出國報告（出國類別：開會）

# 參加斯德哥爾摩 (POPs) 公約締約國、工作小組及相關會議

服務機關：行政院環境保護署毒物及化學物質局

姓名職稱：黃佑榮技士

派赴國家/地區：義大利羅馬

出國期間：**107** 年 **9** 月 **13** 日至 **107** 年 **9** 月 **25** 日

報告日期：**107** 年 **12** 月 **14** 日

# 摘　要

聯合國為呼籲全球應針對持久性有機污染物採取一些必要之行動，故於 1995 年起開始研擬相關管制措施，於 2004 年 5 月 17 日斯德哥爾摩公約正式生效。目前共規範 28 種持久性有機污染物，而公約列管屬於附件 A、B 及 C 中之持久性有機污染物，均由持久性有機污染物審查委員會(Persistent Organic Pollutants Review Committee, POPRC)定期進行審議。

本次赴義大利羅馬參加「聯合國斯德哥爾摩公約第 14 次持久性有機污染物審查委員會(POPRC14)」，會議日期為 2018 年 9 月 17 日至 9 月 21 日，與會人員包含各國代表、相關政府組織、非政府組織等約 100 人。

本次會議達成多項結論，包括：

一、通過全氟己烷磺酸(Perfluorohexane sulfonic acid, PFHxS)之風險資訊草案（附件 E），認定其具有遠距離環境遷移特性會造成人體健康與環境的影響，因此有必要針對其採取全球性的行動。

二、通過全氟辛酸(Perfluorooctanoic acid, PFOA)及其鹽類和相關化合物之風險管理評估草案（附件 F），並建議締約國大會將其列入公約附件 A 列管，且針對半導體及相關電子裝置之製造、用於底片的攝影塗層、用於可保護工作人員避免接觸到有害液體，可防水防油之紡織品、侵入或植入之醫療器材、已經完成安裝（包含固定式及移動式）且可適用於液態燃料蒸氣抑制或液態燃料滅火之消防泡沫給予 5 年之特定豁免；使用於老舊設備或老舊翻新零件中含有殘留 PFOA 之含氟聚合物或氟化橡膠給予 10 年之特定豁免。

透過參與此次會議，已大致掌握國際間對於上述尚未規範之持久性有機污染物質之管理情形與未來處置建議，同時亦蒐整分析目前國際最新管理資訊予國內相關部會，作為未來與國際公約接軌及本署施政之參考。

# 目次

# 一、目的

由於持久性有機污染物(Persistent Organic Pollutants, POPs)兼具生物累積性、高毒性、長距離遷移及在環境中難以分解特性，聯合國環境規劃總署(UNEP)遂訂定全球性之「持久性有機污染物斯德哥爾摩公約」（Stockholm Convention on Persistent Organic Pollutants，簡稱 POPs 公約），2004 年 5 月 17 日公約生效，截至目前已列管 28 種 POPs，該公約主要針對此些已列管之採取必要國際行動， 如禁用、限用或減少、消除無意排放等。現階段共計有 152 個簽署國及 182 個公約締約方，而斯德哥爾摩公約締約國大會(Conference of the Parties, COP)係依據公約第 19 條成立，為公約實質管理主體，COP 成員每兩年開會一次，討論公約列管物質及其他相關議題。此外，對於具 POPs 特性卻尚未納入列管物質，為逐步減少其對人類及環境不利影響，公約設立持久性有機污染物審查委員會(Persistent Organic Pollutants Review Committee, POPRC)，依據公約篩選標準、原則及流程，持續對其他化學物質進行審議，以提出是否納入公約列管意見。

截至 2017 年，斯德哥爾摩公約已完成召開 13 次 POPs 審查委員會，雖然我國並非公約締約國，但為使我國管理與國際接軌，仍需掌握公約最新動態，借鏡國外作法與管理方式，即時調整我國管制方式或預先因應。同時，我國目前已透過「毒性化學物質管理法」、「農藥管理法」及相關法規嚴格管制或禁限用公約列管之 POPs，並已完成制定「國家實施計畫(National Implementation Plan, NIP)」，若能透過如審查委員會類型之國際性會議，預期可藉此向國際分享我國長年努力成果與執行經驗。

基於上述原因，本次將依循以往作法，以非政府組織(Non-Governmental Organization, NGO)觀察員身分出席參與今年（2018 年）召開之第 14 次 POPs 審查委員會(POPRC14)，主要欲達成之目標包括：

（一）掌握斯德哥爾摩公約審議全氟己烷磺酸(Perfluorohexane sulfonic acid, PFHxS)、全氟辛酸(Perfluorooctanoic acid, PFOA)及全氟辛烷磺酸(Perfluorooctanesulfonic acid, PFOS)等物質之最新評估進度，以做為國內未來管理、施政及策略擬定之參考依據。

（二）加強與國際間專家學者之交流，並與國際接軌，藉此增加我國於國際間之能見度，促成未來各類型國際合作之可能性。

# 二、過程

## （一）出國行程內容概要

本次派員參加斯德哥爾摩 (POPs) 公約締約國、工作小組及相關會議之行程規劃詳如表 1，所示。

**表 1　出國行程內容概要**

| 日　期 | 工作內容概要 |
|---|---|
| 107 年 9 月 13 日 | 去程，出發至義大利羅馬 |
| 107 年 9 月 14 日<br>~<br>107 年 9 月 15 日 | 抵達義大利羅馬，準備辦理雙邊會談相關事項 |
| 107 年 9 月 16 日 | 辦理報到 |
| 107 年 9 月 17 日<br>~<br>107 年 9 月 21 日 | 參加「聯合國斯德哥爾摩公約第 14 次持久性有機污染物審查委員會(POPRC14)」<br>會議地點：義大利羅馬聯合國農糧組織總部<br>(Food and Agriculture Organization of the United Nations) |
| 107 年 9 月 22 日<br>~<br>107 年 9 月 23 日 | 1.整理會議資料與結論<br>2.完成辦理雙邊會談 |
| 107 年 9 月 24 日<br>~<br>107 年 9 月 25 日 | 回程，返回臺北 |

**圖 1　會議現場照片**

## （二）聯合國斯德哥爾摩公約第 14 次持久性有機污染物審查委員會(POPRC14)主要議程

本屆（第 14 屆）持久性有機污染物審查委員會會議於 2018 年 9 月 17 日至 21 日於義大利羅馬召開，主要與會人員包含各國代表、相關政府組織、非政府組織等約 100 人參加，會議現場照片如圖 1 所示。議程如下。

