made available which enable the Committee to properly evaluate the need for an exemption.
7. Information was also specifically requested on applications/uses and timelines foreseen as needed for potential related exemptions for medical devices. The European restriction (EU 2017/1000) allows an exemption for all medical devices (excluding implantable medical devices, which have a non-time limited exemption) of 15 years. A report by ECHA (2015a) as part of the European restriction estimates total quantities in use for medical devices amounts to <5kg of PFOA globally. Medtech (2018) and Euromed (2015) both highlighted the difficulty in producing detailed lists of specific applications within healthcare due to the diverse ways in which PTFE is used, though alternatives for PFOA and PFOA-related compounds in medical devices are already available. However, due to the stringent regulations for substitution in the healthcare sector, if changes are made to articles this can trigger the need for a new round of clinical trials (taking years to complete). Based on the information compiled and discussed within the RME (UNEP/POPS/POPRC.13/7/Add.2) and further elaborated upon within the current addendum, a time-limited exemption may be needed for medical devices to prevent loss of critical applications. However further detail on specifically which applications are critical is needed for further resolution.
8. According to the RME, an exemption with or without time limit for the production of implantable medical devices under the Stockholm Convention, should be considered. Quantities of PFOA and PFOA-related substances used in implantable medical devices (largely in the form of PTFE) are small (20g in the EU and 100g worldwide) and concentrations are low in the final product (PFOA in PTFE is stated to range from 0.001 to 0.5%). Limited additional information has been provided on the extent of transport, risks and socio-economic impacts of a possible restriction however the low quantities presently being used in implantable medical devices would also mean low potential for exposure. Similarly, additional information on the use of PFOA in medical implants in developing countries is unknown. A time-limited exemption for this use should be considered.

At POPRC-13, industry provided information for the RME that suggested time-limited exemptions for photographic coatings applied to paper and for use in printing are no longer needed. Non-perfluorinated alternatives have successfully replaced some uses in the imaging and printing industry and the move to digital imaging will replace the need for PFOA. I&P Europe (2016) comment that use of PFOA compounds in photo imaging has decreased globally by 95% since 2000 and only limited critical applications still use PFOA. However, it was also noted that for developing countries, such information was lacking. New information provided by the Netherlands (2018), IPEN and ACAT (2018) and Healthcare Without Harm (HCWH, 2018) indicates that analogue printing is being phased out and replaced rapidly by digital, including in developing countries. However, critical uses for military and medical applications with high photosensitivity remain at risk if current conventional photographic products in the paper and print sector become restricted. No chemical alternative currently exists largely due to the economic cost and time investment necessary for development in what is a small commercial use sector and this is likely to result in phase out of products before an alternative can be found. Based on the anticipated transition towards digital imaging and the further reduction in use of PFOA in this sector, no exemptions for paper and printing should be considered necessary. However, the members of the POPRC could consider a specific time-limited exemption for specific named applications only, such as medical and military sectors.

1. According to the RME, an exemption for automotive service and replacement parts could be considered under the Stockholm Convention. However, specification of relevant automotive service and replacement parts as well as sound justification for any exemption is required. Relevant information was submitted by the Canadian Vehicles Manufacturing Industry (CVMA) and IPEN and ACAT. Furthermore Canada (2018) indicated that the drafters should look at paragraphs 79, 89 and 232 of the RME as being relevant to the addendum. Based on the evaluation of updated information a time limited exemption seems not necessary for automotive service and replacement parts. This, however, depends on whether additional information will be made available by the automotive industry, in particular the specificity of the use of PFOA compounds in North America compared to other regions of the world.
2. Firefighting foams were identified as a key use of PFOA in the RME. The Secretariat requested additional information to be provided on chemical composition of mixtures and the volumes of pre-installed amount of firefighting foam mixtures globally. Information was provided by Belarus (2018), Netherlands (2018), Sweden (2018), the Fire-Fighting Foams Coalition (FFFC, 2018), and IPEN and ACAT (2018) as a joint submission. Only limited information on the existing stockpiles of PFOA based fire-fighting foams was available. A report by ECHA (2015a) estimated 50 – 100 tonnes of a PFOA-related compound (CAS No: 70969-47-0, C8-C20-ω-perfluoro telomer thiols with acrylamide) within foam concentrates present across Europe in 2014. The FFFC (2018) provided estimates for PFOS based foams in the USA, assuming similar magnitude for PFOA based foams. In 2011 this included 3.3 million gallons (12.5 million litres) of concentrates with a PFOS concentration at 1–6% wt/wt. Seow (2013) comments that in 2007, 14 tonnes of perfluorocarboxylic acid (PFCA) based foam was imported into Australia, this included 1.3 tonnes of PFOS based foams. No further disaggregation for PFOA based foams was provided. Data on other regions was not identified. Alternatives to all uses of PFOA in fire-fighting foams exist and include fluorine-free solutions as well as fluorosurfactants with C6-fluorotelomers, however only limited information exists to quantify PFOA-based fire-fighting foams already placed on the market. Under the USEPA stewardship program eight major manufacturers based in Japan, Europe and North America agreed to the phase-out of long chain perfluoro compounds (including PFOA). Wang et al (2014) also note that new manufacturers in Asia (primarily India and China) have subsequently begun PFOA manufacture, although largely to meet demands for fluoropolymers such as PTFE. Overall the costs associated with destruction and replacement can be perceived to be significant, one estimate by Seow (2013) quotes $1 AUD/ 1.5E per litre of concentrate. However, costs associated with clean-up for sites contaminated by perfluorinated compounds are also significant, with examples quoted in the RME as millions of euros per site. IPEN (2018) commented that the life span of foams varied depending on climate and storage and therefore a 20–year derogation would not be acceptable for the Stockholm Convention. The FCCC (2016) state that foams do not have an expiry date but have a shelf life of 10–25 years. Based on the information compiled and reviewed within the RME, the size of in-use stockpiles may be significant and socio-economic impacts of an immediate ban may be equally significant, a time-limited exemption is therefore warranted. However, the impacts of release to ground water and socio-economic costs of clean-up mean that efforts should be made to phase out as soon as possible. Therefore, the time-limited exemption should reflect this
3. Based on the review of information within the RME and elaborated on in the addendum, only time-limited exemptions are envisaged. Furthermore, within the European restriction (EU 2017/1000) only one non-time limited exemption exists (implantable medical devices). Medtech (2018) commented that a transition period up to 2030 would be needed for implantable medical devices, suggesting that a time-limited exemption would be sufficient. Therefore, in accordance with paragraph 9 of Article 8 of the Convention, the Conference of the Parties to the Stockholm Convention should consider listing and specifying the related control measures of PFOA, its salts and PFOA-related compounds: (a) In Annex A, with specific exemptions accompanied if needed with a specific part of Annex A that details actions.

# Introduction

Overview of actions to date

1. In June 2015, the European Union (EU) and its member States submitted a proposal to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and   
   PFOA-related 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 Committee adopted the risk profile (UNEP/POPS/POPRC.12/11/Add.2) and decided to establish an intersessional working group to prepare a risk management evaluation dossier (RME) 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. By decision POPRC-13/2, the Committee adopted the RME on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2) and decided, in accordance with paragraph 9 of Article 8 of the Convention, to recommend to the Conference of the Parties that it consider listing PFOA, its salts and PFOA-related compounds in Annex A or B to the Convention with specific exemptions for the following:

(a) For five years from the date of entry into force of the amendment in accordance with Article 4:

(i) Manufacture of semiconductors or related electronic devices:

a. Equipment or fabrication plant related infrastructure containing fluoropolymers and/or fluoroelastomers with PFOA residues;

b. Legacy equipment or legacy fabrication plant related infrastructure: maintenance;

c. Photo-lithography or etch processes;

(ii) Photographic coatings applied to films;

(iii) Textiles for oil and water repellency for the protection from dangerous liquids for the protection of workers from risks to their health and safety;

(b) For ten years from the date of entry into force of the amendment for manufacture of semiconductors or related electronic devices: refurbishment parts containing fluoropolymers and/or fluoroelastomers with PFOA residues for legacy equipment or legacy refurbishment parts;

(c) For use of perfluorooctane iodide, production of perfluorooctane bromide for the purpose of producing pharmaceutical products with a review of continued need for exemptions. The specific exemption should expire in any case at the latest in 2036.

1. .
2. The Committee invited Parties and observers, including the relevant industries, to provide, by 12 January 2018, information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds in particular in the following applications:

(a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment: information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects;

(b) Transported isolated intermediates in order to enable reprocessing in another site than the production site: information on the quantities used, extent of transport and risks, and use;

(c) Medical devices: information on specific applications/uses and timelines foreseen as needed for potential related exemptions;

(d) Implantable medical devices: information on the quantities used, extent of transport and risks, and use;

(e) Photo imaging sector: information on paper and printing, and information relevant for developing countries;

(f) Automotive industry: information on spare parts;

(g) Firefighting foams: information on chemical composition of mixtures and the volumes of pre-installed amount of firefighting foam mixtures.

1. For the applications above, information regarding socio-economic aspects as well as other relevant information is also welcomed.
2. Furthermore, the Committee invited Parties and observers to provide, information that would assist the Committee to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds, in particular from primary aluminium production and from incomplete combustion. Finally, the Committee invited Parties and observers to provide information that would assist the Committee to further evaluate the chemical identity of PFOA-related compounds chemical list.

This document represents an *addendum* to the adopted RME of PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2) considering the information received from parties and observers. The RME will not be re-opened. To aid readers, the present document addendum to the RME contains references to the RME and repeats selected essential details from the RME (in italics). Structure of this document

1. For ease of reference this document has been set out in a chronological fashion to answer the questions set out by the Secretariats request for new information. Section 2 will provide an overview of information on substance identity. Section 3 will provide information on unintentional releases, and section 4 will provide information on each of the seven uses identified by the Secretariats information request in the RME. To provide as complete a narrative as possible and for ease of reference, where necessary sections of the RME have been included in the addendum. Where this is the case, text will be marked in italics to clearly denote text taken directly from the RME.

Data sources

1. The addendum to the RME is primarily based on information that has been provided by Parties to the Convention and observers. Information was submitted by the following Parties:
2. Parties: Belarus, Brazil, Canada, Ecuador, Monaco, Netherlands, Philippines, Sweden and United Kingdom;
3. Observers: Associação brasileira dos fabricantes de iscas inseticidas (ABRAISCA), FluoroCouncil (Archroma), Canadian Vehicles Manufacturers’ Association (CVMA), Fire Fighting Foam Coalition, Health Care Without Harm, Medtech Europe, and joint submission by International POPs Elimination Network (IPEN), and Alaska Community Action on Toxics (IPEN/ACAT).
4. In addition to the above-mentioned references and comments received from Parties and observers, information has been used from additional open information sources as well as scientific literature (see list of references). The following key references were used as a basis to develop the RME addendum:
5. The RME for PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2);
6. Supporting information related to the draft RME on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/INF/6)
7. Additional information in relation to the RME of PFOA, its Salts, and Related compounds; Prepared by ETH Zurich on behalf of the Swiss Federal Office for the Environment (FOEN); 2017
8. The non-exhaustive list of substances covered or not covered by the RME is also provided (UNEP/POPS/POPRC.13/INF/6/Add.1)

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

1. The Committee invited Parties and observers to provide information that would assist to further evaluate the chemical identity of PFOA-related compounds chemical list. Relevant information has been submitted by The Brazilian Ministry of Agriculture (Brazil, 2018) and ABRAISCA (2018) (Brazilian association of manufacturer of insecticides) and the Fluoro Council (FluoroCouncil, 2018). No additional information is available for submission from Canada on the chemical identity of PFOA except from the information already presented in the risk profile and RME (Canada, 2018).

Chemical identity according to the RME

1. The chemical identity and related details are outlined in section 1.1 of the RME (UNEP/POPS/POPRC.13/7/Add.2). The following paragraphs in italics are copied from the RME:
2. PFOA, its salts and PFOA-related compounds fall within a family of perfluoroalkyl and polyfluoroalkyl substances (PFASs). Perfluorinated acids, like PFOA, are not degradable in the environment and in biota (including humans). Certain polyfluorinated substances can be degraded to persistent perfluorinated substances like PFOA under environmental conditions and are therefore precursors. Those PFASs that can be degraded to PFOA in the environment and in biota are referred to as PFOA-related compounds.
3. The RME covers:
4. PFOA (pentadecafluorooctanoic acid, CAS No: 335-67-1, EC No: 206-397-9) including any of its branched isomers;
5. Its salts; and
6. 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 based perfluoroalkyl side chains;*[[2]](#footnote-3)*
   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-4)* that are covered by CF3[CF2]n-R’, where R’=any group, n>16;*[[4]](#footnote-5)*
3. Perfluoroalkyl carboxylic and phosphonic acids (including their salts, esters, halides and anhydrides) with ≥8 perfluorinated carbons;
4. Perfluoroalkane sulfonic acids (including their salts, esters, halides and anhydrides) with ≥9 perfluorinated carbons;
5. Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) as listed in Annex B to the Stockholm Convention.
6. To assist the identification of PFOA-related compounds a non-exhaustive list of substances covered or not covered by the RME is provided in UNEP/POPS/POPRC.13/INF/6/Add.1.

Possible exclusion of sulfluramid from the scope of the RME

1. Sulfluramid is manufactured by using PFOSF as an intermediate and is the active ingredient in the manufacture of ant baits and ready-to-use formulations. The use of sulfluramid represents a direct release of PFOS to the environment as 10% of the substance degrades to PFOS (UNEP/POPS/POPRC.3/20/Add.5). Brazil has notified the production and use of PFOSF for the acceptable purpose “insect baits for the control of leaf-cutting ants from *Atta spp*. and *Acromyrmex spp”*.[[5]](#footnote-6) Regarding baits used in Brazil, baits with sulfluramid represent more than 95% (UNEP/POP/POPRC.4/15/Add.6).
2. Brazil (2018), submitted their position related to the inclusion of sulfluramid as PFOA-related compound. According to Brazil (2018), sulfluramid should be excluded from the list of PFOA-related compounds until conclusive information has been obtained. The main concern expressed is that sulfluramid is a compound related to PFOS, it salts and PFOSF and the use of this substance is already covered by the Stockholm Convention as acceptable purpose in Annex B (decision SC-4/17). Besides, the information regarding sulfluramid is consolidated as part of the process for evaluation of the continued need of PFOS, it salts and PFOSF for the various acceptable purpose and specific exemptions in accordance with paragraph 5-6 of part III of Annex B to the Convention. Further, Brazil (2018) states that the inclusion of the substance in the PFOA list took place without extensive discussion and with no technical justification and that papers were cited as justification for the inclusion, which would not be conclusive and would not reflect the conditions that occur in the environment. It would therefore not be possible to conclude, based on this information only, that sulfluramid degrades to PFOA, nor that sulfluramid is a PFOA related compound (Brazil, 2018).
3. The exclusion of sulfluramid from the non-exhaustive list of substances is also supported by ABRAISCA (2018), stating that sulfluramid is a perfluoalkyl sulfonate compound, and not a perfluoroalkyl carboxylate such as PFOA. Thus, according to ABRAISCA, sulfluramid should be in the list of compounds that do not degrade in PFOA. It is known that sulfluramid could be a PFOS related compound and that the production of sulfluramid is obtained from PFOSF.
4. ABRAISCA has submitted a report which in their view demonstrates technical inconsistency of the papers submitted to the working group at POPRC-13 (ABRAISCA, 2018). In the report ABRAISCA submitted commented summaries of peer reviewed studies related to the reactivity of perfluoro alkane sulfonamides (i.e. Martin et al., 2006, D´eon et al., 2006, Plumlee et al., 2009 and Liu et al., 2017).
5. Martin et al. (2006) investigated the possibility that perfluoro octane sulfonamides which are present in the atmosphere and may, via atmospheric transport and oxidation, contribute to perfluorocarboxylic acid (PFCA) and PFOS pollution in remote locations. According to the authors, their results suggest a plausible route by which perfluoro octane sulfonamides may serve as atmospheric sources of PFCAs, including PFOA (Martin et al. 2006). According to ABRAISCA, results from Martin et al. (2006) do not represent atmospheric conditions. In addition, it is criticised that *N*-ethyl-perfluoro butane sulfonamide was used as target material to investigate the gas phase reactivity of perfluoro alkane sulfonamides in the presence of radicals, and not the relevant substance, which has a different volatility (see ABRAISCA, 2018). Even if the experimental conditions were not representative for environmental conditions, Martin et al. (2006) provide scientific evidence that the degradation of perfluoro octane sulfonamides (such as sulfluramid) to PFOA cannot be excluded.
6. The results of D´eon et al. (2006) indicate that N-methyl perfluorobutane sulfonamidoethanol may contribute to the burden of perfluorinated contamination in remote locations. It appears that anthropogenic production of N-methyl perfluoro octane sulfonamidoethanol contributes to the ubiquity of perfluoroalkyl sulfonate and carboxylate compounds in the environment (D´eon et al., 2006). According to ABRAISCA, the results from this study investigating the formation of PFCAs from N-methyl-perfluoro butane sulfonamide ethanol cannot be transferred to perfluoroalkane sulfone amides (such as sulfluramid), which have no hydroxyethyl group attached to a nitrogen atom. According to ABRAISCA this hydroxyethyl group leads to a higher reactivity compared to N-alkyl-perfluoro sulfonamides (ABRAISCA, 2018). Even if the hydroxyethyl group in N-methyl perfluorobutane sulfonamidoethanol leads to a higher reactivity compared to N-alkyl-perfluoro sulfonamides, it cannot be excluded that PFCAs are formed from N-alkyl-perfluoro sulfonamides.
7. Plumlee et al. (2009) irradiated selected perfluorinated surfactants in aqueous hydrogen peroxide solutions using artificial sunlight to study transformation under aquatic environmental conditions. Indirect photolysis mediated by hydroxyl radical was among other observed for sulfluramid. ABRAISCA noted with regard to the study by Plumlee et al. (2009), that the conditions used in the study do not represent environmental conditions. Further, ABRAISCA stated that the formation of perfluoro octane sulfonamide from sulfluramid is by far more favourable than the formation of PFOA (see ABRAISCA, 2018). Even if the experimental conditions were not representative for environmental conditions, Plumlee et al. (2009) provide scientific evidence that the degradation of sulfluramid to PFOA cannot be excluded.
8. Liu et al. (2017) analysed PFOS and PFOA release into the environment in the central and eastern region of China, which accounts for the vast majority of national emission. According to the authors PFOS and PFOA were released to the environment as impurities in sulfluramid. The environmental release of PFOS has been estimated to be 2.6 t/a while the release of PFOA from this source was calculated to be 1.4 t/a based on the annual consumption of sulfluramid, and the transformation rate to PFOA and PFOA content as impurities in sulfluramid (Liu et al., 2017). Regarding this study, ABRAISCA noted that PFOS and PFOA are not present as contaminants in sulfluramid provided that it is synthesized by applying correct experimental procedures. Additionally, ABRAISCA mentioned that annual emissions of PFOS and PFOA from sulfluramid-based pesticides are overestimated and that data regarding degradation rates are missing. Further ABRAISCA stated that no new experimental scientific evidence is presented and that the study should be seen as a modeling paper to estimate emissions (see ABRAISCA, 2018).
9. Regarding the comments from ABRAISCA (2018) with respect to the question whether sulfluramid is a PFOA-related compound, it can be stated that two of the studies (Martin et al., 2006 and Plumlee et al., 2009), though under experimental conditions which are not representative for environmental conditions, provide scientific evidence that sulfluramid can degrade to PFOA and could thus be considered a PFOA related compound. The question whether sulfluramid can degrade to PFOA under environmental conditions is not conclusively clarified.
10. Sulfluramid is manufactured by using PFOSF as an intermediate and is the active ingredient in the manufacture of ant baits and ready-to-use formulations. The use of sulfluramid represents a direct release of PFOS to the environment as 10% of the substance degrades to PFOS (UNEP/POPS/POPRC.3/20/Add.5). Brazil has notified the production and use of PFOSF for the acceptable purpose “insect baits for the control of leaf-cutting ants from *Atta spp*. and *Acromyrmex spp”*.[[6]](#footnote-7) Regarding baits used in Brazil, baits with sulfluramid represent more than 95% (UNEP/POP/POPRC.4/15/Add.6).
11. Sulfluramid has the potential to degrade to PFOA under certain conditions, it can be considered a PFOA-related compound. However, it has to be recognised that, from a structural point of view, sulfluramid is more comparable to PFOS (both consist of a C8F17SO2-unit) than to PFOA and that thus degradation of sulfluramid to PFOS is more likely. Zabaleta et al. (2018) investigate the importance of sulfluramid as a source of environmental PFOS. The authors conclude on the one hand, that observed formation of PFOA is not a result of degradation from sulfluramid, but rather due to the presence of N-ethylperfluorooctanamide, which is known to occur as an impurity in sulfluramid. On the other hand, the experiments performed in the presence of carrot produced PFOS yields of up to 34 % using a technical sulfluramid standard. According to the authors, the data suggest that in the natural environment (and in particular in the presence of a vegetable crop), yields of PFOS from sulfluramid may be considerably higher than 4%.
12. Sulfluramid is manufactured by using PFOSF as an intermediate. From a structural point of view, sulfluramid is related to PFOS. Sulfluramid does not fall under the definition of perfluorooctane sulfonic acid (CAS No: 1763-23-1), its salts and perfluorooctane sulfonyl fluoride (CAS No: 307-35-7) as set out in decision SC-4/17. In the environment it degrades in significant yields to PFOS. However abiotic degradation to PFOA via photo-oxidation may occur given that volatilization of sulfluramid from moist soil surfaces is expected to be an important fate process (HSDB database). Therefore, sulfluramid should be covered under the listing of PFOS, its salts and PFOSF of the Stockholm Convention rather than under the listing of PFOA.

