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**Persistent Organic Pollutants Review Committee**

**Fourteenth meeting**

Rome, 17–21 September 2018

Item 4 (b) of the provisional agenda\*

**Technical work: consideration of a recommendation to the Conference of the Parties on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds**

**Comments and responses relating to the draft assessment of information on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds**

**Note by the Secretariat**

As referred to in the note by the Secretariat on further assessment of information on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds (UNEP/POPS/POPRC.14/3), the annex to the present note sets out a compilation of comments and responses relating to the draft assessment. The present note, including its annex, has not been formally edited.

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\* UNEP/POPS/POPRC.14/1.

## Annex

## Comments and responses relating to the draft assessment of information on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds

Minor grammatical or spelling changes have been made without acknowledgment. Only substantial comments are listed. Text in red denotes suggested amendments or deletions, text in blue comments.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
Canada	7	Additional information on unintentional formation and release of PFOA, its salts and PFOA-related compounds was provided by Austria (2018),	Edits accepted.
Canada	13	The RME for PFOA highlighted a potential need for more information about a potential PFOA exemption for automotive service and replacement parts.	Edits accepted. Paragraph 13 has been further adjusted to cover additional changes and the adjusted conclusion on automotive applications.
Canada	16	<del>-(a)-I</del> in Annex A, with specific exemptions accompanied if needed with a specific part of Annex A that details actions.	Edits accepted.
Canada	42	Sulfluramid is manufactured by using PFOSF (CAS No: 307-35-7) as an intermediate. From a structural point of view, sulfluramid is related to PFOS (CAS No: 1763-23-1) and degrades in the environment to PFOS. However, sulfluramid is not included in the scope of the listing of decision SC 4/17 on PFOS, its salts and PFOSF. <del>Based on the available information sulfluramid could also be considered a PFOA-related substance.</del> However, PFOSF (restricted under the listing of PFOS, its salts and PFOSF according to Annex B to the Stockholm Convention) is used as an intermediate to produce sulfluramid, then used for control of leaf-cutting ants from <i>Atta</i> spp. and <i>Acromyrmex</i> spp, as well as insecticides for control of imported red fire ants and termites. Therefore, we can consider that sulfluramid production is already <del>regulated under covered by an acceptable purpose under</del> the PFOS listing and it should then not be included under the PFOA listing <del>to avoid double regulation.</del> Suggested edits to improve the clarity. Suggest deleting as this is contradictory with the conclusion that sulfluramid should not be included under the PFOA listing. If the sentence is to remain, it should include references.	Sulfluramid may degrade to PFOA, but should only be covered once. Therefore, the paragraph was only partially edited.
Canada	172	The efforts have been focused so far on a selected number of <del>PFOAs-PFOA-related compounds</del> as information was not available on a broad number of other <del>PFOAs-PFOA-related compounds</del> .	Edits accepted.
Canada	189	According to the Stockholm Convention Annex A, part I, note (ii) and Annex B, part I, note (ii) respectively, an exemption is not required for service and replacement parts and vehicles manufactured before the date of entry into force of the listing of PFOA, its salts and related compounds. An exemption would therefore only be relevant for service and replacement parts and vehicles manufactured produced after the entry into force of the obligation.	The Drafter thank Canada for their comments which are duly noted.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>Note that work is currently being carried out by the Secretariat to prepare a document on note (ii) of part I of Annex A to the Convention to make it available to the Committee for consideration at its fourteenth meeting as per decision POPRC-13/2. Furthermore, the interpretation of the Convention remains the prerogative of Parties.</p>	
Canada	240	<p>Based on the information compiled and reviewed within the RME, the size of in-use stockpiles for PFOA based fire-fighting foams may be significant, while PFOA and PFOA-related compounds can also be present as a by-product in shorter chain C6 telomer technologies. Concerns have also been highlighted about the mobility and potential environmental <del>impacts of shorter chain perfluorinated compounds in fire fighting foams. The Committee should discuss if the non-fluorinated alternatives already commercialised and in use can replace the fluorine based AFFFs for all uses.</del> On this basis, the Committee should discuss the need and duration of the time-limited exemption for PFOA and PFOA-related fire-fighting foams to aid phase-out.</p> <p>Suggest differentiating the AFFF already manufactured and ready to be used from new AFFF. It is not clear in the conclusion if the time-limited exemption suggested to phase-out PFOA and PFOA-related fire-fighting foams pertains to AFFF already manufactured and ready to be used or to AFFF to be manufactured or to be acquired.</p> <p>The draft addendum to the risk management evaluation on PFOA, its salts and PFOA-related compounds should contain information on alternatives including non-fluorinated alternatives. The Committee's role would be to assist the possible defining of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds in particular in the following applications.</p> <p>Based on comments received by Fire Fighting Foam Coalition (FFFC), alternatives to PFOS have been the short-chain (C6) fluorosurfactants and fluorine-free foams. Fluorotelomer-based foams are not made with PFOA or any PFOA-based products, but may contain trace quantities as an unintended byproduct of the surfactant manufacturing process. FFFC also concludes that safe and effective alternatives to the use of PFOA and PFOA-related compounds in AFFF are readily available worldwide. Archroma also states that all FluoroCouncil member companies globally phased out PFOA and C8 production at the end of 2015.</p> <p>Based on information submitted, Canada would suggest to not recommend an exemption for new production and use of PFOA for AFFF.</p> <p>It should also be noted that AFFF already manufactured and ready to be used could be considered as an "Article in use" under Note ii of Annex A and B. Parties would therefore need to notify the Secretariat that this particular type of article remains in use and, as this information will be publicly available, it would improve the understanding of the extent of AFFF containing PFOA currently in use.</p> <p>The Committee could discuss a phase-out date for currently in use and any other manufactured AFFF.</p>	<p>Concur with comments from Canada. Much of the discussion at POPRC.13 was about existing stockpiles. The text has been amended to make clear that existing stockpiles and new uses are two separate elements which need to be discussed and a recommendation that covers both parts formulated.</p>
Canada	238	<p>The invitation to Parties and observers to submit information on the additional uses discussed within the current document is intended to assist the Committee in reaching a decision on whether <del>an</del> exemption are <del>is</del></p>	Edits accepted.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		needed, and whether <del>those that</del> exemptions should be a specific exemption (time-limited) or acceptable purpose (non-time limited).	
Japan	16	Agree to decide on POPRC 14. Until then this conclusion would be better to be Annex A or B or put in parentheses or “Annex A”.	The Drafter notes the comment from Japan, however where no acceptable purposes have been identified we believe that an Annex A listing is the most appropriate.
Japan	240	Agree to decide on POPRC 14. Until then this conclusion would be better to be Annex A or B or put in parentheses or “Annex A”.	The Drafter notes the comment from Japan, however where no acceptable purposes have been identified we believe that an Annex A listing is the most appropriate.
Norway	42	Sulfluramid is manufactured by using PFOSF (CAS No: 307-35-7) as an intermediate. From a structural point of view, sulfluramid is related to PFOS (CAS No: 1763-23-1) and degrades in the environment to PFOS. However, sulfluramid is not included in decision SC-4/17 on PFOS, its salts and PFOSF. Based on the available information sulfluramid could also be considered a PFOA-related substance. However, PFOSF (restricted under the listing of PFOS, its salts and PFOSF according to Annex B to the Stockholm Convention) is used to produce sulfluramid, then used for control of leaf-cutting ants from <i>Atta</i> spp. and <i>Acromyrmex</i> spp, as well as insecticides for control of imported red fire ants and termites. Therefore, we can consider that sulfluramid production is already regulated under the PFOS listing and it should then not be included under the PFOA listing to avoid double regulation. Agree. This is also in agreement with para 30 (v) under chemical identity.	Noted.
Norway	68	<del>The fluorinated chemical alternatives to PFOA (6:2 FTOH, PFHxA/PFHxS, 6:2 methacrylate and 6:2 acrylate) do not meet the overall Stockholm Convention POPs criteria.</del> Where is the reference to this statement? PFHxS is under evaluation in the SC and the other substances have not been evaluated under the convention. Sentence should be deleted.	Sentence has been adjusted i.e. ...have not been evaluated under the Stockholm Convention. PFHxS has been removed from the list and further below it is stated that PFHxS is currently under review.
Norway	91	<del>Therefore, the need for an exemption should be assessed under the Stockholm Convention to enable reprocessing at a different site than the production site.</del> This is not reason good enough!	Wrong section name.
Norway	93	Relevant information was submitted by IPEN and ACAT (2018a, 2018b), by the FluoroCouncil (2018a, 2018b), and Norway (2018)). I don't see a reference in the text too information submitted by Norway.	The information was noted and in many cases included in the document. The edits were highly appreciated. Please see the Response to Comments document for the concrete changes that were made based on the comments from Norway.
Norway	93	<del>No further information (in addition to information already included in the RME) was submitted by Canada (Canada, 2018). Comments on the first draft of the current document were submitted by Norway, IPEN/ACAT, and the FluoroCouncil.</del> Unnecessary. Delete-	Partially deleted. The information about the comments on the first draft helps the reader to see who commented.
Norway	94	<del>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</del>	Noted.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		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. This is a very important point.	
Norway	100	in the Republic of Korea as raw materials for the production of fluoropolymers and C6 fluorotelomers. Which according to para 68: " For instance, 6:2 FTOH is found in the Arctic and the Antarctic, has endocrine disrupting properties, is found in indoor air, air of manufacturing plants, house dust, food contact materials and consumer products (based scientific literature studies)."	Noted. Please specify at the meeting which changes should be made in the document.
Norway	108	<del>The fraction -</del> Delete.	Edits accepted.
Norway	115	For the production of implantable medical devices, an exemption without time limitation is given in the EU and. Norway has an exemption in place for medical devices (with no time limit).	Suggested edit rejected. More appropriate to keep as separate sentences
Norway	148	... final product <del>are very low</del> (PFOA in PTFE is stated to range from 0.001	Concur, edits accepted.
Norway	170	CVMA states that these parts represent a small percentage of PFOA use and will decrease naturally over time <del>due to as the</del> vehicle fleet turns-over.	Edits accepted.
Norway	171	It is further stated that 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. Again, as with decaBDE, CVMA do not specify which vehicle part they would need an exemption for. This should be specified such that the possible exemption could be narrowed down.	Yes, this is stated at several points of this chapter (and also included in the conclusion for automotive service and replacement parts).
Norway	172	on a broad number of other PFOAs. PFOA-related compounds	Concur should be PFOA-related compound.
Norway	178	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%. Highlighted but no comment.	Noted.
Norway	180	The CVMA (2018) What about ACEA? Did they not request an exemption? Makes you wonder why the Canadian Auto industry needs exemption and not the European car industry? One has to question why the north American car industry is so different from the European.	ACEA also submitted a position paper basically supporting all statements made by CVMA (also expressing the need for exemption). Their statement is however very short and does not contain a lot of information. Therefore, we have only included in a few paras that ACEA (and also the Indian manufacturers) supports CVMA. There are no differences between the north American and European industry. In addition, the Indian Industry association also requested an exemption This has been now also pointed out at the beginning of the chapter on automotive application.
Norway	218	With respect to firefighting foams, it is estimated in a study (RPA, 2004) that the cost for fluorine-free	Concur, the paragraph on cost comparison has been moved to the end

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>alternatives is approximately 5–10% higher than those for fluorosurfactant foams.</p> <p>This is very old data – newer data should be used to estimate the difference in cost between F-foam and F-free foam.</p>	of the alternatives section and reference to the 2004 data removed. Newer data however on direct comparison of price has not been identified.
Norway	224	<p>Manufacturers and some users mention that fluorine-free firefighting foams do not have comparable extinguishing effects to foams with fluorosurfactants.</p> <p>Reference.</p>	Text has been modified to provide specific details of both the reference (Castro et al, 2017) and the results of the testing carried out.
Sweden	14	The Swedish <del>Environment</del> Chemicals Agency (2015)	Edits accepted.
Sweden	209	<p>...the Swedish <del>Environment</del> Chemicals Agency (2015) and European Chemicals Agency (ECHA, 2014a) highlight the possible continued presence of PFOA as an unintentional contaminant of C6 fluorotelomers. While the manufacture of C6 fluorotelomers does not use PFOA in the production process, the telomerisation of perfluorinated compounds can generate C8 species including PFOA as a by-product. The Swedish <del>Chemicals</del> <del>Environment</del> Agency (2015)</p>	Edits accepted.
Sweden	216	<p>Norstrom (2011)</p> <p>Annual report from the RE-PATH project</p> <p>Not all airports in Sweden at least.</p>	The Drafter thanks Sweden for the new reference, suggested edits have been accepted
Sweden	216	Comments that <del>all</del> commercial airports in Sweden and Norway have replaced PFAS-based firefighting foams with fluorine-free foams	Edits accepted.
Sweden	220	<p>...foams because of environmental safety concerns.</p> <p>Since 2008 AFFF is no longer used at fire drills at the Swedavia airports in Sweden and in 2011 Swedavia started to use a fluorine-free alcohol-resistant foam (Moussol FF 3/6)". (Norström et al., 2015).</p> <p>Sentence added.</p> <p>Final report for RE-PATH:  <a href="http://repath.ivl.se/download/18.343dc99d14e8bb0f58b557e/1443615397431/B2232_RE-PATH%20FINAL_20150923.pdf">http://repath.ivl.se/download/18.343dc99d14e8bb0f58b557e/1443615397431/B2232_RE-PATH%20FINAL_20150923.pdf</a>.</p>	Edits accepted.
Sweden	220	<p><del>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.</del> The Swedish Armed Forces began phasing out the use of perfluorinated substances in firefighting foam in Sweden in 2011 and currently. 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).</p>	Suggested edits for brevity partly accepted.
Sweden	235	The Swedish <del>Chemicals</del> <del>Environment</del> Agency (2015)	Edits accepted.
Sweden	Table 5.1	The Swedish <del>Chemicals</del> <del>Environment</del> Agency (2015) comments that while C6 fluorotelomers are not manufactured using PFOA, it can be created as a by-product of the process. At the concluding step around 20% C8 can be present in C6 mixtures (including PFOA), which then undergoes a clean-up process to reduce C8 species down to trace residues. However,	Edits accepted.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		studies exist suggesting that the concentration of C8 within C6 products can be much higher than a trace (Swedish <del>Chemicals Environment</del> Agency, 2015; Seow, 2013).	
Switzerland	6	...of PFOA related substances Please use the term “PFOA-related compounds” (as contained in the title of the document) throughout the document. Currently, there are also the following versions present: • PFOA-related substance(s) • PFOA related substance(s) • PFOA related compound(s)	Concur, global edit to convert all instances into 'PFOA-related compound/s'
Switzerland	43	<b>1-H-PFO</b> I would suggest to consistently use “1-H-PFO” or “PFOH” (used in section 44) throughout the report, but not both. To be in line with the nomenclature of analogous compounds such as “PFOI” or “PFOB”, using “PFOH” may make it easier for the readers to understand the structural similarities: • C8F17-I > PFOI • C8F17-Br > PFOB • C8F17-H > PFOH	Changed to 1-H-PFO. PFOB was added the first time 1-H-PFO was mentioned.
Switzerland	44	Japan brought forward that it would be an overstatement to conclude that PFOH is among PFOA-related compounds because the reaction rate with OH radicals is negligibly small at the order of 10E(-15)cm <sup>3</sup> molec <sup>-1</sup> s <sup>-1</sup> (Japan, 2018). There is some evidence that 1-H-PFO is relatively stable  The reaction rate is indeed small, but considering that once emitted to air, PFOH remains in the atmosphere (> 99 % based on EPI Suite Level III Fugacity Model with emissions to air only) until transformed, PFOH may be transformed to PFOA over long time scales. I would suggest mentioning the atmospheric lifetime of 24 year that has been estimated by Chen et al. 2011.	Information added. Chen et al. 2011 added
Switzerland	44	156 ° <del>Celsius</del> Correct here and also in paragraph 49 and 50	Edits accepted.
Switzerland	51	...ethers and PFOA. Under unstable conditions polybrominated dibenzo-p-dioxins and dibenzofurans (PBDD/PBDFs) were also found. <del>Delete space after ethers.</del>	Edits accepted.
Switzerland	52	Estimating a yearly emission, using the flow rate of the installation, the total PFOA emission is shown to be 0.057 g/year.  For the sake of transparency and reproducibility, I would suggest mentioning the concentration (0.0312 ng/m <sup>3</sup> ) and the flow rate of the municipal waste incineration plant.	Concentration range has been added. Flowrate of the installation is not known
Switzerland	208	<b>Concentrations of PFASs in AFFF obtained 2012/2013 on the Swiss market (n = 35) were significantly smaller compared to samples (n = 27) taken from fire installations from industrial sites with the last filling date in 1990–2010. The latter demonstrated a majority of PFCAs, PFSAs, FASAs and FASEs with C4–13 alkyl chains. In comparison, the mixtures commercially available in 2012/2013 showed more frequently shorter-chain C4–6 PFCAs, 4:2 and 6:2 FTS as well as 6:2 FTOH. The mean concentration declined from 40 to 0.8 ppm (Favreau et al. 2017). Based on a 2005 estimate that quantified the amounts of AFFF stored in</b>	The Drafter thanks Switzerland for the new data, the most straightforward option will be to add the new paragraph as suggested. This has been checked and added.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		Switzerland to be 2,200–2,600 tonnes, the stockpile of PFOA in AFFF may be in the range of 2–100 kg. Instead of as a new paragraph, (parts of) this information may also be added to existing paragraphs (e.g. 197 or 198).	
Switzerland	208	(Favreau et al. 2017) Philippe Favreau, Chantal Poncioni-Rothlisberger, Benjamin J. Place, Harold Bouchex-Bellomie, Andreas Weber, Josef Tremp, Jennifer A. Field, Marcel Kohler: Multianalyte profiling of per- and polyfluoroalkyl substances (PFASs) in liquid commercial products. 'Chemosphere 171, 2017, p. 491–501, doi:10.1016/j.chemosphere.2016.11.127	See response to comments on other comments from Switzerland relating to the same paragraph
Switzerland	208	2,200–2,600 tonnes, <a href="http://www.news.admin.ch/newsd/message/attachments/21461.pdf">www.news.admin.ch/newsd/message/attachments/21461.pdf</a> , p. 21	See response to comments on other comments from Switzerland relating to the same paragraph
Leaf-Cutting Ant Baits Industries Association (ABRAISCA)	6	<del>In the environment, it degrades in significant yields to PFOS</del> It may degrade to PFOS although Comments: we agree that there is insufficient scientific evidence that sulfluramid does not transform to PFOS. In the same way that there is insufficient scientific evidence that sulfluramid does transform to PFOS. For this reason, it is not possible to affirm that sulfluramid does not transform into PFOS neither that sulfluramid does transform to PFOS. The correct to say is that sulfluramid MAY degrade in PFOS. Besides that, be consistent with what has been widely discussed and agreed upon in the POPRC and approved by COP decision. (Decisions POPRC-12/6 and SC-8/5)	There are several papers describing the degradation of EtFOSA to FOSA and then to PFOS. See for example Nguyen et al. 2013, Avendano and Liu 2015, Beskin et al. 2009. In any case the topic should be discussed under PFOS.
ABRAISCA	32	<del>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). Sulfluramid may degrade to perfluorooctane sulfonic acid., in the environment.</del> Comments: we agree that there is insufficient scientific evidence that sulfluramid does not transform to PFOS. In the same way that there is insufficient scientific evidence that sulfluramid does transform to PFOS. For this reason, it is not possible to affirm that sulfluramid does not transform into PFOS neither that sulfluramid does transform to PFOS. The correct to say is that sulfluramid MAY degrade in PFOS. Besides that, be consistent with what has been widely discussed and agreed upon in the POPRC and approved by COP decision. (Decisions POPRC-12/6 and SC-8/5)	Edits accepted.
ABRAISCA	38	The Liu et al. study also notes the possibility that the main ingredient in sulfluramid, N-ethyl perfluorooctane sulfonamide, can transform to PFOA and PFOS through photolysis, oxidation, and biotransformation indicating that PFOA release can occur in other ways besides impurities in sulfluramid (IPEN and ACAT, 2018b). The Liu et al study refers that the N-ethyl perfluorooctane sulphonamid is the main ingredient sulfluramid, but it is incorrect. N-ethyl perfluorooctane sulphonamide is the own sulfluramid.	The sentence read as follows: The Liu et al. study also notes the possibility that the active ingredient in commercially sulfluramid baits, N-ethyl perfluorooctane sulfonamide, can transform to PFOA and PFOS through photolysis, oxidation, and biotransformation indicating that PFOA release can occur in other ways besides impurities in sulfluramid.
ABRAISCA	40	<del>and up to 277% using a commercial sulfluramid formulation used in Brazil.</del> 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%. <del>The study also demonstrated that sulfluramid is translocated from soil to carrot and that both PFOS and</del>	Partially edited. PFOS was also found when the technical sulfluramid standard was used. The following sentence was added: The authors note that a significant fraction appears to be associated with one or more unidentified PFOS-precursors in the commercial bait.



Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p><del>PFOA were also found in the carrot core, peel, and leaves, indicating that all three substances can contaminate a food crop as a result of sulfluramid use.</del></p> <p>The study was made with sulfluramid containing impurity and this impurity is not found when sulfluramid is manufactured correctly. In addition, it is clear from the study that a number of substances was found and a very small amount of sulfluramid were found in the insect bait (differently from what is stated on the product label) and these other substances were responsible for the large amount of PFOS and other substances formed such as FOSAA, FOSA and PFOA. The study makes clear that further studies should be done with other insect baits present in the market to characterize those insect baits in order to be able to affirm that PFOS originated from the baits with sulfluramid.</p> <p>See the own text from this study:  “...Considering the high yield of PFOS, a significant fraction appears to be associated with one or more unidentified PFOS-precursors in the commercial bait. Ongoing research is focused on identifying this substance (or substances) along with a comprehensive characterization of other Sulfluramid baits currently on the Brazilian market...”.</p> <p>The insect bait Grão Forte used in the study cited by IPEN is a bait registered for urban use only, registered in National Health Surveillance Agency (ANVISA) from Ministry of Health and do not registered for agriculture use. Household products such as Grão Forte are registered only in ANVISA and do not support any evaluation made from the Ministry of Agriculture, Livestock and Food Supply (MAPA) and Ministry of Environmental (IBAMA) such as toxicological evaluation, neither is necessary to prove the origin of the active ingredient used. Different when the product is registered in agriculture use, that has more criteria for registrations. Several household products for urban use, have already been motive for denunciation by ABRAISCA because they do not contain the declared active ingredient. The supervision of trade in those products is responsibility of the Secretariat of Health of each Brazilian States.</p>	
ABRAISCA	42	<p>PFOS (CAS No: 1763-23-1) and <del>may degrade</del> in the environment to PFOS</p> <p>Comments: we agree that there is insufficient scientific evidence that sulfluramid does not transform to PFOS. In the same way that there is insufficient scientific evidence that sulfluramid does transform to PFOS For this reason it is not possible to affirm that sulfluramid does not transform into PFOS neither that sulfluramid does transform to PFOS. The correct to say is that sulfluramid MAY degrade in PFOS. Besides that, be consistent with what has been widely discussed and agreed upon in the POPRC and approved by COP decision (Decision POPRC-12/6 and SC-8/5).</p>	<p>There are several papers describing the degradation of EtFOSA to FOSA and then to PFOS. See for example Nguyen et al. 2013, Avendano and Liu 2015, Beskin et al. 2009. In any case the topic should be discussed under PFOS.</p>
Canadian Vehicles Manufacturers Association (CVMA)	General	<p>Please note that in February 2018, 4 additional PFOAs were added to GADSL, making the total 12 on GADSL. The 4 new entries are as follows:</p> <p>CAS Number:</p> <ul style="list-style-type: none"> <li>· 122402-79-3</li> <li>· 160336-09-4</li> <li>· 206886-57-9</li> </ul>	<p>Para 173 and Table 4.1 have been adjusted based on new information received.</p>

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>· 185701-89-7</p> <p>An initial evaluation of the non-exhaustive list shows that 24 individual CAS numbers have been identified by suppliers as potentially being used in our sector. This is twice as many CAS numbers as are currently listed in GADSL which means the presence of PFOA-related compounds is still not known in parts. This new information supports our comment that there may be other PFOA used in service and replacement parts which the industry is unaware of as the uses have not been declared.</p>	
CVMA	General	<p>Regarding the concentrations and thresholds for PFOAs for parts categories identified, the concentrations are typically less than 1% in the material and many are at concentrations of less than 0.2% of a part. The automotive industry is continuing to take steps to eliminate PFOAs from new vehicle products when identified by the supplier. To illustrate, one company through their supplier found PFOA use in a new vehicle and steps were taken to eliminate the part in new vehicles. However, the replacement part is still needed for maintenance and service purposes for vehicles currently on the road and for a 15-year period. The concentration of PFOA in the part was 5 times lower than the 0.1% declaration under GADSL. Another company identified one PFOA in service and replacement parts in concentrations less than 0.01% (which is below GADSL reporting 0.1 % threshold) and the quantity was less than 1 gram annually for a three-year time period.</p>	<p>Already sufficiently covered. The main statements are already included. The following has been included "Concentrations reported by two CVMA member companies were 5 times lower than the 0.1% GADSL threshold and less than 0.01%, respectively (information on the spare parts and exact PFOA-related substance was not disclosed)". Case studies not specific enough. It would be good to also know in which parts PFOA was measured/detected and which CAS Nr., etc.</p>
CVMA	General	<p>Also, the report does not indicate that PFOA continues to be manufactured as a product in the global market. The risk exists of it entering the auto supply chain without the automotive manufacturers' knowledge. This, too, needs to be added to the report so that there is an accurate picture on PFOA.</p>	<p>This is already covered in the report in several sections. Different applications (besides the automotive sector are discussed) ...Manufacturers can still specify that PFOA should not be contained.</p>
CVMA	172	<p>A key point that is missing is that generally auto manufacturers are users and purchasers of a large number of chemicals and products which are supplied locally or imported from around the world for the purpose of assembling vehicles. The information on PFOA and other substances is derived from information disclosed by the supply base through the International Material Data System (IMDS) or provided in Safety Data Sheets, and the level of information disclosed is dependent on thresholds for disclosure limits and the availability of CAS numbers. Without access or availability of information, the industry is not able to confirm the presence of a substance. Furthermore, it is important to highlight that PFOA is not a material specified by automotive manufacturers in any automotive applications including service and replacement parts. These points are not addressed in the report but must be captured as they are the foundation of our concerns.</p>	<p>First statement included in para 172. Second statement related to performance specifications is covered in para 193.</p>
CVMA	178	<p>In those letters, information was provided on where PFOA is sometimes found in vehicle components; this information was derived from searches of the IMDS system based on the 8 PFOAs listed on the Global Automotive Declarable Substance List (GADSL) or identified through company specific means. CVMA had committed to see if more information could be provided. A more detailed list of component categories where PFOA could be found in new vehicles</p>	<p>New information has been added to the already available information in para 178.</p>

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>and/or in service and replacement parts is provided below. This list has new additions to those areas previously identified:</p> <ul style="list-style-type: none"> <li>Specialized gasket seals and weather-strippings (new)</li> <li>Linings in engine, fuels and transmissions systems</li> <li>Vehicle safety restraint systems and air bag systems</li> <li>Windshield washer arms (new)</li> <li>Hoses, wiring, o-rings, cables (new)</li> <li>Other areas not yet identified</li> </ul> <p>We wish to emphasize that the list of parts identified above could be subject to change based on new information from the supply chain or findings from our evaluation of the non-exhaustive PFOA list which has been made available by the Secretariat.</p>	
CVMA	189	<p>Even with these provisions in Annex A and Annex B on service and replacement part exemptions, an alternative timing for the phase-out of automotive service and replacement parts applications is still needed for the following reasons: The industry cannot assume that a substance is not present given disclosure thresholds and other limitations. Service and replacement parts for current and previously produced vehicles are made available for a minimum of 15 years. The non-exhaustive PFOA list of over 200 substances could potentially identify parts and components previously not known, placing the industry in a challenging position especially if found after the Stockholm obligations come into force. The breadth or level of detail regarding all PFOA related compounds in the automotive sector is not available within the industry as it had been for decaBDE. In the case where service and replacement parts have already been manufactured and contain PFOA at very low concentrations were restricted, they would have to be prematurely destroyed creating a potential unnecessary risk to the environment.</p>	<p>Additional information included. Last bullet point has not been included as this would be, according to our understanding, covered by provisions in Annex A/B (service and replacement parts which have been already manufactured).</p>
CVMA	190	<p>Inclusion of comments that the automotive industry did not participate in the PFOA RME process is not appropriate. Service and replacement parts are an important issue for our industry which needs to be addressed under the Stockholm Convention.</p>	<p>Statement has been deleted here (based on a proposal by CVMA and also POPRC member). This is already mentioned previously in para 180.</p>
CVMA	193	<p>Item 193 indicates that a list of relevant spare parts/categories could be a starting point for the possible exemption. While this may be seen as a way to alleviate industry's concerns, it is problematic as it sets out an unrealistic expectation that the auto industry, as users of materials and components, knows exactly where PFOA is used and the amounts or concentrations now and in the past which is incorrect. As mentioned above, the industry can only provide information based on supplier disclosed information. Automotive manufacturers do not specify that PFOAs must be used for an application, but rather the performance and other specifications that the part or component must meet.</p>	<p>Main points are already covered. The readers are aware that this is not an easy task (but also not an impossible one). No further information included to para 193.</p>
CVMA	195	<p>The conclusion section (4.7.6, page 33) in this document needs to be revised as we have provided the information to support our request for a time limited exemption for new vehicles and service and replacement parts. The conclusion needs to indicate that a provision for a time limited exemption should be added. Other automotive associations have raised similar concerns on PFOA. PFOA is not an issue that is only limited to North America.</p>	<p>Conclusion adjusted. Time limited exemption proposed but further details/information would be required to support discussions on international level and justify a consideration of a recommendation for an exemption. Readers should now also be aware that this is not an issue that is only limited to North America.</p>

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
FluoroCouncil/ Archroma	44	<p>The bond dissociation energy of C-H is 338 kJ/mol (for C-Cl it is C-Cl 395 kJ/mol and 318 kJ/mol for C-Br) (Luo, 2007).</p> <p>Next to this bond strength, the intramolecular shielding of the H-C bond makes degradation extremely unlikely. As a matter of comparison, 8:2 FTOH does not have a similar shielding. In the case of 8:2 FTOH, the degradation process starts with the oxidation of the alcohol (-CH<sub>2</sub>OH) functionality, while in the case of 1-H-PFO, the degradation would have to take place at the fully fluorinated chain (no alcohol function in 1-H-PFO). Furthermore, in atmospheric conditions, the probability of a reaction with OH radicals is further reduced by the existence of a competing reaction with NO<sub>x</sub> that does not result in PFOA.</p>	Information added to the paragraph
FluoroCouncil/ Archroma	44	<p>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.</p> <p>Archroma does not believe that the study is conclusive on the degradation of 1-H-PFO into PFOA. Unusually, the study does not include a final conclusion. This contradicts the following statement that specific data for the transformation of 1-H-PFO to PFOA is not available.</p>	Not edited. The document does not claim that the study is conclusive on the degradation of 1-H-PFO into PFOA and clarifies that specific data for the respective transformation is not available. In our opinion there is no contradiction.
FluoroCouncil/ Archroma	45	<p>In conclusion, 1-H-PFO should be considered a PFOA-related compound since scientific evidence indicates that a transformation to PFOA is possible and should be included in the non-exhaustive list of PFOA-related substances.</p> <p>Archroma challenges the conclusion that scientific evidence is available and recalls the prior statement that specific data for the transformation of 1-H-PFO to PFOA is not available.</p>	The fact that specific data is not available does not exclude that the possibility of a transformation is indicated by more general studies. Moreover, a recent OECD list identifies 1-H-PFO as a potential precursor of PFAAs.
FluoroCouncil/ Archroma	91	<p>The conditions could be similar to what is established under the EU restriction (see the RME).</p> <p>Archroma supports establishing such strictly controlled conditions to the exemption.</p>	Noted.
FluoroCouncil/ Archroma	99	<p>As regards the volume of the PFOI fraction to be covered by the exemption proposed by the FluoroCouncil, a R&amp;D project is reported to be ongoing with the aim to further reduce this fraction (by a factor of 3 to 6). By 2020, it is expected that the volume of PFOI is generated as unintended side fraction (by-product) in the production of C<sub>6</sub> fluorotelomers at sites of Archroma will range between 50 and 100 tonnes per year (FluoroCouncil, 2018a). <del>No information was provided on current volumes and on the volume of the whole C<sub>8</sub>/long-chain fluorotelomer, PFOI side fraction.</del></p>	Partially edited
FluoroCouncil/ Archroma	101	<p>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 currently falls under the definition of a PFOA related substance. The FluoroCouncil argues that degradation of 1-H-PFO to PFOA has never been observed. 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, Part I, note (iii) or Annex B, Part I, note (iii) for the use of on-site intermediates under closed system in the production of non-POP substances (FluoroCouncil, 2018a). An exemption</p>	Edits accepted.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>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 a transported intermediate in the production of TFE and HFP (FluoroCouncil, 2018a). 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 then need to be transported for reprocessing. However, 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. However, this argument on the non-PFOA-related status of 1-H-PFO was not supported under section 2.3 of the current document. 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, Part I, note (iii) or Annex B, Part I, note (iii) for the use of on-site intermediates under closed system in the production of non-POP substances (FluoroCouncil, 2018a). 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 section 2 on chemical identity).</p> <p>Significant track change edits to the whole of this paragraph. See original submission.</p>	
FluoroCouncil/ Archroma	105	<p>According to IPEN and ACAT, the proposed exemption would allow unrestricted transport including across borders in violation of the provisions of the Convention.</p> <p>Archroma disagrees with the assessment that the proposed exemption would allow "unrestricted" transport and would like to recall that this would fall under the strict rules of Article 3 of the Convention. Article 3 (2) of the Convention specifically references both import and export provisions for specific exempted uses; the production or use of specific exemptions or acceptable purposes are explicitly referenced for export. Article 3 (6) additionally addresses parties with specific exemptions to take appropriate measures to ensure that any production or use under such exemption or acceptable purpose is carried out in a manner that prevents or minimizes human exposure and release into the environment.</p>	Suggest text deleted.
FluoroCouncil/ Archroma	105	<p>...unspecified C6 fluorotelomers</p> <p>TFE and HFP do not exhibit POP properties. C6 fluorotelomers are well defined substances.</p>	The substances produced at the German site are not specified.
FluoroCouncil/ Archroma	106	<p>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".</p> <p>Archroma disagrees with this statement. If covered by an exemption, this material would not qualify as waste but would be subject to the strict rules of Article 3 of the Convention.</p>	The statement of Archroma was added.
FluoroCouncil/ Archroma	106	<p>IPEN and ACAT argue that this exemption could result in significant further releases of PFOA</p> <p>Archroma disagrees with this generic/ unspecified qualification.</p>	The statement is kept as it clearly marked as a statement of an interest group.
FluoroCouncil/ Archroma	108	When considering impacts on society, potential negative e.g. effects in case of a (accidental) release of PFOI have to be taken into account.	Noted. However, the possibility of an accident will always exist - also when BATs are in place. This does not exclude the possibility of an exemption,

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		Archroma would like to recall that all steps of the process covered by the exemption request apply the best available techniques. They are conducted in closed systems with 1/ no contact with water and 2/ incineration of off-gases. The only exception relates to the loading/unloading of containers used for the transport of the PFOI fraction, where strict safety measures are in place.	but should be taken into account in the decision-making process.
Image and Printing Association Europe (I&P Europe)	12	This sentence, introduced in the second draft, refers to photographic coatings on film and is hence not relevant in the envisaged discussion on use of PFOA in “(e) Photo imaging sector: information on paper and printing, and information relevant for developing countries; “. Consequently, this sentence can/should be deleted.	Concur, edits accepted and sentence deleted.
I&P Europe	150	The exemption for five years from the date of entry into force recommended to the COP in the RME is for “photographic coatings applied to films”. The wording used in the RME should be respected in §150 serving as an introductory § in the section on the “4.6 (e) photo imaging sector”.  While it is right that in some films for medical and military applications PFOA or PFOA-related substances are used they are only examples of a small number of remaining critical applications of photographic coatings on film for which no alternatives are currently available.	Removed reference to medical and military applications.
International POPs Elimination Network (IPEN)	6	PFOS although it also has the potential to degrade to PFOA under certain conditions <b>and significant releases of PFOA from sulfluramid use have been estimated in China. Sulfluramid is not explicitly included in listing decision SC-4/17 on PFOS, its salts and PFOSF</b> Therefore, <b>the implications of including sulfluramid as PFOA-related substance in light of the PFOS and PFOSF listing should be discussed at POPRC14</b> <del>sulfluramid should be dealt with under the listing of PFOS, its salts and PFOSF according to Annex B to the Stockholm Convention rather than under the listing of PFOA.</del>	Not edited.
IPEN	7	They 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, <b>open burning and other sources of unintentional formation</b> would be desirable. It is also noted that in developing and transition countries there is a far greater prevalence of open burning and other <b>uncontrolled</b> combustion processes, and these should also be considered <b>since they vast much higher quantities of unintentionally produced POPs</b> . The POPRC member (2018) highlighted that an addition to Annex C would need to not only be justified but proportionate, highlighting that many POPs not listed under Annex C (e.g. decabromodiphenyl ether (decaBDE)) also have potential emissions linked to incineration. <b>However, the criteria for listing a POP in Annex C is if it is formed and released unintentionally from anthropogenic sources.</b>  This is not really a valid reason under the Convention *not* to list a substance in Annex C. The question is if PFOA can be formed unintentionally.	"Open burning and other sources of unintentional formation" included in the text. Would be desirable but probably very unlikely that such information is available or will be available soon... "uncontrolled" included in the text "since they vast much higher quantities of unintentionally produced POPs". Not edited as no information/reference on the quantities available. Last sentence not included. Other POPs are also formed and released but not automatically included in Annex C. Para 7 has been further adjusted also based on information from other parties and observers (see changes in the document). It has been also included that "a higher emission estimation of about 0.1 g/y has been reported by IPEN and ACAT"
IPEN	8	non-fluorine containing alternatives and non-chemical alternatives have been identified in the RME, including	Added.