1、 會議開幕。

2、 組織事項：

（1） 通過議程；

（2） 工作安排。

3、 成員輪換。

4、 技術工作：

（1） 審議全氟己烷磺酸(CAS No: 355-46-4，PFHxS)、其鹽類及其相關化合物的風險簡介草案；

（2） 審議將提交締約方大會的關於十五氟辛酸(CAS No: 335-67-1，PFOA，全氟辛酸)、其鹽類及其相關化合物的建議；

（3） 依照《公約》附件 B 第三部分第 5 和第 6 段對全氟辛烷磺酸、其鹽類和全氟辛基磺醯氟進行評價的程序。

5、 彙報為促進有效參與委員會的工作而開展的活動。

6、 委員會第 14 次和第 15 次會議之間閉會期間的工作計畫。

7、 委員會第 15 次會議的舉行日期和地點。

8、 其他事項。

9、 通過報告。

10、 會議閉幕。

## （三）主要會議結論

1、通過全氟己烷磺酸(PFHxS)之風險資訊草案（附錄二），認定其具有遠距離環境遷移特性會造成人體健康與環境的影響，因此有必要針對其採取全球性的行動，並決定成立工作小組負責編制風險管理評估草案及商定工作計畫。

2、針對全氟辛酸(PFOA)及其鹽類和相關化合物列入公約及特定用途設置豁免議題得出結論，並向締約方大會提出建議：

（1） 通過全氟辛酸及其鹽類和相關化合物之風險管理評估草案（附錄三），並建議締約國大會(COP9)列入公約附件 A 列管，且給予特定豁免：

（A）以下用途將給予 5 年之特定豁免：

（a）半導體及相關電子裝置(electronic device)之製造（設備或工廠相關設施含有殘留 PFOA 之含氟聚合物(fluoropolymers)或氟化橡膠(fluoroelastomers)、老舊設備或老舊加工廠相關設施維護、光刻或蝕刻製程)

（b）用於底片的攝影塗層

（c）用於可保護工作人員避免接觸有害液體，可防水防油之紡織品

（d）侵入或植入之醫療器材

（e）已經完成安裝（包含固定式及移動式）且可適用於液態燃料蒸氣抑制或液態燃料滅火之消防泡沫

（B）以下用途將給予 10 年之特定豁免：

（a）半導體及相關電子裝置之製造：老舊設備或老舊翻新零件中含有殘留 PFOA 之含氟聚合物或氟化橡膠

（2） 對於全氟辛基碘（perfluorooctane iodide，簡稱 PFOI，CAS No：2043-57-4）之使用，建議給予特定豁免：使用於作為藥物生產目的之全氟辛烷溴化物(perfluorooctane bromide, PFOB)生產，並於 2036 年前終止。

（3） 建議鼓勵締約國不要使用短鏈全氟烷基物質(perfluoroalkyl substances, PFAS)替代含有PFOA及其鹽類與化合物之消防泡沫，因 PFAS 同樣具有持久性及移動性及對健康及環境造成負面影響之疑慮。

3、關於全氟辛烷磺酸及其鹽類和全氟辛烷磺醯氟的評估程序，委員會通過以下建議：

（1）決議將 PFOS 替代品之評估報告送至 COP9 締約方大會，並要求公約秘書處依據本次 POPRC14 之討論結果，於 2018 年 10 月 31 日前完成修正，請締約國及觀察員於 2018 年 11 月 30 日前提供意見。

（2）建議締約大會修正附件 B，將審議委員會決議附件中之建議事項（將氟硫胺(sulfluramid)及其 CAS No. 納入公約附件 B 全氟辛烷磺酸列表的範疇）納入考量，並建議締約國大會鼓勵締約方，當使用氟硫胺(sulfluramid)作為防治切葉蟻所使用之昆蟲餌劑時，應事先向公約秘書處登記可接收用途。

（3）建議締約國大會取消附件 B 中下列可接受用途：照相顯影、滅火泡沫、半導體光阻劑和防反射塗層、化合物半導體和陶瓷過濾器蝕刻劑、航空液壓油、某些醫療設備（如乙烯四氟乙烯共聚物(Ethylene tetrafluoroethylene, ETFE)層和放射線不透性 ETFE 生產，體外診斷醫療設備和感光耦合元件(Charge-coupled Device, CCD)顏色過濾器。

（4）建議澄清附件 B 內容「氟硫胺作為蟲餌有效成分僅限於在農業使用進行控制切葉蟻」。

（5）建議使用全氟辛烷磺酸及其鹽類和全氟辛烷磺醯氟生產消防泡沫之可接受用途轉換為特定豁免使用於液態燃料蒸氣抑制或液態燃料滅火之消防泡沫。以及改以使用 PFAS 作為消防泡沫以人體健康與環境觀點是不恰當的，可能需要改以不含 PFAS 的替代使用。

4、預告 POPRC15 將於 2019 年 9 月 30 日至 10 月 4 日義大利羅馬舉行，斯德哥爾蒙公約、鹿特丹公約及巴賽爾公約之締約方大會將於 2019 年 4 月 29 至 5 月 10 日舉行。

## （四）雙邊會談交流

為進一步瞭解國際間公約發展趨勢，於會議期間邀集瑞典、德國及加拿大官方代表進行雙邊會談，針對審議中物質及去(2017)年新增列管之短鏈氯化石蠟(SCCP)之管制現況進行討論及交流，雙邊會談照片如圖 2。相關討論議題成果如後，各國回覆情形詳表 2。

**圖 2　我團與外國代表合影**

1、瑞典、德國代表團雙邊交流：

（1）大克蟎(Dicofol)：瑞典在公約禁用前已禁用大克蟎，並有進行環境監測；德國大克蟎已禁用 15 年以上。

（2）歐盟 REACH 指令多年前已有 PFOA、PFHxS 及 PFOS 規範限制，故瑞典、德國在多年前已禁用。另兩國皆有訂定 PFOA 及 PFHxS 之相關環境、飲用水、地表水及地下水相關標準。