Possible exclusion of 1-H-PFO from the scope of the RME

1. The status of 1-H-PFO (1-Hydroperfluorooctane, CAS No: 335-65-9) as a PFOA related substance is questioned by FluoroCouncil (FluoroCouncil, 2018). Currently, all substances with the formula C8F17–X are considered PFOA-related substances except if the X consists in either Fluorine, Chlorine or Bromine (i.e. C8F17-F, C8F17-Cl or C8F17-Br) ending. As a result, 1-H-PFO is considered a PFOA-related compound. FluoroCouncil (2018) argues that C8F17-H (1-H-PFO) is even less accessible to biological and chemical degradation compared to the exempted molecules C8F17-Cl and C8F17-Br. FluoroCouncil further states that 1-H-PFO has comparable temperature and chemical inertness to the fully fluorinated perfluorooctane C8F18 and that the C8F17-H structure and excellent thermal stability which shows no evidence of degradation to PFOA under foreseeable conditions. 1-H-PFO’s transformation into PFOA would require the loss of the hydrogen as well as two Fluor atoms on the carbon (see Figure 2.1). FluoroCouncil states that this has never been observed considering the remarkable stability of the C-F bond and the fact that the hydrogen is surrounded by 3 large atoms of Fluor (FluoroCouncil, 2018).

Figure 2.1 chemical structure of 1-H-PFO and PFOA



1. FluoroCouncil argues that 1-H-PFO should not be considered a PFOA-related compound (see section 4.3 on transported isolated intermediates). FluoroCouncil believes that the scientific basis for the status of 1-H-PFO as PFOA-related compound should be further investigated (FluoroCouncil, 2018).
2. As the FluoroCouncil pointed out, there is some evidence that 1-H-PFO is relatively stable. However, Chen et al. (2003) showed that CF3CF2CF2CF2CF2CHF2 can react with OH radicals over the temperature range -23 to 156°Celsius (reported in Chen et al as Kelvin: 250-430 K). This shows for a shorter-chained HFC compound with a -CHF2 moiety that a H-abstraction reaction by OH radicals takes place and the carbon-oxygen bond degrades. Young et al. (2009) showed that PFCAs can be formed from atmospheric reactions of CF3CF2H and CF3CF2CF2CF2H in absence of NOx. Accordingly, HFCs with the –CHF2 moiety (e.g., HFC-329ccb and HFC 52-13p) can react with OH radicals and form a perfluoroalkyl radical [CF3(CF2)n•],which can further react to form PFCAs (under low NOx conditions) (see Wang et al. 2014). These results suggest that a transformation from 1-H-PFO to PFOA is possible. Specific data for the transformation of 1-H-PFO to PFOA is not available.
3. In conclusion, 1-H-PFO should not be excluded from the scope of PFOA-related compounds since scientific evidence indicates that a transformation to PFOA is possible.

Inclusion of 8:2 fluorotelomer methacrylate, polymer with methyl methacrylate in the scope of the RME

1. Based on information submitted by Australia (2018), 8:2 fluorotelomer methacrylate (CAS No: 93705-98-7), polymer with methyl methacrylate could be included to the list of non-exhaustive substances. According to the information contained in the submission, a NICNAS assessment under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework concluded that PFOA is expected to be the major product of environmental biodegradation for the following five long-chain fluorinated chemicals on the Australian Inventory of Chemical Substances (AICS) (NICNAS undated): CAS No: 678-39-7 (8:2 fluorotelomer alcohol), CAS No: 1996-88-9 (8:2 fluorotelomer methacrylate), CAS No: 93705-98-7 (8:2 fluorotelomer methacrylate, polymer with methyl methacrylate); CAS No: 68187-42-8 (Propanamide, 3-[(.gamma.-.omega.-perfluoro-C4-10-alkyl)thio] derivatives) and CAS No: 53515-73-4 (7:1 fluoroalcohol methacrylate, polymer with acrylic acid). The remaining 4 chemicals indicated are already included in the list of non-exhaustive substances.
2. In conclusion, (CAS No: 93705-98-7), polymer with methyl methacrylate should be included to the non-exhaustive list of substances.

# Information on unintentional formation and release

1. The Committee invited Parties and observers to provide information that would assist to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds from incomplete combustion and primary aluminium production. Relevant information in response to the request for information was only submitted by IPEN and ACAT (2018). The United Kingdom (2018) stated that PFOA is not a substance that is reported within the UK’s Pollution Inventories, and therefore no relevant data on its releases is available. The same also applies to emissions from primary aluminium production (United Kingdom, 2018). No additional information (in addition to the already included information in the RME) is available from Canada (Canada, 2018).

Unintentional formation and release from incomplete combustion

1. During the development of the RME, Switzerland supplied information on unintentional formation of PFOA from inadequate incineration of fluoropolymers with inappropriate incineration or open burning facilities at moderate temperatures. Recent studies have been summarized*, showing measurable amounts of PFOA and a wide range of other PFCA homologues that can be generated during the thermolysis of PTFE (polytetrafluoroethylene) at temperatures between 250 and 600°Celsius. It has been concluded that this may be particularly relevant for developing countries and countries in transition, where wastes are often not incinerated to sufficiently high temperatures and without proper treatment of flue gases* (FOEN, 2017).
2. High temperature incineration (e.g., at 1000°C) is effective to destroy PFOA and to prevent the formation of PFOA from the thermolysis of highly fluorinated polymers. It is however, currently unclear to what extent formation of PFOA may occur in municipal waste incinerators where (1) flue gases may reach temperatures of 850°Celsius or greater and may result in different degradation products; (2) other substances coexist and may interfere with the thermolysis of fluoropolymers (e.g., thermolysis of PTFE is inhibited by a hydrogen or chlorine atmosphere in contrast to steam, oxygen or sulfur dioxide, which accelerate decomposition; and (3) technologies such as activated carbon injection (ACI) coupled with baghouse filtration (BF) may be installed to remove dioxin or mercury and may also trap PFCAs. A study from the US concluded that waste incineration of fluorotelomer-based polymers does not lead to formation of detectable levels of PFOA under conditions representative of typical municipal waste incineration in the US. However, a recent study found PFOA in flue gases from a state of the art incinerator of Harlingen, the Netherlands (see the RME).
3. Information provided by IPEN and ACAT (2018) in their current submission mainly supports information provided by Switzerland which has already been considered for the development of RME. According to IPEN and ACAT (2018), PFOA can be unintentionally generated as a product of incomplete combustion arising from open burning and waste incineration processes. In laboratory experiments, high temperature incineration is effective to destroy PFOA and prevent formation of PFOA, however, in practise PFOA may be formed in currently operating incinerators (a link to raw data from the above-mentioned incinerator in Harlingen has been provided as reference[[7]](#footnote-8)). IPEN and ACAT (2018) conclude that stringent adherence to BAT/BEP[[8]](#footnote-9) techniques is needed to avoid PFOA generation and release and that PFOA should be listed in Annex C as an unintentional POP to capture potential formation and unintentional release from anthropogenic sources (IPEN and ACAT, 2018).

Unintentional formation and release from primary aluminium production

1. According to the RME, referring to a study from the EU Parliament from 2008, perfluorocarbons (PFCs) are widely used in aluminium production and emissions of PFCs (possibly including PFOA; not specified in the study) occur during specific electrolysis processes in aluminium manufacturing[[9]](#footnote-10). This can be reconfirmed by several information sources, for instance Gibbs et al (2001) stating that the primary aluminium production process has been identified as the largest anthropogenic source of emissions of two PFCs: tetrafluoromethane (CF4) and hexafluoroethane (C2F6). It is further explained that primary aluminium is produced using the Hall-Héroult electrolytic process, where the smelting pot itself acts as the electrolysis cell during the reduction process. When the alumina ore content of the electrolytic bath falls below critical levels required for electrolysis, rapid voltage increases occur, termed “anode effects”. Anode effects cause carbon from the anode and fluorine from the dissociated molten cryolite bath to combine, producing CF4 and C2F6. Further, the International Aluminium Institute provides among other statistics, information on global PFCs emissions from aluminium production. The available data refers to emissions of gases containing CF4 and C2F6[[10]](#footnote-11). It was not possible to identify relevant information indicating that also PFOA may be released from aluminium production. It seems that most of the available information relates to emissions of CF4 and C2F6 from aluminium production. No additional information has been submitted by parties and observers on potential releases of PFOA from aluminium production.

Summary and conclusion related to unintentional formation and release

1. In summary, the Committee invited Parties and observers to provide additional information to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds from incomplete combustion and primary aluminium production. New information was only provided by IPEN and ACAT (2018). The United Kingdom (2018) stated that PFOA is not a substance that is reported within the UK’s Pollution Inventories, and therefore no relevant data on its releases is available. The same also applies to emissions from primary aluminium production (United Kingdom, 2018).
2. Information from the RME indicates that PFOA may be unintentionally formed and released from inadequate incineration or open burning at moderate temperatures. Switzerland provided recent studies (FOEN, 2017), showing small, but measurable amounts of PFOA detected at incineration temperatures between 250°C and 600°C. Therefore, it has been concluded that this may be particularly critical for developing countries and countries in transition, where wastes are often not incinerated to sufficiently high temperatures and without proper flue gas treatment. The current submission from IPEN and ACAT (2018) is in line with information submitted by Switzerland and further includes information on PFOA detected in a state of the art incineration facility in the Netherlands (at concentrations about 0.01-0.04 ng/m3). IPEN and ACAT (2018) therefore conclude that stringent adherence to BAT/BEP techniques is needed to avoid PFOA generation and release and that PFOA should be listed in Annex C as an unintentional POP.
3. No information has been submitted by parties and observers on potential releases of PFOA, its salts and PFOA-related compounds from primary aluminium production.
4. In conclusion, available information to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds from incomplete combustion and primary aluminium production is limited. Additional information and preferably also measurements / quantitative data from other incinerators would be desirable to justify a possible listing of PFOA, its salts and PFOA-related compounds in Annex C based on more specific evidence. The same applies to potential PFOA releases from aluminium production. Most of the information identified in literature relates to emissions of CF4 and C2F6 during aluminium production. From the currently available information it is not possible to conclude that aluminium production represents a relevant source of PFOA releases to the environment.

# Uses of PFOA, salts and PFOA-related compounds where further exemptions may be needed

## Introduction

1. The RME identified a range of uses[[11]](#footnote-12) covering applications for fluoropolymers (primarily PTFE), use as surfactants and one use involving the generation of intermediates for further processing. All seven of the uses documented in the RME have the potential to generate releases during production, use and end of life for articles. During POPRC.13 in October 2017, the members of the POPRC discussed each of these uses and whether an exemption was necessary, but were unable to reach a conclusion. The Secretariat to the Convention invited members to provide further information around specific aspects of each use (see section 1.1) which are presented in this addendum to aid the discussion of the members at POPRC.14 in September 2018.
2. Existing national and regional control actions differ with regard to their chemical scope and exemptions. Table 2 shown in Annex 1 of this document (taken from the RME) gives an overview of the regulatory risk management approaches and exemptions in Canada, the EU and Norway. Section 3 of the background document (UNEP/POPS/POPRC.13/INF/6) provides further details on the legislative approaches in these countries.

(a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment

Introduction

1. According to the RME, specific exemptions could be considered for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. Additional information to clarify the scope of the applications, used amounts, availability of alternatives and socio-economic aspects is needed to allow for an exemption.
2. The POPRC invited parties and observers to submit further information on the scope of the applications, used amounts, availability of alternatives, socio-economic aspects and other relevant information. Specific information on membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment has been provided by Canada (2018) and IPEN and ACAT (2018). Furthermore, additional information has been identified in the submissions from HealthCare Without Harm Europe (HCWH, 2018) and MedTech Europe (2018), providing information related to medical devices.

Efficacy and efficiency of possible control measures

1. According to IPEN and ACAT (2018), each use of PFOA should be specifically identified and no consideration of specific exemptions should be considered if uses cannot even be named. IPEN and ACAT (2018) therefore conclude that no exemption for PFOA use in membranes for filtration in water treatment, production processes and effluent treatment should be recommended. The same has been also concluded for application in medical textiles (IPEN and ACAT, 2018).
2. A possible presence of PFOA in surgical drapes was confirmed by MedTech; “The presence of PFOA is mainly related to the use of fluoropolymers such as PTFE” (MedTech Europe, 2018). According to information submitted by HCWH (2018), PFOA can be found in several products in health care including textiles. A complete picture on PFOA use in the sector is however not yet available. For this reason, HCWH believes that it is crucial as a first step to collect further information and determine which fluorinated compounds are present in products used in the healthcare sector (HCWH, 2018).
3. According to information submitted by Canada (2018), commercial filter membranes can be made of different materials, some based upon fluorochemicals such as polyvinylidene fluoride (PVDF), poly(ether sulfone) (PES) and polytetrafluoroethylene (PTFE). PFOA can be used as a surfactant in the emulsion polymerization of PTFE. PTFE membranes are used in pharmacy brewing, manufacture of purified water and special need water, beverage and dairy, chemical regent, biochemical regent, air filtration of fermentation tank, purification and filtration in microelectronic plants, filtration and separation of antibacterial fluid, production of medicine, air conditioning of hospitals and commercial buildings[[12]](#footnote-13) (Canada, 2018).
4. A possible use of membranes intended for medical textiles was identified in publicly available information as PTFE fibres and filaments (PTFE yarns)[[13]](#footnote-14) used for bed sheets to prevent decubitus / pressure ulcer. However, no information on this use has been submitted and no request for exemption has been expressed by parties and observer.

Information on alternatives

1. All members of the FluoroCouncil have agreed under the US EPA 2010/15 Stewardship program to manufacture fluoropolymers without using PFOA (as processing aid) by the end of 2015. The objective of the proposal is to restrict the placing on the market, import, and use of fluoropolymers manufactured with PFOA, while allowing the use of the same the same fluoropolymers when they are not manufactured with PFOA. The substitution was reportedly being carried out by around 70% of the global market for fluoropolymers in 2015 (ECHA, 2014a).
2. According to the RME, for filter materials for oil and fuel filtration some companies claim that no alternatives are available. No further information has been submitted during the current submission period.
3. Several alternatives for use in textiles such as short-chain fluorinated alternatives, non-fluorine containing alternatives and non-chemical alternatives have been identified in the RME. In the following relevant alternatives are briefly summarized (see the RME for full details, not for discussion).

### Short-chain fluorinated alternatives

1. Information on short-chain fluorinated alternatives was identified in the RME. Fluorotelomer products based on 8:2 fluorotelomer alcohol (8:2 FTOH), the short-chain 6:2 FTOH are used as alternatives for a variety of uses including textiles. 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). The fluorinated chemical alternatives to PFOA (6:2 FTOH, PFHxA/PFHx, 6:2 methacrylate and 6:2 acrylate) do not meet the overall Stockholm Convention POPs criteria. Concerns that short-chain fluorinated alternatives meet POP criteria were already addressed in the RME for instance in paragraph 179.
2. During the development of the RME, industry associations noted that especially in the field of professional, technical and protective textiles and other advanced textiles, no alternatives meeting the high demand by legal requirements and by customers are currently available. However, those textile products that must only fulfil low-performance requirements, which were formerly treated with PFOA-related compounds, may be treated by C6-products or even fluorine-free alternatives (see the RME).
3. According to the RME, over the life-cycle, technical textiles treated with 6:2 fluorotelomer-based finishes often exhibit 4-8 times higher total PFAS emissions compared to the observed emissions using the C8-chemistry (see the RME).