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		those that meet regulatory requirements and are in current use.	
IPEN	9	Additional information was submitted by IPEN and ACAT and Archroma (a member of FluoroCouncil). Archroma reported about the risk management measures in place. However, the Convention only exemptions for closed-system, site-limited intermediates. Archroma's proposal requires both an exemption for PFOI transport as an intermediate and the reclassifying of 1-H-PFO as not being a PFOA-related compound, but present information indicates that 1-H-PFO should be considered a PFOA-related compound. PFOI is a PFOA-related compound that is predicted to become an Arctic contaminant, disrupts the endocrine system, and may cause long lasting harmful effects to aquatic life. Furthermore, SK Capital, the private equity owner of Archroma, has recently put the company up for sale. Based on Convention requirements, the properties of PFOI, a PFOA-related substance, the eventual generation of a 1-H-PFO, another PFOA-related substance, and the imminent sale of Archroma, no the evaluation of available information a time limited exemption should be considered for perfluorooctane iodide (PFOI) as an isolated intermediate to enable reprocessing at another site than the production site.	Not edited. An exemption is possible. A potential sale of Archroma is not relevant. More information is provided in the respective section.
IPEN	10	For medical devices, the RME states that alternatives have been developed and commercialized, including Zero PFOA PTFE. The European restriction (EU 2017/1000) allows an exemption for all medical devices (excluding implantable ones) of 15 years and a non-time limited exemption for implantable medical devices. 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) suggest that PTFE might be manufactured using PFOA even though modern methods have eliminated this use and both highlighted the difficulty.	Having checked the RME the term 'zero PFOA PTFE' is not used, rather the RME further to alternatives with shorter chain/lower fluorination. The drafters concur however that these alternatives have been commercialized and are available. First suggested edit accepted with wording changed to align to the RME. Regarding the second suggested edit is rejected as the existing text already makes clear that comments from Medtech suggest that PFOA may still be in use for PTFE used in medical devices.
IPEN	10	Based on the information compiled and discussed within the RME and further elaborated upon within the current document, alternative medical devices made without PFOA are available on the market and in use. However, the evidence reviewed suggests that for some manufacturers phase-out is still ongoing for some uses while others have already completed it. Not granting an exemption rewards those companies that have proactively phased-out PFOA from medical products. a time-limited exemption may be needed for medical devices to prevent loss of critical applications. However further detail on specifically which specific applications are critical is needed before the Committee should consider an exemption for PFOA and PFOA-related compounds in medical devices for further resolution.	The first suggested edit which recognises that alternatives are in use while some uses are still in transition is accepted with some amendment and added to match the conclusions in section 4.4. The suggest edit regarding rewarding certain manufacturers is rejected on the basis that this is not the aim of the Convention. The final edits regarding specific details are rejected on the basis that the existing wording already makes these aspects clear.
IPEN	11	The RME for PFOA highlighted a potential need for more information about a possible exemption for medical implantable devices due to its possible presence in PTFE. Quantities of PFOA and PFOA-related substances used in the production of PTFE found in implantable medical devices are small. According to a manufacturer, a total estimate for the EU is 20g in all devices put on the market during the period 2018-2025. This would lead to an estimation of 100g worldwide (ECHA, 2014a).	First suggested edit to clarify that PFOA is present as a by-product of PTFE accepted. Second suggested edit to delete data on quantities rejected, however, the drafters recognise the point made by IPEN and have added text to make clear this is an indicative order of magnitude.

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		There is too much uncertainty in this number to put in a summary.	
IPEN	11	Limited additional information has been provided on the extent of transport, risks and socio-economic impacts of a possible restriction however <del>not granting an exemption rewards those companies that have proactively phase-out PFOA from implantable medical products. the low quantities presently being used in implantable medical devices would also mean low potential for exposure.</del> Similarly, additional information on the use of PFOA in medical implants in developing countries is unknown. Further detail on specific applications is needed before the Committee should consider an exemption for PFOA and PFOA-related compounds in implantable medical devices including whether such exemption could be narrowed to a specific use such as cardiovascular implantable medical devices. A time limited exemption for this use should be considered	Suggested edits rejected as per similar comments on non-implantable medical devices.
IPEN	14	22. Fire-fighting foams were identified as a dispersive use of PFOA in the RME <del>resulting in direct release to the environment.</del>	Edits accepted.
IPEN	15	the size of in-use stockpiles may be significant and socio-economic impacts of an immediate ban may be equally significant. However, the continued dispersive use of extremely persistent POP and, <del>potentially justifying a time limited exemption. However,</del> the significant impacts of release to ground water and socio-economic costs of clean-up mean that <del>continued use is not consistent with Convention objectives efforts should be made to phase out as soon as possible. On the other hand</del> Furthermore, the use of fluorinated alternatives could lead to contamination of water from short-chain PFAS, which is even more difficult to remediate than the contamination from the long chain ones	Suggested edits have been accepted with some changes to mirror the text in the synthesis and conclusion of section 4.8. The added text recognises that while the socio-economic impacts of an immediate ban may be significant, the continued use and loss to environment represent equally if not more significant impacts, and that such continued dispersive use is not in line with the aims of the Convention.
IPEN	15	The Committee should discuss if the non-fluorinated alternatives already commercialized and in use can replace the fluorine-based AFFFs for all uses <del>and the issues surrounding existing stockpiles.</del> On this basis, the Committee should <del>formulate a recommendation that covers both PFOA and PFOA-related fire-fighting foams and existing stockpiles</del> <del>discuss the need and duration of the time limited exemption.</del>	Suggested edits accepted.
IPEN	16	Based on the review of information within the RME and elaborated on in the current document, only time-limited exemptions are envisaged. <del>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.</del> Therefore, in accordance with paragraph 9 of Article 8 of the Convention,	Suggested edits rejected to maintain continuity with section 5.2.
IPEN	32	<del>Possible exclusion of</del> How to address sulfluramid <del>from</del> in the scope of the RME [title] Language more consistent with paragraph 8 of decision POPRC-13/2.	Not changed. The original heading is more informative.
IPEN	33	The main concern expressed is that sulfluramid is a compound related to PFOS, its 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). However, the listing of PFOS and PFOSF in Annex B refers only to an “intermediate in the production of chemicals” and does not explicitly name	Edits accepted.



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		<p>sulfluramid or provide its CAS number. <del>Besides Brazil states that</del>, the information regarding sulfluramid is consolidated as part</p> <p><a href="#">UNEP/POPS/COP.4/38 and POPRC-13/2, para 7</a></p>	
IPEN	33	<p>paragraphs 5–6 of part III of Annex B to the Convention. <del>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.</del></p> <p>Simply not true. The POPRC did not decide on “the inclusion of the substance in the PFOA list.” The POPRC decided to determine how to address sulfluramid during the intersessional period.</p>	Not edited. It is marked as a statement.
IPEN	35	<p>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).</p> <p><a href="#">This para is redundant with the paras that follow going through each publication</a></p>	Deleted.
IPEN	36	<p>Martin et al. (2006) investigated the possibility that perfluorooctane sulfonamides which are present in the atmosphere <del>and</del> 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 perfluorooctane sulfonamides may serve as atmospheric sources of PFCAs, including PFOA (Martin et al. 2006). According to ABRAISCA (<a href="#">Leaf-cutting Ant Baits Industries Association</a>),</p>	Partially edited. The name of the Association is already mentioned before.
IPEN	37	<p>Plumlee et al. (2009), that the conditions used in the study do not represent environmental conditions, <del>however, the study authors note that conditions simulated natural sunlight and that the relatively high peroxide concentration was only used to observe significant decay during the experimental time period.</del></p> <p><a href="#">It is important to include the reasoning behind the study authors’ choice for these conditions and not just leave the reader with the impression that the authors somehow chose conditions for no particular reason.</a></p>	Edits accepted.
IPEN	38	<p>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). <del>Regarding this study, ABRAISCA claimed 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</del></p> <p><a href="#">Based on what data? Can anyone just claim anything and have it appeared in this document as a valid argument?</a></p>	It is made clear that it is a claim.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
IPEN	38	can transform to PFOA and PFOS through photolysis, oxidation, and biotransformation indicating that PFOA release can occur in other ways besides impurities in sulfluramid (Liu et al. (2017) <del>IPEN and ACAT, 2018b</del> ).	Partially edited.
IPEN	40	Sulfluramid is more structurally related to PFOS (both consist of a C8F17SO2-unit) than to PFOA <del>and that</del> thus degradation of sulfluramid.	Edits accepted.
IPEN	41	<del>ABRAISCA (2018b) provided information about a new study that is currently prepared by the Stockholm Convention Regional Center (CETESB) and the Brazilian Agricultural Research Corporation (Embrapa) with the aim to verify the degradation of sulfluramid in representative soils of reforestation areas in order to determine the transformation to PFOS. ABRAISCA argues that information about the transformation of sulfluramid into PFOS is scarce, in particular for soils in Brazil or tropical environments (ABRAISCA 2018b). ABRAISCA argues that the statement that the use of insect bait may represents a release of PFOS in the environment lacks scientific evidence and that more information is needed. ABRAISCA informed that they are working with the Universidade Estadual Paulista "Júlio de Mesquita Filho" on the following project: "Assessment of the behaviour and degradation of Sulfluramid, applied in the form of ant bait for the control of leaf-cutting ants, in Brazilian soils" (ABRAISCA, 2018b).</del> Irrelevant to sulfluramid formation from PFOA and POPRC-13/2	The generation of new information on Sulfluramid can also be beneficial for other related questions such as PFOA formation.
IPEN	42	Sulfluramid is manufactured by using PFOSF (CAS No: 307-35-7) as an intermediate. From a structural point of view, sulfluramid is related to PFOS (CAS No: 1763-23-1) and degrades in the environment to PFOS. <del>However, sulfluramid is not included in listing decision SC-4/17 on PFOS, its salts and PFOSF. Based on the available information sulfluramid could also be considered a PFOA related substance. However,</del> PFOSF (restricted under the listing of PFOS, its salts and PFOSF according to Annex B to the Stockholm Convention) is used to produce sulfluramid, then used for control of leaf-cutting ants from <i>Atta</i> spp. and <i>Acromyrmex</i> spp, as well as insecticides for control of imported red fire ants and termites. <del>However, sulfluramid is not explicitly included in listing decision SC-4/17 on PFOS, its salts and PFOSF. Significant releases of PFOA from sulfluramid use have been estimated in China (Liu et al. (2017) and in vitro studies have indicated that PFOA formation can occur through different mechanisms. Based on the available information sulfluramid could also be considered a PFOA-related substance. The implications of including sulfluramid as PFOA-related substance in light of the PFOS and PFOSF listing should be discussed at POPRC14. Therefore, we can consider that sulfluramid production is already regulated under the PFOS listing and it should then not be included under the PFOA listing to avoid double regulation.</del> Not true. As noted in POPRC-13/2, sulfluramid is not even named in the listing decision and it is essentially unregulated. Consumer use in Brazil is widespread and export to other Latin American countries occurs regularly though none of that is apparent because it is not even registered. Sulfluramid represents a direct release of PFOS to the environment.	Partially edited.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
IPEN	43	<del>Possible exclusion of</del> How to address 1-H-PFOA <del>in from</del> the scope of the RME	Not changed. The original heading is more informative.
IPEN	49	During the development of the RME, Switzerland supplied information on unintentional formation of PFOA from <del>inadequate incineration of</del> fluoropolymers	Sentence has been adjusted as proposed
IPEN	50	<p>. A <del>laboratory-scale</del> study from the US concluded that waste incineration of fluorotelomer-based polymers does not lead to formation of detectable levels of PFOA, <del>however the experimental conditions, measurement times, and temperature were not typical of</del> <del>under</del> conditions representative of typical municipal waste incineration in the US. <del>However, a</del> recent study found PFOA in flue gases from a state of the art incinerator of Harlingen</p> <p>This is important to mention because the DuPont/Taylor study is a lab study that is simply not comparable to a full-size operating municipal waste incinerator with its large variety of waste inputs. In addition, the experimental conditions used in DuPont/Taylor are not really comparable to a full-size operating municipal waste incinerator (oxygen, methanol, hydrogen fluoride etc.) and the time for measuring is also not comparable (6 minutes vs. 672 hours). Finally, there are two standards in incineration regulations, combustion at 850 or 1100 degrees. Taylor used 1000C which is strange and not standard.</p>	<p>"laboratory scale study" included (it is also mentioned in Yamada et al. 2005), however, still representing conservatively typical combustion conditions.</p> <p>Incineration temperatures are discussed in the same para and it is also stated that it is currently unclear to what extent formation of PFOA may occur in municipal waste incinerators... (among others other substances which exist and may interfere...).</p> <p>According e.g. to the Waste Incineration BREF "To achieve good burn out of the combustion gases, a minimum gas phase combustion temperature of 850 °C (1100 °C for some hazardous wastes) and a minimum residence time of the flue-gases, above this temperature, of two seconds after the last incineration air supply have been established in legislation (Directive 2000/76/EC and earlier legislation). Derogations from these conditions are allowed in legislation if they provide for a similar level of overall environmental performance. [74, TWG Comments, 2004]" Therefore, the applied temperature and residence time are quite standard and not "strange" as indicated. Nevertheless, it can be agreed that further studies/measurements in other incinerators would be necessary.</p>
IPEN	52	<p>Compared to the amounts mentioned in other places in this document (most are in kg's or tonnes) this amount is negligible and the costs to monitor and reduce the emissions are disproportionate.</p> <p>Comparing the incinerator to DuPont's production facility is not the question at hand. The question is can PFOA be generated unintentionally, even in a modern state of the art incinerator? The data shows that it can and that has implications for actions under the Convention – even if open burning is ignored.</p>	<p>Does not relate to DuPont's study but to measurements from NL facility. This is also the case for other POPs which are currently not listed in Annex C.</p> <p>According to NL, the Question is also whether the emission of PFOA is relevant compared to all the other sources present and whether the measures to be taken are proportional related to that emission.</p> <p>As also mentioned previously, additional data would be necessary but probably not possible to obtain (e.g. emissions from open burning).</p>
IPEN	52	<p>Proposed new para after paragraph 52:</p> <p>New data indicates that the Harlingen incinerator in the POPRC member can release 0.1 g/yr PFOA, significantly more than previously measured. In addition, non-optimal incinerator operating conditions that vastly increase pollutant releases can be common including filter bypass mode and start up and shut down processes. Furthermore, in most of the world, open burning with no pollution control of any kind is an extremely common practice and can be a significant source of POPs releases to the environment.</p>	<p>The first suggested addition regarding 0.1 g/yr has been rejected as it is unclear whether this is a genuinely new value or simply the 0.057 g/yr value rounded up.</p> <p>The second suggested edit on optimal performance rejected. It is obvious that non-optimal incinerator operating conditions may increase pollutant release. Quite general statement.</p>