（3）短鏈氯化石蠟在歐盟已於 2003 年禁用，但禁用前因該物質為工業常用物質，在禁用前需與業界進行風險溝通。

（4）瑞典代表團提供該國國家實施計畫，計畫裡針對含溴化阻燃劑之廢棄物篩選、篩選含溴化阻燃劑之方式、專業人員以及最終處置方案均有相關規劃及執行內容做為參考。

（5）瑞典在各種化學物質禁用前會透過各種管道邀集相關業者及團體進行溝通，於確定禁用時，將至少提供業者 3 年半以上緩衝期。且更重要的是需教育民眾及業者，促使民間力量監督業者善盡自身之社會企業責任。

（6）德國代表團表示其國家法律往往同時會涉多個相關部會共同執行，但於法律通過前需先取得相關部會之同意，待法律通過後，各部會各依其執掌規劃執行其內容。

2、加拿大代表團雙邊交流：

（1）大克蟎在加拿大已禁用，目前並已參與全球環境監測計畫，針對食品亦有定期監測及訂定每日容許攝取量(acceptable daily intake)上限。

（2） PFOA 在加拿大已禁用多年，且禁止 PFOA 於原料、半成品之製造、進口，但對含 PFOA 之製成品尚未管制，產品之 PFOA 含量亦尚未訂有標準。PFOS 亦在加拿大已禁用多年，但有針對極少數用途有豁免，如軍隊演習所殘留之消防泡沫等。PFHxS 目前尚未進行環境風險評估程序，如後續公約列管，則會配合進行相關管制。

（3） SCCPs 亦在加拿大已禁用，邊境管制人員會進行抽測，對於執行人員亦會進行教育訓練。

（4） 加拿大一般會先針對特定化學物質進行環境風險評估，再依風險評估結果，決定應採取之管理手段，但對於國際公約列管之物質，若經評估需遵守，可不經風險評估程序逕行管制。

（5） 部分公約列管物質在加拿大議會尚未完成批准程序，因此在這些物質目前尚無遵約之限制，其他國家亦有相同情形。

**表 2 雙邊會談之討論議題及各國回覆情形**

| 議題 | 議題說明 | 瑞典 | 德國 | 加拿大 |
|---|---|---|---|---|
| **大克蟎有機氯農藥管制交流** | 對於今年公約正審議之大克蟎，臺灣曾少量用於落花生、豆類及柑橘類之害蟎防治，鑒於其對於人體及環境之污染危害已於近期公告自 2018 年 8 月 1 日起禁止製造、使用、販賣及輸出入。<br>1. 請問針對已禁用之有機氯農藥是如何防止跨國銷售或間接之影響（如網路販賣、透過農產品進口造成環境流布）？<br>2. 是否有針對已禁用之有機氯農藥如大克蟎持續進行環境監測，了解農藥在環境中之殘留情形，監測介質及調查位置為何？<br>3. 是否訂有土壤或底泥環境等管制標準？ | 在公約禁用前已禁用，並有進行環境監測，但監測頻率須進一步查證。 | 已禁用 15 年以上，因執行年代久遠，現行均已不需對業者進行管理。 | 1.在加拿大已禁用，若民眾非蓄意自網路購得大克蟎作為殺蟲劑，經查獲將先給予警告，可能不會處以罰鍰；如為公司行為，則會處以罰鍰並將進入後續訴訟程序。<br>2.已參與全球環境監測計畫，針對環境監測部分尚不確定是否有進行大克蟎之監測，但針對食品有定期監測及訂定每日容許攝取量上限，但不確定監測頻率。 |
| **全氟辛酸及全氟己烷磺酸管制交流** | 雖然全氟辛酸(PFOA)及全氟己烷磺酸(PFHxS)目前仍為公約審議中物質，但考量未來可能列入公約列管，故臺灣於今(2018)年 6 月 29 日公告將全氟辛酸列為第四類毒性化學物質，全氟己烷磺酸目前尚未列入我國毒管法管理。目前臺灣於環境水體及食品中皆能檢測出 PFOA 及 PFHxS，尚未有相關環境、食品等法規管制標準。<br>1. 請問是否有訂定全氟辛酸及全氟己烷磺酸禁限用法規？法規管理內容（含豁免規定）及其管理策略？未來精進管制方向？<br>2. 若尚未制定禁限用法規，目前的國內使用現況及因應公約之作法為何？ | 1.歐盟 REACH 指令已有規範限制，且瑞典、德國在多年前皆已禁用。<br>2.瑞典、德國皆已訂定 PFOA 及 PFHxS 之相關環境、飲用水、地表水及地下水相關標準。<br>3.德國針對全氟辛烷磺酸之消防泡沫替代品進行說明，有民營公司已開發出不含氟、可生物降解之消防泡沫，並且實際使用成效佳，並有實際使用於應變案例，惟該泡沫成分為商業機密，無法得知其使用化合物。 |  | 1.PFOA 已禁用多年，且禁止 PFOA 於原料、半成品之製造、進口，但對含 PFOA 之製成品尚未管制，產品之 PFOA 含量亦尚未訂有標準。<br>2.PFOS 亦已禁用多年，但有針對極少數用途有豁免，如軍隊演習所殘留之消防泡沫等。<br>3.PFHxS 目前尚未進行環境風險評估程序，如後續公約列管，則會配合進行相關管制。 |

| 議題 | 議題說明 | 瑞典 | 德國 | 加拿大 |
|---|---|---|---|---|
| **短鏈氯化石蠟管制交流** | 短鏈氯化石蠟(Short-Chain Chlorinated Paraffins, SCCPs)已於去(2017)年召開之 COP8 決議列入附件 A 管理。為因應公約管理趨勢，短鏈氯化石蠟已於今年 11 月 6 日預公告增列為第一類毒性化學物質，及參考公約規範增列得使用用途及禁止運作事項，但尚未訂定相關環境、商品等管制標準。<br>1. 請問針對短鏈氯化石蠟訂定之禁限用法規管理策略為何？未來精進管制方向？<br>2. 針對含短鏈氯化石蠟產品之進口管制，請問貴國是如何具體執行？<br>3. 如何在進口時查驗或證明？（如進行含量檢測或請進口商出具相關短鏈氯化石蠟含量之檢測報告，以示證明） | 短鏈氯化石蠟在歐盟已於 2003 年禁用，但因 SCCPs 為工業常用物質，在禁用前需與業界進行風險溝通。 |  | SCCPs 在加拿大已禁用，邊境管制人員會進行抽測，對於執行人員亦會進行教育訓練。 |