### Non-fluorine-containing alternatives

1. According to the RME, non-fluorine containing alternatives in the textile industry include paraffins, alpha olefin modified siloxanes, fatty-acid modified melamine resins and fatty-acid modified polyurethanes exist for textiles with low required levels of water repellency. In some cases, when applying fluorine-free alternatives, quality requirements of technical textiles cannot be fulfilled due to, for example, a lack of chemical-, oil- and/or dirt-repellent properties, inadequate abrasion and/or wash resistance. Available alternatives for grease- and dirt-repellent agents are limited. Most prominent water-repellent alternatives are reported to be silicone-based agents. These include 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 that are being developed to imitate the ability of the lotus blossom to repel water. Alternatives to provide similar stain- and water-repellency are available and include textile surface treatment applications based on acrylate, methacrylate adipate and urethane polymers (see the RME).
2. According to the RME, 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 SchoellerTechologies AG, Sevelen/Switzerland (see the RME).
3. According to the RME, paraffin repellents are liquid emulsions that should not be classified as hazardous to health according to the producers. However, some of the identified ingredients seem to be harmful. The main ingredient in most products is paraffin oil/wax (mixtures of long chain alkanes), which is considered harmless in pure form. Some products also contain isocyanates, dipropylene glycol, metal salts, which may be harmful (see the RME).
4. According to the RME, PDMS are inert and have in general no adverse effects. Various siloxanes, especially the cyclic siloxanes known as D4, D5 and D6 and specific linear siloxanes are intermediates for the synthesis of silicone polymers used for textile impregnation. Certain siloxanes are persistent and widespread in the environment. Mostly, they are detected in urban areas and in the aquatic environment. High levels have been found in livers of fish, which were caught close to outlets of sewage treatment plants. Siloxanes are generally removed from the aqueous phase by sedimentation, and exhibit a long half-life in sediments. In soils, siloxanes are transformed depending on the conditions into hydroxylated forms, which still may be persistent. In Canada, it is concluded that D4 is entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity (see the RME).
5. IPEN and ACAT (2018) submitted information that technically feasible alternatives that meet regulatory requirements but do not contain PFOA are available. These include surgical gowns and drapes.[[14]](#footnote-15) [[15]](#footnote-16) [[16]](#footnote-17) [[17]](#footnote-18) According to Wang et al (2015) Rudolf Group (2018), “non-fluorinated water-repellent textile finishes that are based on high molecular weight and highly branched polymers known as dendrimers have been commercialized” for use in textile pre-treatment, coating, sizing, and finishing and may have application for medical textiles.
6. According to the RME, there are no data on health properties of the active substances and other components of dendrimer-based repellents, but producers of commercial products have provided health data in the material safety data sheets and made some proposals for classification of the product. According to information from producers these products should not be classified as harmful for the environment, but it is not possible to evaluate these statements on the basis of available information. 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 available information for this group of chemicals is insufficient for an assessment of the possible health effects of the impregnation agents (see the RME).
7. The RME identified alternatives to PFOA for use in reverse osmosis membranes for water and effluent treatment. It notes that for membranes an alternative to PTFE is a composite of a hydrophobic polyester and a hydrophilic polymer forming a microstructure, which allows the fabric to breathe (see the RME).
8. According to IPEN and ACAT (2018), Syndar Filtration manufactures membranes for a wide variety of purposes, including water filtration, effluent treatment, production processes, and medical applications. They use fluorine-free materials for these applications including: polyacrylonitrile (PAN)—most often used for oil/water separations and similar applications; polyethersulfone (PES)—most often used for protein concentration and purification; and thin film composite (TFC)—these membranes use PES with polyamide coatings that are used for various concentrating and purifying applications[[18]](#footnote-19) (IPEN and ACAT, 2018).

### Non-chemical alternatives

1. Ceramic membranes are also used in water treatment and desalination and were shown to be effective with fluorine-free modifiers in the desalination process using the membrane distillation (MD) technique. (IPEN and ACAT, 2018).

Information on impacts on society

1. According to the RME, the technical textile sector has to fulfil many different performance standards in particular medical, chemical and environmental protection. Textiles have to be certified in long procedures, which could take years and several textiles are regulated by various other EU- and national laws (see the RME).
2. According to ECHA (2014), the introduction of alternatives in the fluoropolymers production industry has been carried out by around 70 % of the global market which took place with a moderate price increase.
3. No new information on possible impacts on society has been provided by parties or observers in the current submissions.

Synthesis of Information

1. According to HCWH (2018) and IPEN and ACAT (2018), membranes intended for use in medical textiles could include products that function as a barrier to exposure to blood or fluids such as surgical drapes, in which the presence of PFOA is mainly related to the use of fluoropolymers.
2. According to information submitted by Canada (2018), PFOA can be used as a surfactant in the emulsion polymerization of PTFE. PTFE membranes are used in pharmacy brewing, manufacture of pure water and special need water, beverage and dairy, chemical regent, biochemical regent, air filtration of fermentation tank in microelectronic, purification and filtration in microelectronic plants, filtration and separation of antibacterial fluid, production of medicine, air conditioning of hospitals and commercial buildings.
3. According to the RME, for filter materials for oil and fuel filtration some companies claim that no alternatives are available. Specific information is, however, not available.
4. According to the information available, technical and/or economically feasible alternatives exist for membranes intended for use in medical textiles and filtration in water treatment, production processes and effluent treatment. No specific application has been identified that requires C8‑chemistry.
5. No information on impacts on society has been provided by parties or observers. 70 % of the fluoropolymer producing market has already replaced the use of PFOA by the end of 2015 at a moderate price increase (ECHA, 2014a). This indicates that membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment can possibly be produced without PFOA.
6. The Committee requested information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects. Information was submitted on the scope of the applications and the availability of alternatives by HCWH (2018), Canada (2018) and IPEN and ACAT (2018). No new information was submitted or could be identified on used amounts and socio-economic aspects. Used amounts for specific applications and related information which would enable the socio-economic aspects and information on the possible non-availability of alternatives to be evaluated would be needed to further evaluate possible exemptions. In conclusion, more specific information on the scope of the applications, used amounts, non-availability of alternatives and socio-economic aspects is still lacking and the information reviewed does not substantially help to enable the Committee to evaluate whether there is a specific need for an exemption.

Conclusion

1. Based on the evaluation of available information a time limited exemption could be considered for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. This, however, depends on whether additional information will be made available by the industry.

## (b) Use of PFOI (perfluorooctane iodide) as intermediate to enable reprocessing at another site than the production site to TFE (tetrafluoroethylene) and HFP (hexafluoropropylene)

1. According to the information from the RME, for transported isolated intermediates, an exemption without time limit is included in the EU restriction (EU 2017/1000 amending EC 1907/2006) according to its paragraph 4(c), provided that specific conditions are met (described further below). Therefore, the need for an exemption should be assessed under the Stockholm Convention to enable reprocessing in another site than the production site. The conditions could be similar to what is established under the EU restriction (see the RME).
2. The Committee invited parties and observers to provide information that would assist the possible defining of specific exemptions, in particular for transported isolated intermediates, in order to enable reprocessing in another site than the production site. The Committee requested information related to the quantities used, extent of transport and possible risks, and use.
3. Relevant information was submitted by IPEN and ACAT (2018) and by the FluoroCouncil (2018). No additional information (in addition to information already included in the RME) was submitted by Canada (Canada, 2018).

Efficacy and efficiency of possible control measures

1. An exemption should be considered under the Stockholm Convention with similar conditions to those established under the EU restriction (EU 2017/1000) approach, “*i.e. that an exemption can be granted where the synthesis of (an)other substance(s) from an intermediate takes place on other sites under the following strictly controlled conditions: (1) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage; (2) procedural and control technologies are used that minimise emission and any resulting exposure; (3) only properly trained and authorised personnel handle the substance; (4) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered; (5) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures; (6) substance-handling procedures are well documented and strictly supervised by the site operator”* (see the RME). IPEN and ACAT (2018) note that the proposal to exempt transport of isolated intermediates at the global level undermines the integrity of the Stockholm Convention. The Convention limits generic exemptions relating to intermediates to strictly closed-system site-limited intermediates that are 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 POPs.[[19]](#footnote-20). According to IPEN and ACAT, the proposed exemption would allow unrestricted transport including across borders in violation of the provisions of the Convention. Furthermore, IPEN and ACAT state that the proposed transport exemption would undermine the integrity of the Stockholm Convention in that (they argue) the fluorochemical industry proposed the exemption to enable production of unspecified C6 fluorotelomers, but these substances have not been evaluated (or even named) to determine if they meet the POPs criteria in Annex D, making it impossible to take the POPs criteria into account as required for closed-system, site-limited intermediates. The data that do exist for commonly manufactured C6 fluorotelomers indicates that these substances have properties that raise concerns for POPs properties (IPEN and ACAT, 2018). As an example, IPEN and ACAT provided information from peer-reviewed publications on the properties of 6:2 fluorotelomer alcohol (6:2 FTOH) (IPEN and ACAT, 2018).
2. In conclusion, IPEN and ACAT (2018) suggest that the POPRC should not recommend an exemption for non-site-limited isolated intermediates. The proposed exemption would, according to IPEN and ACAT, also open the door to waste dumping in developing and transition countries under the guise of “reprocessing”. In many countries, they suggest that none of the “stringent” measures required in the EU would be effectively implemented or enforced. IPEN and ACAT argue that this exemption could result in significant further releases of PFOA (IPEN and ACAT, 2018).
3. An exemption for transported isolated intermediates is already considered in the RME for the transport of PFOI (perfluorooctyl iodide, CAS No: 2043-57-4) that is produced during the production of 6:2 fluorotelomer-based substances, whereby a fraction of the isolated intermediate PFOI is then transported to another site in Japan to produce PFOB (see RME para 204).
4. The FluoroCouncil (2018) submitted a request for an exemption for the “use of PFOI as intermediate in the production of TFE and HFP (tetrafluoroethylene, CAS No: 116-14-3) and HFP (hexafluoropropylene, CAS No: 116-15-4)”. The FluoroCouncil provides information on the processes of the concerned member company, the research and development (R&D) activities of the company as well as the strict conditions of use of PFOI from its generation as an unintended side chain fraction (by-product) of C6 fluorotelomer production to its reprocessing into TFE. They also question the status of 1-H-PFO as a PFOA related substance (see Chapter 2 on chemical identity) (FluoroCouncil, 2018).
5. A member of the FluoroCouncil, produces C6 fluorotelomers at one single site, located in Germany. During the C6 telomerisation, as an unintended side fraction of C8/ long-chain fluorotelomers, PFOI, is generated. This fraction is sent in closed barrels to a facility in South Korea where iodine recovery and reprocessing to TFE and HFP take place under closed system conditions.
6. In the EU, PFOI is registered as a transported intermediate under REACH[[20]](#footnote-21) for the purpose of its off-site reprocessing and is exempted from the REACH restriction on PFOA (FluoroCouncil, 2018). According to the FluoroCouncil, PFOI cannot be directly reprocessed via pyrolysis to obtain the desired products TFE and HFP due to iodine contamination which prevents use in downstream polymerisation reactions (FluoroCouncil, 2018).
7. As regards the volume of the PFOI fraction to be covered by the exemption proposed by the FluoroCouncil, a R&D project is reported to be ongoing with the aim to further reduce this fraction. By 2020, it is expected that the volume of PFOI produced by the member of the FluoroCouncil will range between 50 and 100 tonnes per year (FluoroCouncil, 2018). No information was provided on current volumes and on the volume of the whole C8/long chain fluorotelomer, PFOI side fraction.
8. According to the submission of the FluoroCouncil, reprocessing of PFOI to TFE and HFP takes place via iodine recovery and subsequent pyrolysis (FluoroCouncil, 2018). TFE and HFP are both non-POP substances. They are used by the South Korean facility as raw materials for the production of fluoropolymers and C6 fluorotelomers. No significant additional releases of PFOI are expected from this process compared to PFOI incineration, particularly as transport would be required in the absence of on-site iodine recovery and given possible emissions from incineration. In the event that the exemption request is not granted, Archroma argued that PFOI could only be stock-piled. As stockpiling is not a viable option, a closure of the production site may have to be envisaged (FluoroCouncil, 2018).

Figure 4.1 PFOI closed-system reprocessing (FluoroCouncil, 2018)



1. According to the FluoroCouncil, developing a technology to conduct the on-site iodine extraction by their member would take several years after the entry into effect of the Convention’s provisions on PFOA and lead to the production of 1-H-PFO that falls under the definition of a PFOA related substance. An exemption would be required to cover the time gap. The FluoroCouncil therefore submits an exemption request relating to the need of its member for the use of PFOI as an intermediate in the production of TFE and HFP (FluoroCouncil, 2018). Furthermore, the viability of on-site iodine extraction will depend on the status of the substance, 1-H-PFO, that would result from the process. 1-H-PFO, not PFOI, would be transported for reprocessing. Due to its formula C8F17-H, 1-H-PFO presently falls in the scope of PFOA-related substances. The FluoroCouncil argues that degradation of 1-H-PFO to PFOA has never been observed and that it remains to be shown that 1-H-PFO can degrade to PFOA. Provided 1-H-PFO would not be identified as a PFOA-related substance, the transformation of PFOI to 1-H-PFO under a closed system may become eligible to the general exemption provided for in Annex A (iii) or Annex B (iii) for the use of on-site intermediates under closed system in the production of non - POP substances (FluoroCouncil, 2018). Additional information on the status of 1-H-PFO as a PFOA related substance can be found in the section on the chemical identity (see chapter 2 on chemical identity).

Figure 4.2 Current off-site reprocessing procedure (red dotted line) and on-site processing option (green dotted line) (FluoroCouncil, 2018)



1. The FluoroCouncil’s submission (FluoroCouncil, 2018) explains the intention of one of their members to transport PFOI as an intermediate for reprocessing at another site at least for a transitional period. However, inconclusive information regarding the volumes of production and transport is given as well as about the possible risks, releases and socio-economic consequences as requested by the Committee. Alternative options other than stock-piling PFOI on-site that cannot be considered a viable option are not presented (e.g. to dispose of the PFOI fraction as waste). More information about the possible risks and risk management measures (such as fulfilment of the criteria of Article 18 (4) of the REACH Regulation), about possible releases and possible measures to minimise them, and about quantities intended to be transported off-site as an isolated intermediate would be required to enable the Committee to properly evaluate the need for an exemption.

Information on alternatives

1. The FluoroCouncil does not mention alternative substances; however, they mention the possibility of on-site treatment of PFOI. This process will reportedly not be available in due time and would lead to the generation of 1-H-PFO, which currently falls under the definition of a PFOA related substance. The FluoroCouncil argues that 1-H-PFO should not be considered a PFOA-related substance.

Information on impacts on society

1. The FluoroCouncil argues that the need for on-site storage if an exemption is not granted might lead to closure of the production site of their member company. Specific information on socio-economic impacts was not provided in the submission. However, the PFOI fraction could also be treated as a POP-containing waste to be disposed of (destruction or irreversible conversion of the POP-content).
2. Specific impacts on society are difficult to evaluate based on available information.

Synthesis of information

1. A member of the FluoroCouncil produces PFOI as an unintended side fraction (by-product) in the production of C6 fluorotelomers. An exemption was recommended in the RME for the off-site transport of PFOI that is produced during the production of 6:2 fluorotelomer-based substances, whereby a fraction of the isolated intermediate PFOI is then transported to another site in Japan to produce PFOB (see RME para 204). According to the FluoroCouncil, their member can currently not process PFOI on-site to TFE and HFP. An exemption would therefore be needed for transporting PFOI as an isolated intermediate to another site for reprocessing to TFE and HFP.
2. Developing a technology to conduct the on-site iodine extraction would take several years after the entry into effect of the Convention’s provisions on PFOA and would lead to the production of 1-H-PFO which currently falls under the definition of a PFOA-related compound. If on-site iodine extraction were in place, 1-H-PFO would be transported for reprocessing. Provided that *1-H-PFO would not be considered a PFOA-related compound*, a transitional exemption would be needed for transporting PFOI as an isolated intermediate to another site for reprocessing to TFE and HFP until on-site iodine extraction is possible.
3. If 1-H-PFO can be considered a non-PFOA-related compound such a transitional exemption would be required. However, 1-H-PFO should not be excluded from the scope of PFOA-related substances since studies suggest that 1-H-PFO can degrade to PFOA. It should be noted that 1-H-PFO is presumably more stable than PFOI. Thus, the off-site transport of 1-H-PFO might lead to lower risks compared to the off-site transport of PFOI.
4. The FluoroCouncil provides relevant information about the process of their member. However, additional information about the specific volumes of the PFOI-containing fraction, release quantities and possible risks and risk management measures would be required to enable the Committee to properly evaluate the need for an exemption.

Conclusion

1. Based on the evaluation of available information a time limited exemption could be considered for PFOI as a isolated intermediate to enable reprocessing at another site than the production site for the production of TFE and HFP, if additional relevant information about the specific volumes of the PFOI-containing fraction, release quantities and possible risks and risk management measures are made available which enable the Committee to properly evaluate the need for an exemption.

(c) Medical devices other than implantable devices

Introduction

1. The RME for PFOA highlighted a potential need for an exemption for medical devices. The request for information specifically requested information on specific applications/uses and timelines foreseen as needed for potential related exemptions.
2. Relevant information was submitted by Canada (2018), IPEN and ACAT (2018) and Medtech Europe (2018). Information related to medical devices including implantable medical devices was also provided by Healthcare Without Harm (HCWH, 2018)
3. Medtech Europe (2018) provided details in their submission to the secretariat stating that PFOA and PFOA-related compounds are used within medical settings as both non-polymeric substances and side-chain fluorinated polymers[[21]](#footnote-22) such as fluoroacrylate polymers (including PTFE). A report by ECHA (2015a) as part of the European restriction estimated global usage of PFOA within medical devices as <5kg p/a (extrapolated from an EU estimate of <1kg p/a and assumed 20% global market share).
4. Within the EU restriction (EU 20171000 amending EC 1907/2006), a time limited exemption (until 7 July 2032) is given for medical devices other than for certain implantable medical devices within the scope of Directive 93/42/EEC (EU Directive concerning medical devices). For the production of implantable medical devices, an exemption without time limitation is given. Norway has an exemption in place for medical devices (with no time limit). The import, use, sale and offer for sale of medical devices containing PFOA, its salts or PFOA-related compounds are not restricted in Canada. According to the information submitted by IPEN and ACAT (2018), possible exemptions for these uses could be considered but consultation with health professionals using these medical devices should be considered.
5. The RME for PFOA noted that an exemption (with or without time limit) could be considered for use of medical devices. However a conclusion was not reached at POPRC.13. Following POPRC.13 the Secretariat invited parties and observers to submit further information on specific applications/uses and timelines foreseen as needed for potential related exemptions.