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IPEN	57	Additional information and preferably also further measurements / quantitative data from other waste incinerators, <del>open burning, and other sources of unintentionally-produced POPs would be desirable to justify a possible listing based on more specific evidence</del> useful for a discussion on this topic at POPRC14.	Adjusted as proposed.
IPEN	63	surgical drapes were confirmed by MedTech <del>industry association:</del>	Not edited
IPEN	68	The fluorinated chemical alternatives to PFOA (6:2 FTOH, PFHxA/PFHxS, 6:2 methacrylate and 6:2 acrylate) <del>do not meet the overall</del> have not been evaluated by the POPRC to determine if they meet all Stockholm Convention POPs criteria. However, <del>IPEN and ACAT provide there are</del> several related scientific literature sources <del>and conclude</del> that <del>indicate</del> these alternatives raise various concerns including persistence, <del>long-range transport</del> , high mobility in water and soil and potential toxic properties.	Edited (also based on other comments received); Sentence has been adjusted i.e. ...have not been evaluated under the Stockholm Convention. PFHxS has been removed from the list and further below it is stated that PFHxS is currently under review. Requested delete 'IPEN and ACAT' rejected as this was the source of the statement,
IPEN	71	quality requirements of technical textiles cannot be fulfilled due to, for example, <del>a lack of decreased</del> chemical-, oil- and/or dirt-repellent properties, inadequate abrasion and/or wash resistance.	Edits accepted.
IPEN	89	In conclusion, more specific information on the scope of the applications, used amounts, <del>non-availability of alternatives</del> and socio-economic aspects is still lacking, <del>however the information received indicates that feasible alternatives are available and in use. and the information reviewed does not substantially help to enable the Committee to evaluate whether there is a specific need for an exemption.</del>	Can still be asked for more information. It has been already mentioned previously that feasible alternatives are in use. Based on the information currently available it is concluded that <i>an exemption should not be considered.</i>
IPEN	91	(b) Use of perfluorooctane iodide (PFOI) as isolated intermediate in order to enable reprocessing to tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) in another site than the production site. <del>Drafters might consider shortening this section, which consumes ~ 4 pages and has a lot of repetition.</del>	Suggested edit not accepted. Title needs to match the Convention text.
IPEN	91	Therefore, the need for an exemption should be assessed under the Stockholm Convention to enable reprocessing at a different site than the production site. The conditions could be similar to what is established under the EU restriction: (1) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage; (2) procedural and control technologies shall be used that minimize emission and any resulting exposure; (3) only properly trained and authorized 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 minimize 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 <del>(see the RME).</del>	Edits accepted.
IPEN	94	An exemption <del>should could</del> be considered under the Stockholm Convention with similar conditions to those established under the EU restriction (EU 2017/1000) approach. , <del>“i.e. that an exemption can be granted where the synthesis of (an) other substance(s) from an</del>	Partially edited.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p><del>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). However, 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 Stockholm 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. 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.</del></p>	
IPEN	96	<p>as well as the strict conditions of use of PFOI from its generation as an unintended side chain fraction (by-product) of C6 fluorotolomer production to its reprocessing into TFE. <del>They also question the status of 1-H PFO as a PFOA related substance (see section 2 on chemical identity)</del> (FluoroCouncil, 2018a). Covered elsewhere.</p>	A reference to the section concerning the chemical identity is helpful for the reader.
IPEN	96	<p><del>Proposed new para after paragraph 96: PFOI is a PFOA-related compound and is one of 120 substances predicted to become an Arctic contaminant based on modelling studies. PFOI has an OH thalf greater than 2 days and matches the structural profile of known Arctic contaminants. In vivo studies in male medaka fish show that PFOI upregulates estrogenic genes in a dose-dependent manner indicating that it is an endocrine disruptor. In human adrenocortical cells in vitro, PFOI upregulates 10 steroidogenic genes at uM levels of PFOI. GHS hazard statements for PFOI note that it “may cause long lasting harmful effects to aquatic life” and EU precautionary statement codes include P273 (avoid release to the environment).</del></p>	Suggested edits partially accepted, with re-wording for brevity.
IPEN	97	<p>The composition of the residual fraction is projected to shift further from C12 and C10 towards C8 as of 2020 as a result of the reduction effort. This fraction that also consists of C10F21-I and possibly C12F25-I is sent in closed barrels to an Archroma facility in the Republic of Korea</p>	Not edited. The facility does not belong to Archroma, but is owned by a separate company.
IPEN	99	<p><del>As regards FluoroCouncil did not report the current volume of the PFOI fraction to be covered by their proposed exemption proposed by the FluoroCouncil, but stated a R&amp;D project is reported to be ongoing with the aim to further reduce this fraction. By 2020, it is</del></p>	Partially edited

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		<del>expected</del> Archroma estimates that the volume of PFOI is generated as unintended side fraction (by-product) in the production of C6 fluorotelomers at their manufacturing sites of Archroma will range between 50 and 100 tonnes per year (FluoroCouncil, 2018a).	
IPEN	100	TFE and HFP <del>are both non-</del> have not been evaluated by the Committee for their POP <del>substances-</del> properties. They are used by the Archroma facility in the Republic of Korea as raw materials for the production of fluoropolymers and C6 fluorotelomers. <del>No Archroma does not expect</del> significant additional releases of PFOI <del>are expected-</del> from this process compared to PFOI incineration, but did not provide any information or references to support this claim, 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, 2018a). Corporate scaremongering on behalf of a single company is not appropriate for a Risk Management Evaluation.	It is a statement and mentions a possible consequence. It is up to the committee to decide whether the statement should be taken into account.
IPEN	101	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. FluoroCouncil wants a <del>An exemption for Archroma would be required</del> to cover the time gap. <del>The FluoroCouncil therefore submits an exemption request relating to the need of its member for the use of PFOI as a transported intermediate in the production of TFE and HFP (FluoroCouncil, 2018a). Furthermore, the viability</del> One consequence of on-site iodine extraction <del>will depend on the status of the substance</del> is that, 1-H-PFO, <del>that</del> would result from the process. Apparently, Archroma then wants to transport 1-H-PFO, not PFOI, <del>would then need to be transported</del> for reprocessing. Redundant.	Not edited.
IPEN	101	However, this argument was not supported under section 2.3 of the current document. Archroma's transport exemption proposal depends on removing <del>Provided</del> 1-H-PFO <del>would not be identified</del> from the list of as a PFOA-related substances and then having the Conference of the Parties agree to a proposal from a Party to obtain an exemption under, the transformation of PFOI to 1-H-PFO under a closed system may become eligible to the <del>general exemption provided for in</del> Annex A, Part I, note (iii) or Annex B, Part I, note (iii) <del>for the use of on-site intermediates under closed system in the production of non-POP substances-</del> a closed system site-limited intermediate (FluoroCouncil, 2018a).	1-H-PFO is currently not listed. By making reference to the FluoroCouncil it is clear that it is a statement. The para was not changed.
IPEN	102	The FluoroCouncil's submission (FluoroCouncil, 2018a) explains the intention of one of their members, Archroma, to transport PFOI as an intermediate for reprocessing at another site at least for a transitional period. The member of the FluoroCouncil submitted information regarding risk management measures to avoid releases. Archroma <del>informed</del> claims that all steps of the process covered	Edited.
IPEN	102	The only exception relates to the loading/unloading of containers used for the transport of the PFOI fraction, where they claim that strictly controlled conditions are	The suggested wording has been amended to show that independent verification of this information was not provided. The proposed edit suggests an

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		in place. (FluoroCouncil, 2018b) <b>None of the company's claims could be independently verified.</b>	investigation has already been conducted without verification proved.
IPEN	103	<b>Suggestion to delete whole paragraph. Consumes a lot of space and is redundant with previous para. If it is not possible to delete whole paragraph, further suggested edits are made as per below.</b>	Edited as suggested below.
IPEN	103	Maintenance operations, (typically unclogging), are conducted with products which are incinerated after use. <b>Archroma claims that t</b> he C6 production from which the PFOI fraction results, takes place in a closed system, with all production units being linked by closed pipes. Between the units there are vessels buffering the products. <b>Archroma also claims that i</b> n 2016, <b>Archroma they</b> made significant investments which have terminated any contact with water during production, thereby preventing any presence of fluorinated chemistry in waste water (FluoroCouncil, 2018b). <b>Archroma claims They report</b> that the only possible emissions are in the off-gases which are incinerated.	Edited.
IPEN	103	The loading and unloading steps for transport in containers take place with local ventilation. Archroma <b>indicate claims</b> that the PFOI fraction is in a liquid form with a very low volatility which further reduces the risk of emissions. The air flow is then filtered by activated carbon adsorption. Filters are incinerated. The workers conducting the operation wear a protective gear. <b>Archroma claims that t</b> he transport of the entire unintentional side fraction takes place in dedicated containers and with an experienced specialised shipment company for chemicals. <b>The company also claims that</b> transformation of PFOI into TFE and HFP including intermediary steps of iodine extraction, pyrolysis and distillation, take place under closed system and in inert gas conditions <b>and that: t</b> he process is water free. <b>Archroma claims that t</b> he only possible emissions are in the residual off-gases which are incinerated; <b>according to Archroma</b> (2018). <b>None of the company's claims could be independently verified. A review of maritime accidents notes that the HASREP project reviewed chemical accidents in EU waters above 70 tonnes from 1994 – 2004 and found 18 major accidents. On-site or off-site?</b>	Partially edited. The text as written suggests that an assessment has been carried out already which could not verify whether the text provided by Archroma is true. I do not believe that such an assessment has been completed. Better to state that an independent verification of processes was not provided.  Addition of text regarding the numbers of maritime accidents and activities of one operator seems speculative. Edit not included.
IPEN	104	A summary of <del>the Archroma's</del> <b>claimed</b> risk-management measures in place are displayed below. <b>None could be independently verified:</b> <b>Redundant with the previous para – One should be selected and the other deleted to save space.</b>	Suggested edit rejected. Previous edit on independent verification already accepted. For sake of brevity it is not necessary to include this at each juncture.
IPEN	104	<b>Suggestion to delete figure 4.3</b>	Not edited. The figure is a summary and can be helpful for the reader.
IPEN	106	In conclusion, IPEN and ACAT (2018) suggest that the Committee should not <b>contravene the Convention by recommending</b> an exemption for non-site-limited isolated intermediates	Not edited. Exemptions are possible under the Convention
IPEN	108	A treatment of the PFOI fraction in an incineration facility without iodine extraction is not possible as the iodine content causes rapid corrosion of installations at elevated temperatures (FluoroCouncil, 2018b) <del>The fraction.</del> <b>Positive impacts on society if the exemption is not granted include economic benefits for companies making safer, non-fluorinated alternatives. In addition, the possibility of maritime accidents and/or waste dumping would be completely avoided. Finally, SK Capital, the private equity owner of Archroma, has</b>	Suggested edits rejected. It is not the role of the Stockholm Convention to provide economic benefits to companies. Additionally, it is inaccurate to draw comparisons to the number of maritime accidents and safety versus whether one operator continues to operate or otherwise.

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		recently put the company up for sale, indicating that negative economic impacts on the company are unlikely. <del>When considering impacts on society, potential negative e.g. effects in case of a (accidental) release of PFOI have to be taken into account.</del>	
IPEN	110	the company might invest in the on-site iodine extraction and then 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. <b>In summary, Archroma's proposal requires both an exemption for PFOI transport as an intermediate and the reclassifying of 1-H-PFO as not being a PFOA-related compound.</b>	Edits accepted.
IPEN	110	<b>Proposed new paragraph after 110: [1]</b> PFOI is a PFOA-related compound that is predicted to become an Arctic contaminant, disrupts the endocrine system, and may cause long lasting harmful effects to aquatic life.	Edits accepted., with reference to Brown and Wania added.
IPEN	110	<b>Proposed new paragraph after 110: [2]</b> The Stockholm Convention permits exemptions only for closed-system site-limited intermediates.	Not edited. Exemptions can be granted also for other cases.
IPEN	112	Based on Convention requirements, the properties of PFOI, a PFOA-related substance, the eventual generation of a 1-H-PFO, another PFOA-related substance, and the imminent sale of Archroma, <del>no the evaluation of available information a specific time limited</del> exemption should be considered for the use of PFOI (perfluorooctane iodide) as isolated intermediate in order to enable reprocessing to TFE (tetrafluoroethylene) and HFP (hexafluoropropylene) in another site than the production site. <del>Based on the information provided, the Committee has to decide whether an exemption should be given.</del>	Not edited. The information was included before and the potential sale of Archroma is considered to be irrelevant.
IPEN	115	MedTech Europe <del>industry association</del> (2018) provided details	Concur, but Medtech are mentioned several times during the addendum, for the sake of brevity have added this once at the first mention of Medtech and thereafter will be mentioned as Medtech or Medtech Europe only.
IPEN	115	... both non-polymeric substances and side-chain fluorinated polymers (including PTFE). <b>Claims about bioavailability and safety have not been evaluated by the POPRC and should not be included. The RME is not a sales brochure for FluoroCouncil companies.</b>	Concur, footnote amended. The point of the footnote is to make clear what is meant by 'side chains'
IPEN	116	[footnote] These polymers are used to treat textiles, carpets, nonwovens and paper to provide water, soil, oil and stain resistance. <del>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.</del> <a href="https://fluorocouncil.com/fluorotechnology/terminology/">https://fluorocouncil.com/fluorotechnology/terminology/</a>	Edits accepted.
IPEN	118	MedTech (2018) and Euromed (2015) <del>industry associations</del> commented that medical device manufacturers encompass up to 11,000 suppliers, with supply chains up to five to seven tiers globally.	Edit rejected. See previous comment on the same edit. For brevity, this is mentioned once.



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IPEN	119	<p>as a raw material input for the production of the applied polymers (<del>Euromed, 2015</del>). Wang et al. (2014) <del>note that 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;</del> new PFOA production had begun post-2006 in Asia (particularly India and China) primarily driven by the demand for production of fluoropolymers including PTFE. <del>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,</del> but no disaggregation is provided for uses specifically in medical devices, <del>so it is not clear if products manufactured for MedTech association companies used PFOA in production.</del></p> <p>This information is supposed to back-up MedTech claims about the possibility of production in China and India – but then at the very end it is clear that “no disaggregation is provided.” So, MedTech says their products *might* use PFOA and then the Wang et al paper says we are not sure if any of the PTFE is used in medical devices. It does not seem honest to make these kinds of inferences.</p>	<p>Suggestion to delete Euromed 2015 as a reference is rejected on the basis that it is the correct reference for the text in this paragraph. Suggestion to delete the text after Wang accepted for brevity. Suggestion to delete text relating to quantities rejected as this is salient information. The final suggested additional is also rejected on the basis that Medtech only represent the European area. The text related to Wang presents a wider geographic area therefore it is unfair to draw reference between production and use in China and India to ongoing activities in Europe.</p>
IPEN	122	<p><del>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). 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.</del> A report by ECHA for the European restriction (ECHA, 2015a) comments</p> <p>The sentence says that PFOA *might* be used to make PTFE which *might* be used in kidney dialysis treatment. Then sends the reader to a reference that says nothing about PTFE or use of PFOA. That is simply not acceptable scientific practice in a POPRC document or any other technical report.</p>	Edits accepted.
IPEN	126	<p>Some technical issues <del>have been</del> experienced with PFOA free PTFE alternatives used for implantable medical devices (detailed further in section 4.5) <del>largely linked to delamination upon prolonged exposure to blood and saline solutions. For medical devices not used for implantable applications have been resolved.</del> It is unclear whether the <del>technical issues experienced with implantable devices are relevant to other medical devices. operating parameters will be similar, and if there is a need for resistance to delamination from saline or other bodily fluids such as blood.</del></p> <p>It would be clearer and fairer to save the details on this issue for the section below on implantable devices. Highlighting the problems without indicating their resolution does not provide a fair, complete picture.</p>	<p>Concur, the issue reported related to delamination and flaking of coatings from PFOA-free PTFE in guidewires immediately around the heart. For clarity reference to issue is now reserved to only the implantable device section. Paragraph deleted.</p>
IPEN	130	<p>MedTech Europe (2018) commented that health risks of medical devices are adequately assessed during regulatory procedures before the placing on the market. <del>MedTech Europe claims that 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.</del> The European medical device industry commented that they fully supported a phase out of PFOA but requested a</p>	<p>The first suggested edit to delete text is accepted, on the basis that PFOA has been identified as a POP and the sentence that follows it makes clear the European medical industry are asking efforts for phase out. The second suggested edit to add text about economic benefits to PFOA-free manufacturers is rejected on the basis</p>

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		<p>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 considered to be small and it can be expected that most medical devices would be disposed of according to the stringent waste disposal requirements applicable to hospitals. However, the stringency of medical waste disposal practices will vary.</p> <p><del>Positive impacts on society if the exemption is not granted include economic benefits for companies making safer, non-fluorinated alternatives which are already approved and in use. Eliminating a highly persistent toxic chemical such as PFOA within the healthcare sector is also consistent with the health professional creed to “first do no harm.”</del></p> <p>These types of claims are made about all toxic chemicals for which no studies of health impacts have been performed. Absence of studies is not proof of safety. This sentence should either be deleted or kept only with a sentence following it that states that no studies have been performed. As currently written it is not honest.</p>	<p>that it is speculative and is not substantiated within the suggested addition.</p>
IPEN	134	<p>The RME states that alternatives have been developed and commercialised, including Zero PFOA PTFE.</p> <p><del>However, SSG (2017) and Nesbitt (2017) highlight performance issues for some alternatives within implantable medical devices relating to delamination after prolonged contact with blood and saline. It is unclear which non-implantable medical devices might have similar performance issues.</del></p> <p>It would be clearer and fairer to save the details on this issue for the section below on implantable devices. Highlighting the problems without indicating their resolution does not provide a fair, complete picture.</p>	<p>Concur, as per the previous comment on the say topic reference to performance issues of PFOA-free PTFE alternatives is now reserved to the implantable medical devices only. Suggested deletion accepted.</p>
IPEN	136	<p><del>The main societal effects 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.</del> Medtech Europe (2018) and Euromed (2015)</p> <p>Confusing as written. The societal effect of granting or not granting an exemption is availability? That statement ignores the widely available devices already approved that do not use PFOA.</p>	<p>Suggested edit rejected. The Drafter’s are concerned that there is a lack of evidence to show that transition and availability of PFOA-free alternatives in all global geographies has occurred.</p>
IPEN	136	<p>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. <del>This reportedly delays the transition to alternative products.</del> However, alternatives that do not use or contain PFOA have already passed these stringent regulations and are on the market and in use. .</p>	<p>Suggested deletion rejected as the point made is valid. However, concur that alternatives are available, but unclear if this represents all geographies. Text regarding availability of alternatives added.</p>
IPEN	137	<p>However, the evidence reviewed suggests that <del>for some manufacturers phase-out is still ongoing for some uses while others have already completed it uses and therefore a time limited exemption may be needed for medical devices to prevent loss of critical applications.</del> Not granting an exemption rewards those companies that have proactively phased-out PFOA from medical products. Further detail on specific applications is needed before the Committee should consider an exemption for PFOA and PFOA-related compounds in medical devices.</p>	<p>First suggested edits around phase-out and some companies rejected as it reduces the clarity of the text. Second suggested edit regarding rewarding non-PFOA PTFE manufacturers rejected on the basis that this is not the aim of the Convention.</p>