## 三、心得及建議

（一）經參與本次審查委員會議，可得知國外多已針對公約審議物質進行源頭禁止或限制使用、產品含量限值及其他相關規定，建議我國應持續透過跨部會會議與國內相關單位一同加強源頭管制，商品規範制定，強化進出口管制，降低國人暴露機率，進行環境流布、市售食品、田間農、畜及水產品等調查檢測，鼓勵廠商研發替代技術（或替代品）及推廣應用，減緩產業經濟衝擊。

（二）持久性有機污染物之管理仰賴各部會主管機關依據其權責辦理，目前國內除本局主掌之毒性化學物質管理法外，包括本署、衛生福利部、農業委員會、經濟部、勞動部、財政部等單位一同辦理，鑑於斯德哥爾摩公約列管之持久性有機污染物種類將依據締約國大會決議持續新增，未來除了在第一時間掌握最新公約管理規定，亦可持續強化目前跨部會溝通及合作管理機制，定期邀集各相關部會進行討論，增修訂國內相關管制法規強度與國際同步接軌，並據以執行。

（三）本次與瑞典、德國及加拿大代表針對公約新列管物質及審議中化學物質進行交流，大部份物質於公約列管前皆已在該國禁用。交流中各國皆提及在禁用過程中，執法人員之專業訓練、業者及民眾之風險溝通、機關間之橫向聯繫合作都是新政策實施應加強之重點。

（四）本次出國主要目的除汲取先進國家對於持久性有機污染物之管理方式外，亦希望加強與國外學者或政府機關之交流，藉此宣揚我國長期致力於持久性有機污染物管理之努力成效。會議期間，本代表團已成功與瑞典、德國及加拿大等官方代表進行雙邊會談，初步建立起溝通管道。建議未來可以這些國家為基礎，加深與先進國家於化學品管理之交流，逐步建立起互信且可互相分享經驗之國家或非政府組織溝通網路，並持續向其他國家擴展，使我國可與國際有效接軌，為全球環境保護盡一份力。

# 附錄一、聯合國斯德哥爾摩公約第 14 次持久性有機污染物審查委員會會議紀錄

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Stockholm Convention
on Persistent Organic
Pollutants

**Persistent Organic Pollutants Review Committee**
**Fourteenth meeting**
Rome, 17–21 September 2018

# Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting

## I. Opening of the meeting

1. The fourteenth meeting of the Persistent Organic Pollutants Review Committee was held at the headquarters of the Food and Agriculture Organization of the United Nations, Viale delle Terme di Caracalla, Rome, from 17 to 21 September 2018.

2. The Chair, Ms. Estefania Moreira (Brazil), declared the meeting open at 9.45 a.m. on Monday, 17 September 2018. Welcoming the members of the Committee and observers, she invited Mr. Rolph Payet, Executive Secretary of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade and the Stockholm Convention on Persistent Organic Pollutants, to deliver opening remarks.

3. In his remarks, Mr. Payet said that the scientific work under the Stockholm Convention had triggered and further catalysed persistent organic pollutant research activities worldwide, and had enabled increased awareness and knowledge of those chemicals and their presence in humans and the environment. Expressing appreciation for the highly scientific and technical contributions of the members of the Committee, he said that the Convention was one of the most dynamic global environment treaties, as new chemicals were continuously being added to the list of persistent organic pollutants in its Annexes. The complexity and challenges associated with the evaluation of polyfluorinated chemicals under consideration required careful review of the relevant information in order to provide the Conference of the Parties with a solid basis for decision-making.

4. While scientific monitoring data collected by the global monitoring plan confirmed decreasing trends in concentrations of most legacy persistent organic pollutants over time, and several of the newly listed chemicals, with real gains for human health and the environment, sustained efforts were needed to tackle global pollution and contamination. The global relevance and timeliness of the Committee’s work was underlined by the themes selected for the third and fourth sessions of the United Nations Environment Assembly, on combating pollution and on sustainable consumption and production, respectively. In conclusion, he expressed his confidence that the transparent, inclusive, balanced, precautionary and science-based approach to decision-making adopted by the Committee over the years would continue at the current meeting.

# II. Organizational matters

## A. Adoption of the agenda

5. The Committee adopted the agenda set out below on the basis of the provisional agenda (UNEP/POPS/POPRC.14/1):

1. Opening of the meeting.
2. Organizational matters:
    (a) Adoption of the agenda;
    (b) Organization of work.
3. Rotation of the membership.
4. Technical work:
    (a) Consideration of a draft risk profile on perfluorohexane sulfonic acid (CAS No: 355-46-4, PFHxS), its salts and PFHxS-related compounds;
    (b) 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;
    (c) Process for the evaluation of perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride pursuant to paragraphs 5 and 6 of part III of Annex B to the Convention.
5. Report on activities for effective participation in the work of the Committee.
6. Workplan for the intersessional period between the fourteenth and fifteenth meetings of the Committee.
7. Venue and date of the fifteenth meeting of the Committee.
8. Other matters.
9. Adoption of the report.
10. Closure of the meeting.

## B. Organization of work

6. The Committee agreed to conduct the meeting in accordance with the scenario note prepared by the Chair (UNEP/POPS/POPRC.14/INF/1) and the proposed schedule set out in document UNEP/POPS/POPRC.14/INF/2, subject to adjustment as necessary. The Committee also agreed to conduct its work in plenary session and to establish contact, drafting and friends of the chair groups as necessary. In considering the matters on its agenda the Committee had before it the documents listed in the annotations to the agenda (UNEP/POPS/POPRC.14/1/Add.1/Rev.1) and the list of pre-session documents by agenda item (UNEP/POPS/POPRC.14/INF/12/Rev.1).