Efficacy and efficiency of possible control measures

### Identification of uses for PFOA and PFOA-related compounds in medical devices

1. Medtech (2018) and Euromed (2015) commented that medical device manufacturers encompass up to 11,000 suppliers, with supply chains up to five to seven tiers globally. They suggest that the global supply chain makes collection of information on specific applications difficult. Medtech (2018) further commented that the diverse set of applications and complexity of supply chains makes development of detailed lists of uses extremely challenging. However, Medtech (2018) noted that based on a survey of their members the primary use of PFOA and PFOA-related compounds within medical devices will be present as a by-product of PTFE. The use of PTFE within medical devices is selected based on its chemical resistance, heat resistance, lubrication and biocompatibility.
2. The 2010/15 PFOA stewardship program (which is chaired by the US EPA) which includes eight major manufacturers of PFOA globally, has seen the manufacture of PFOA cease in the EU and decrease dramatically in the US and Japan[[22]](#footnote-23). However, Medtech (2018) also commented that the main component production is outside of Europe and may use PFOA (produced in China and India) as a raw material input for the production of the applied polymers (Euromed, 2015). Wang et al (2014) further commented that, while the production of PFOA and PFOA-related compounds by eight major producers based in Japan, Europe and North America had declined since the creation of the US EPA 2010/2015 stewardship program in 2006; new production had begun post-2006 in Asia (particularly India and China) primarily driven by the demand for production of fluoropolymers including PTFE. The paper by Wang et al (2014) estimates production of PFOA and PFOA-related products in China as 50-80 tonnes per annum in 2009, but no disaggregation is provided for uses specifically in medical devices.
3. Medtech (2018) stated that the use of PFOA in generic components means that trace quantities can end up in medical equipment such as:
4. Cable and wiring,
5. Electronics (insulators, solder sleeves, vapour phase soldering media),
6. Photographic applications (see section 4.6), and

Medical articles (non-woven medical garments; stain- and water-repellents for surgical drapes and gowns (see section 4.2); surgical patches; cardiovascular grafts; vascular catheters; and raw material for implants in the human body (see section 4.5).

1. The above-mentioned components result in applications within a wide range of medical devices including sensors, cardiovascular devices, vascular catheters, protection tubing, implants and orthopaedic devices.
2. A producer of membranes for use in medical devices further cites a possible use of PTFE-based membranes in kidney dialysis treatment (noting that PFOA is used in the manufacture of PTFE and is present in the finished product)[[23]](#footnote-24). Such membranes are used in haemodialysis blood lines to keep the blood side of the circuit separated from the machine side, and to prevent contamination of the machine by the blood flowing through the circuit. A report by ECHA for the European restriction (ECHA, 2015a) comments that the total usage of PTFE and quantities of PFOA or PFOA-related compounds in medical devices are unknown. However, based on the survey conducted with industry, ECHA (2015a) estimates that total quantities of PFOA in medical devices in use across Europe would not exceed 1kg. ECHA (2015a) also comments that the use within the European Union makes up 20% of total global demand for PTFE, and therefore by extrapolation total quantities of PFOA in medical devices globally would not exceed 5 kg.

### Timescales foreseen for potential exemptions

1. Medtech Europe (2018) noted that the substitution of substances within the medical sector is likely to differ from substitution in other sectors. This is because of the scrutiny and stringent regulatory requirements for medical equipment. Medtech Europe (2018) go on to state that a change in materials could be perceived as affecting the reliability of the device and would thus trigger the need for evaluation as if the device were a new piece of equipment, including the potential need for clinical trials which would delay the transition. Medtech Europe (2018) state that products that have already entered the supply chain would have a shelf-life of 3 to 5 years, mainly relating to product sterility and therefore an exemption would be needed for a similar period of time. It is not clear whether this relates only to implantable medical devices or to all medical devices.
2. The European restriction (EU 2017/1000) allows an exemption for all medical devices (excluding implantable medical devices, which have a non-time limited exemption) of 15 years. This is expected to expire on 7 July 2032. ECHA considered comment (within ECHA, 2015a) that the reason for the length of the exemption relates to the stringent regulatory requirements for medical equipment which can delay the substitution with alternatives and that a shorter exemption may mean certain critical applications would become unavailable to the healthcare sector.

Information on alternatives

1. Canada (2018) stated as part of the invitation for submissions that the main use of PFOA within medical devices is as a process aid in the emulsion polymerisation of PTFE; however, Canada states that Zero PFOA PTFE products are now available on the market. IPEN and ACAT (2018) also comment that PFOA-free PTFE products have been commercialised and are available on the market within the USA. The majority of examples provided in response to the Secretariat’s request for information relate to the use of PTFE within implantable devices such as guidewires and catheters. SSG, (2017) and Nesbitt (2017) discuss issues with delamination of PFOA-free PTFEs in the USA during 2016, in particular these issues related to exposure to saline and other body fluids for implantable medical devices. Nesbitt (2017) further comments that improvements have since been made to prevent ‘flaking’ of PTFE from implantable devices, although technical issues still remain over low friction properties. Nesbitt (2017) also comments that as this is an evolving area of science and therefore the shelf-life of replacement goods is unknown compared to PFOA based PTFEs which had been in use for 50 years. Further discussion on physical properties of PFOA-free PTFE and delamination are provided under section 4.5.2 for alternatives to medical implantable devices.
2. For medical devices not used for implantable applications, it is unclear whether the operating parameters will be similar, and if there is a need for resistance to delamination from saline or other bodily fluids such as blood.
3. The RME (UNEP/POPS/POPRC.13/7/Add.2) provided an overview of the main PFOA-free PTFE goods available on the market. In absence of further new information and for ease of reading this information is provided from the RME in the following paragraphs.
4. Three PFOA-alternatives with ether moieties (GenX, ADONA and EEA-NH4) that are generally shorter and/or less fluorinated were assessed in the EU restriction process (ECHA, 2015b, section C3). C3 Dimer salt*[[24]](#footnote-25)*, 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, 2015b). 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, 2015b). Fluoropolymer manufacturers stated during the EU public consultation that the production costs varied from none to 20% increase when applying the alternatives (ECHA, 2015b). 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.
5. Further information around the PBT properties of potential alternatives is further detailed within the RME.

Information on impacts on society

1. Medtech Europe (2018) commented that health risks of medical devices are adequately assessed during regulatory procedures before the placing on the market. Such medical devices that contain PTFE (and PFOA) have been on the global market for over 50 years and no negative health effects on patients have been observed or reported. The European medical device industry commented that they fully supported a phase out of PFOA but requested a limited time exemption in order to avoid market disruption and allow for a substitution that is properly enforceable Regarding waste implications, the amount of PFOA in question is reportedly very small and it can be expected that most medical devices would be disposed of according to the stringent waste disposal requirements applicable to hospitals.
2. ECHA (ECHA, 2015a) further noted that, based on consultation with industry, the quantities of PFOA and PFOA-related compounds within medical devices would be small (<5kg globally), therefore the potential for emissions would also be small. ECHA noted (ECHA, 2015a) that an extended transitional period of 15 years seemed to be necessary for non-implantable medical devices in order to avoid the situation that some critical applications might not remain available to the healthcare sector.

Other considerations

1. None.

Syntheses of information

1. Medtech Europe (2018) noted that, based on a survey of its members, PFOA will mainly be present in medical devices as a by-product of PTFE manufacture. Further to this, Medtech Europe (2018) and Euromed (2015) both highlighted the difficulty in producing detailed lists of specific applications within healthcare due to the diverse ways in which PTFE is used. Generic details of the type of uses where PTFE may appear include cables and wiring, electronics (such as insulators, solder sleeves, and vapour phase soldering media), photographic applications, medical articles (such as non-woven garments, stain and water repellents for surgical drapes and gowns, surgical patches, cardiovascular grafts; vascular catheters; and raw material for implants in the human body. ECHA (2015) made estimates to quantify PFOA and PFOA-related compounds in medical devices are at or below 1kg for Europe and are at or below 5kg globally.
2. ECHA (2015a) noted that substitution to alternative substances may be more challenging in the healthcare sector due to the stringent regulations applied, which can include the need for clinical trials. This was a point also made by Medtech (2018) and Euromed (2015). The European restriction includes a 15 year exemption for medical devices due to expire on 7 July 2032. ECHA commented (ECHA, 2015a) that such an exemption was needed to aid transition and prevent critical applications becoming unavailable.
3. The RME (UNEP/POPS/POPRC.13/7/Add.2) states that alternatives have been developed and commercialised, including Zero PFOA PTFE. However, SSG (2017) and Nesbitt (2017) highlight performance issues for some alternatives, which resulted in a product recall for guidewires in the USA in 2016. The issues identified by Nesbitt (2017) relate to implantable medical devices and delamination as a result of sustained exposure to saline solutions (including bodily fluids). It is unclear which non-implantable medical devices might have similar performance issues.
4. The RME (UNEP/POPS/POPRC.13/7/Add.2) indicates that three key alternative products exist with ether moieties (GenX, ADONA and EEA-NH4) that are generally shorter and/or less fluorinated than what was assessed in the EU restriction process (ECHA, 2015a, section C3). C3 Dimer salt, ADONA and EEA-NH4 are applied as alternatives for the use of PFOA as a polymerisation processing agent where it is applied as an 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, 2015b). 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, 2015b). Fluoropolymer manufacturers stated during the EU public consultation that the production costs varied from zero to a 20% increase when applying the alternatives (ECHA, 2015b). The increase is a result of higher prices of the alternatives as well as higher quantities 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 (ECHA, 2015b).
5. The main societal effect related to the continued use of PFOA-based PTFE or a restriction on PFOA-based PTFE for medical devices relates to the availability of devices for use in the healthcare sector. Medtech Europe (2018) and Euromed (2015) both highlight that regulations within the healthcare sector are stringent, and that alteration of substances within devices can mean the need for retesting, including potentially clinical trials. This reportedly delays the transition to alternative products. The European restriction (EU 2017/1000) granted a 15 year exemption for medical devices to allow transition to alternatives, with ECHA commenting that a shorter exemption period could mean that critical applications may become unavailable to the healthcare sector.

Conclusion

1. Based on the information compiled and discussed within the RME (UNEP/POPS/POPRC.13/7/Add.2) and further elaborated upon within the current addendum, suggests that a time-limited exemption may be needed for medical devices to prevent loss of critical applications. However further detail on specifically which applications are critical is needed for further resolution. The members of the POPRC should consider an exemption for PFOA and PFOA-related compounds in medical devices.

(d) Implantable medical devices

1. According to the RME, an exemption with or without time limit for the production of implantable medical devices under the Stockholm Convention, should be considered. The POPRC invited parties and observers to submit further information on the scope of the applications of use, used amounts, extent of transport and risks and other relevant information on socio-economic aspects. Additional information is needed to determine whether an exemption is warranted. Relevant information was submitted by Canada (2018), IPEN and ACAT (2018), Healthcare Without Harm (HCWH, 2018) and Medtech Europe (2018).
2. Within the EU restriction (EU 2017/1000), a time-limited exemption (until 4 July 2032) is given for medical devices other than implantable medical devices within the scope of Directive 93/42/EEC. In the same document, an exemption without time limitation is currently given for the production of certain implantable devices. Norway has an exemption in place for medical devices (with no time limit) and the import, use, sale and offer for sale of medical devices containing PFOA, its salts or PFOA-related compounds are not restricted in Canada.

Efficacy and efficiency of possible control measures

1. Information submitted to ECHA (2015a) indicates that amounts of PFOA and PFOA-related substances related to this use are extremely low. In implantable devices, a manufacturer previously estimated that the total amount of PFOA present in all devices put on the market in the EU during the period 2018-2025 without the restriction would amount to 20 g (it is however unclear if this amount includes only PFOA or also PFOA-related substances). This was extrapolated to 100g total worldwide (Medtech Europe, 2018). The concentration of PFOA in PTFE is stated to range from 0.001 to 0.5% for emulsion route material (ECHA, 2015b) and total annual emissions to the environment are expected to be much lower than quantities used (ECHA, 2015a, ECHA, 2015b).
2. Medtech Europe (2018) commented that a derogation for implantable cardiovascular devices until 2030 would be sufficient to allow transition to alternatives without impacting the healthcare sector. ECHA (2015a) commented that a derogation for implantable medical devices was needed given the very low amounts of PFOA and PFOA-related substances involved and high costs reported for immediate transition.
3. Further information and data on quantities used, extent of transport and risks, and use of PFOA in implantable medical devices was not provided in response to the request for information.

Information on alternatives

1. Implantable medical devices, such cardiovascular devices catheters and guidewires, can contain PFTE made from PFOA. However, PFTE can be made without PFOA (HCWH, 2018) and alternatives are reportedly now commercially available, approved by US FDA, and are a feasible and effective alternative to the use of PFOA. (IPEN and ACAT, 2018).
2. The main issue for alternatives is the resistance to saline solutions. In 2016, a US-EPA recall on PFOA-free PTFE products used for medical implants occurred in the US[[25]](#footnote-26) due to problems with flaking and delamination in the body. If these flakes pass to the bloodstream they have the potential to cause serious health effects such as heart attack, stroke and blood clots (Nesbitt, 2017). The second generation of PFOA-free PTFE products seem to have resolved the bonding issue by using a better coating process of the guidewires, but it is unclear what products are in use and on the market are considered first generation and second generation. (SSG, 2017)
3. The RME indicates that the use of alternatives induces a low to moderate increase in production costs (0-20%). This increase arises from the higher costs and/or the higher amounts of alternatives that will be used, however during a previous request (in 2015) for information EU Industry stated that there is no change in the quality of the PTFE manufactured with the alternatives (ECHA, 2015b).
4. In the EU public consultation, stakeholders indicated that substitution is ongoing but is a lengthy process given the complexity of the supply chains and the certification processes (ECHA, 2015a). In the specific case of implantable medical devices, a manufacturer requested a transition period of 15 years (ECHA, 2015c). This request was supported by a socio-economic analysis comparing the costs of not using the devices with the avoided emissions. ECHA found that, even if all costs are not clearly justified and might include some overestimation, this SEA demonstrates that a shorter transition period than requested would not be cost-effective (ECHA, 2015a).
5. Further information on the alternatives to PTFE can be found in the medical devices section 4.4.3.

Information on impacts on society

1. Implantable medical devices range from synthetic vascular grafts, endovascular and interventional devices, surgical meshes for hernia repair, to sutures for use in vascular, cardiac, and general surgery procedures. These devices allow for example for minimally invasive insertion, and the innovative materials are biocompatible, homogenous and versatile. MedTech Europe (2018) suggest that, should those implantable medical devices lack availability as a result of possible measures under the Stockholm Convention, there is expected to be an increase in risks to future patients as a consequence, as it is assumed that surgeons would have to switch to using (sometimes unfamiliar) implantable medical devices, or carry out different surgical procedures that may involve more risk to the patient, such as open-heart surgery (Medtech Europe, 2018).

Syntheses of information

1. Quantities of PFOA and PFOA-related substances used in implantable medical devices (largely in the form of PTFE) are small (20g in the EU and 100g worldwide) and concentrations are low in the final product (PFOA in PTFE is stated to range from 0.001 to 0.5%). In addition, the development of alternatives for substitution is complex due to stringent regulatory requirements for material changes to medical devices but alternative PTFE coating methods are available and already in use. The performance of PFOA-free PTFE alternatives has been subject to concern by the US-EPA (due to problems with flaking and delamination in the body) however a better coating process has now been developed to resolve quality issues. The RME indicates that the use of alternatives also induces a low to moderate increase in production costs (0-20%) and is paired with a net benefit to society in terms of human health impacts, through the reduced use of PFOA in human implants.

Conclusion

1. Cost competitive alternatives, such as PFOA free PTFE products have already undergone clinical testing, been approved and have been implemented for use in medical implants. This indicates that replacement is technically feasible in some medical implant applications and would result in decreased exposure of humans to PFOA in these instances. However, replacement of PFOA in all types of implantable medical devices is not known to have taken place and clinical testing of any alternatives will be necessary on a case by case basis (taking many years) to establish the feasibility and effectiveness of any alternative prior to being medically approved. The extent of transport of PFOA from implantable medical devices into the body is not well understood, but the REACH Annex XV restriction report (ECHA, 2014a) suggests that the low quantities present would also mean low potential for exposure. Additional information on the use of PFOA in medical implants in developing countries is lacking. A possible time-limited exemption for this use could be considered.

(e) Photo-imaging sector

Introduction

1. The RME (UNEP/POPS/POPRC.13/7/Add.2) identifies a small number of relevant uses of PFOA in the photo-imaging sector. Within the European Union an exemption under the REACH regulation is in place for photographic coatings applied to films, papers or printing plates without time limitation (EU 2017/1000). Specific exemptions applied in Norway and Canada until 2016 but are now obsolete (See Annex 1). The Norwegian risk management approach only applies to consumer products and the Canadian approach does not apply to manufactured items.
2. At POPRC-13, industry provided information for the RME that suggested time-limited exemptions for photographic coatings applied to paper and for use in printing are no longer needed. Non-perfluorinated alternatives have successfully replaced some uses in the imaging and printing industry and the move to digital imaging will replace the need for PFOA. PFOA use in photo-imaging has been reduced by more than 95% worldwide since 2000 (I&P Europe). However, it was also noted that for developing countries, such information was lacking.
3. A conclusion was not reached at POPRC-13 and the Secretariat invited members of the POPRC to provide information on photo imaging, specifically in relation to the paper and printing sector and in developing countries.
4. Relevant information was submitted by the Netherlands (2018), IPEN and ACAT (2018) and Healthcare Without Harm (HCWH, 2018).

Efficacy and efficiency of possible control measures

1. This section provides information on PFOA used in the paper and printing sector of photo-imaging and additional evidence on use in developing countries.

### *Paper and printing sector*

1. PFOA and PFOA-related substances are used as surfactants in the manufacture of silver halide photographic film for professional and consumer applications. Professional applications include the use by photographers (e.g. when using traditional black and white film) as well as medical or military photographic imaging where PFOA is used as an anti-static agent for applications with high photosensitivity (e. g. x-rays). Consumer uses (for instance by hobby photographers) are reported to only play a minor role (REACH Stakeholder Consultation, 2013/14). Industry expect that the use of PFOA and PFOA-related substances is likely to cease within 10 years (from 2014) when stocks are exhausted and remaining applications will have been replaced by digital techniques (ECHA, 2014a).
2. In these uses, PFOA and PFOA-related substances are bound to a coating matrix, which is covered by other layers of the photographic material. The concentration of PFOA in articles is stated to be in the range of 0.1-0.8 μg/cm² (ECHA, 2014a). The use of PFOA in photographic applications is strongly decreasing owing to the transition to digital techniques. According to European industry, < 0.1 t of PFOA and <0.1 t of PFOA-related substances were used in the EU in 2013 in photographic applications (ECHA, 2014a). Environmental releases and exposure potential are also assumed to be low during manufacturing (I&P Europe, 2015).
3. The submission by the Netherlands (2018) provided information that PFOA has been replaced in most applications within the EU. Analogue applications have largely been replaced by digital, but precise percentages are not available. Forecast numbers previously indicated a further reduction of PFOA and PFOA-related substance use in Europe to about 0.12 t/yr in 2015 and 0.088 t/yr in 2016 (ECHA, 2015b), amounting to a further reduction of the use of PFOAs in the whole photographic industry to respectively 96.4% and 97.5% since 2000 (I&P Europe, 2015).