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		Not <del>*one*</del> critical application has been described in the RME or in this document.	
IPEN	140	In implantable devices, <del>a one</del> manufacturer previously estimated that the total amount of PFOA	Edits accepted.
IPEN	141	ECHA (2015a) commented that a derogation for implantable medical devices <del>in the EU</del> was needed given the very low amounts of PFOA and PFOA-related substances involved	Edits accepted.
IPEN	144	(Nesbitt, 2017). Nesbitt (2017) also notes that processes following these practices have resulted in zero Class 1 FDA recalls. <del>However, it is unclear which products on the market are considered first generation or second generation (SSG, 2017).</del> The reference does not say this and makes no reference to first or second-generation products.	Concur, suggested edit accepted
IPEN	148	MedTech Europe (2018) noted that they had concerns regarding patient safety if critical implantable medical devices became unavailable due to lack of transition time to PFOA free alternatives. <del>However, PFOA-free alternatives for implantable medical devices have passed all regulatory requirements and are already in use. Positive impacts on society if the exemption is not granted include economic benefits for companies making safer, non-fluorinated alternatives which are already approved and in use. Eliminating a highly persistent toxic chemical such as PFOA within the healthcare sector is also consistent with the health professional creed to “first do no harm.”</del>	Suggested edits partially accepted. The drafters are deeply concerned about assertions that PFOA-free alternatives are available in all global geographies, evidence for this has not been provided. Furthermore, it is not the role of the Convention to provide economic benefits for companies. Text has been added to illustrate that cases of substitution have been provided, but unclear how advanced globally we are towards this aim.
IPEN	149	Quantities of PFOA and PFOA-related substances used in implantable medical devices (largely for production of PTFE) are small ( <del>estimated to be</del> 20g in the EU and 100g worldwide) and concentrations are low in the final product <del>are very low</del> (PFOA in PTFE is stated to range from 0.001 to 0.5%;	Edits accepted.
IPEN	150	While industry representatives (MedTech, 2017) have indicated significant progress has been made towards the phase-out of PFOA within implantable medical devices, industry indicates that supply chains are complex and that articles are subject to stringent regulatory testing requirements. <del>Not granting an exemption rewards those companies that have proactively phase-out PFOA from implantable medical products. Further detail on specific applications is needed before the Committee should consider an exemption for PFOA and PFOA-related compounds in implantable medical devices including Therefore, the Committee could consider the need for a time limited exemption to aid the transition to safer alternatives. It could also consider whether such exemption is needed only for could be narrowed to a specific use such as cardiovascular implantable medical devices.</del>	Suggested edits rejected. A listing within the Convention even with an exemption makes a clear and bold statement about the future of PFOA use. The aim of the Convention is not to provide economic rewards to companies.
IPEN	151	Specific exemptions applied in Norway and Canada until 2016 but are now <del>obsolete ended</del> (See appendix).	Concur, edit accepted.
IPEN	157	<del>The European industry assumes e</del> Environmental releases and exposure potential <del>are also assumed</del> to be low during manufacturing (I&P Europe, 2015).	Concur, edit accepted.
IPEN	162	photographic applications cannot be estimated and no further up to date information has been received in response to the call for information. <del>This may be due to the extensive transition to digital technologies that has already occurred.</del>	Concur, edit accepted.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
IPEN	164	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 <b>for I&amp;P Europe member companies</b> , replacements do not currently exist for the remaining few applications, further reduction in use of PFOA-related compounds is anticipated as the <b>rapid</b> transition continues towards digital imaging. I&P Europe believes that additional control measures for ongoing uses of PFOA are not necessary – <b>a view that contrasts with Stockholm Convention objectives to eliminate POPs</b> (I&P Europe, 2016).	This paragraph is from the original RME and therefore is not going to be re-opened/amended here
IPEN	164	The largest barriers to development reportedly remain technical and cost of R&D. They suggest that substitution of PFOA typically amounts to 500–1,000,000 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). <b>For these reasons, the industry has shifted to digital technologies.</b>	Concur, edit accepted but added in non-italics after sentence from RME
IPEN	166	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). <b>However, positive impacts on society would result from eliminating all emissions of PFOA for this use and this is feasible since digital technologies have already largely replaced PFOA for this use.</b>	Suggested edits rejected, the use of language here is vague and makes some bold assumptions which based on the evidence reviewed cannot be upheld.
IPEN	167	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. <b>On that basis, I&amp;P Europe commented that additional control measures for ongoing uses are not necessary (I&amp;P Europe, 2016).</b>	Concur, edit accepted.
IPEN	171	During the development of the RME, the CVMA requested specific exemptions for automotive service and replacement parts <b>to satisfy customer demand</b> . According to the CVMA, the industry has been proactively phasing out PFOA use for some time. However, according to CVMA, service and replacement parts might still contain PFOA. CVMA states that these parts represent a small percentage of PFOA use and will decrease naturally over time as the vehicle fleet turns-over. <b>Automotive manufacturers indicated the need to ensure the availability of original equipment and spare parts to satisfy customer demand (see the RME).</b>	The statement is basically the same. No reason to change.
IPEN	172	In their recent submissions, CVMA <b>specifies that requests an exemption is required</b> 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. The request for exemption in new vehicles is related to potential use of PFOAs that are not listed on the Global Automotive Substance List (GADSL) or listed on GADSL but used below the declaration concentration of 0.1%. It is further stated that <b>the POPRC recommended an exemption for the automotive industry for the production and use of c-decaBDE is limited to parts</b>	Not edited. This is a statement made by CVMA and we cannot simply change it. Additional sentence added that the recommended exemption by POPRC is limited to parts used in legacy vehicles.

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		used in legacy vehicles <del>was provided for service and replacement parts when the Convention was deliberating the addition of decaBDE</del> and the same exemption should be applied for PFOA. The issues and challenges would reportedly be similar (CVMA, 2018). POPRC-12/4	
IPEN	173	CVMA further <del>explains-claims</del> that it is <del>difficult</del> <del>challenging</del> to provide meaningful information in support of the required exemption <del>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</del> because PFOA does not have a single CAS number. As noted in the Risk Profile, the CAS number of PFOA is 335-67-1. <del>The efforts have been focused so far on a selected number of PFOAs as information was not available on a broad number of other PFOAs.</del> 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. This has also been expressed by ACEA (2018) and SIAM stating that this would require a great amount of time (SIAM, 2018). <del>A list of specific PFOA-related substances with CAS numbers was provided to the POPRC in 2015 in UNEP/POPS/POPRC.11/5.</del>	Not edited. This is a statement made by CVMA and we cannot simply change it. What is meant here is PFOA and related substances and in particular is the non-exhaustive list of PFOA related substances provided in October 2017 (i.e. UNEP/POPS/POPRC.13/INF/6/Add.1)
IPEN	175	Further, it is important to highlight that the 8 PFOA-related substances are included in GADSL	Edits accepted.
IPEN	176	Regarding service and replacement parts, CVMA has indicated that most likely service and replacement parts still contain PFOA, its salts and PFOA-related compounds. <del>These</del> According to CVMA these parts represent a small percentage of the PFOA use and the amount will decrease naturally over time as the vehicle fleet turns over.	Edits accepted.
IPEN	176	The cost of replacing a class of substances in a small number of parts is according to CVMA prohibitive. <del>However, the continued use of PFOA also results in costs except that these would be paid by governments and taxpayers. It is also incompatible with the objectives of the Stockholm Convention to grant an exemption for continued use of a POP simply because an industry does not wish to absorb certain costs.</del> It should be noted that repair parts need to meet the same performance specifications as the original parts.	Additional sentence has been included that "no further information on costs has been provided." This is also again highlighted later in the summary and conclusion section
IPEN	178	Re-developed replacement parts must function identically to the original part to ensure the vehicle's functionality and safety are not adversely impacted. <del>The cost of replacing a class of substances in a small number of parts is prohibitive according to CVMA</del> Stated above.	Edits accepted.
IPEN	179	Further, SIAM reports use of PFOA in vehicles safety restraints an air bag systems, fuel and transmission systems, fuel hoses, wire insulations and bearings (SIAM, 2018). <del>These parts could all be retrofitted with new parts that do not contain PFOA or PFOA-related substances, which is efficient since testing results can be applied to both new and old</del>	Not edited. Please note already manufactured parts can still be used. No direct need to retrofit.
IPEN	180	The CVMA (2018) further commented that while efforts had been made to engage with the Committee's process, there have been limitations to providing further information in this case because PFOA and PFOA-related compounds covers many substances and	This is a statement made by CVMA and we cannot simply change it. What is meant here is PFOA and related substances and in particular is the non-exhaustive list of PFOA related

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		therefore represents a significant challenge for data gathering compared to decaBDE which was based on a single substance. <b>However, a list of PFOA-related substances was provided three years ago when PFOA was proposed for listing. The auto industry added PFOA to the GADSL ten years ago in 2008. If the auto industry had pursued actions beginning on that date, then substitution would be completed and there would be no need for any discussion about possible exemptions for any parts</b>	substances provided in October 2017 (i.e. UNEP/POPS/POPRC.13/INF/6/Add.1)
IPEN	182	<b>The auto industry was aware of the need to phase-out PFOA in 2008 and has the technical capacity to retrofit parts for specific uses that do not contain PFOA, indicating IPEN and ACAT therefore advice that</b> no exemption for PFOA use in the automotive industry should be recommended (IPEN and ACAT, 2018).	Para 181 has been merged with paragraph 180. Statement is basically the same. See previous comment in para 180 related to the list of substances.
IPEN	183	Technical and/or economically feasible alternatives for PFOA exist at least in part for the automotive industry. <b>However, for exemptions to be considered, the auto industry needs to propose specific uses and thus far, that information is lacking.</b>	Automotive industry has provided additional information. A complete overview is however, not available due to several reasons stipulated by the industry. Sentence added: "The typical areas of application have been indicated by the automotive industry, however, a complete overview is not available, yet."
IPEN	184	These <b>unstated</b> costs are considered prohibitive by the automotive industry; however, no further information has been provided by the industry related to associated costs. <b>Externalizing industry costs onto governments through use of exemptions is not consistent with the objectives of the Stockholm Convention.</b>	Not edited
IPEN	187	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). <b>However, retrofitting autos with new parts that do not contain PFOA is efficient since testing results can be applied to both new and old vehicles.</b>	partly edited as proposed
IPEN	188	<del>According to IPEN and ACAT (2018), P</del> prohibiting PFOA use for automotive applications would have a positive impact on human health and the environment by limiting further PFOA releases and exposures and have a positive impact on businesses making alternatives, particularly non-fluorinated alternatives (IPEN and ACAT, 2018).	edited (reference available at the end of the sentence)
IPEN	190	In their recent submissions, CVMA <b>specifies that requests an exemption is required</b> for automotive vehicle service and replacement parts as well as for current production vehicles	Edits accepted.
IPEN	191	CVMA, indicated any exemption interest during the year-long process of developing the PFOA RME, despite being fully aware of the Committee's process due to their involvement with decaBDE. <b>Furthermore, the industry was aware of the need to phase out PFOA in 2008 when the substance was added to the GADSL.</b>	Entire paragraph 190 has been deleted. Not further edited. Additional information is not really supportive for discussions.
IPEN	194	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. <b>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</b>	No justification provided why sentences should be deleted. Last sentence edited as proposed.

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		<del>categories could be established similar to the approach for decaBDE. The starting point for this could be</del> This information should be provided for 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 <del>along with information about substitutions already in place.</del>	
IPEN	196	This, however, could be revised depending on whether additional information (see above) will be made available by the automotive industry, specifically data on tonnages and uses (specific parts or categories of parts), time for phase-out and economic impacts <del>and information about alternatives in place and retrofitting capacity.</del>	Paragraph amended following comments from other Parties. Suggested edits now redundant.
IPEN	198	Queensland Government (2016a) comments on a study from 2014 where 103 different fluorinated compounds were identified within 10 commercial AFFF products available on the Australian market. <del>Barzen-Hanson et al. 2017 demonstrated the complexity of AFFF mixtures, indicating that more than 240 individuals per- and polyfluoroalkyl substances (PFAS) can now be associated with AFFF, with the discovery of forty novel classes of PFAS and additional detection of 17 classes of previously reported PFAS. The authors stated that these newly discovered PFAS will pose challenges for effective remediation due to the presumed wide range of solubility. Systems designed to capture PFOS and PFOA (such as granulated active carbon) will not be effective because shorter-chained substances will likely break through.</del>	The Drafter thanks IPEN for the new reference which has been reviewed. We note the primary focus of the research was on groundwater, however AFFFs (both ECF and fluorotelomer) manufactured in the 1980s and 90s were also analyzed. The forty novel classes highlighted by the suggested text largely relate to ECF based AFFF and therefore we believe this is an important point to make clear. Suggested edit is accepted with amendments to that fact.
IPEN	201	Furthermore, responses from <del>manufacturers for fluorinated foams industry</del> suggested that an exemption for fire-fighting foams may be needed for stockpiles of in-use goods to aid phase-out.	Suggested edit rejected, the drafter believes the industry involved was broader than the suggested edit indicates.
IPEN	204	The Fire-fighting Foam Coalition <del>industry association</del> (FFFC, 2004 and FFFC, 2011) provides details of an inventory for PFOS based AFFF fire-fighting foams in the USA as a potential proxy for quantities of PFOA within fire-fighting foam stockpiles assuming that both PFOS and PFOA have been used within C8 perfluorinated products, <del>though no specific proportions were provided.</del>	First suggested edit to recognize the FFFC as an industry association accepted. Second suggested edit regarding specific proportions rejected on the basis that this is apparent in the text.
IPEN	206	This was based on data from the Norwegian product register and extrapolated to EU-wide quantities based on population, <del>and provides an order of magnitude estimate due to uncertainties arising from the method.</del>	Concur, suggested edit accepted
IPEN	210	The Fire-fighting Foam Coalition (2016) provided details of best practice for use of Class B fire-fighting foams, which includes <del>both non-fluorinated and</del> the PFOA based AFFF types of product. The guidance focuses on measures which can be grouped into one of three categories:	Suggested edit accepted, with further caveat to include fluorotelomer foams also
IPEN	214	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. <del>Other costs for both plasma-arc facilities and cement kilns include those associated with stringent implementation of BAT/BEP including continuous monitoring to avoid generating further fluorinated or other toxic substances.</del>	Concur, suggested edit accepted.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
IPEN	215	The RME highlighted that many viable chemical alternatives, including fluorine-free formulations, to PFOA-based AFFF are available and commercially in use globally.	Suggested edit rejected.
IPEN	217	It should be noted that contamination of water from short-chain PFAS is very difficult, if not impossible, to remediate. Although remediation techniques such as granular activated carbon (GAC) treatment are “reasonably effective” for longer chain PFCs such as PFOS and PFOA, it is very poor at removing short-chained perfluorinated substances. Significant evidence of potential environmental and health effects has emerged that demonstrates that short-chained C6 and lower PFAS are difficult to capture and may result in increasing levels of exposure, are far more mobile in the aquatic environment, concentrate preferentially in grasses and crops with the potential to contaminate food sources, and bioaccumulate and bind to proteins. Furthermore, short-chained C6 are regrettable substitutes from an economic as well as environmental perspective, given the likelihood that they are associated with the same environmental and health problems as the older AFFFs.	The Drafter thanks IPEN for the new reference which has been reviewed. The suggested edits have been partially accepted, Holmes quotes on a serious of fire industry myths, which is where the issue of environmental performance of C6 has come from. This has been accepted verbatim from the original reference. The reference to GAC appears to relate to one specific technique used in remediation, extrapolation to all GAC techniques is therefore inappropriate. Suggested edit rejected. Final suggested edit regarding regrettable substitutions also rejected on the basis that the reference provided does not provide sufficient detail to draw such conclusions.
IPEN	220	Development of fluorine free foams capable of managing Class B type fires represents a significant challenge and has prompted need for innovation (Cousins, 2016). However, Cousins (2016) and Hetzer (2014) comment that encouraging progress has been made, with some foam manufacturers stating that AFFF is no longer needed. Recent independent test results published in 2017 by the Southwest Research Institute found that the fluorine-free foam Re-Healing RF3 (manufactured by Solberg) met the Performance Level B Fire Test Standard of the International Civil Aviation Organization (ICAO). Tests at the Dallas-Fort Worth Airport in the US demonstrated that the extinction efficiency of fluorine-free foam was indistinguishable from that of AFFF. The report noted that “criticisms from some parts of the industry that fluorine-free products suffer from fuel pickup with foam flammability and poor burn-back resistance or drainage characteristics proved to be unfounded.” The tests confirm that fluorine-free foam is “totally suitable for aviation firefighting.” Testing at research facilities in France with participation of regulators, manufacturers, and firefighters showed that fluorine-free foam was just as efficient as AFFF.	The first suggested edit regarding challenges and innovation rejected on the basis that this is taken directly verbatim from what Cousins reports in 2016. The second suggested edit is partially accepted. Paragraph 221 already contains text regarding the Re-Healing foams. Therefore, this has been expanded to further include the suggested text around levels of testing.
IPEN	220	Norwegian airports, military properties and several offshore companies have also introduced fluorine-free foams (Norway Comments on 3rd draft RME). At the Copenhagen Airport, fluorine-free Solberg RF Re-Healing Foam was used to replace AFFF for environmental and aviation safety reasons, as well as for the occupational health and safety of firefighters. The London Heathrow Airport in the UK switched to fluorine-free foam in 2012 after extensive public testing that were independently evaluated by representatives of the civil aviation authority. “The Norwegian and Danish air forces now use fluorine-free foam, as does the oil and gas sector in the North Sea; countless firefighting brigades around the world; as well as 47 corporations including 3M, Exxon Mobil, Statoil, and ConocoPhillips; and at least 77 airports.”	Suggested edits rejected as these cases are already included in the text for paragraphs later in the same section.