## C. Attendance

7. The meeting was attended by the following Committee members: Mr. Sylvain Bintein (Austria), Ms. Tamara Kukharchyk (Belarus), Ms. Estefania Gastaldello Moreira (Brazil), Mr. Jean-François Ferry (Canada), Mr. Jianxin Hu (China), Mr. Luis G. Romero Esquivel (Costa Rica), Ms. Rikke Donchil Holmberg (Denmark), Ms. Thabile Ndlovu (Eswatini), Mr. Sam Adu-Kumi (Ghana), Mr. Manoj Kumar Gangeya (India), Mr. Agus Haryono (Indonesia), Mr. Amir Nasser Ahmadi (Islamic Republic of Iran), Ms. Helen Jacobs (Jamaica), Mr. Mineo Takatsuki (Japan), Ms. Caroline Njoki Wamai (Kenya), Ms. Mantoa Sekota (Lesotho), Ms. Ingrid Hauzenberger (Luxembourg), Mr. Adama Tolofoudye (Mali), Ms. Amal Lemsioui (Morocco), Mr. Rameshwar Adhikari (Nepal), Mr. Martien Janssen (Netherlands), Mr. Peter Dawson (New Zealand), Ms. Vilma Morales Quillama (Peru), Ms. Anna Graczyk (Poland), Ms. Victorine Augustine Pinas (Suriname), Mr. Andreas Buser (Switzerland), Mr. Nadjo N'ladon (Togo), Mr. Youssef Zidi (Tunisia), Ms. Svitlana Sukhorebra (Ukraine).

8. The following States and regional economic integration organizations were represented as observers: Australia, Botswana, Brazil, Canada, China, Colombia, Croatia, Czechia, European Union, Finland, France, Germany, Indonesia, Japan, Kenya, Norway, Poland, Qatar, Republic of Korea,

Russian Federation, Serbia, Slovakia, South Africa, Sweden, United Kingdom of Great Britain and Northern Ireland, United States of America.

9. The United Nations Environment Programme was represented as an observer. Non-governmental organizations were also represented as observers. The names of those organizations are included in the list of participants (UNEP/POPS/POPRC.14/INF/14).

# III. Rotation of the membership

10. Introducing the item, the representative of the Secretariat drew attention to the information provided in document UNEP/POPS/POPRC.14/INF/3 on the newly appointed members of the Persistent Organic Pollutants Review Committee and forthcoming rotation of the membership in May 2020. The Conference of the Parties, by decision SC-8/9, had appointed the 14 experts who had been designated by Parties to serve as members of the Committee with terms of office from 5 May 2016 to 4 May 2020, together with 17 new experts to serve with terms of office from 5 May 2018 to 4 May 2022. Following the eighth meeting of the Conference of the Parties, the Governments of Austria, Luxembourg and Pakistan had informed the Secretariat of the replacement of the experts they had designated to serve as members of the Committee. The curricula vitae of those replacement experts, a summary on the rotation of the membership and the contact information of the current and newly appointed members were set out in the document before the Committee. At its thirteenth meeting, the Committee had elected Ms. Sukhorebra (Ukraine) to serve as Vice-Chair of the Committee with a term of office commencing on 5 May 2018. Finally, he said that the terms of office of the remaining 14 members would expire on 4 May 2020. Pursuant to paragraph 2 of the terms of reference of the Committee, the Conference of the Parties at its ninth meeting would need to appoint new members to fill those forthcoming vacancies on the Committee with a term of office running from 5 May 2020 to 4 May 2024.

11. The Committee took note of the information presented.

# IV. Technical work

## A. Consideration of a draft risk profile on perfluorohexane sulfonic acid (CAS No: 355-46-4, PFHxS), its salts and PFHxS-related compounds

12. In considering the sub-item, the Committee had before it a note by the Secretariat on the draft risk profile for perfluorohexane sulfonic acid (CAS No: 355-46-4, PFHxS), its salts and PFHxS-related compounds (UNEP/POPS/POPRC.14/2); and notes by the Secretariat containing additional information on those substances (UNEP/POPS/POPRC.14/INF/4) and a compilation of comments and responses relating to the draft risk profile (UNEP/POPS/POPRC.14/INF/5).

13. Introducing the sub-item, the representative of the Secretariat recalled that by decision POPRC-13/3 the Committee had established an intersessional working group to further review the proposal to list PFHxS, its salts and PFHxS-related compounds in Annexes A, B and/or C to the Stockholm Convention, and to prepare a draft risk profile pertaining to the chemical in accordance with Annex E to the Convention. The draft risk profile prepared by the intersessional working group, along with additional information and comments, were set out in the documents before the Committee.

14. Mr. Dawson, chair of the intersessional working group, gave a presentation on the work of the group in developing the draft risk profile.

15. In the ensuing discussion, several members remarked on the size and complexity of the task undertaken by the intersessional working group, and there was agreement that the draft risk profile provided a sound basis for further discussion of the matter by the Committee. One member said that further consideration needed to be given to several issues, including clear definition of which chemicals, with their specific names, might be considered for further control; uncertainty regarding analytical methods used in studies of long-range transport; and ensuring that supportive data, in particular production data, were up to date and accurate. Another member agreed that additional information was needed on the complex matter of PFHxS-related compounds.

16. One member said that the greater occurrence of the chemicals in the environment than the reported levels of production indicated the possibility of there being unidentified major sources of emission, which needed to be identified for the risk management evaluation phase. Further discussion was also needed on the use of the read-across approach to compare data on PFHxS with those on other per- and polyfluoroalkyl substances (PFAS), in order to ensure consistency and to fill data gaps, for example on toxicity. Another member said that it would be instructive to obtain further information on the main sources of release of the chemical into the environment; and on the accumulation in humans

# Annex II

## Composition of an intersessional working group (2018–2019)

### Working group on perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds

**Committee members**

Mr. Sylvain Bintein (Austria)

Ms. Tamara Kukharchyk (Belarus)

Ms. Estefania Moreira (Brazil)

Mr. Jean-François Ferry (Canada)

Ms. Rikke Holmberg (Denmark) **(Drafter)**

Ms. Thabile Ndlovu (Eswatini)

Mr. Sam Adu-Kumi (Ghana)

Mr. Manoj Gangeya (India)

Mr. Amir Nasser Ahmadi (Iran (Islamic Republic of))

Ms. Helen Jacobs (Jamaica)

Mr. Mineo Takatsuki (Japan)

Ms. Caroline Njoki Wamai (Kenya)

Ms. Mantoa Sekota (Lesotho)

Ms. Ingrid Hauzenberger (Luxemburg)

Mr. Rameshwar Adhikari (Nepal)

Mr. Martien Janssen (Netherlands)

Mr. Peter Dawson (New Zealand) **(Chair)**

Ms. Anna Graczyk (Poland)

Ms. Victorine Augustine Pinas (Suriname)

Mr. Andreas Buser (Switzerland)

Mr. N'Ladon Nadjo (Togo)

Mr. Youssef Zidi (Tunisia)

Ms. Svitlana Sukhorebra (Ukraine)

**Observers**

Ms. Cynthia Bainbridge (Canada)

Mr. Zhiyuan Ren (China)

Mr. Yangzhao Sun (China)

Ms. Mingyu Qin (China)

Mr. Mario Vujić (Croatia)

Mr. Pavel Čupr (Czechia)

Ms. Valentina Bertato (European Union)

Mr. Alexander Potrykus (European Union)

Mr. Timo Seppälä (Finland)

Ms. Sandrine Andres (France)

of different ages, to shed light on the long half-life of PFHxS in humans compared to PFOS and PFOA; and the implications for control of the concentration levels found for PFHxS in products and articles.