### *Use in developing countries*

1. IPEN and ACAT (2018) provided multiple examples (from countries such as Gabon, South Africa, Bolivia, Kenya, Latin America, Kazakhstan and remote Arctic communities) where digital imaging has been adopted in developing countries in favour of hardcopy printing. The International Atomic Energy Agency (IAEA) and the World Health Organization (WHO) note that medical diagnostic imaging began in the 1970s and the momentum has grown to the extent that “digital image management is currently the preferred method for medical imaging.” IAEA and WHO note that the rapid adoption of digital technology in healthcare results from “efficiencies inherent in digital capture, storage and display and the competitive cost structures of such systems when compared to alternatives involving film.” Developing countries are adopting digital technology in favour of film due to advantages in price, ease of use, immediate image acquisition, image manipulation including feature extraction and mobility of information (between physicians and health experts).
2. Further information on use of PFOA or PFOA-related compounds in developing countries in other industry sectors (other than healthcare) was not received in response to the call for information.

### *Control measures*

1. It is indicated by I&P Europe member companies that most photo-imaging products do not contain PFOA or PFOA-related compounds (I&P Europe, 2015). The RME provides text which states that for waste materials, which are associated with the manufacture of a small number of films containing PFOA or PFOA-related compounds, are typically disposed of 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, 2016). This represents the situation in Europe (IPEN Comments on 1st draft RME). Information for other geographies has not been identified.
2. Due to lack of data, substitution costs in response to a restriction for photographic applications cannot be estimated and no further up to date information has been received in response to the call for information.
3. Monitoring data linked directly to the photographic sector is very limited and no additional data has been submitted in response to the recent call for information.

Information on alternatives

1. According to I&P Europe, since 2000, European industry has reformulated/ discontinued a large number of products, resulting in a world-wide reduction in the use of PFOA-related compounds of more than 95%. Although replacements do not currently exist for the remaining few applications, further reduction in use of PFOA-related compounds is anticipated as the transition continues towards digital imaging. I&P Europe believes that additional control measures for ongoing uses are not necessary (I&P Europe, 2016).A study by van der Putte et al. (2010) suggests that no alternative currently exists and the significant investment required in R&D to switch to an alternative means it is likely that manufacture and use of PFOA or PFOA-related compounds in the photo-imaging sector could cease (ECHA, 2014a). The largest barriers to development reportedly remain technical and cost of R&D. They suggest that substitution of PFOA typically amounts to 500-1000 k Euro for a single photographic material. The economic cost associated with substitution of PFOA in the few remaining critical photographic uses has in most cases become prohibitive, the small remaining critical uses being niche products in markets that I&P Europe members anticipate to further decline (I&P Europe, 2015).
2. The Netherlands (2018) provided information stating that they have created a replacement programme for PFOA. For substitution the first option is to look at non-fluorine substances if applicable. The PFOA products concerned (Amfluk and Kapri) were replaced where possible by a combination of non-fluorinated products and / or degradable fluorinated compounds where no PFOA arises following degradation. Both the medical and graphical range is, with the exception of a few niche products, almost completely switched over.

Information on impacts on society

1. According to representatives of the European photo industry, control measures implemented by the photo-imaging industry, including reformulation and product discontinuance, have reduced the use of PFOA-related compounds worldwide by more than 95%. The emissions from the small number of ongoing uses by the photo-imaging industry have been assessed by a number of competent authorities in the EU, including ECHA, and determined not to pose a relevant risk to the environment or human health (I&P Europe, 2016).
2. Michiels (2018) commented that the remaining use of PFOA for photo-imaging in Europe related to applications with high photosensitivity and need for high contrast in the grey scale such as diagnostic x-rays used for mammograms in the medical sector and surveillance imaging by air military crews. Lack of availability for these applications could pose issues for the healthcare and military sectors.
3. The impact of a possible restriction to PFOA use in photographic products will be larger in developing countries and in certain EU countries such as Italy, Spain, Portugal, Greece and a number of Eastern European countries (I&P Europe, 2016) due to higher usage in the medical sector. Also in view of the healthcare sector, discontinuation of current conventional photographic medical products because of the non-availability of PFOA would impact EU Member States where keeping hard copy images in medical files is a legal requirement, such as in France (I&P Europe, 2016).

Syntheses of information

1. Analogue printing is being phased out and replaced rapidly by digital, including in developing countries. However, critical uses for military and medical applications remain at risk if current conventional photographic products in the paper and print sector become restricted. No chemical alternative currently exists largely due to the economic cost and time investment necessary for development in what is a small commercial use sector and this is likely to result in phase out of products before an alternative can be found. I&P Europe comment that use of PFOA compounds in photo imaging has decreased globally by 95% since 2000 and only limited critical applications still use PFOA. On that basis I&P Europe commented that additional control measures for ongoing uses are not necessary (I&P Europe, 2016).

Conclusion

1. Based on the anticipated transition towards digital imaging and the further reduction in use of PFOA in this sector, no exemptions for paper and printing should be considered necessary. Alternatively the members of the POPRC could consider a specific time- limited exemption for named specific applications such as the medical and military sectors. This, however, depends on whether additional information will be made available by the relevant sectors.

(f) Automotive industry

Introduction

1. According to the RME, an exemption for automotive service and replacement parts could be considered under the Stockholm Convention. However, specification of relevant automotive service and replacement parts as well as sound justification for any exemption is required. No related exemptions have been given in the EU and Norway (see the RME).
2. The POPRC invited parties and observers to submit further information on automotive spare parts and other relevant information. Information was submitted by the Canadian Vehicles Manufacturing Industry (CVMA) and IPEN and ACAT (2018). Furthermore, Canada (2018) indicated that the use has been described in paragraphs 79, 89 and 232 of the RME and that apart from the information already included in the RME, no new information is available for submission from Canada.

Efficacy and efficiency of possible control measures

1. During the development of the RME, the CVMA requested specific exemptions for automotive service and replacement parts. According to the CVMA, the industry has been proactively phasing out PFOA use for some time. However, service and replacement parts might still contain PFOA. These parts represent a small percentage of PFOA use and will decrease naturally over time as the vehicle fleet turns-over. Automotive manufacturers reportedly need to ensure the availability of original equipment and spare parts to satisfy customer demand (see the RME).
2. In their recent submission, CVMA specifies that an exemption is required for automotive vehicle service and replacement parts as well as current production vehicles given the complexity of the sector and the actions already undertaken by the industry. An exemption was provided for service and replacement parts when the Convention was deliberating the addition of decaBDE and the same exemption should be applied for PFOA, according to CVMA. The issues and challenges would reportedly be similar (CVMA, 2018).
3. The CVMA further explains that it is challenging to provide meaningful information in support of the required exemption for PFOAs used in the automotive industry. According to CVMA, this is in particular challenging as PFOA is unlike other substances examined under the Stockholm Convention identifiable by a single CAS number. CVMA doubts that it would be possible, as a manufacturer of a finished product (a vehicle) to collect information from a large, complex, tiered global supply chain without using clear and accurate identifiers for substances (CVMA, 2018).
4. According to CVMA, the automotive industry has recognised the concerns with certain PFOAs and has taken proactive efforts to track and reduce those substances in products. Five (5) PFOAs were added to the Global Automotive Declarable Substance List (GADSL; www.gadsl.org) in 2008 and another 3 substances in 2016 (see the list of substances below). Given this, the industry has some information on 5 substances and only preliminary information on 3 new substances. At least 1 of the 5 substances listed on GADSL is identified as being used in the sector. Another PFOA which is not been listed on GADSL has been identified by at least one original equipment manufacturer (OEM) or a supplier as being used in the industry not further specified). These substances tend to be used at very low levels and probably not all uses have been identified (CVMA, 2018).

Figure 4.3 list of alternative substances provided by CVMA (2018)



1. PFOAs when used are found in applications that are important within the sector. For example, PFOA, its salts and PFOA-related compounds tend to be used in gaskets or seals in coatings or lubricants and in other instances where water or dirt repellent properties are critical to the safe and efficient functioning of the part. The level of PFOA usage in the sector is currently unknown. However, CVMA expects that the use quantities are very small. A complicating factor in determining the level of usage is uncertainty about the list of PFOA, its salts and precursors and associated CAS numbers (CVMA, 2018).
2. As mentioned above, only 8 PFOA salts and precursors are declarable under GADSL and therefore many of the other PFOA salts and precursors could potentially be present in production vehicles without the knowledge of the manufacturers. Further, it is important to highlight that the 8 PFOA substances are included in GADSL if they are used at a concentration above 0.1%. Consequently, all uses may not be known and sufficient lead time is required in the automotive industry to collect meaningful information. This process typically takes at least one full design cycle of approximately 5 years (CVMA, 2018). No further information has been submitted by CVMA related to the eight known PFOA substances included in the GADSL.
3. Regarding service and replacement parts, CVMA assumes that most likely service and replacement parts still contain PFOA, its salts and PFOA-related compounds. These parts represent a small percentage of the PFOA use and the amount will decrease naturally over time as the vehicle fleet turns over. Vehicle manufacturers normally ensure the availability of the Original Equipment (OE) service and replacement parts for a minimum of 15 years to satisfy consumer demand and potentially certification and quality requirements. Typically, parts may be built and stocked at the time of vehicle production or built to the original specifications, including compositions, in short production runs after the new vehicle production ends. The cost of replacing a class of substances in a small number of parts is according to CVMA prohibitive. It should be noted that repair parts need to meet the same performance specifications as the original parts. Based on replacement part availability obligations as noted above, the vehicle manufacturers are working to address the 8 PFOAs listed from replacement parts by 2036 provided the effective date of the ban is 2021; for PFOAs substances not known, this would take much longer (CVMA, 2018).
4. CVMA further explains that each vehicle manufacturer in general carries over 250,000 active replacement parts, with roughly 20,000 new service parts added annually. The number of parts maintained in inventory and its location (Canada or U.S.) depends on expected consumption and future ability to manufacture. To the extent that customers need replacement parts beyond what is initially stocked, there is a “production-on-demand market” whereby suppliers continue to produce replacement parts using original tools, materials and production processes. (CVMA, 2018).
5. Re-developed replacement parts must function identically to the original part to ensure the vehicle’s functionality and safety are not adversely impacted. The cost of replacing a class of substances in a small number of parts is prohibitive according to CVMA. It could also result in parts being purchased by consumers from jurisdictions where the original type part or an inferior performing variant could be obtained (CVMA, 2018).
6. Additionally, the vehicle manufacturers do not have the capability to stock every potential part in sufficient quantities in inventory to meet unexpected demand. As such, service parts are stored at distribution centres in Canada, the U.S., and other global centres, to ensure customer requirements are met. Integration with this type of parts distribution centres increases delivery efficiency and speed. There are no plans to pull ahead the existing stock of replacement parts. From a sustainability standpoint, the consideration of disposing of PFOA-containing parts currently in inventory is counterintuitive to environmental protection because PFOA was broadly used in a variety of replacement parts. It poses a far more negative impact than providing the sale of a statistically small number of replacement parts (CVMA, 2018).
7. Regarding the quantity of PFOA in spare parts (manufactured articles in a finished vehicles), CVMA is not able to provide this information given the limited information and CAS numbers. Based on the typical function of PFOAs which is to repel dirt and water/moisture, it is typically found in areas such as vehicle safety restraint and air bag systems, as well as gaskets, seals and linings in engine, fuel and transmission systems. Concentrations tend to be less than 1% in the material and many are at concentrations less than 0.2%. The mass of PFOA in various components as a result of these low concentrations is also very small (CVMA, 2018). No specific information (e.g. quantities of the eight PFOA substances from the GADSL contained in spare parts) has been provided by CVMA.
8. While there may be alternatives available, CVMA is not sure that they can be eliminated as the industry typically needs a full design cycle (typically 5 years) to address product substitution. Alternatives are cost-prohibitive for spare parts according to CVMA (CVMA, 2018).
9. Regarding recycling activities of articles containing PFOA, no information is available (CVMA, 2018).
10. In contrast to the request for exemption information submitted by CVMA, IPEN and ACAT (2018) stipulate that key automotive industry associations have notified company members and suppliers that PFOA will be listed in the Stockholm Convention as well as being regulated in the EU and that “these substances should be substituted.”[[26]](#footnote-27) The automotive industry also notes that, “most suppliers producing relevant articles, like waterproofed convertible roofs or PTFE-coated seals, no longer use PFOA or other long-chained perfluorinated chemicals.” [[27]](#footnote-28) In the past PFOA has been used to make fluoropolymers used in automotive fuel systems but several companies have alternative emulsifiers so that PFOA has been eliminated in this class of automotive products.[[28]](#footnote-29) As a result of the automotive industry’s proactive approach to PFOA, during the year-long process of developing the PFOA RME the industry did not indicate any exemption interest, despite being fully aware of the POPRC process due to their involvement with DecaBDE (IPEN and ACAT, 2018).
11. IPEN and ACAT therefore claim that no exemption for PFOA use in the automotive industry should be recommended (IPEN and ACAT, 2018).

Information on alternatives

1. The information from the RME and the new submissions confirms that the phase-out of PFOA, its salts and PFOA-related compounds is ongoing in the automotive industry. Technical and/or economically feasible alternatives for PFOA exist at least in part for the automotive industry.
2. CVMA states in their response to the information request that while there may be alternatives available, they are not sure that PFOA, its salts and PFOA-related compounds can be eliminated as the industry typically needs a full design cycle (typically 5 years) to address product substitution. Alternatives are also cost-prohibitive for spare parts according to CVMA.
3. Information gathered indicates that the key obstacle towards a complete phase-out of PFOA in automotive service and spare parts by the entry does not appear to be the lack of alternatives but rather other obstacles such as costs, because additional costs arise for the certification of PFOA free alternative spare parts. These costs are considered prohibitive by the automotive industry.

Information on impacts on society

1. According to the RME, concerns of EU industry stakeholders are related to placing on the market and use of spare parts already manufactured. 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.
2. CVMA states, that vehicle manufacturers normally ensure the availability of the OE for service and replacement parts for a minimum of 15 years. Typically, parts may be built and stocked at the time of vehicle production or built to the original specifications, including compositions, in short production runs after the new vehicle production ends. It should be noted that repair parts need to meet the same performance specifications as the original parts.
3. Re-developed replacement parts must function identically to the original part to ensure the vehicle’s functionality and safety are not adversely impacted. The cost of replacing a class of substances in a small number of parts is prohibitive according to industry. It could also result in parts being purchased by consumers from jurisdictions where the original type part or an inferior performing variant could be obtained (CVMA, 2018).
4. No additional information on impacts on society has been provided by relevant parties or observers in the current submissions.

Syntheses of information

1. The information from the RME and the new submissions confirms that the phase-out of PFOA, its salts and PFOA-related compounds is ongoing in the automotive industries.
2. In their recent submission, CVMA specifies that an exemption is required for automotive vehicle service and replacement parts as well as for current production vehicles. No justification for the request of an exemption for current production vehicles was found in the submission by CVMA. According to their statement in the RME, the Canadian automotive industry has been proactively phasing out PFOA use for some time. This information suggests that no exemption is needed for current production vehicles.
3. The proposal by CVMA for critical spare parts was noted by IPEN and ACAT, which pointed out that up until now, no automotive industry, including CVMA, indicated any exemption interest during the year-long process of developing the PFOA RME, despite being fully aware of the POPRC process due to their involvement with decaBDE.
4. According to CVMA, a key obstacle in a complete phase-out of PFOA in automotive service and spare parts by the entry into force of a possible amendment of Annex A appears to be the prohibitive costs. However, no information on possible cost implications has been submitted. In addition, the Canadian automotive industry has concerns regarding practical challenges related to the numerous CAS numbers of affected substances.
5. According to CVMA’s recent submission, the level of PFOA usage in the sector is unknown. However, CVMA have declared 8 PFOA salts and precursors under GADSL. Given this, the industry has some information on 8 substances and at least 1 of the 5 substances listed on GADSL is identified by CVMA as being used in the sector. Another PFOA related-substance, which is not been listed on GADSL has been identified by at least one OEM or a supplier as being used in the industry. No specific information (e.g. quantities of the eight PFOA substances from the GADSL) has been provided by CVMA.
6. For these identified PFOAs and other substances on the non-exhaustive list of substances ((UNEP/POPS/POPRC.13/INF/6/Add.1), specific uses in typical service and spare parts as well as quantities should be made available to enable the evaluation of a possible exemption. This is especially the case if this exemption should take a similar approach as for decaBDE, as requested by CVMA in their recent submission. Based on specific information about relevant spare parts a list of relevant spare parts and categories could be established similar to the approach for decaBDE. The starting point for this could be the parts/categories already specified above, i.e. vehicle safety restraints and air bag systems, gaskets or seals in coatings or lubricants, gaskets, seals and linings in engine, fuel and transmission systems.
7. The Committee requested specification of relevant automotive service and replacement parts as well as sound justification as to why an exemption is required. The POPRC invited parties and observers to submit further information on automotive spare parts and other relevant information available. Limited information was submitted on socio-economic aspects and the availability of alternatives by CVMA and IPEN and ACAT. No conclusive information was submitted on the specification of relevant automotive service and replacement parts and on the quantities of relevant substances used in different applications. Further information such as used amounts in different parts is considered necessary to justify a recommendation for an exemption.

Conclusion

1. Based on the evaluation of updated information a time limited exemption seems not necessary for automotive service and replacement parts. This however depends on whether additional information will be made available by the automotive industry, in particular the specificity of the use of PFOA compounds in North America compared to other regions of the world.

(g) Fire-fighting foams

Introduction

1. The RME (UNEP/POPS/POPRC.13/7/Add.2) identifies a key use of PFOA in firefighting foams. This raised concerns at POPRC.13 due to the way that fire-fighting foams are used resulting in the potential dispersive and direct release to the environment. Alternatives to all uses of PFOA in fire-fighting foams exist and include fluorine-free solutions as well as fluorosurfactants with C6-fluorotelomers.
2. Within the EU restriction for PFOA (ECHA, 2015a), a limited exemption is given in order to provide an exemption for foams already placed on the market[[29]](#footnote-30). In addition, Canada provides exemptions for PFOA containing Aqueous Film-Forming Foam Concentrates (AFFFs) used in firefighting applications. Furthermore, in Europe the related compound PFOS had a time limited[[30]](#footnote-31) exemption for foams that were already installed or placed on the market under the EU POPs Regulation.
3. During the discussions held at POPRC.13 it was suggested that an exemption may be needed for PFOA within fire-fighting foams similar to the exemption used with the EU (for goods already placed on the market)[[31]](#footnote-32). However, a conclusion was not reached, and following the details of the RME, the Secretariat to the Convention invited members of the POPRC to provide information on chemical composition of mixtures and the volumes of pre-installed fire-fighting foam mixtures in use.
4. Relevant information was submitted by the Belarus (2018), Canada (2018), Netherlands (2018), Sweden (2018), the Fire-Fighting Foams Coalition (FFFC, 2018) and IPEN and ACAT (2018).

Efficacy and efficiency of possible control measures

1. This section provides information on total quantities of PFOA-based fire-fighting foams in use, control measures adopted to limit release and details around the final destruction of fire-fighting foams containing PFOA.