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IPEN	222	<p>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, <b>although this cost comparison is outdated.</b></p> <p><b>This citation is not provided in the References section, so cannot be verified. Moreover, the cost comparison in the reference cited is unacceptably outdated. More recent cost comparisons are necessary as it is very likely that fluorine-free alternatives costs are comparable or even more economical than AFFF, especially given internalized costs for monitoring, clean-up, and long-term environmental and health consequences of AFFF. There has also been a significant increase in the market for fluorine-free alternatives since 2004. The information should either be updated or amended to acknowledge that this cost estimate is outdated and does not reflect current cost comparisons.</b></p>	As noted in the previous draft we concur that the RPA 2004 reference is outdated. This specific issue has been reviewed in more detail at this round. Discussion on cost comparison has been moved to the end of the alternatives section and reference to 2004 data removed.
IPEN	224	<p>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 fluorosurfactants foam manufacturers</p> <p><b>Reference needed to substantiate these claims.</b></p>	Text has been modified to provide specific details of both the reference (Castro et al, 2017) and the results of the testing carried out.
IPEN	224	<p>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.</p> <p><b>According to an independent report, “neither the fluorine-free foam nor all of the PFAS-containing foams met the 30-second standard [in the US Navy tests]. At its fastest, the fluorine-free foam put out the fire in 39 seconds. For the PFAS foams, the times ranged between 25 and 36 seconds.” Although close in performance and with evidence that the fluorine-foams would prove comparable and did not contain the chemicals that were contaminating drinking water throughout the world, “the Navy made no effort to work further on the fluorine-free foam.”</b></p>	The Drafter thanks IPEN for the new reference which has been reviewed. The salient information regarding extinguishment times has been added and accepted to the text. The other suggested additions regarding environmental effects are already covered in the text, for the sake of brevity these are not included here.
IPEN	225	<p><b>Auxquimia, a Spanish <del>foam</del> manufacturer of fluorinated and non-fluorinated foams 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. <del>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).</del> Independent fire tests conducted by the Southwest Research Institute found that Re-Healing RF3 foam was effective in extinguishing Jet A fuel, meeting the Performance Level B testing requirements of ICAO Fire Test Standard. <del>However, fluorine-free foams certified to different ICAO levels (required for use at civilian airports)</del></b></p> <p><b>This statement is not true.</b></p>	This paragraph has been modified following comments from other parties. Suggested edits now redundant.
IPEN	225	<p>For example, the UK Civil Aviation Authority notes that fluorine-free foams are ICAO Level B approved and</p>	Suggested edits accepted.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		found that fluorine-free foams were just as efficient as AFFF in large-scale fire tests; while the Copenhagen Airport replaced AFFF with Solberg RF Re-Healing foam for environmental reasons. <b>Manufacturers of fluorine-free foams that are currently on the market include: National Foam (Jetfoam—used in aviation applications; and Respondol—a Class B product); Bioex (Ecopol); Fomtec (Enviro 3x3 Plus); Solberg (Re-Healing Foam RF6/RF3); and Dr. Sthamer (Moussol F-F3/6), Auxquimia (Unipol); Vsfocum (Silvara); Biosafety Technology (Trident); 3F (Freefor SF, Hyfex SF, Freedol SF). Bioex asserts that their Ecopol, Bio For, Bio T, and Bio Foam fluorine-free foams are as effective as the best AFFF foams and that they obtained the best 1A performance classification under EN 1568-3 standard (certified 1 A/freshwater and 1 A/seawater). Soberg Re-Healing RF3 Foam meets fire performance test criteria of Underwriters Laboratory (UL Standard 162), Underwriters Laboratories of Canada (Standard S564), FM Approval Standard 5130, European Standard EN 1568 Part 3 and International Civil Aviation Organization Level B.</b>	
IPEN	231	Others include cost of analytical monitoring of PFAS, <del>incineration</del> destruction of old stockpiles, clean-up of equipment contaminated by previous use, costs of developing and commercializing sustainable alternatives, funding new research, health costs, legal costs, etc.	Edits accepted.
IPEN	233	<b>Proposed new paragraph after 233:</b> <b>Eliminating all uses of PFOA in firefighting foams would provide an economic benefit to manufacturers of non-fluorinated firefighting foams.</b>	Suggested edit rejected. Comment is speculative.
IPEN	239	A similar exemption could be adopted for the Stockholm Convention, <b>but a continued dispersive use of an extremely persistent POP that requires very expensive clean-up measures is not consistent with Convention objectives.</b> 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	Suggested edit has been partially accepted, PFOA has already been identified as a POP 'extremely persistent' is therefore redundant.
IPEN	240	Concerns have also been highlighted about the mobility and potential environmental impacts of shorter chain perfluorinated compounds in fire-fighting foams <b>and the very high costs of clean-up.</b> The Committee should discuss if the non-fluorinated alternatives already commercialized and in use can replace the fluorine-based AFFFs for all uses and the issues surrounding existing stockpiles. On this basis, the Committee <b>should formulate a recommendation that covers both <del>discuss the need and duration of the time limited exemption for</del> PFOA and PFOA-related fire-fighting foams <del>to aid phase-out and existing stockpiles.</del></b>	Text of the conclusion amended in part by comments from other Parties. The suggested addition regarding clean-up costs has been added, but not 'very high' is qualitative use of language. We would prefer to use 'high'. The second edit regarding new uses and existing stockpiles has been accepted.
IPEN	Table 5.1	Limited information on the scope of the applications <b>was provided making it difficult to fully discuss <del>and</del> the availability of alternatives <del>has been submitted.</del> However, alternatives including non-fluorinated alternatives for these uses are in current use.</b> No relevant information has been provided or could be identified on used amounts in relevant applications.	Partly edited as proposed
IPEN	Table 5.1	Used amounts in specific applications and related information which would also enable the socio-economic aspects and information on <b><del>the possible non-availability of</del></b> alternatives to be further evaluated would be required to justify exemptions.	Can still be asked for information.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
IPEN	Table 5.1	In summary, <del>there is a lack information reviewed about specific uses and amounts but indications that alternatives are available for a variety of uses. does not substantially help to enable the Committee to evaluate whether there is a specific need for an exemption for these uses.</del>	Adjusted as proposed.
IPEN	Table 5.1	Both submitters and Norway commented on the first draft. IPEN and ACAT also expressed concerns that an exemption for transported isolated intermediates <del>is prohibited by the Stockholm Convention and</del> could “open the door to waste dumping in developing and transition countries under the guise of “reprocessing”	Not edited. An exemption is possible.
IPEN	Table 5.1	PFOI is currently transported in closed barrels to a facility in South Korea where <del>the company claims that</del> iodine recovery and reprocessing to TFE and HFP, take place under closed system conditions.	Edited.
IPEN	Table 5.1	Archroma is developing a method for on-site iodine extraction, a prerequisite for reprocessing PFOI. <del>Archroma is requesting aA</del> transitional exemption for the transport of PFOI as a transported isolated intermediate <del>would be necessary</del> , 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, <del>that also falls under the definition of</del> a PFOA related substance (questioned by the FluoroCouncil) and is therefore not a viable solution, <del>if since 1-H-PFO is considered a PFOA related substance.</del>	Not edited.
IPEN	Table 5.1	Archroma submitted information about risk management measures during taken to avoid releases and informed that all steps of the process covered by the exemption request apply the best available techniques and are conducted in closed systems <del>with (1) no contact with water and (2) incineration of off gases. The only exception relates to the loading/unloading of containers used for the transport of the PFOI fraction, where they claim that strictly controlled conditions are in place.</del> The volume of the PFOI fraction to be covered by their proposed exemption was not provided. SK Capital, the private equity owner of Archroma, has recently put the company up for sale.	An estimate for 2020 was provided. A potential sale is not relevant for the exemption request.
IPEN	Table 5.1	Archroma’s proposal requires both an exemption for PFOI transport as an intermediate and the reclassifying of 1-H-PFO as not being a PFOA-related compound. However, present information indicates that 1-H-PFO should be considered a PFOA-related compound. PFOI is a PFOA-related compound that is predicted to become an Arctic contaminant, disrupts the endocrine system, and may cause long lasting harmful effects to aquatic life. The Stockholm Convention permits exemptions only for closed-system site-limited intermediates. Based on Convention requirements, the properties of PFOI, a PFOA-related substance, the eventual generation of a 1-H-PFO, another PFOA-related substance, and the imminent sale of Archroma, no exemption should be considered <del>the evaluation of available information a time limited exemption could be considered</del> for the use of PFOI (Perfluorooctane iodide) as isolated intermediate <del>in order to enable reprocessing to TFE (tetrafluoroethylene) and HFP (hexafluoropropylene) in another site than the production site. Based on the information provided, the Committee has to decide whether a specific exemption should be given.</del>	First sentence added. Parts of the proposed text were included in the summary.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
IPEN	Table 5.1	MedTech (2018) and Euromed (2015) commented that gathering information on specific applications was challenging and indicated that PFOA may be used in manufacture of PTFE used in. <del>However, the main presence of PFOA within medical equipment will be as is likely to occur as a by-product of PTFE.</del> MedTech (2018) also provided a summary of generic potential uses.	Suggested edit for clarity accepted with some changes.
IPEN	Table 5.1	ECHA (ECHA, 2015) estimated in use quantities of <1kg in the EU extrapolated to <5kg globally. <del>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 under the REACH restriction. This exemption was needed to prevent critical applications from being lost in healthcare.</del> These comments were made years ago in the context of an EU regulatory decision – not the current process. The claim about losing applications may have been relevant at the time of the EU consideration but is not appropriate currently considering the current availability of alternatives that have passed all regulatory requirements.	Text has been amended to reflect that a 15-year exemption was granted under REACH. This mirrors the text repeated in the earlier sections. Inference to time needed to develop alternatives has been removed.
IPEN	Table 5.1	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, though even small amounts of PFOA <del>will not degrade, can travel long distances</del> and have the capacity to bioaccumulate.	Suggested edit accepted but term 'persistent' replaces 'will not degrade' to be more closely aligned to Convention text.
IPEN	Table 5.1	<del>Proposed new paragraph in conclusion of medical devices: Alternative medical devices made without PFOA have passed all stringent regulatory requirements and are available on the market and in use.</del>	Suggested addition accepted with the caveat that alternatives are in use for some geographies. We still have very little data for large regions of the globe.
IPEN	Table 5.1	<del>Further detail on specific applications is needed before the Committee should consider an exemption for PFOA and PFOA-related compounds in medical devices. Potential issues with stringent medical regulations may also delay the transition processes and this would suggest that a time-limited exemption may be appropriate.</del>	Suggested edits rejected as the summary table needs to match the text of the preceding chapters.
IPEN	Table 5.1	ECHA (ECHA, 2015a) indicates that amounts of PFOA and PFOA-related substances related to this use are extremely low. <del>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).</del> This seems like a lot of uncertain information for a summary.	Concur, edits accepted.
IPEN	Table 5.1	<del>Proposed new paragraph in the conclusion of implantable medical devices: Further detail on specific applications is needed before the Committee should consider an exemption for PFOA and PFOA-related compounds in implantable medical devices including whether a specific exemption could be narrowed to a specific use such as cardiovascular implantable medical devices.</del>	Concur, edits accepted and paragraph added to the summary table.
IPEN	Table 5.1	the EU, including ECHA, and determined not to pose a relevant risk to the environment or human health (I&P Europe, 2016). <del>However, positive impacts on society</del>	Suggested edit rejected as per similar comments under the photo-imaging section.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		would result from eliminating all emissions of PFOA for this use and this is feasible since digital technologies have already largely replaced PFOA for this use.	
IPEN	Table 5.1	The request for exemption is also supported by ACEA (Europe) and SIAM (India) industry associations.	Edits accepted.
IPEN	Table 5.1	However, no information on possible cost implications has been submitted and continued use of PFOA also results in costs paid by governments and taxpayers	Sections amended following comments from other Parties. Suggested edits are now redundant.
IPEN	Table 5.1	company members and suppliers that PFOA will be listed under the Stockholm Convention and that the auto industry added PFOA to the GADSL in 2008 indicating that if the auto industry had pursued actions beginning on that date, then substitution would be completed. In addition, a list of PFOA-related substances was provided three years ago when PFOA was proposed for listing, as well as being regulated in the EU and that these substances should be substituted.	See responses to same comments in the respective sections of the document.
IPEN	Table 5.1	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. Furthermore, spare parts could all be retrofitted with new parts that do not contain PFOA or PFOA-related substances, which is efficient since testing results can be applied to both new and old vehicles.	Has been included in the text. Not edited in Table 5.1
IPEN	Table 5.1	Limited information has been submitted on specific applications, socio-economic aspects and the availability of alternatives. No conclusive information was submitted so far 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. CVMA indicates in their recent submission that they are currently working to see if any further information can be provided.	Conclusion has been adjusted. Sentence has been removed.
IPEN	Table 5.1	The FFFC (2018) provided details of best practice for class B fire-fighting foams including non-fluorinated and PFOA based AFFF which included selective use,	Edits accepted.
IPEN	Table 5.1	The RME provided details of very high clean-up costs for contaminated ground water where PFOS based foams had been used.	Suggested edit rejected as the text already gives a quantitative indication of costs.
IPEN	Table 5.1	Equally costs associated with destruction and replacement could be significant, but are likely to be far lower than remediation costs for contaminated sites following environmental release of PFOA.	Suggested edit rejected, speculative.
IPEN	Table 5.1	The size of in-use stockpiles of PFOA-based fire-fighting foams may be significant, suggesting an immediate ban could have socio-economic impacts. However, direct release of PFOA to the environment also has significant cost implications and is not consistent with Convention objectives.	Suggested edit partly accepted. Concur that the direct release would have significant implications not only related to cost. This concern has been added. Reference to the aims of the Convention have been mentioned multiple times for the sake of brevity this is not included.
IPEN	Table 5.1	Therefore, the Committee should discuss the viability of non-fluorinated fire-fighting foams and formulate a recommendation that covers both to PFOA and PFOA-related fire-fighting foams and existing stockpiles. <del>cover all necessary applications and whether there is a need for a time limited exemption for use of PFOA containing AFFFs.</del>	Suggested edit accepted.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
IPEN	242	Based on a review of the information submitted and the RME, work is already ongoing for many of the applications identified to develop and commercialize alternatives to PFOA, its salts or PFOA-related compounds <b>and alternatives are already in use.</b>	Concur, edit accepted.
IPEN	244	On the basis of the information reviewed and compiled within the current document, the exemptions that may be required all relate to time-limited options, which best match specific exemptions under the Convention. <b>with no uses identified needing an acceptable purpose.</b> On that basis, it can be concluded that a listing of <b>PFOA, its salts and PFOA-related compounds</b> in Annex A is most appropriate.	First suggested edit rejected. Second suggested edit accepted.
MedTech Europe	General	<b>Position paper on time limited exemption until 2030 for medical devices and implantable medical devices.</b>	The Drafters thank Medtech for the further commentary that has been provided. This has been reviewed and considered as part of the dossier update. However, we do note that much of this information has been provided previously and has already been included.
POPRC member (Mr. Martien Janssen)	General	<p>The drafters made a good way forward with this addendum to the Risk Management Evaluation and PFOA and related compounds is one of the more complicated substance groups to be added to the Convention. Thanks for that.</p> <p>I think a good way forward is the transparency where data are lacking. For instance, in Para 63 “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.” Such statement can also be added in the case of the fluoropolymers in general, although I think some information is available in Posner, Roos and Olsson (2009). Survey of the extent of use and occurrence of PFNA (perfluorononanoic acid) in Norway, Knepper et al (2014). Understanding the exposure pathways of per- and polyfluoralkyl substances (PFASs) via use of PFASs-containing products – risk estimation for man and environment and in Prevoudorus et al 2006.</p> <p>Thanks for Table 5.1 which provides overview and the amounts used/released for each application. That is a good way forward for prioritizing the attention! Also, thanks for the long explanation on the use of perfluorooctane iodide (PFOI) as isolated intermediate, which clarifies a lot. Information on applications, not only this one, is inevitable to understand why PFOA is or has been applied and the possible alternatives.</p>	Comments from the POPRC member duly noted.
POPRC member	General	<p>I observe there is still confusion around the chemical identity as described in chapter 2.1 and around the Non-exhaustive list of PFOA-related substances.</p> <p>I understand the compilation of the entry and also the rationale behind it. Because of confusion about the original entry during discussing the risk profile a new entry was proposed, which found its place in the RME and also a Non-exhaustive list of PFOA-related substances was drafted. From a precautionary approach, and for matters of simplicity, I can follow composing the new entry. This however raises questions, whether you should maintain an entry in case science proceeds and show that either a listed substance does not degrade to PFOA or its degradation to PFOA can be considered</p>	The list aims to reflect the current discussions and the status quo of these discussions. It is a non-exhaustive list, where new substances can be added. In case new scientific evidence appears, a substance can also be removed. However, it should be kept in mind that the Stockholm Convention follows a precautionary approach. Concerning the mentioned substances - 1-H-PFO and Sulfluramid - there is evidence that a degradation is possible. PFOS is explicitly mentioned as not being considered as a PFOA related substance.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>to be irrelevant. For instance, because the ultimate degradation route leads to another substance.</p> <p>I should say that the status of the list is not very clear and the scientific back-up of the substances listed is also not very clear. The list does not describe whether it has been made on a theoretical basis as for instance in KLIF (2012) report TA-number 2944/2012 where the terminology ‘potential PFOA precursors’ is used, or whether literature data and observations were used.</p> <p>This confusion comes back in the remarks of Brazil in paragraph 33 on the fact that the list was accomplished without extensive discussion and with no technical justification and in the remarks of the FluoroCouncil in paragraph 43 where the status of 1-H-PFO as a PFOA-related substance is questioned. Justified questions in a science-based approach. The that 1-H-PFO is in the entry and thus a PFOA-related substance as responded is definitely not a science-based approach.</p> <p>Two other points of attention. In paragraph 43, one of the entries is taken from chapter 2.1, but these entries cannot be read independently. Read without all the other exclusions generates confusion when you look at the formula of PFOS: CF<sub>3</sub>(CF<sub>2</sub>)<sub>7</sub>SO<sub>3</sub>H. SO<sub>3</sub>H is neither fluorine, nor chlorine or bromine, but still PFOS is not considered a PFOA related substance. So, I would recommend deleting or rewrite the para 43.</p> <p>Paragraph 30 indicates that Sulfluramid is not included as a PFOA-related compound, luckily enough with an explanation why. Paragraph 43 states “Therefore, we can consider that sulfluramid production is already regulated under the PFOS listing and it should then not be included under the PFOA listing to avoid double regulation.” However, it is still present in Non-exhaustive list of PFOA-related substances (UNEP/POPS/POPRC.13/INF/6/Add.1) as last entry in the list of PFOA related compounds. Either it should be removed there, or the text in the Addendum should clarify this.</p> <p>I am of the opinion that this precautionary approach, the lack of scientific backing for the complete entry including the List and its consequences should be mentioned in paragraph 2.1. This may partly be accomplished by stating that the list comprises ‘potential’ precursors based on structural characteristics. That still leaves question whether science should prevail or precaution in case new data become available and that should be addressed as well in the document as it provides clarity on the approach.</p>	<p>A precautionary approach is also science based.</p>
<p>POPRC member</p>	<p>General</p>	<p>For insight on the firefighting foams it would be good to mention that fluorinated substances were only used in foam for class B fires, liquid fuel fires. Furthermore, that there were two types of F-containing firefighting foam: the ones on basis of PFOS (made for instance by 3M) and the fluorotelomer based AFFFs. Backe et al 2013 remark in their supporting information that they did not detect Perfluorinated chemicals (e.g. PFOS) in newly-identified PFAS and fluorotelomer sulfonates in 6 fluorotelomer-based aqueous film-forming foam formulations (2002-2009) from different manufacturers. PFOA was detected in the PFOS based foams from 3M (1989-2001) in concentrations 50-100x lower than PFOS: 83-150 mg PFOA/L. The data submitted by the Mineraloelwirtschaftsverband, Industry or trade association, Germany in the public commenting round for PFHxS under REACH, and submitted to the</p>	<p>The Drafter thanks the POPRC member for these comments. The use of AFFF on liquid fires is already made clear within the existing text, but this has been made clearer. The Drafter’s have located a paper by Backe et al (2013): Zwitterionic, Cationic, and Anionic Fluorinated Chemicals in Aqueous Film Forming Foam Formulations and Groundwater from U.S. Military Bases by Nonaqueous Large-Volume Injection HPLC-MS/MS, Env. Sci &amp; Tech, 47, 5226-5234, however having reviewed the paper cannot find the specific details eluded to. In this case we have not included the suggested addition. The reference to the PFHxS REACH process</p>