17. One member said that experimental evidence from studies on PFHxS, supported by equivalent studies on PFOA and PFOS, indicated adverse effects on human health. The European Human Biomonitoring Initiative aimed to provide better evidence of the exposure of citizens to those and other chemicals, and the possible health effects. Another member said that while there had not been a long history of research into PFHxS, its salts and PFHxS-related compounds, experimental studies, including those on the combined effects of chemicals (including PFHxS), indicated a clear risk to human health.

18. The Committee established a contact group, chaired by Mr. Dawson, to further revise the draft risk profile on PFHxS, its salts and PFHxS-related compounds and to prepare a draft decision, taking into account the discussions in plenary.

19. Subsequently, the Committee adopted decision POPRC-14/1, by which it adopted the risk profile for perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds, and decided to establish an intersessional working group to prepare a risk management evaluation that included an analysis of possible control measures for perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds in accordance with Annex F to the Convention. The decision is set out in annex I to the present report and the risk profile is set out in document UNEP/POPS/POPRC.14/6/Add.1.

## B. 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

20. In considering the sub-item, the Committee had before it a 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), as well as comments and responses relating to the draft assessment of information on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.14/INF/7). It also had before it a note by the Secretariat containing information on note (ii) of part I of Annex A to the Convention and the scope of the reference to stockpiles in accordance with Article 6 of the Stockholm Convention (UNEP/POPS/POPRC.14/INF/6).

21. Introducing the sub-item, the representative of the Secretariat recalled that by decision POPRC-13/2, the Committee had recommended to the Conference of the Parties that it consider listing PFOA, its salts and PFOA-related compounds in Annex A or B to the Convention with specific exemptions as described in paragraph 2 of that decision. In the same decision, it had also invited Parties and observers to provide additional information to assist the Committee in defining specific exemptions for the production and use of the chemicals in a number of specified applications; in further evaluating the chemicals’ unintentional formation and release; and in further evaluating the chemical identity of PFOA-related compounds. It had also established an intersessional working group to assess the additional information provided by Parties and observers.

22. As use in fire-fighting foams was one of the most complicated applications for which it had sought additional information, the Committee agreed to hear presentations by a fire-fighting foam expert panel, including an invited expert, who would provide the perspective of producers, users and regulators, as well as information on alternatives.

23. Mr. Adhikari, chair of the intersessional working group, first presented the outcome of the group’s work. The Committee then heard presentations by: Mr. John-Olav Otterson of the European Committee of the Manufacturers of Fire Protection Equipment and Fire Fighting Vehicles presented the producer’s perspective; Mr. Niall Ramsden from LASTFIRE, a consortium of international oil companies developing best practice in storage tank fire hazard management, provided the user’s viewpoint; Mr. Kalle Kivelä of the European Chemicals Agency spoke from the regulator’s standpoint; and Mr. Roger Klein of the John Jay College of Criminal Justice, City University of New York, provided an overview of alternatives. Following the presentations, the panel responded to questions from members.

24. In the ensuing discussion, several members spoke about the complications surrounding PFOA and the difficulty of gathering complete information on its applications. One said that there were so many sectors involved in using the substance that it would be difficult to compile all its uses, and another said that although the intersessional work and presentations at the current meeting had

answered many questions, information was still lacking on many of the applications and on the exemptions that would be needed. Even in the case of fire-fighting foams, where members had access to good information and the manufacturers and end users had made strong arguments for an exemption, the consequences of using the foams merited discussion, as an exemption would result in large amounts being released into the environment. A third member said that acquiring full evidence for all PFOA-related compounds might not be possible, but as alternatives were available, the Committee should take a holistic view of the chemical and aim for no exemptions, leave no room for manipulation by chemists and restrict even unintentional releases.

25. A few members mentioned the importance of providing the best possible advice to the Conference of the Parties based on the information the Committee had before it. One said that in doing so, the members should aim to maximize the management of risk by choosing control measures that would achieve the greatest reduction in PFOA use globally. Another stressed the need for the Committee to be as consistent as possible in deciding whether uses required an exemption.

26. One member provided new estimates of PFOA levels in the environment in Europe, saying that they should be taken into account in the discussion on listing the chemical in Annex C.

27. The Committee established a contact group, chaired by Mr. Ferry, to further revise the draft assessment of the information on PFOA, its salts and PFOA-related compounds, and to prepare a draft decision, taking into account the discussions in plenary.

28. Subsequently, the chair of the contact group reported back on the group's work and introduced a revised draft assessment for adoption as an addendum to the risk management evaluation on PFOA, its salts and PFOA-related compounds. He also introduced a draft decision on the matter, which combined elements of decision POPRC-13/2 and new text.

29. The representative of the Secretariat drew attention to the footnote in the draft decision, which was aimed at harmonizing the name used for the chemical in work being done under both the Stockholm Convention and the Rotterdam Convention.

30. During the discussion on the matter, all those who spoke expressed support for the proposed decision, describing it as a good compromise arrived at through lengthy discussion. One member said that it was particularly important to quickly limit or prohibit the use of fire-fighting foams containing PFOA compounds for training purposes, and another observed that the issue of fire-fighting foams was cross-cutting and the approach used for PFOA would be applicable to future discussions on other chemicals. One member proposed that the footnote relating to the name of the chemical in the draft decision also be included in the proposed addendum to the risk management evaluation.

31. One member, while supporting the decision text, said that a five-year exemption for replacing all fire-fighting foams might prove insufficient, as all associated equipment might need to be replaced. Another said, however, that the proposed staged phase-out of PFOA and PFOA-related fire-fighting foams was realistic and easily achievable.