### Stockpiles already placed to market

1. The Fire Fighting Foam Coalition (FFFC, 2004 and FFFC, 2011) provide details of an inventory for PFOS based AFFF fire-fighting foams in the USA. The 2004 PFOS-based AFFF inventory estimated that 4.6 million gallons (17.4 million litres) of concentrate were in use in the USA. This was largely dominated by military and federal installations (2.1 million gallons, primarily for navy and air force), petro-chemical industries (1 million gallons) and oil refineries (0.95 million gallons). The concentrates had a fluorine content of 0.3 – 1.8% wt/wt. The concentrates used would be mixed with water to provide a mixture ready for use. The concentrates made up 3% or 6% w/wt of the final mixture depending on the specific product (FFFC, 2004). The 2011 update of the USA PFOS based AFFF inventory notes remaining stocks of in-use PFOS based AFFF concentrate as 3.3 million gallons (12.5 million litres). The manufacture of PFOS based AFFF in the USA reportedly ceased in 2002 (FFFC, 2011), and no new stocks were placed on the market between 2004 and 2011. While the inventory developed by the Fire Fighting Foam Coalition and submitted as part of the response to the Secretariat’s invitation for information relates to PFOS-based AFFF and not PFOA-based AFFF, it provides a useful reference for indicative quantities of PFOA-based fire-fighting foams on the market in the USA.
2. ECHA (ECHA, 2014a) estimated that 50-100 tonnes of PFOA-related compounds (CAS No: 70969-47-0 C8-C20-ω-perfluoro telomer thiols with acrylamide) were in use for fire-fighting foams in 2014. This was based on data from the Norwegian product register and extrapolated to EU-wide quantities based on population. Sontake and Wagh (2014) commented that AFFF, supplied as a concentrate (which is then mixed with water ready for use during incidents/training exercises) contains PFOS at concentrations of 1, 3, or 6% wt/wt of concentrate. An EU report (ECHA, 2014a) assumes similar concentrations for PFOA. Sontake and Wagh (2014) further comment that for AFFF concentrates after mixing with water (and therefore ready to use) have PFOS concentrations of 0.03 – 0.45% wt/wt ready to use fire-fighting foam. The EU report (ECHA, 2014a) assumes similar concentrations for PFOA in mixed foams. For means of comparison with the US inventory this quantity has been converted into US gallons[[32]](#footnote-33) based on the active concentration of 1 – 6% wt/wt in fire-fighting foams. This would equate to between 0.2 - 2.3 million gallons (0.75 – 8.7 million litres) of fire-fighting foams in Europe containing PFOA-related compounds.
3. Belarus (2018) noted that PFOA based AFFF foams are not used in Belarus, with the main product in use being a Fluoro telomer (C6:2) product called Forafac 1157. The same product is also used in Russia.
4. Seow (2013) comments on a survey completed for Australia by NICNAS to assess PFOS-containing fire-fighting foams. In 2007 14 tonnes of perfluoroalkyl (PFA) fire-fighting foams were imported into Australia (1.3 tonnes of which contained PFOS). In 2006, 8 tonnes of PFA fire-fighting foams were imported into Australia (of which 0.76 tonnes contained PFOS). The quantity of PFOA-based fire-fighting foams is not disaggregated from the PFA total. Seow (2013) also commented that Australia have never manufactured PFOA and that PFA based stockpiles of fire-fighting foam are undergoing a process of phase-out.
5. Further information on stockpiles of PFOA-based AFFF fire-fighting foams already placed on the market is more limited. Wang et al (2014) provide estimates for a global emission inventory for perfluoroalkyl carboxylic acid (PFCAs) homologues in the C4-C14 range including PFOA. Wang et al (2014) comment that, in 2006, eight major manufacturers of PFCAs joined the US EPA 2010/15 stewardship program targeted at the phase-out of long chain PFCAs including PFOA. While the stewardship program includes major producers in Japan, Europe and North America, new producers began manufacturing PFCAs subsequent to 2006, largely in Asia. The appearance of new production facilities in India and China was largely driven by demand for PTFE rather than use in fire-fighting foams; Wang et al (2014) note that the manufacture of PFOA-based products in China increased from negligible amounts in the 1990s to 50-80 tonnes per annum by 2009, with at least five major facilities in China.

### Control measures for in-use stockpiles of PFOA fire-fighting foam

1. The Fire Fighting Foam Coalition (2016) provided details of best practice for use of Class B fire-fighting foams[[33]](#footnote-34), which includes the PFOA based AFFF types of product. The guidance focuses on measures which can be grouped into one of three categories:
2. I) Selection of when to make use of Class B fire-fighting foams. The FFFC (2016) comments that Class B fire-fighting foams should only be used when the most significant flammable liquid hazards are identified. For facilities that have potential liquid flammable risks, hazard assessments should be used in advance to investigate whether other non-fluorinated techniques can achieve the required extinguishment and burnback resistance. This includes consideration of the potential shortfalls that alternative methods may have. Furthermore training exercises should not use fluorinated fire-fighting foams.
3. II) Containment of environmental release during use of Class B fire-fighting foams for live incidents. The FCCC (2016) notes the variability of potential incidents and highlights that it is not possible to contain and collect fire runoff in all situations. However, the FCCC (2016) also highlight that runoff from liquid flammable fires will contain a mixture of water, residual hydrocarbon products, fire-fighting foam and therefore loss to environment should be avoided. For facilities that make use of flammable liquids (such as fuel farms and petroleum/chemical processing, airport operations, specific rail transportation, marine and military storage and industrial facilities) the FCCC (2016) best practice guidance states that a firewater collection plan should be developed in advance, and for fixed systems with automatic release triggers containment should be built into the system design.
4. III) Disposal of contaminated runoff and foam concentrate. The FFFC (2016) comments that Class B fire-fighting foam concentrates (which include PFOA based foams) do not carry expiry dates, but generally have a service life of 10 – 25 years. It is also possible to have testing completed routinely to assess whether the foam in stock still meets requirements. Destruction of Class B fire-fighting foam concentrate should be through thermal destruction. For contaminated fire-water from use of foams the FCCC (2016) guidance highlights that the solution will contain a mixture of chemicals and that thermal destruction is the preferable option. Other options include a combination of coagulation, flocculation, electro-flocculation, reverse osmosis, and adsorption on granular activated carbon (GAC).
5. Klein (2013) provides some further information on the likely costs incurred for the thermal destruction of Perfluorinated fire-fighting foams (including PFOS and PFOA). This varies depending on technical approach with plasma-arc facilities likely more expensive than using cement kilns (noting that cement kilns operate at high temperatures[[34]](#footnote-35)). Klein provides a general estimate of cost for Europe as €0.77 per litre of concentrate. For Australia costs within cement kilns ranged from $1 – 1.5 per litre and in plasma-arc $17-20 per litre. Klein (2013) also comments that the use of GAC, electroc-coagulation, or reverse osmosis can be effective at reducing costs as these processes reduce the fluorochemical content. Capital costs for setting up treatment plants using these methodologies varies between €92,000 - €230,000. Klein (2013) comments that the significantly high costs of managing disposal for perfluoro based fire-fighting foams had encouraged one major aviation industry operator to switch to fluorine free fire-fighting foams at all of its national airports.

Information on alternatives

1. The RME (UNEP/POPS/POPRC.13/7/Add.2) highlighted that many viable chemical alternatives to PFOA-based AFFF are available and commercially in use globally. The paragraphs below are taken from the RME for ease of reference. New reference material is included where indicated.

### Short-chained fluorinated alternatives

1. During the last several years, manufacturers of fluorotelomer-based AFFFs have been replacing long-chain fluorinated surfactants with short-chain fluorinated surfactants (UNEP, 2017). AFFFs based on pure 6:2 fluorotelomers were developed to replace early products based on a mixture of mainly 6:2 and 8:2 fluorotelomers (Klein, 2012; Kleiner and Jho, 2009). DuPont, for example, commercialized two AFFFs based on 6:2 fluorotelomer sulfonamidealkylbetaine (6:2 FTAB) or 6:2 fluorotelomer sulfonamideaminoxide (Wang et al., 2013). Suppliers offering a portfolio of short-chain fluorotelomer-based surfactants include Chemguard, Chemours and Dynax (UNEP, 2017).
2. Chemical alternatives include C6-fluorotelomers such as 6:2 fluorotelomer sulfonyl betaine, sometimes combined with hydrocarbons and the 3M product dodecafluoro-2-methylpentan-3-one. The direct release of substances to the environment and the detection of C6 compounds in the environment including the Arctic, human and wildlife make this use of fluorinated alternatives undesirable (see UNEP/POPS/POPRC.13/INF/6) (IPEN, 2016).
3. The EU Annex XV restriction report (ECHA, 2014a) highlighted that, while PFOA or PFOA-related compounds are not used in the manufacture of 6:2 fluorotelomer based fire-fighting foams, fluorotelomer based foams can contain trace quantities of PFOA as a by-product. The restriction implemented under the EU REACH regulation applies an exemption for PFOA-based fire-fighting placed on the market on or before 4 July 2020. However, after this date maximum concentrations of 25 ppb for PFOA or 1000 ppb for PFOA and PFOA-related compounds are imposed for fire-fighting foams placed to market in the EU.
4. Mil Tech (2017) (quoted within Canada (2018)) notes that the USA department of defence has amended specifications for use of AFFF fire-fighting foams used in military facilities (including marine), so that AFFF fire-fighting foams must not contain more than 800 ppb of PFOA

### Non-fluorine containing alternatives

1. A variety of fluorine-free Class B foams are on the Swedish market indicating the technical feasibility of this alternative. The firefighting foam Moussoll-FF 3/6 was introduced at a Swedish airport and is degraded to carbon dioxide and water in the environment. It is considered effective in fire suppression required at airports where high safety standards have to be fulfilled. Swedavia, which owns ten Swedish airports, including Arlanda and Landvetter, had previously used fluorine-based firefighting foams but in June 2011 switched to a fluorine-free alternative. The Swedish Armed Forces began phasing out the use of perfluorinated substances in firefighting foam in Sweden in 2011. Nowadays the Swedish Armed Forces use a fluorotelomer-based firefighting foam, i.e. the substance that is broken down to perfluorinated substances (further details see Swedish Chemicals Agency, 2015). Norwegian airports, military properties and several offshore companies have also introduced fluorine-free foams (Norway Comments on 3rd draft RME).
2. With respect to firefighting foams, it is estimated in a study (RPA, 2004) that the cost for fluorine-free alternatives is approximately 5-10% higher than those for fluorosurfactant foams. Based on information provided by a manufacturer of the fluorine-free alternatives, the cost would fall in case of an increased market size (Poulsen et al., 2005). This study does not consider the internalized costs of continued reliance on fluorosurfactant foams, including the costs of groundwater remediation, contamination of aquatic environments, subsistence and commercial fisheries, and environmental and public health (IPEN Comments on 2nd draft RME). Lifetime costs for using AFFF, fluoroprotein (FP), or film forming fluoroproteins (FFFP) far outweigh those of fluorine-free foams because of legal and financial liabilities of using a fluorochemical based foam (see Queensland Gov., 2016a and 2016b) as indicated above which include infringement of operating license conditions, reputational and brand image damage (see Klein 2013). Increasing evidence suggests that fluorochemical contamination of groundwater is an ongoing serious issue impacting agriculture, fisheries, property prices, with considerable political and public concern fallout resulting in hugely expensive and damaging and legal challenges. Remediation costs are still substantial, especially off-site, compounded by high analytical and consultancy costs in the case of environmental contamination with fluorinated breakdown products from an AFFF, FP or FFFP (see e.g. Klein 2013).
3. The BAT/BEP Guidance for use of PFOS and related chemicals under the Stockholm Convention on POPs (UNEP, 2017) confirms that non-fluorinated foams exist and are in use. According to a review undertaken by the Queensland Government in Australia, many fluorine-free foams are acknowledged as meeting the toughest amongst the firefighting standards and exceeding film-forming fluorinated foam performance in various circumstances and that fluorine-free foams are widely used by airports and other facilities including oil and gas platforms (see Queensland Gov., 2016b). According to the Swedish Armed Forces it is difficult to find fluorine-free alternatives which meet specific safety requirements (see Swedish Chemicals Agency, 2016).
4. Manufacturers and some users mention that fluorine-free firefighting foams do not have comparable extinguishing effects to foams with fluorosurfactants. Compared to fluorine-based firefighting foams approximately twice as much water and foam concentrate are needed when extinguishing liquid fires. According to some fluoro surfactants foam manufacturers, some analysis confirmed that fluorine-free firefighting foams may offer less protection against re-ignition, which makes it impossible to apply this alternative for some operations (Swedish Chemicals Agency, 2015). According to the Fire Fighting Foam Coalition (FFFC) AFFF agents containing fluorotelomer-based fluorosurfactants are the most effective foam agents currently available to fight flammable liquid fires in military, industrial, aviation and municipal applications. Test data provided by the United States Naval Research Laboratories (NRL, 2016) showed that, in pool fire tests, an AFFF agent achieved extinguishment in 18 seconds compared to 40 seconds for the fluorine-free foam. In foam degradation tests, fluorine-free foam degraded after 1-2 minutes, while the AFFF lasted 35 minutes before it has been degraded. The FFFC does not support the opinion that AFFF agents are no longer needed and recommends the use of AFFF only in specific circumstances where a significant flammable liquid hazard occurs and that all available measures to minimize emissions to the lowest possible level should be implemented when using AFFF agents (FFFC, 2017). However, blockage factors (i.e. vapour suppression) were indistinguishable between a fluorine-free-foam and two AFFFs tested (Williams et al. 2011). Airports and offshore companies around the world have introduced fluorine-free foam and are satisfied by the performance.
5. A Spanish foam manufacturer presented results from a series of new fire tests (Wilson, 2016) run on five commercially available short-chain (C6) AFFF agents and five commercially available fluorine-free foams (tests were run with the four different fuels: gasoline, heptane, jet A1 and diesel). It was shown that the short-chain AFFF foams performed significantly better compared with fluorine-free foams on all fuels except diesel. None of the fluorine-free foams managed to extinguish the jet A1 fire (the fuel used in the International Civil Aviation Organization (ICAO) fire tests that determine the acceptability of foams for airport use in many countries) (FFFC, 2017). However, fluorine-free foams certified to different ICAO levels (required for use at civilian airports) are available on the market (see FFFP, 2017) and are already introduced at airports in practice (see above).
6. The institute for fire and disaster control Heyrothsberge in Germany tested six fluorine free alcohol resistant firefighting foams and one PFAS containing foam for their ability to extinguish fires of five different polar liquids. The authors conclude that there are fluorine-free foams available which show a similar performance compared with PFAS containing foams (see Keutel and Koch, 2016).
7. The evidence presented within the RME suggests that chemical alternatives to PFOA based AFFF exist and are actively in use globally. The FFFC (2017) highlights concerns for non-fluorinated alternatives when managing specific kinds of fire incidents where a significant risk is posed, but also that non-fluorinated alternatives are still useful for other types of incident.

Information on impacts on society

1. The RME (UNEP/POPS/POPRC.13/7/Add.2) highlighted concerns related to the dispersive and direct way in which fire-fighting foams are used. The RME also noted that the continued use of PFOA in firefighting foams would result in the ongoing contamination of groundwater and soil surrounding facilities where PFOA-based AFFF was used (mainly military sites and airports). The RME provides examples of such cases with an indication of the magnitude of the contamination and remediation costs. As part of the request for information, the paragraphs below include further details on ground contamination linked to use of PFOA-based AFFF fire-fighting foam.
2. Military.com (2017) (quoted within IPEN, 2018) provides details of discussions held in the US senate regarding around 400 military facilities where PFOS and PFOA based fire-fighting foams had been previously used and lost to the environment causing ground contamination such as that Fairchild Air Force base. Total estimated remediation costs for ground contamination are cited within the article as being as high as $2 billion dollars.
3. Klein (2013) provides examples of a number of cases of groundwater contamination at facilities (military, airports and petroleum refineries) where Perfluoroalkyl (chiefly PFOS) fire-fighting foams have been used for training or live incidents. In particularly Klein refers to a case study at US military fire training grounds where PFOS had been previously used. Even 10 – 15 years after use had ceased groundwater monitoring found that groundwater would still produce foam with high concentrations of fluorotelomer detected (14.6 mg/l fluorotelomer sulphonate). Another case study at Jersey Airport, Jersey Island, details the use of PFOS-based AFFF on fire training grounds which contaminated the island’s aquifer and drinking water. Remediation costs were estimated to be between £3.7 to £30 million pounds sterling (based on 1999-2000 prices) dependent on options selected. This included the potential removal and destruction of soil to a depth of 30 metres and reconstruction of the site.
4. Cousins (2016) (quoted within IPEN (2018)) further highlighted that the costs of cleaning up the contaminated site is only one of many costs associated with the contamination legacy from PFAS-containing firefighting foams; others include analytical costs of monitoring of PFAS concentrations, incineration of old stockpiles, clean-up of equipment contaminated by previous use, costs of developing and commercializing sustainable alternatives, costs of funding new research, health costs, legal costs, etc. Most of these costs will be borne by taxpayers, as it is challenging and often costly to identify the principal responsible party or parties in practice.

Other considerations

1. ECHA (ECHA, 2015a) allows a derogation for existing PFOA-based fire-fighting foams placed on the market on or before 4 July 2020, which allows further use for a period of 20 years. This derogation is consistent with the exemption for foams already in use, and will avoid the need for early replacement of exempted foams (UNEP/POPS/POPRC.13/7/Add.2). IPEN commented within the RME and discussions at POPRC.13 that the normal lifetime of firefighting foam varies considerably with temperature and storage conditions. According to them, 20 years is an inappropriate length of time for continued dispersive use of POPs, a use which has led to massive contamination of groundwater in many countries. The FFFC (2016) best practice guidance commented that PFOA-based fire-fighting foam does not have an expiry date but will have a shelf life of 10 – 20 years.