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>Stockholm Secretariat, contain data from one PFOS containing AFFF and 14 other foams. The PFOS containing one contains 220 mg PFOA/L, about 20x lower than PFOS. The other foams, two of which contained one or more telomers (4:2 FTS, 6:2 FTS or 8:2 FTS) contained all less than 1.2 mg PFOA/L. Detection limit in these samples varied between 0.010 and 0.050 mg/L (10 and 50 ppb). Take also account of measurements and text in Herzke et al 2012.</p> <p>The estimations in paragraph 203 are erroneously based on PFOS or APFO concentrations of 1, 3 and 6%. These percentages are the application rates of foam not the PFOS or PFOA concentrations. The original sources (Sontake &amp; Wagh, 2014 and ECHA 2014a) clearly indicate that these are not concentrations. Please change text and estimations accordingly.</p>	<p>and German industry data has been reviewed and included in section 4.8.1. Reference to the calculation of stockpiles and application rates has been checked and corrected, thank you for bringing this to our attention.</p>
POPRC member	General	<p>Remark on the much longer shelf life.</p> <p>The Dutch CA mentioned in the comments of the previous round that shelf life of the perfluorinated is much longer than that of the protein based AFFFs. The drafter indicated not to take that aboard because the foam is already used before the end of shelf life. Unfortunately, an underpinning of that statement was lacking.</p> <p>1. I did ask a colleague who is also active as a safety manager at the Safety region Gelderland, one of the 25 in the POPRC member, on that. Together with someone from the Firebrigade Bilthoven they stated that in most cases these foams are not used before the end of shelf life. My own experience with the AFFF foam at the institute is similar. I cannot remember that in the 25 years' service here, foams have been used.</p> <p>2. Another argument is the reason for the US Ministry of Defense to change from protein foam in the 1960's to fluorinated foam. Although the price of the fluorinated was 10 times more expensive. The reason was that the stocks they had to maintain were much smaller than for the protein foams. Please read US GAO 1969 for further info. <a href="https://www.gao.gov/products/B-168044(1)#mt=summary">https://www.gao.gov/products/B-168044(1)#mt=summary</a></p> <p>3. In para 217 I have incorporated some comments on the Australian airports and the Australian Airport Association. The AAA acknowledges that some airports may have tenants (hangars and fuel depots) that have legacy fire suppression systems containing PFOS and PFOA, however in the vast majority of these circumstances these systems have not been activated and have not been the cause of any existing contamination on or around the airport. The AAA also understands that those airports that may have tenants with these legacy systems are already commencing discussions on how to responsibly manage this issue moving forward.</p> <p>Although I am not a promoter of fluorinated based foams, I would recommend incorporating this information in the risk management evaluation for sake of transparency and as it reflects the real world we have to deal with. I have also incorporated the information from the US Ministry of Defense to the Congress on the cleaning costs for some balance. Some information on costs may also be found in the Hearings for the Australian Parliament in 2016, but probably my Australian colleagues can tell more about that. <a href="https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign">https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign</a></p>	<p>Comments from the POPRC member on the frequency of use at private installations, shelf-life of AFFF, and shelf-life of protein based non-fluorinated foams has been added in the other considerations section as a personal comment from the POPRC member. This also makes comment about costs and cost comparison, although viable data is exceptionally rare on this topic.</p>



Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
POPRC member	General	In para 89 and 90 two opposite conclusions are drawn. 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. And subsequently: "Based on the evaluation of available information, an exemption for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment should not be considered". Based on the information I have read in the RME, I understand that most PFOA has already been replaced (70% of the global market in 2014). As we are now four years further, and before this exemption can be implemented it is 2020, I can imagine that the replacement nearly reaches 100%. The only critical issue I see is the possible stocks to be sold, and which may contain PFOA as unintentional trace contaminants, and the level of unintentional trace contaminants allowed. Unfortunately, I have not seen any data in the RME on the PFOA concentration to be expected in these articles.	The conclusion is based on all information currently available on the topic. This takes also other information into account and not only the last sentence from previous para. No party and observer has actually commented that exemption is needed. The 70% apply not only to medical textiles. Specific information on replacement in this area is limited. The already produced stocks can still be used according to Annex A/B, Part I of the SC.
POPRC member	General	In Para 94 a statement is made on the closed system site-limited intermediates and exemptions. This statement is incorrect. The note referred to in annex A part I states that without an exemption for the purpose of para 2 of article 3, a Party may produce and use a substance without an asterisk (Hexachlorobenzene in this case) for a closed-system site-limited intermediate etcetera upon notification of the Secretariat. Thus, Parties are still free to request for an exemption under article 3 para 2 for any other case if they justify its need. I consider the interpretation as it is worded in para 94 misleading and would propose to delete it.	For clarification, the following sentence was added in paragraph 94: However, exemptions for the transport of intermediates can still be requested
POPRC member	6	Based on the further information submitted, 1-H-PFO should not be excluded from the scope of PFOA related substances since studies suggest that a transformation to PFOA is possible. Please indicate which information.	The information can be found in the respective section.
POPRC member	7	<b>The POPRC member (2018) highlighted that an addition to Annex C would need to not only be justified but proportionate, highlighting that the emission is negligible (0.057 g/yr) compared to all the other sources many POPs not listed under Annex C (e.g. decabromodiphenyl ether (decaBDE)) also have potential emissions linked to incineration.</b> Text change proposed: The data submitted contain emissions of decaBDE. Question is whether the emission of PFOA is relevant compared to all the other sources present and whether the measures to be taken are proportional related to that emission. Therefore, a comparison to the other sources of PFOA seems to be a better justification than a comparison with other POPs. The other POPs may be brought forward as an additional argument.	Text adjusted as proposed.
POPRC member	30	<b>...since it is produced from PFOSF and it is then already covered under the listing of PFOS, its salts and PFOSF.</b>	Sulfluramid should be covered under PFOS to avoid double regulation. Some

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>This is not a scientific argument.</p> <p>Sulfluramid is produced by the transfer of CF<sub>3</sub>(CF<sub>2</sub>)<sub>7</sub>SO<sub>3</sub>H into CF<sub>3</sub>(CF<sub>2</sub>)<sub>7</sub>NHC<sub>2</sub>H<sub>5</sub>.</p> <p>Sulfluramid may degrade to CF<sub>3</sub>(CF<sub>2</sub>)<sub>7</sub>SO<sub>2</sub>NH<sub>2</sub> = PFOSA = perfluorooctane sulfonamide</p> <p>Degradation to PFOA is not to be expected because one CF<sub>2</sub> combination has to be transferred to a COOH combination, as the PFOA smiles is CF<sub>3</sub>(CF<sub>2</sub>)<sub>6</sub>COOH</p>	studies indicate that a degradation to PFOA cannot be excluded.
POPRC member	31	<p>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.</p> <p>Sulfluramid, CAS No 4151-50-2, is included in the list of PFOA related substances in document UNEP/POPS/POPRC.13/INF/6/Add.1 on page 12.</p> <p>Please make a clear statement somewhere whether sulfluramid is included or not included and check the other substances in this document (INF-6-Add.1), which has not been subject to discussion in POPRC13</p>	It is suggested to add a footnote in the non-exhaustive list stating that Sulfluramid is explicitly excluded from the scope of the PFOA RME.
POPRC member	32	<p>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).</p> <p>Please add a proper scientific reference or otherwise remove. The POPRC document used does not carry scientific proof of the statement.</p> <p>Furthermore, the statement should carry both percentage and time indication to be of use.</p>	Removed as suggested.
POPRC member	36	<p>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.</p> <p>But Martin et al 2006 state at the end: “While it is clear that many uncertainties exist, the experimental observations and the discussion above demonstrate that atmospheric oxidation of perfluorooctanesulfonamides is a plausible source of at least some of the perfluoroalkancarboxylate burden in remote locations. Future studies will be necessary to determine whether perfluoroalkanesulfonic acids may be formed in the gas-phase from perfluoroalkanesulfonamides.”</p>	The statement of Martin et al. does not contradict the conclusion in the para.
POPRC member	38	<p>However, PFOSF is used to manufacture sulfluramid and when electrochemical fluorination is used to make PFOSF, there are a significant number of organic and inorganic by-products.</p> <p>Please add reference.</p>	Edits accepted.
POPRC member	40	<p>Zabaleta et al. (2018)</p> <p>Please add to reference list and add the title of publication.</p>	Added to the reference list.
POPRC member	42	<p>Based on the available information sulfluramid could also be considered a PFOA-related substance.</p> <p>The big question here is how fast degradation takes place under environmental circumstances and which amount goes to where.</p>	Agreed. We would welcome more information about degradation processes and environmental fate.
POPRC member	43	<p>Currently, all substances with the formula C<sub>8</sub>F<sub>17</sub>-X are considered PFOA-related substances except if the X consists in either fluorine, chlorine or bromine (i.e. C<sub>8</sub>F<sub>17</sub>-F, C<sub>8</sub>F<sub>17</sub>-Cl or C<sub>8</sub>F<sub>17</sub>-Br) ending. As a result, 1-H-PFO is considered a PFOA-related compound.</p> <p>It is not clear whether the statement is based on the fact that this is literally the entry of PFOA, which would lead</p>	The listing of F, C and Br is laxative and therefore other compounds are considered to be PFOA-related substances. The making and prerequisites for a definition of a PFOA-related substances are subject to discussion. In the making of a general

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		to the conclusion that 1-H-PFO does not carry an F, Cl or Br and thus is in, or whether there is a scientifically rationale behind the exclusion. When we have a scientific discussion here, there should be a scientific answer and not the statement “As a result, 1-H-PFO is considered a PFOA-related compound” Point is that we have not discussed the Non-exhaustive list of precursors during last POPRC. See also my remark at the start of the RME.	definition scientific evidence is taken into account. In addition, there is evidence that a transformation to PFOA is possible (which is the prerequisite of a PFOA-related substance)
POPRC member	46	Australia’s National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the Inventory Multi-tiered Assessment and Prioritization (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): 8:2 fluorotelomer alcohol (CAS No: 678-39-7), 8:2 fluorotelomer methacrylate (CAS No: 1996-88-9), 8:2 fluorotelomer methacrylate, polymer with methyl methacrylate (CAS No: 93705-98-7); propanamide, 3-[(gamma.-.omega.-perfluoro-C4-10-alkyl)thio] derivatives (CAS No: 68187-42-8); and 7:1 fluoroalcohol methacrylate, polymer with acrylic acid (CAS No: 53515-73-4). <a href="#">Are there scientific data available on which Australia decided to add these substances and are these available to POPRC?</a>	As far as we know, detailed information supporting the decision for inclusion is not available and has not been made available to POPRC. This could however probably be requested to support further discussions and the final decision on the inclusion of the substance in the scope of the RME.
POPRC member	51	Further, according to information provided by Austria (2018), there is evidence given in literature from the POPRC member that flue gas from waste incineration also contains brominated flame retardants, polybrominated diphenyl ethers and PFOA. Under unstable conditions polybrominated dibenzo-p-dioxins and dibenzofurans (PBDD/PBDFs) were also found. There is also evidence from laboratory experiments that fluoropolymers have to be regarded as possible sources of halogenated organic compounds generated during waste incineration. <a href="#">The reference 13 only mention the presence, but does not provide any data. I would recommend removing this reference and use the refence note 12 as source. This source does contain measurements. The PBDD/PBDFs emissions are a few mg/year. Question is if we should keep this wholepart as it does not any to the information above in para 51 or in para 52.</a>	Reference changed as proposed. Proposal to keep paragraphs as they contain important information and have already been commented by other parties and observers during the commenting period / rounds.
POPRC member	55	The POPRC member (2018), in contrast, indicates that adding PFOA to Annex C is not the right way forward as estimated yearly emissions, appear to be negligible (0.057 g/year), and costs to reduce the emission are disproportionate.	Emissions seem to be higher (see submission from IPEN) but still at a low scale (0.1g/a). Proposal not to include figures in the summary. It is already mentioned in the text.
POPRC member	60	4.2 (a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment <a href="#">Are there any measurements available on the amounts present in these products that can support the risk management evaluation?</a>	Contents in products are not known.
POPRC member	62	<a href="#">According to IPEN and ACAT (2018), and in line with the provision of the Convention, the use of PFOA should be specifically identified to enable consideration of a specific exemption. 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</a>	In line with the provisions of the Convention text has been removed to avoid confusion. Exact use needs to be specified according to IPEN and ACAT which has not been done yet. In the case of medical textiles, the scope of the exemption is not quite clear. Possibly

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>recommended, since no specific use has been named in the evaluation process. The same has been also concluded for application in medical textiles (IPEN and ACAT, 2018).</p> <p>The only requisite necessary for an exemption is provided in article 4.3. Any State may, on becoming a Party, by means of a notification in writing to the Secretariat, register for one or more types of specific exemptions listed in Annex A or Annex B.</p> <p>So, it is not clear to me what should be specifically identified nor to what evaluation process the statement is referring to. It may refer to the review process in article 3.6, but that takes place when a decision on prolongation have to be made.</p> <p>I would appreciate to hear whether my interpretation of the Convention text is correct and in that case, please remove the text in paragraph 62</p>	<p>presence e.g. in surgical drapes has been confirmed but information is in general quite limited on other application areas. The same also applies to concentrations of PFOA and related substances in medical textiles.</p>
POPRC member	63	<p>...presence of PFOA</p> <p>Please indicate in what?</p>	<p>It is stated at the beginning of the sentence (i.e. surgical drapes)</p>
POPRC member	64	<p><b>IPEN and ACAT (2018) highlight that modern methods have eliminated this use</b></p> <p>In para 65 the fact that PFOA has been phased out for polymerization by the producers under the Stewardship program is already reflected correctly elsewhere.</p> <p>Furthermore, this statement here conflicts with the fact that in para 65 it is stated that it has been 70% of the global market. Please remove the sentence</p>	<p>Sentence has been removed as already reflected in chapter 4.2.3. Please note that 70% is related to all application areas and not exclusively to medical textiles.</p>
POPRC member	79	<p>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)</p> <p>Please add a reference, otherwise delete.</p>	<p>Sentence has been removed (additional information only)</p>
POPRC member	82	<p>IPEN and ACAT (2018) state in their recent submission, that prohibiting the use in these applications would have a positive impact on human health and the environment by limiting further PFOA releases and exposures and a positive impact on businesses making alternatives, particularly non-fluorinated alternatives.</p> <p>This is a statement, not scientific information, nor does it contain reference to literature that can be checked.</p>	<p>Yes, this is a statement from IPEN which is also stated at the beginning of the sentence. Proposal to keep the statement. Information cannot be always supported by scientific literature sources.</p>
POPRC member	85	<p>...applications (see e.g. Canada, 2018). However, IPEN and ACAT (2018) state that modern methods have eliminated this use.</p> <p>See remark to para 64, please remove because factual incorrect.</p>	<p>Removed (has been already mentioned); This is however, not clear in the area of medical textiles.</p>
POPRC member	89	<p>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.</p> <p>Full support</p>	<p>Noted.</p>
POPRC member	90	<p>Based on the evaluation of available information, an exemption for membranes intended for use in medical textiles, filtration in water treatment, production</p>	<p>This is based on all information currently available on the topic and it is concluded that an exemption should not be considered. This takes also other</p>