32. One member informed the Committee that with respect to fire-fighting foams, Japan had already intended to submit a notification of articles in use before or on the date of entry into force, in accordance with note (ii) to Annex A should PFOA, its salts and PFOA-related compounds be listed therein.

33. The Committee then adopted decision POPRC-14/2, by which it adopted the addendum to the risk management evaluation for PFOA, its salts and PFOA-related compounds as orally amended; decided to recommend to the Conference of the Parties that it consider listing PFOA, its salts and PFOA-related compounds in Annex A to the Convention with specific exemptions; and recommended to the Conference of the Parties that it consider encouraging Parties not to replace fire-fighting foam that contained or might contain PFOA, its salts and PFOA-related compounds with short-chain per- and polyfluoroalkyl substances due to their persistence and mobility, as well as their potential negative environmental, human health and socioeconomic impacts. The decision is set out in annex I to the present report and the addendum to the risk management evaluation is set out in document UNEP/POPS/POPRC.14/6/Add.2.

## C. Process for the evaluation of perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride pursuant to paragraphs 5 and 6 of part III of Annex B to the Convention

34. In considering the sub-item, the Committee had before it a note by the Secretariat on the process for the evaluation of perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) pursuant to paragraphs 5 and 6 of part III of Annex B to the Stockholm

Convention (UNEP/POPS/POPRC.14/4), a note by the Secretariat on a draft report on the assessment of alternatives to PFOS, its salts and PFOSF (UNEP/POPS/POPRC.14/INF/8) and an addendum thereto (UNEP/POPS/POPRC.14/INF/8/Add.1), as well as a note by the Secretariat on the draft report on the evaluation of PFOS, its salts and PFOSF (UNEP/POPS/POPRC.14/INF/9).

35. Introducing the sub-item, the representative of the Secretariat recalled that under paragraph 5 of part III of Annex B to the Convention, the Conference of the Parties to the Stockholm Convention was required to evaluate the continued need for PFOS, its salts and PFOSF for the various acceptable purposes and specific exemptions listed in Annex B on the basis of available scientific, technical, environmental and economic information. For its part, paragraph 6 of part III of Annex B required that the evaluation take place no later than in 2015 and every four years thereafter, in conjunction with a regular meeting of the Conference of the Parties.

36. She further recalled that the Conference of the Parties, by its decision SC-6/4, had adopted a process for the evaluation of PFOS, its salts and PFOSF, and had subsequently amended, through its decision SC-7/5, the schedule for the evaluation process and decided to undertake the next evaluation of PFOS, its salts and PFOSF at its ninth meeting.

37. Accordingly, by its decision POPRC-13/4, the Committee had established an intersessional working group to undertake the activities in the process set out in the annex to decision SC-6/4 and agreed to work in accordance with the terms of reference set out in the annex to document UNEP/POPS/POPRC.13/INF/9. In its decision POPRC-13/2, the Committee had further decided to address how to proceed with sulfluramid within the process for the evaluation of PFOS, its salts and PFOSF, while noting that there was evidence that sulfluramid degraded to PFOA and that sulfluramid was included in the risk profile on PFOS, its salts and PFOSF.

38. In line with the above-mentioned decisions, the intersessional working group had prepared a draft report on the assessment of alternatives to PFOS, its salts and PFOSF (UNEP/POPS/POPRC.14/INF/8, annex). Following the release of the draft report, the chair of the group, Mr. Janssen, had revised four sections of chapter 3 and prepared additional draft text to be inserted in the executive summary and chapter 2, as well as new appendices 3 and 4. The additional and revised draft text was set out in the annex to document UNEP/POPS/POPRC.14/INF/8/Add.1.

39. The Secretariat had prepared a draft report on the evaluation of PFOS, its salts and PFOSF (UNEP/POPS/POPRC.14/INF/9, annex), and would revise and finalize the report for consideration by the Conference of the Parties at its ninth meeting on the basis of the discussion at the current meeting and any additional submissions from Parties. The proposed action by the Committee on the sub-item was contained in the note by the Secretariat (UNEP/POPS/POPRC.14/4).

40. Mr. Janssen presented the draft report on the assessment of alternatives to PFOS, its salts and PFOSF (UNEP/POPS/POPRC.14/INF/8, annex) and the proposed changes to the draft report (UNEP/POPS/POPRC.14/INF/8/Add.1, annex).

41. In the ensuing discussion, members expressed appreciation to the intersessional working group and its chair for the draft report, which they said was encouraging in that it showed that alternative products or processes existed for most of the uses of PFOS, its salts and PFOSF.

42. Concern was expressed that, as was shown in the report, a full assessment of alternatives to PFOS, its salts and PFOSF was still hampered by confidential business information, and the suggestion was made that when screening potential alternatives to PFOS, its salts and PFOSF used as pesticides, the Committee could rely on information provided in the most comprehensive pesticide assessments conducted by the European Union.

43. With regard to the draft report, one member suggested that for the screening assessment of permethrin and cyfluthrin the outcome of the assessment of alternatives to endosulfan conducted by the Committee at its eighth meeting should be considered.

44. Responding to questions from members, Mr. Janssen clarified that the choice of alternatives depended on their function, rather than their chemical composition, so while in the case of fire-fighting foams alternative substances tended to be fluorinated and structurally similar to PFOS, when it came to pesticide uses chemicals with very different structures could serve the same purpose. In the case of hydraulic fluids, it was unclear whether alternatives to PFOS, its salts and PFOSF contained fluorinated substances because the full list of ingredients of such products was considered confidential business information and was not provided in the product material safety data sheets.

45. One member expressed support for further narrowing the acceptable purposes for PFOS, its salts and PFOSF, and sought clarification regarding the process that the Committee and the Conference of the Parties had to follow to eliminate or modify certain acceptable purposes set out in Annex B to the Convention.

46. The representative of the Secretariat invited the Committee to take note of document UNEP/POPS/COP.8/8, in which the Secretariat provided information on the possible actions that could be taken by the Conference of the Parties, should the Conference of the Parties conclude that there was no continued need for the various acceptable purposes for PFOS, its salts and PFOSF.

47. The Committee established a contact group, chaired by Mr. Janssen, to further revise the draft report and to prepare a draft decision on PFOS, its salts and PFOSF based on an initial text to be prepared by the Secretariat, taking into account the discussions in plenary.