Syntheses of information

1. Only limited information exists to quantify the PFOA-based fire-fighting foams already placed on the market. ECHA (ECHA, 2014a) suggested that 50-100 tonnes of PFOA related compounds (CAS No: 70969-47-0) were in-use within fire-fighting foams in 2014, which has been calculated to be equivalent to 0.2 – 2.3 million US gallons (0.75 – 8.7 million litres) of concentrate for AFFF. The FFFC (2011) inventory of PFOS concentrates quotes 3.3 million US gallons (12.5 million litres) in use for 2011. This assumes that similar quantities of PFOA based concentrates were in use. Seow (2013) comments that 14 tonnes of perfluoroalkyl fire-fighting foams were imported into Australia in 2007, of which 1.3 tonnes were PFOS-based. Further detail of the PFOA quantity is not available. Data for other geographies has not been identified. However, Wang et al (2014) highlight that under the USEPA stewardship program eight major manufacturers based in Japan, Europe and North America agreed to the phase-out of long chain perfluoro compounds (including PFOA). Wang et al (2014) also note that new manufacturers in Asia (primarily India and China) have subsequently begun PFOA manufacture, although largely to meet demands for fluoropolymers such as PTFE.
2. The FFFC (2016) best practice guidance for use of class B fire-fighting foams, which include PFOA based fire-fighting foams. This included selection of foams only where most needed and avoiding the use of class B fire-fighting foams for training. The best practice also included forward planning for facilities that use flammable liquids to put in place capture and containment systems for runoff. However the FCCC (2016) guidance does also indicate the variability of incidents and that capture of runoff is not possible in every situation. The guidance also provides details on suitable destruction for fire-fighting runoff and foam concentrates; with thermal destruction the preferred option. Klein (2013) provides indicative costs for destruction of foam concentrates at around €0.77 per litre or $1 – $1.5 Australian dollars per litre.
3. The RME (UNEP/POPS/POPRC.13/7/Add.2) details that multiple alternatives to PFOA based fire-fighting foams are already commercialised and readily available. This includes fluorinated options based around fluorotelomers (C6:2) and fluorine free alternatives. ECHA (ECHA, 2014a) noted that the manufacture of fluorotelomer based fire-fighting foams can contain trace amounts of PFOA as a by-product. The restriction sets limits of 25ppb for PFOA and 1000ppb for PFOA and PFOA-related compounds.
4. The RME (UNEP/POPS/POPRC.13/7/Add.2) provided details regarding groundwater contamination with perfluorinated fire-fighting foams (primarily PFOS) indicating the significant costs and efforts required to clean up contaminated sites and potential long-lasting effects of contamination. This included a case on the island of Jersey, where clean up options for contamination of an aquifer with PFOS based foams was in the order of £3.7 - £30 million pounds. Other examples from the USA highlighted cases where groundwater contaminated with PFOS was still able to produce foam when extracted 10– 5 years after contamination.
5. Finally, ECHA (ECHA, 2015a) discusses the length of the derogation needed for PFOA based fire-fighting foam placed on the market. A 20-year derogation would be in line with other fire-fighting foams and avoid the need for early retirement. IPEN (2018) commented that the life span of foams varied depending on climate and storage and therefore a 20-year derogation would not be acceptable for the Stockholm Convention. The FCCC (2016) state that foams do not have an expiry date but have a shelf life of 10-25 years.

Conclusion

1. Based on the information compiled and reviewed within the RME, the size of in-use stockpiles may be significant and socio-economic impacts of an immediate ban may be equally significant, a time-limited exemption is therefore warranted. However, the impacts of release to ground water and socio-economic costs of clean-up mean that efforts should be made to phase out as soon as possible. Therefore, the time-limited exemption should reflect this.

# Synthesis of information

## Summary of information and concluding statement for uses

1. The Committee invited Parties and observers, including the relevant industries, to provide information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds. Table 5.1 provides a summary of key information within this addendum and concluding statements.

Table 5. Summary of evaluation of uses and conclusions regarding specific exemptions for PFOA, its salts and PFOA-related compounds

| **Use** | **Requested information** | **Summary of key points** | **Conclusion** |
| --- | --- | --- | --- |
| Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment | Information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects | According to the RME, a time limited exemption could be considered for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. However, additional information to justify a possible exemption is needed.  The Committee requested information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects. Limited information has been submitted by parties and observers on the scope of the applications and the availability of alternatives by HCWH Europe (Health Care Without Harm), Canada, IPEN and ACAT. No relevant information has been provided or could be identified on used amounts and socio-economic aspects.  Used amounts for specific applications and related information which would also enable to evaluate socio-economic aspects and information on the possible non-availability of alternatives would be needed to further evaluate possible exemptions. | Based on the evaluation of available information a time limited exemption could be considered for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. This, however, depends on whether additional information will be made available by the industry.  Specific information on the scope of the applications, used amounts, non-availability of alternatives and socio-economic aspects is still lacking which would enable the Committee to evaluate the need for an exemption. |
| Transported isolated intermediates in order to enable reprocessing in another site than the production site | Information on the quantities used, extent of transport and risks, and use | IPEN and ACAT and the FluoroCouncil) provided relevant information as response to the current information request. IPEN and ACATs concerns regarding POP properties C6 fluorotelomers were already addressed in the RME. IPEN and ACAT also expressed concerns that an exemption for transported isolated intermediates could “open the door to waste dumping in developing and transition countries under the guise of “reprocessing”.”  The FluoroCouncil requests an exemption on behalf of a member company for the transport of PFOI, an unintended side fraction in the production of C6 fluorotelomers, as a transported isolated intermediate.  The respective company argues that they cannot reprocess PFOI, a PFOA related substance, on-site as a closed-system site-limited intermediate. PFOI is currently transported in closed barrels to a facility in South Korea where iodine recovery and reprocessing to TFE and HFP, take place under closed system conditions.  The company is developing a method for on-site iodine extraction, a prerequisite for reprocessing PFOI. A transitional exemption for the transport of PFOI as a transported isolated intermediate would be necessary, since the process will not be available on-site before the entry into effect of the Convention’s provisions on PFOA. Moreover, the process leads to the production of 1-H-PFO, that also falls under the definition of a PFOA related substance (questioned by the FluoroCouncil) and is therefore not a viable solution, if 1-H-PFO is considered a PFOA related substance.  A possible alternative to treat PFOI as POP waste has not been discussed. | Based on the evaluation of available information a time limited exemption could be considered for PFOI as a isolated intermediate to enable reprocessing at another site than the production site for the production of TFE and HFP, if additional relevant information about the specific volumes of the PFOI-containing fraction, release quantities and possible risks and risk management measures are made available which enable the Committee to properly evaluate the need for an exemption. |
| Medical devices | Information on specific applications/uses and timelines foreseen as needed for potential related exemptions | Medtech (2018) and Euromed (2015) commented that gathering information on specific applications was challenging. However, the main presence of PFOA within medical equipment will be as a by-product of PTFE. Medtech (2018) also provided a summary of generic potential uses.  IPEN (2018) commented that a specific list of applications is needed to help maintain clarity and enforcement of the Convention. Otherwise this would cause confusion at the Conference of the Parties.  ECHA (ECHA, 2015) estimated in use quantities of <1kg in the EU extrapolated to <5kg globally. ECHA (ECHA, 2015) further comments that due to stringent regulatory requirements in the healthcare sector substitution may take longer than other sectors and granted an exemption of 15 years for non-implantable medical devices. This exemption was needed to prevent critical applications from being lost in healthcare.  The RME noted that PFOA free PTFE options have already been developed and commercialised. The ECHA Annex XV restriction report comments that 70% of global PTFE production is now PFOA free under the PFOA product stewardship programme chaired by the US EPA which covers Japan, Europe and the USA. However many medical devices are manufactured outside of these areas (Medtech, 2018). | Specific lists of applications for medical devices have not been identified. Although information on a generic basis has been included.  Quantities of PFOA still in use and required up to the point of transition are low compared to other uses such as fire-fighting foams.  Potential issues with stringent medical regulations may also delay the transition processes and this would suggest that a time-limited exemption may be appropriate. |
| Implantable medical devices | Information on the quantities used, extent of transport and risks, and use; | ECHA (ECHA, 2015a) indicates that amounts of PFOA and PFOA-related substances related to this use are extremely low. In implantable devices, a manufacturer previously estimated that the total amount of PFOA present in all devices put on the market in the EU during the period 2018-2025 without the restriction would amount to 20 g (it is however unclear if this amount includes only PFOA or also PFOA-related substances).  Further information and data on quantities used, extent of transport and risks, and use of PFOA in implantable medical devices was not provided in response to the request for information.  Implantable medical devices, such cardiovascular devices catheters and guidewires, can contain PFTE made from PFOA (MedTech 2018). However, PFTE can be made without PFOA and alternatives are reportedly now commercially available, approved by US FDA, and are a feasible and effective alternative to the use of PFOA. | Cost competitive alternatives, such as PFOA free PTFE products have already undergone clinical testing, been approved and have been implemented for use in some specific medical implant devices. However, replacement of PFOA in all types of implantable medical devices is not known to have taken place and clinical testing of any alternatives will be necessary on a case by case basis (taking many years) to establish the feasibility and effectiveness of any alternative prior to being medically approved.  Possible time-limited exemptions for this use therefore could be considered. |
| Photo imaging sector | Information relevant for paper and printing sector and use in developing countries; | I&P Europe (2018) state that non-perfluorinated alternatives have successfully replaced some uses in the imaging and printing industry and the move to digital imaging will replace the need for PFOA.  PFOA use in photo-imaging has been reduced by more than 95% worldwide since 2000 (I&P Europe) due to reformulation and discontinuation of PFOA related compounds.  Indeed, digital imaging has been adopted in developing countries in favour of hardcopy printing especially in medical diagnostic imaging (IPEN and ACAT, 2018).v 143.148. Further information on use of PFOA or PFOA-related compounds in other industry sectors (other than healthcare) was not received in response to the call for information.  The emissions from the small number of ongoing uses by the photo-imaging industry have been assessed by a number of competent authorities in the EU, including ECHA, and determined not to pose a relevant risk to the environment or human health (I&P Europe, 2016). | Previously suggested time-limited exemptions for photographic coatings applied to paper and for use in printing are no longer necessary.  However alternatively the members of the POPRC could consider a specific time-limited exemption for specific named applications only, such as medical and military sectors. |
| Automotive industry | Information on spare parts | During the elaboration of the RME, the Canadian automotive association CVMA requested specific exemptions for automotive service and replacement parts. According to CVMA, the industry has been proactively phasing out PFOA use for some time. However, service and replacement parts might still contain PFOA. According to CVMA, these parts represent a small percentage of PFOA use and will decrease naturally over time as the vehicle fleet turns-over. Automotive manufacturers reportedly need to ensure the availability of original equipment and spare parts to satisfy customer demand.  Further, according to the Canadian automotive industry, a key obstacle in a complete phase-out of PFOA in automotive service and spare parts appears to be the prohibitive costs. However, no information on possible cost implications has been submitted. In addition, the Canadian automotive industry has concerns regarding practical challenges related to the issue that a conclusive list by CAS number of affected substances has not yet been provided.  In contrast to the request for exemption, IPEN and ACAT stipulate that key automotive industry associations have notified company members and suppliers that PFOA will be listed under the Stockholm Convention as well as being regulated in the EU and that these substances should be substituted. The automotive industry also notes that, most suppliers producing relevant articles no longer use PFOA or other long-chained perfluorinated chemicals. In the past PFOA has been used to make fluoropolymers used in automotive applications but several companies have alternative emulsifiers so that PFOA has been eliminated in this class of automotive products.  In summary, the Committee requested specification of relevant automotive service and replacement parts as well as sound justification as to why an exemption is required. Limited information has been submitted on socio-economic aspects and the availability of alternatives. No conclusive information was submitted on the specification of relevant automotive service and replacement parts and on the quantities of relevant substances used in different applications. | Based on the evaluation of updated information a time limited exemption seems not necessary for automotive service and replacement parts. This however depends on whether additional information will be made available by the automotive industry, in particular the specificity of the use of PFOA compounds in North America compared to other regions of the world.  No conclusive information was submitted on the specification of relevant automotive service and replacement parts and on the quantities of relevant substances used in different applications. Further information such as used amounts in different parts is considered necessary to justify a recommendation for an exemption. |
| Fire-fighting foams | Information on chemical composition of mixtures and the volumes of pre-installed amount of fire-fighting foam mixtures | Only limited further information has been identified on the chemical composition of PFOA and PFOA-related compounds used in fire-fighting foams. ECHA (ECHA, 2015) estimates 50-100 tonnes of PFOA related compounds (CAS 70969-47-0) were in use in 2014, calculated to be between 0.2 – 2.3 million US gallons of concentrate (assuming 1 – 6% wt/wt active ingredient in concentrates). The FFFC (2011) estimated 3.3 million gallons of PFOS based firefighting concentrates in use for the USA in 2011, which is indicative of PFOA based stocks. Australia imported 14 tonnes of PFCA based fire-fighting foams in 2008, of which 1.3 tonnes was PFOS based. No further disaggregation for PFOA based stocks.  The FFFC (2018) provided details of best practice for class B fire-fighting foams including PFOA based AFFF which included selective use, containment of runoff and appropriate destruction. The guidance did however note that runoff cannot be contained in all incidents due to variability  The RME provided details of clean-up costs for contaminated ground water where PFOS based foams had been used. Similar costs can be expected for PFOA based fire-fighting foams. For one example this amounted to between £3.7 – £30 million pounds (Klein, 2013)  The EU Annex XV restriction report (ECHA, 2015) commented that a 20 year exemption for goods placed to market on or before 4th July 2020to avoid early loss in service of goods in use. | Only limited information on potential stockpiles exists which does not cover all geographies. However, based on the data identified the potential stockpiles in use could be significant (10s of millions of US gallons of concentrate, equivalent to hundreds of tonnes of PFOA and PFOA-related compounds).  Equally costs associated with destruction and replacement can be perceived to be significant.  Evidence provided within the RME highlighted however that remediation costs for ground contamination are also significant, and potentially higher than destruction and replacement.  On the basis that the size of in-use stockpiles may be significant and socio-economic impacts of an immediate ban may be equally significant, a time-limited exemption is warranted. However the impacts of release to ground water and socio-economic costs of clean-up mean that efforts should be made to phase out as soon as possible. Therefore the time-limited exemption should reflect this. |

## Discussion on listing in Annex A/B

1. The request for members to submit information on the additional uses discussed within this addendum is intended to assist the POPRC members in reaching a decision on whether an exemption is needed, and whether that exemption should be a specific exemption (time-limited) or acceptable purpose (non-time limited). Based on a review of the information submitted and the RME, work is already ongoing for many of the applications identified to develop and commercialise alternatives to PFOA, its salts or PFOA-related compounds.
2. Furthermore, the European restriction for PFOA, its salts and PFOA-related compounds (EU 2017/1000 amending EC 1907/2006) grants only one use, implantable medical devices, with a non-time limited exemption. Canada also has a non-time limited exemption for fire-fighting foams (RME). The information from Medtech Europe (2018) suggests the transition for implantable medical devices will be complete by 2030. For fire-fighting foams, alternatives are already in use globally (see section 4.8) with the main obstacle being economic management of in-use stocks.
3. On the basis of the information reviewed and compiled within this addendum, the exemptions that may be required all relate to time-limited options, which best match specific exemptions under the Convention with no uses identified needing an acceptable purpose. On that basis it can be concluded that a listing with Annex A is most appropriate.

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

|  | Canada | EU | Norway |
| --- | --- | --- | --- |
|  | Prohibit manufacture, use, sale, offer for sale or import of the substances and products containing these substances | Prohibit manufacturing, use or placing on the market (1) as substances, as constituents of other substances and (2) articles or any parts thereof containing one of the substances | Prohibit to manufacture, import, export and make available on the market (1) textiles, carpets and other coated consumer products that contain the substances and (2) consumer products that contain the substances |
| Chemical scope | 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 Commission 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 No: 335-67-1, 3825-26-1,  335-95-5, 2395-00-8,  335-93-3, 335-66-0,  376-27-2, 3108-24-5)  (See Norway, 2016) |
| Exemptions for photo-imaging | Photo media coatings until 31 December 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 (until 4 July 2022);  - Photo-lithography processes for semiconductors or in etching processes for compound semiconductors;  -semiconductors or compound semiconductors. | Adhesives, foil or tape in semiconductors until 2016 |
| Exemptions for firefighting | Aqueous film-forming foams used in firefighting applications | - Concentrated firefighting foam mixtures that were placed on the market before 4 July 2020 and are to be used, or are used in the production of other firefighting foam mixtures;  - Firefighting foam mixtures which were: a) placed on the market before 4 July 2020; or b) produced in accordance with paragraph 4(e), provided that, where they are used for training purposes, emissions to the environment are minimized and effluents collected are safely disposed of. | Not covered by the restriction |
| Exemptions for medical uses | Partially captured under exemptions for manufactured items | - Medical devices (until 4 July 2032);  - Production of implantable medical devices within the scope of Directive 93/42/EEC. | Medical devices are exempted from restrictions |
| Exemptions for textiles | Partially captured under exemptions for manufactured items | - Textiles for the protection of workers from risks to their health and safety (until 4 July 2023);  - Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment (until 4 July 2023). | Textiles for consumer use are restricted when PFOA concentration is above 1ug/m2 for any part of the product. |
| Exemptions for inks | Water-based inks until 31 December 2016 | Latex printing inks (until 4 July 2022) |  |
| Exemptions for nano-coating | Partially captured under exemptions for manufactured items | Plasma nano-coating (until 4 July 2023) |  |
| Exemptions for food packaging | Partially captured under exemptions for manufactured items |  | Food packaging, food contact materials are exempted from this regulation |

1. The scope of the regulatory actions presented in Table 1 differ in scope compared to each other and the scope set out in the RME based on the principles of the Stockholm Convention. The RME covers degradation to PFOA from long-chain PFASs with more than eight perfluorinated carbon atoms except for those explicitly excluded in the definition of PFOA-related compounds as they do not degrade to PFOA under natural conditions. This goes beyond the EU risk management approach which does not cover the degradation to PFOA from long-chain PFASs. The degradation from long-chain PFASs is also not considered in the Norwegian risk management approach. The Canadian risk management approach also applies to long-chain PFCAs, their salts, and their precursors. However, long-chain PFASs have been included on Norway’s priority list of substances whose release to the environment should be eliminated by 2020, and they are included in the US Stewardship Program (IPEN Comments on 2nd draft RME).
2. A general definition of “long-chain PFCAs” (CnF2n+1COOH, n≥7) is provided by the OECD (OECD, 2017). As a result of the existing production processes, fluorotelomer-based substances have been generally manufactured as mixtures of homologues with a range of perfluoroalkyl chain lengths (for examples, see DuPont, 1998), including those that have more than eight perfluorinated carbon atoms[[35]](#footnote-36). Therefore, the information provided in the RME covers to a certain extent also those fluorotelomer-based substances with longer chain PFAS (longer than 8:2).