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		processes and effluent treatment should not be considered. <a href="#">This is a very strange conclusion when considering the last sentence of the previous para.</a>	information into account and not only the last sentence from previous para. No party and observer has commented that exemption is needed.
POPRC member	94	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. The note referred to in annex A part I states that without an exemption for the purpose of para 2 of article 3, a Party may produce and use a substance without an asterisk (Hexachlorobenzene in this case) for a closed-system site-limited intermediate etcetera upon notification of the Secretariat. Thus, Parties are still free to request for an exemption under article 3 para 2 for any other case if they justify its need. <a href="#">I consider the interpretation as it is worded here misleading and would propose to delete it.</a>	For clarification, the following sentence was added: However, exemptions for the transport of intermediates can still be requested.
POPRC member	95	An exemption to Daikin Industries Ltd for transported isolated intermediates has already been considered in the RME for the transport of PFOI (perfluorooctyl iodide, CAS No: 2043-57-4) that is generated 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, used for pharmaceutical applications (see RME para 89 and 201). <a href="#">It would be good if FluoroCouncil or Achroma could indicate if the amounts are in grammes, kilogrammes or tonnes.</a>	The respective exemptions concern Daikin Industries.
POPRC member	105	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. <a href="#">See the remark to paragraph 94. The use as a closed-system site-limited intermediate conform note iii in annex A list I is not necessary to go for an exemption. A Party may still request for an exemption as described here making use of article 3 para 2. Please remove the text.</a>	It was included as a statement of IPEN and ACAT. The first sentence was deleted
POPRC member	115	According to the information submitted by IPEN and ACAT (2018), and in line with the provisions of the Convention, a use of PFOA should be specifically identified to enable consideration of a specific exemption. Limited data on specific uses within medical devices has been provided. <a href="#">See my remark to paragraph 62 which reads the same as this sentence.</a> <a href="#">The only requisite necessary for an exemption is provided in article 4.3. Any State may, on becoming a Party, by means of a notification in writing to the</a>	The Drafters concur with the comments from the POPRC member that the requisite for exemptions is covered within Article 4. (3). The highlighted text was originally suggested by IPEN and ACAT with we believe the main issue being that if there is not clarity over what use is being added as a specific exemption it makes it difficult for the ratified parties to enforce. The

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		<p>Secretariat, register for one or more types of specific exemptions listed in Annex A or Annex B.</p> <p>So, it is not clear to me what should be specifically identified nor to what evaluation process the statement is referring to. It may refer to the review process in article 3.6, but that takes place when a decision on prolongation have to be made.</p> <p>I would appreciate to hear whether my interpretation of the Convention text is correct and in that case, please remove the text.</p>	text has been amended to make this aspect clearer.
POPRC member	143	<p>The main issue for alternatives is the resistance to saline solutions, but also some low friction technical issues may still exist (Nesbitt, 2017). In 2016, a US FDA recall on PFOA-free PTFE products used for medical implants occurred in the US 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).</p> <p>Very good to describe what happens when alternatives are not tested extensively in practice with drastic consequences as a result: Between January 2014 and November 2015, the FDA received approximately 500 Medical Device Reports—including reports of nine deaths—attributed to PTFE coating delaminating from guidewires.</p>	No response necessary. No edits suggested.
POPRC member	143	<p>The second generation of PFOA-free PTFE products have resolved the bonding issue by using best practices in surface preparation, coating viscosity and solids content, humidity, airborne particulates, spray pressure, temperature, electrostatic voltage, spray pattern, coating line humidity and line speed, among others (Nesbitt, 2017).</p> <p>See also Gupta et al 2016 In vivo delamination of coronary guidewire polytetrafluoroethylene layer – A dreaded complication.</p> <p>All PTFE coatings used on medical devices must comply with the EPA mandate. PFOA free PTFE has less firm adhesion to underlying stainless steel so that hydrophobic guidewire becomes “less hydrophobic” and vulnerable to delamination. This problem was first noticed when flakes of aqueous green PTFE were discovered in saline tanks of operating rooms during procedures using guidewires for passing stents, balloons, etc.</p>	Gupta reference added into the text alongside Nesbitt
POPRC member	158	<p>As another example, the International Atomic Energy Agency (IAEA) and the World Health Organization (WHO) note that there has been a marked transition towards digital technologies in developing and transition countries. In particular the 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”</p> <p>Please add a reference.</p>	Following reference added: IAEA, WHO (2015) Worldwide implementation of digital imaging in radiology, IAEA Human health series No. 28, <a href="http://www-pub.iaea.org/MTCD/Publications/PDF/pub1647web.pdf">http://www-pub.iaea.org/MTCD/Publications/PDF/pub1647web.pdf</a>
POPRC member	180	<p>IPEN and ACAT (2018) commented that during the year-long process of developing the PFOA RME the industry did not indicate any exemption interest, despite being fully aware of the Committee’s process due to their involvement with decaBDE (IPEN and ACAT, 2018).</p>	This is the opinion/comment from by IPEN and ACAT (even though not scientific) it can be presented at this point. Similar statement has been made; however, it was removed (entire para 190).

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		This is no scientific information and it does not contribute to the risk management evaluation, please delete.	
POPRC member	181	IPEN and ACAT therefore advice that no exemption for PFOA use in the automotive industry should be recommended (IPEN and ACAT, 2018). This is no scientific information. Furthermore, it is not clear to which 'therefore' refers. Please delete it.	Proposal to merge para 180 and 181 and remove therefore (automotive industry is requesting an exemption and IPEN has the opinion that no exemption is needed). These two positions should be presented (even though not entirely scientific based)
POPRC member	190	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 Committee's process due to their involvement with decaBDE. See remark on para 180.	See remark on para 180 (entire para 190 has been removed)
POPRC member	196	4.8 (g) Fire-fighting foams Castro, J. (2017). Fuel for thought. Ind Fire Journal 2nd Quarter 2017 34-36. "Extensive fire testing has revealed that the difference in performance between aqueous film-forming foam and fluorine-free foam can be significant depending on the type of fuel. From an environmental point of view, today's debates revolve around setting lower levels of PFOA, following the ban of PFOS, which now has a maximum limit of 10 parts per million. PFOA is not a raw material used in foam concentrate formulations, but rather a by-product or impurity that originates in the manufacturing process of fluorinated raw materials."	The Drafter thanks the POPRC member for this reference which has now been added into the section on alternatives for non-fluorinated compounds.
POPRC member	200	Additionally, the REACH restriction allows for the presence of PFOA and PFOA-related compounds as by-product up to a maximum concentration of 25 ppb for PFOA or 1000 ppb for PFOA and PFOA-related compounds in fire-fighting foams placed to market in the EU, which is likely related to trace contamination within fluorotelomer based AFFF.	Information regarding limits imposed in Australia have been added to the addendum
POPRC member	204	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. Australia maintains a maximum concentration of 50 ppm as F and remarks: 50 ppm limit is moderate compared to ECHA limits of 0.025 ppm for free PFOA and 1 ppm for precursors. Australian Department of Environment and Heritage Protection, 2016 Operational Policy Environmental Management of Firefighting Foam. The document further remarks: Firefighting foams that contain PFOA, PFOA precursor compounds or their higher homologues, where the total organic fluorine content equivalent to PFOA and higher homologues exceeds that listed in Table 6.2.2 A in foam concentrate must be withdrawn from service as soon as practicable and any held stocks (and any other related wastes) must be secured pending disposal. These materials are to be managed and disposed of as regulated waste***. 1,3 and 6% are NOT the PFOS concentrations in foam. They are the application rates of foam with water. Please read Sontake & Wagh (2014): "The formulations of 6%, 3%, and 1% AFFF concentrates are based on	Concur with comments from the POPRC member, further review indicates that the 1, 3, 6% are the concentration of the foam product when mixed with water, not the concentration of PFOS/PFOA within the concentrate. At the point of mixing the ready to use foam/water mix has perfluorinated compounds present at 0.03 - 0.45 % wt/wt of the ready to use goods. Text amended to reflect this.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		performance, not on the constituents.” The PFOS concentrations I have seen are all below 1% except a very old foam from 1989 which contained 1.5% (Backe et al 2013). See for instance the submission by the POPRC member (Schaumloschmittelanalysen German Mineralolindustrie), Backe et al 2013 and Herzke et al 2012. PFOA concentrations in these foams are often lower than 1/10th of that. Please correct text accordingly and also on other places of the document.	
POPRC member	204	An EU report (ECHA, 2014a) assumes similar concentrations for PFOA. Please see the Annex XV dossier (ECHA 2014a): Foam concentrations (6%, 3%, 1%) are mixed with water and the final solution contains usually 0.03 to 0.45 % fluorosurfactants (Sontake and Wagh, 2014).	Calculation has been amended as per the other comments from the POPRC member on the same topic.
POPRC member	204	Based on active concentrations of 1, 3 and 6% APFO within AFFF fire-fighting foams, the global production estimates from Prevedouros et al. (2006), and assumption that all APFO produced is used in fire-fighting foams gives an estimate of global AFFF concentrates containing APFO produced between 1951–2004 as between 51 million litres and 490 million litres. Prevedouros et al (2006) state: POSF-based products replaced PFCAs as AFFF surfactants and became the products of choice for fire protection companies and suppliers from the 1970s forward. These products contained between 0.1 and 1.0 wt % of PFCAs with PFO as the largest component. Please correct text and estimations accordingly.	Calculation has been amended as per the other comments from the POPRC member on the same topic.
POPRC member	205	...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. Please correct according to remarks made in para 203.	Amended as per other comments from the POPRC member.
POPRC member	217	...at the 23 capital and major regional cities airports, out of the total of 260 airports Contamination of Australian Defence Force facilities and other Commonwealth, state and territory sites in Australia Submission 120 - Attachment 2. The AAA represents the interests of 260 airports and Aerodromes Australia wide.	Suggested edit accepted
POPRC member	217	...throughout Australia that are under the auspices of Airservices Australia (Hemming Fire, 2010). Letter from the Airservices Australia 2016 Contamination of Australian Defence Force facilities and other Commonwealth, state and territory sites in Australia Submission 120 - Attachment 5. <a href="https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Affairs_Defence_and_Trade/ADF_facilities">https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Affairs_Defence_and_Trade/ADF_facilities</a> While the AAA and its members acknowledge that products containing PFOS and PFOA are used in a range of applications across a number of industries, in relation to airport sites the primary user of PFOS and PFOA products has been Air services through its legacy firefighting foams (3M Lightwater and Ansulite). The AAA acknowledges that some airports may have tenants (hangars and fuel depots) that have legacy fire suppression systems containing PFOS and PFOA, however in the vast majority of these circumstances these systems have not been activated and have not been the cause of any existing contamination on or around the	New reference has been reviewed, in this case the paragraph deals with alternatives while the reference refers to legacy stockpiles and remaining in-use systems of PFOS/PFOA at Australian airports. Text from this document is therefore not suited to this section. Text added to efficacy and control measures.



Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
		<p>airport. The AAA also understands that those airports that may have tenants with these legacy systems are already commencing discussions on how to responsibly manage this issue moving forward.</p>	
POPRC member	218	<p>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).</p> <p>Remark on the much longer shelf life. The Dutch CA mentioned in the comments of the previous round that shelf life of the perfluorinated is much longer than that of the protein based AFFFs. The drafter indicated not to take that aboard because the foam is already used before the end of shelf life. Unfortunately, an underpinning of that statement was lacking.</p> <p>I did ask a colleague who is also active as a safety manager at the Safety region Gelderland, one of the 25 in the POPRC member, on that. Together with someone from the Firebregade Bilthoven they stated that in most cases these foams are not used before the end of shelf life.</p> <p>My own experience with the AFFF foam we have at the institute is similar. I cannot remember that in the 25 years' service here, foams have been used.</p> <p>Another argument is the reason for the US Ministry of Defense to change from protein foam in the 1960's to fluorinated foam. Although the price of the fluorinated was 10 times more expensive. The reason was that the stocks they had to maintain were much smaller than for the protein foams. Please read US GAO 1969 for further info.</p> <p><a href="https://www.gao.gov/products/B-168044(1)#mt=summary">https://www.gao.gov/products/B-168044(1)#mt=summary</a></p> <p>A further underpinning can be found in the comment to para 217 where the AAA remarks of F-containing AFFF systems: however, in the vast majority of these circumstances these systems have not been activated and have not been the cause of any existing contamination on or around the airport.</p> <p>Although I am not a promoter of fluorinated based foams, for sake of transparency, I would recommend incorporating this information in the risk management evaluation.</p> <p>I have also incorporated the information form the US Ministry of Defense to the Congress on the cleaning costs for some balance.</p> <p>Some information on costs may also be found in the Hearings for the Australian Parliament in 2016, but probably my Australian colleagues can tell more about that.</p> <p><a href="https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Affairs_Defence_and_Trade/ADF_facilities/Submissions">https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Affairs_Defence_and_Trade/ADF_facilities/Submissions</a></p>	<p>Comments from the POPRC member on the frequency of use at private installations, shelf-life of AFFF, and shelf-life of protein based non-fluorinated foams has been added in the other considerations section as a personal comment from the POPRC member. This also makes comment about costs and cost comparison, although viable data is exceptionally rare on this topic.</p>
POPRC member	230	<p>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 10–25 years.</p> <p>See comments on para 218 and add some text here on the topic</p>	<p>Some additional text about use and shelf life of AFFF vs protein based fire-fighting foams has been added as a personal communication on the second draft addendum from the POPRC member.</p>

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
POPRC member	240	Concerns have also been highlighted about the mobility and potential environmental impacts of shorter chain perfluorinated compounds in fire-fighting foams. <a href="https://www.internationalairportreview.com/article/40575/aff-hangar-spill-better-outcomes-minimal-environmental-impacts/">https://www.internationalairportreview.com/article/40575/aff-hangar-spill-better-outcomes-minimal-environmental-impacts/</a>	The Drafter concurs, these issues are already highlighted within the dossier.
POPRC member	240	The Committee should discuss if the non-fluorinated alternatives already commercialized and in use can replace the fluorine-based AFFFs for all uses. <a href="#">Mandate is to discuss PFOA not the fluorine based AFFFs for all uses. So, some questions in relations to this phrasing and the discussion in POPRC.</a>	Concur, however based on a review of the information reviewed and compiled we believe this is the most appropriate way forward for this group of substances.
POPRC member	240	The Committee should discuss if the non-fluorinated alternatives already commercialized and in use can replace the fluorine-based AFFFs for all uses. On this basis, the Committee should discuss the need and duration of the time-limited exemption for PFOA and PFOA-related fire-fighting foams to aid phase-out. The firefighting foams are probably the most extensive source of PFOA in the environment, although that could be much more highlighted in the Addendum. Numbers to provide that insight are lacking unfortunately. What I understand from various sources is that shelf life of F-containing foam is much longer than the protein ones, which introduce a cost aspect that is also lacking in the dossier. References provided above in the document. <a href="#">A good overview of firefighting practice and the use of PFOA or telomere containing foams is lacking as well, and I have the opinion that insight in that is inevitable to make a good decision in September.</a> What I understand from practitioners is that besides for liquid fuel fires the AFFFs are also used for covering chemical spills. This application is completely lacking in the document. Some on spills: <a href="http://www.chemguard.com/pdf/General-Foam-Information.pdf">http://www.chemguard.com/pdf/General-Foam-Information.pdf</a>	The addendum has been further amended to make clear the issues on shelf-life eluded to by the POPRC member on a number of comments. The dossier also contains data in a number of places regarding the concerns for short chained fluorinated AFFF and environmental effects. Table 5.1 now also contains data on likely quantities involved which also makes clear that the fire-fighting foams are likely the major source of emission to environment.
POPRC member	Table 5.1	<a href="#">PFOA and PFOA-related compounds as by-product in C6 assumed as 50–100 tonnes of concentrate for EU.</a> <a href="#">Is 50-100 tonnes the foam or is it the PFOA and related compounds?</a>	From the REACH restriction dossier: "Based on information from industry and data from the Norwegian Product register (see Appendix B.2.2.6 for details) it is estimated that 50 - 100 t/a of PFOA-related substances are used in fire-fighting agents to be used for further calculations" We believe this confirms it is PFOA-related compounds as active.
POPRC member	Table 5.1	Only limited information has been identified stockpiles for in-use intentionally added PFOA fire-fighting foams. 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. Conversely Norway (2007) report on a global inventory for APFO manufactured between 1951–2004, with between 3,700–5,600 tonnes produced. Assuming similar usage rates as PFOS (1, 3, or 6% wt/wt active ingredient) would equate to between 51 and 490 million litres of concentrate produced between 1951–2004. Based on annual average production and shelf-life of 10–25 years, would estimate remaining stockpiles of 9.6–231 million litres of concentrate. <a href="#">See comments on para 203 and correct text here.</a>	Text amended as per re-worked calculations earlier in the document.

Source of Comment	Para	Comments on the second draft of the assessment of information on PFOA, its salts and PFOA-related compounds	Response
POPRC member	Table 5.1	ECHA (ECHA, 2015) estimates 50–100 tonnes of PFOA related compounds (CAS No: 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). <a href="#">See comments on para 203 and correct text here.</a>	Text amended as per re-worked calculations earlier in the document.
POPRC member	Table 5.1	<a href="http://www.hemmingfire.com/">http://www.hemmingfire.com/</a> <a href="#">Not retrievable.</a>	The original reference was provided as a Case study taken from hemming fire. However, having searched their website we not it difficult to find. The reference has been reattributed to the Australian Parliament which confirms the same details.