**References**

|  |  |  |
| --- | --- | --- |
| ABRAISCA | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| Belarus | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| Brazil | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| Canada | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| CVMA | 2018 | Submission from Canadian Vehicle Manufacturer's Association of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| FFFC | 2018 | Submission from the Fire-Fighting Foam Coalition of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| FluoroCouncil | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| HCWH | 2018 | Submission from Healthcare Without Harm of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| IPEN and ACAT | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| Medtech Europe | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| Netherlands | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| Sweden | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |
| United Kingdom | 2018 | Submission of information specified in Annex F of the Stockholm Convention pursuant to Article 8 of the Convention. |

**Other References:**

|  |  |  |
| --- | --- | --- |
| Chen et al | 2003 | Rate constants for the gas-phase reaction of CF3CF2CF2CF2CF2CHF2 with OH radicals at 250-430 K. International Journal of Chemical Kinetics, 36(1), pp.26-33 |
| Cousins | 2016 | The precautionary principle and chemicals management: the example of perfluoroalkyl acids in groundwater. Environment International 94:331-340.  UNEP (2017) Report of the Persistent Organic Pollutants Review Committee on the work of its thirteenth meeting, UNEP/POPS/POPRC.13/7 |
| D'eon et al | 2006 | Atmospheric Chemistry of N-Methyl Perfluoro butane sulfonamide ethanol, C4F9SO2N(CH3)CH2CH2OH: Kinetics and Mechanism of Reaction with OH, Environ. Sci. Technol. 2006, 40, 1862-1868 |
| ECHA | 2014a | EU ANNEX XV Restriction report on a Proposal for a restriction of PFOA, it salts and PFOA-related compounds under the REACH regulation EC 1907/2006 |
| ECHA | 2014b | Registered substances. Available from: https://echa.europa.eu/ de/information-on-chemicals/registered-substances Cited in Wang et al, 2015 |
| ECHA | 2015a | RAC and SEAC opinion on Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances under the REACH regulation EC 1907/2006 |
| ECHA | 2015b | Background document to the RAC and SEAC opinion on Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances under the REACH regulation EC 1907/2006 |
| ECHA | 2015c | Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) – Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances. Compiled version prepared by the ECHA Secretariat of RAC’s opinion (adopted 8 September 2015) and SEAC’s opinion (adopted 4 December 2015). Available from: https://echa.europa.eu/documents/10162/2f0dfce0-3dcf-4398-8d6b-2e59c86446be. |
| EFSA | 2011 | EFSA panel on food contact materials. Scientific opinion on the safety evaluation of the substance , 3H-perfluoro-3-[(3-methoxy-propoxy)propanoic acid] ammoniumsalt, CAS No: 958445-44-8, for use in food contact materials. EFSA J. 9 (6), 1–11. |
| Euromed | 2015 | ECHA public consultation on the proposed restriction on the manufacturing, use and placing on the market of Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances. Joint EDMA-Eucomed Input, 17th June 2015. |
| FFFC | 2004 | Estimated Quantities Of Aqueous Film Forming Foam (AFFF) In The United States, Report prepared for the Fire-Fighting Foam Coalition. |
| FFFC | 2011 | 2011 update to the 2004 report entitled “Estimated Quantities of Aqueous Film Forming Foam (AFFF) In The United States” Prepared for the Fire-Fighting Foams Coalition |
| FFFC | 2016 | Best Practice Guidance for Use of Class B Firefighting Foams, Guidance document by the Fire-fighting foams coalition |
| FFFC | 2017 | Submission to the Secretariat as part of the call for information in development of the RME |
| FOEN | 2017 | Additional Information in Relation to the Risk Management Evaluation of PFOA, its Salts, and Related Compounds. Prepared by ETH Zurich on behalf of the Swiss Federal Office for the Environment (FOEN). Available at http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC12/POPRC12Followup/PFOAComments/tabid/5950/Default.aspx |
| Gibbs et al | 2001 | PFC emissions from primary aluminium production, International Panel on Climate Change: Good Practice Guidance and Uncertainty Management in National Greenhouse Gas Inventories, |
| Gordon | 2011 | Toxicological evaluation of ammonium 4,8-dioxa-3H-perfluorononanoate, a new emulsifier to replace ammonium perfluorooctanoate in fluoropolymer manufacturing. RegulToxicolPharmacol 59(1): 64-80. |
| I & P Europe | 2015 | ECHA public consultation on the proposed restriction on the manufacturing, use and placing on the market of Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances. Imaging and Printing Europe, 2015. |
| I & P Europe | 2016 | Imaging & Printing Association Europe. Annex F form. Submitted 24 November 2016. Available from: http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC12/POPRC12Followup/PFOAInfo/tabid/5453/Default.aspx. |
| IPEN | 2016 | Submission to the Secretariat as part of the call for information in development of the RME |
| Keutel and Koch | 2016 | Untersuchung fluortensidfreier Löschmittel und geeigneter Löschverfahren zur Bekämpfung von Bränden häufig verwendeter polarer (d. h. schaumzerstörender) Flüssigkeiten. Brandschutzforschung der Bundesländer. Forschungsbericht 187 von Karola Keutel und Mario Koch. Available at https://idf.sachsen-anhalt.de/fileadmin/Bibliothek/Politik\_und\_Verwaltung/MI/IDF/ IBK/Dokumente/Forschung/Fo\_Publikationen/imk\_ber/bericht\_187.pdf |
| Klein | 2012 | Comments on the draft technical paper on the identification and assessment on alternatives to the use of perfluorooctane sulfonic (PFOS) acid in open applications.POPRC7 Follow-up.Published by the Stockholm Convention Secretariat |
| Klein | 2013 | the cost and still counting - fire fighting foam, disposal, remediation, and lifetime costs. Industrial Fire Journal. |
| Kleiner and Jho | 2009 | Recent developments in 6:2 fluorotelomer surfactants and foam stabilizers.4th Reebok Foam Seminar. 6-7 July 2009. Bolton, UK..[Krippner et al., 2014] Krippner J, Brunn H, Falk S, Georgii S, Schubert S, Stahl T (2014) Effects of chain length and pH on the uptake and distribution of perfluoroalkyl substances in maize (Zea mays), Chemosphere 94:85-90 |
| Liu et al | 2017 | Pollution pathways and release estimation of perfluoro octane sulfonate (PFOS) and perfluoro octanoic acid (PFOA) in central and eastern China, Sci. Total Environ. 2017, 580, 1247-1256 |
| Martin et al | 2006 | Atmospheric Chemistry of Perfluoro alkane sulfonamides: Kinetic and Product Studies of the OH Radical and Cl Atom Initiated Oxidation of N-Ethyl-perfluoro butane sulfonamide, Environ. Sci. Technol.2006, 40, 864-872 |
| Michiels | 2018 | Personal communication during development of addendum with Eddy Michiels at I&P Europe. |
| Mil Tech | 2017 | Performance specification, fire extinguishing agent, aqueous film forming foam (AFFF) liquid concentrate for fresh and sea water. MIL-PRF-24385F(SH) w/AMENDMENT. Available from: http://quicksearch.dla.mil/qsSearch.aspx |
| Military.com | 2017 | <https://www.military.com/daily-news/2017/09/07/cleanup-bill-firefighting-chemicals-bases-could-cost-2-billion.html> |
| Nesbitt | 2017 | PTFE Guidewire Application Process Eliminates Delamination’, Article for Medical Products Outsourcing.  https://www.mpo-mag.com/contents/view\_online-exclusives/2017-12-06/ptfe-guidewire-application-process-eliminates-delamination/ |
| NRL | 2016 | Evaluating the Difference in Foam Degradation between Fluorinated and Fluorine-free Foams for Improved Pool Fire Suppression. Katherine Hinnant, RamagopalAnanth, Michael Conroy, Bradley Williams. Naval Research Laboratory. Presented at the 2016 ACS Symposium.[Oda et al., 2007] Negative results of umu genotoxicity test of fluorotelomer alcohols and perfluorinated alkyl acids. Environ Health Perspect 12:217-9. |
| Plumlee et al | 2009 | Indirect Photolysis of Perfluoro chemicals: Hydroxyl Radical-Initiated Oxidation of N-Ethyl Perfluoro octane Sulfonamide Acetate (N-EtFOSAA) and Other Perfluoro alkane sulfonamides, Environ. Sci. Technol.2009, 43, 3662–3668 |
| Poulsen et al | 2005 | Danish Ministry of Environment.More environmentally friendly alternatives to PFOS-compounds and PFOA. Available from: http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/udgiv/Publications/ 2005/87-7614-668-5/html/default\_eng.htm |
| Queensland Gov | 2016a | Environmental Management of Firefighting Foam Policy. 7 July 2016 |
| Queensland Gov | 2016b | Environmental Management of Firefighting Foam Policy. Explanatory Notes, Revision 2. State of Queensland. Revision 2.2 – July 2016. Available at http://www.ehp.qld.gov.au/assets/documents/regulation/firefighting-foam-policy-notes.pd |
| Rudolf Group | 2018 | <http://www.rudolf.de/en/> |
| Seow | 2013 | Fire fighting foams with perfluorochemicals - a review, report by Dr Seow on behalf of the Australian NICNAS |
| Sontake and Wagh | 2014 | The Phase-out of Perfluorooctane Sulfonate (PFOS) and the Global Future of Aqueous Film Forming Foam (AFFF), Innovations in Fire Fighting Foam. Chemical Engineering and Science 2, 11-14. |
| SSG | 2017 | Perfecting PFOA-free PTFE Coat ing Adhesion on Stainless Guidewires, Industry paper produced by Surface Solutions Group Inc. |
| Swedish Chemicals Agency | 2015 | Occurrence and use of highly fluorinated substances and alternatives. 2015 |
| The Intercept | 2016 | Available from: https://theintercept.com/2016/03/03/how-dupont-concealed-the-dangers-of-the-new-teflon-toxin/. (Online access: 2 March 2017). |
| UNEP | 2017 | Guidance on best available techniques and best environmental practices for the use of perfluorooctane sulfonic acid (PFOS) and related chemicals listed under the Stockholm Convention on Persistent Organic Pollutants. Available from: http://chm.pops.int/Implementation/NIPs/Guidance/GuidanceonBATBEPfortheuseofPFOS/tabid/ 3170/Default.aspx. |
| Van der Putte | 2010 | Analysis of the risk arisng from the industrial use of Perfluorooctanoic Acid (PFOA) and Ammonium Perfluorooctanoate (AFPO) and from their use in consumer articles. Evaluation of the risk reduction measures for potential restrictions on the manufacture, placing on the market and use of PFOA and APFO. European Commission.DG Enterprise and Industry. Report TOX08.7049.FR03. |
| Wang et al | 2013 | Fluorinated alternatives to long-chain perfluoroalkyl carboxylic acids (PFCAs), perfluoroalkane sulfonic acids (PFSAs) and their potential precursors. Environ Int 60: 242-8 |
| Wang et al | 2014 | Global emission inventories for C4–C14 perfluoroalkyl carboxylic acid (PFCA) homologues from 1951 to 2030, Part I: production and emissions from quantifiable sources, Environment International 70 (2014) pp62–75 |
| Wang et al | 2015 | Hazard assessment of fluorinated alternatives to long-chain perfluoroalkyl acids and their precursors: Status quo, ongoing challenges and possible solutions. Environment International 75:172-179 |
| Williams et al | 2011 | Extinguishment and Burnback Tests of Fluorinated and Fluorine-free |
| Wilson | 2016 | Can F3 agents take the fire security heat?. Mike Wilson. International Airport Review 20(6). |
| Young et al | 2009 | Atmospheric chemistry of CF3CF2H and CF3CF2CF2CF2H: Kinetics and products of gas-phase reactions with Cl atoms and OH radicals, infrared spectra, and formation of perfluorocarboxylic acids. Chemical Physics Letters, 473(4-6), pp.251-256. |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. PFOA-related compounds are differently defined according to the chemical scope in different approaches. In this document, the term “PFOA-related compounds” is used as defined in section 1.1. If quoted from other information sources the original wording of analogue terms, such as “PFOA-related substances” (e.g. used in ECHA 2015a), is maintained. [↑](#footnote-ref-2)
2. DuPont, 1998. Technical information: Zonyl fluorochemical intermediates. [↑](#footnote-ref-3)
3. Fluoropolymers have a carbon-only polymer backbone with F directly attached to backbone C atoms. [↑](#footnote-ref-4)
4. Such as PTFE (polytetrafluoroethylene), FEP (fluorinated ethylene propylene polymer) and PFA (perfluoroalkoxy polymer). [↑](#footnote-ref-5)
5. See register of acceptable purposes available at <http://chm.pops.int/Implementation/Exemptions/AcceptablePurposes/AcceptablePurposesPFOSandPFOSF/tabid/794/Default.aspx> [↑](#footnote-ref-6)
6. See register of acceptable purposes available at <http://chm.pops.int/Implementation/Exemptions/AcceptablePurposes/AcceptablePurposesPFOSandPFOSF/tabid/794/Default.aspx> [↑](#footnote-ref-7)
7. www.harlingen.nl/recloket and https://www.harlingen.nl/recloket/monitoring-in-de-schoorsteen\_42638/ [↑](#footnote-ref-8)
8. Best available technology / Best Environmental Practices [↑](#footnote-ref-9)
9. <http://www.europarl.europa.eu/RegData/etudes/etudes/join/2008/393524/IPOL-ENVI_ET(2008)393524_EN.pdf> [↑](#footnote-ref-10)
10. <http://www.world-aluminium.org/statistics/perfluorocarbon-pfc-emissions/> [↑](#footnote-ref-11)
11. A number of the uses covered have applications in healthcare. The RME disaggregates healthcare uses based on different applications, for example membranes covers all uses of PFOA within membranes, some of which will include medical applications. To maintain this distinction uses relating to healthcare can be found under the following headings by application, section 4.2 for membranes, section 4.6 for photo-imaging, section 4.5 for implantable medical devices and section 4.4 for all other medical devices. [↑](#footnote-ref-12)
12. Medical Design & Outsourcing (June 23, 2015), *PFOA-Free PTFE Ready for Catheter Applications*. Available from: <https://www.medicaldesignandoutsourcing.com/pfoa-free-ptfe-ready-for-catheter-applications/> [↑](#footnote-ref-13)
13. see: <https://www.lenzing.com/fileadmin/template/pdf/konzern/lenzinger_berichte/ausgabe_91_2013/Paper_10_Biladt_Durz.pdf> (last accessed on 01.02.2017) [↑](#footnote-ref-14)
14. <http://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSu9n_zu8l00xm8mBl8t94v70k17zHvu9lxtD7xt1evSSSSSS-> [↑](#footnote-ref-15)
15. <https://www.daikinchem.de/products-and-performance/water-oil-repellency> [↑](#footnote-ref-16)
16. <https://products.halyardhealth.com/surgical-solutions/surgical-gowns/breathable-high-performance-gowns/halyard-microcool-breathable-high-performance-surgical-gown-with-secure-fit-technology.html> [↑](#footnote-ref-17)
17. <https://www.agcchem.com/news/2016/june-1-2016-asahiguard-ag-e600-repellent-provides-sustainable-solution-for-nonwoven-medical-textiles> [↑](#footnote-ref-18)
18. <http://synderfiltration.com/> and personal communication with Kevin Donohue, Global Sales Manager, Syndar Filtration 9 January 2017. [↑](#footnote-ref-19)
19. Note (iii) of Part I of Annexes A and B to the Stockholm Convention. [↑](#footnote-ref-20)
20. EU regulation EC 1906/2006 on the Registration, Evaluation, Authorisation and restriction of Chemicals. [↑](#footnote-ref-21)
21. Polymeric Fluorotelomer-based Products are also known as “side-chain fluorinated polymers.” These products consist of hydrocarbon backbones with polyfluoroalkyl side chains that stick out like teeth on a comb. These polymers are used to treat textiles, carpets, nonwovens and paper to provide water, soil, oil and stain resistance. The polymers are of a sufficient molecular weight that they are not readily bioavailable or biodegradable, similar to other polymers such as polyethylene. The short-chain polymeric fluorotelomer-based products are safe for their intended uses, and offer a significantly improved health and environmental profile over the long-chain fluorotelomer-based products. <https://fluorocouncil.com/fluorotechnology/terminology/> [↑](#footnote-ref-22)
22. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfass#tab-3 [↑](#footnote-ref-23)
23. see: https://www.membrane-solutions.com/transducer\_protector.htm. [↑](#footnote-ref-24)
24. IUPAC name: Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoate; CAS No: 62037-80-3. [↑](#footnote-ref-25)
25. Nesbitt, 2017 comments that in October 2016 Medtronic a major supplier of guidewires used in medical implants had to recall 84,000 units after problems. Nesbitt notes that Medtronic was not the only supplier that needed to issue a recall as part of the US FDA recall. [↑](#footnote-ref-26)
26. <http://www.acea.be/uploads/publications/20160704_INFORMATION_LETTER_TO_SUPPLIERS_ON_PFOA.pdf> [↑](#footnote-ref-27)
27. <http://www.acea.be/uploads/publications/20160704_INFORMATION_LETTER_TO_SUPPLIERS_ON_PFOA.pdf> [↑](#footnote-ref-28)
28. <http://atozplastics.com/upload/literature/Fluoropolymers-application-automotive-fuel-engine-systems.asp> [↑](#footnote-ref-29)
29. Under the EU REACH regulation PFOA based fire-fighting foams placed on the market by or before the 4th July 2020 would be permitted for use. [↑](#footnote-ref-30)
30. Under EC 757/2010, fire-fighting foams containing PFOS placed on the market within the EU before 27 December 2006 were allowed to be used until 27 June 2011. [↑](#footnote-ref-31)
31. Please note that under para 6 of decision POPRC-13/2: that a request to the Secretariat has been made to prepare a document on note (ii) of part I of Annex A to the Convention and scope of the reference to stockpiles within Article 6 of the Convention and make it available to the Committee for consideration at its fourteenth meeting. This is intended to clarify the Convention scope for goods already placed to market. [↑](#footnote-ref-32)
32. The EU proposal for restriction estimates 50 – 100 tonnes of PFOA-related compounds, equivalent to 50,000 – 100,000 kgs. Specific gravity of C8-C20-ω-perfluoro telomer thiols with acrylamide is 1.12 g/cm (<http://www.interstateproducts.com/fire_fighting/home/FS%20MSDS/FS-818-11.pdf>) 50,000 kg / 1.12 specific gravity = 44,640 litres. 100,000 kg / 1.12 specific gravity = 89,300 litres. One US gallon is equivalent to 3.785 litres. 44,640 litres / 3.785 litres per gallon = 11,800 gallons of PFOA-related. 89,300 litres / 3.785 gallons per litre = 23,600 US gallons. PFOA and PFOA-related compounds are used at between 1 – 6% wt/wt in fire-fighting concentrates. 11,890 gallons of PFOA-related = 198,000 – 1,190,000 US gallons of concentrate. 23,600 US gallons of PFOA-related = 393,000 – 2,360,000 US gallons of concentrate. [↑](#footnote-ref-33)
33. Internationally fires are classified into groups based on the nature of the fire. This in turn defines what kind of fire-fighting media is most appropriate to be used. Class B fires relate to flammable liquids, where fire-fighting foams may be needed to suppress the fire (e.g. oil based fires). http://surreyfire.co.uk/types-of-fire-extinguisher/ [↑](#footnote-ref-34)
34. BREF, 2010, comments on the general operating conditions within European cement kilns with temperatures up to 2000 degrees Celsius. Materials within sintering zone reach temperatures of 1450 degrees Celsius and retention times of not less than eight seconds. [↑](#footnote-ref-35)
35. Commercial products containing primarily >99% of one individual homologue may exist; this requires additional purification processes. [↑](#footnote-ref-36)