48. Subsequently, the Committee adopted decision POPRC-14/3, in which it decided, among other things, to submit the report on the assessment of alternatives to PFOS, its salts and PFOSF to the Conference of the Parties for consideration at its ninth meeting; to request the Secretariat to finalize its report on the evaluation of information on PFOS, its salts and PFOSF on the basis of comments and suggestions provided by the Committee and to submit it to the Conference of the Parties for consideration at its ninth meeting; to recommend that the Conference of the Parties consider amending Annex B to the Stockholm Convention taking into account the recommendations set out in the annex to the decision; and to recommend that the Conference of the Parties encourage the Parties that were using sulfluramid as insect bait for the control of leaf-cutting ants to register for an acceptable purpose by notifying the Secretariat in accordance with Annex B to the Convention. The decision is set out in annex I to the present report.

49. One member, requesting that his statement be reflected in the present report, said that while he had supported the adoption of the decision in the light of the precautionary principle and in a spirit of compromise, cost-effective and environmentally sound alternatives to PFOS were not available for all uses and, when it came to the use of PFOS in fire-fighting foam, there was a need to strike a balance between the possible environmental benefits obtained from phasing out such use on the one hand and the benefits of saving lives and property on the other.

# V. Report on activities for effective participation in the work of the Committee

50. The representative of the Secretariat introduced a report on activities for effective participation in the work of the Committee (UNEP/POPS/POPRC.14/INF/10), outlining the capacity-building and training activities carried out and planned since the previous meeting of the Committee. She drew special attention to a joint regional workshop for the Central and Eastern European region that had been held in Brno, Czechia, from 6 to 8 February 2018, to enhance the effective participation of Parties to the Rotterdam and Stockholm conventions in the work of the Chemical Review Committee of the Rotterdam Convention and the Persistent Organic Pollutants Review Committee of the Stockholm Convention, with financial support provided by the European Union, Germany and Norway. She drew attention to awareness-raising materials on newly listed POPs developed by the Secretariat, including recordings of webinars conducted, which were available on the website of the Stockholm Convention. She stressed that, subject to the availability of resources, the Secretariat was planning to organize similar joint regional workshops in other regions during the biennium 2018–2019.

51. In the ensuing discussion, members expressed appreciation to the Secretariat for the activities conducted and said that enhancing the effective participation of members and others in the work of the Committee was critical to enhancing the effectiveness of the Stockholm Convention by ensuring that the deliberations of the Conference of the Parties had a strong scientific basis. As for potential future activities, support was expressed for the planned joint regional workshops, and one member suggested that thematic workshops on specific chemicals or issues would be very useful in helping the Parties to acquire the necessary technical and scientific knowledge ahead of relevant meetings.

52. The Secretariat took note of the suggestions and the Committee took note of the information presented.

# VI. Workplan for the intersessional period between the fourteenth and fifteenth meetings of the Committee

53. In its consideration of the item, the Committee had before it a note by the Secretariat on a draft workplan for the intersessional period between the fourteenth and fifteenth meetings of the Committee (UNEP/POPS/POPRC.14/5). The representative of the Secretariat introduced the item, outlining the information in the note, following which the Committee adopted the workplan without amendment.

54. In accordance with paragraph 29 of the annex to decision SC-1/7, the Committee established an intersessional working group to carry forward the work necessary to implement its decision.

55. The composition of the intersessional working group is set out in annex II to the present report, and the workplan is set out in annex III.

# VII. Venue and date of the fifteenth meeting of the Committee

56. The Committee decided that its fifteenth meeting would be scheduled to be held at the headquarters of the Food and Agriculture Organization of the United Nations in Rome from 30 September to 4 October 2019, back to back with the fifteenth meeting of the Chemical Review Committee of the Rotterdam Convention. It was further understood that the Chair, in consultation with the Vice-Chair and the Secretariat, might adjust the meeting arrangements to accord with the work requirements.

# VIII. Other matters

## A. Suggestions for improving the ways of presenting information in risk profile and risk management evaluation documents

57. In considering the sub-item, the Committee had before it a note by the Secretariat on outlines for risk profiles and risk management evaluations (UNEP/POPS/POPRC.13/INF/11), which had been presented to the Committee at its thirteenth meeting but the discussion of which had been deferred to the current meeting.

58. Introducing the sub-item, the representative of the Secretariat noted that, when drafting risk profiles and risk management evaluations, intersessional working groups had been using the risk profile outline agreed upon by the Committee at its first meeting and the risk management evaluation outline agreed upon by the Committee at its third meeting, which covered the information required under, respectively, Annex E and Annex F to the Stockholm Convention. In line with the two outlines, which were reproduced in document UNEP/SC/POPRC.13/INF/11, intersessional working groups had done their utmost to limit the length of the risk profiles and risk management evaluations while providing all the information made available to the Committee on specific chemicals, for instance by using tables, figures and information documents. At the current meeting, the Committee was invited to discuss possible ways of further improving the presentation of the information contained in risk profiles and risk management evaluations in order to meet the needs of the Conference of the Parties while ensuring conformity with the requirements of the above-mentioned outlines.

59. In the ensuing discussion, members made a number of suggestions for improving risk profiles and risk management evaluations, taking into account the past experience of intersessional working groups. Proposals presented by members included the examination, in risk management evaluations dealing with several related substances, of the information available on such substances by use or by application; the specification in risk profiles of the most reliable scientific data that had been compiled and which supported the Committee’s conclusions; the inclusion in risk profiles of examples to substantiate the Committee’s statements only in cases where there was uncertainty or dissenting views on such statements; and the careful consideration of alternatives in risk management evaluations to ensure that potential alternatives did not exhibit persistent organic pollutant characteristics.

60. A few members stressed the need to explore ways of incorporating information related to developing countries in risk profiles and risk management evaluations to ensure that the scope of such documents was truly global. One member expressed support for the proposal made by the representative of an observer that, when the Committee made a recommendation to list a chemical and its “related compounds” in the Stockholm Convention, the Secretariat produce and share with the Parties, for instance through the Convention website, an indicative list of chemicals that might be considered “related compounds”.

61. With regard to the drafting process for risk profiles and risk management evaluations, one member stressed the importance of presenting all the information on specific chemicals to be considered at Committee meetings during the intersessional period in order to enable members and observers to analyse such information prior to meetings.

62. While one member stressed the importance of ensuring the quality of scientific data used in risk profiles, another said that there was no need for the Committee to re-evaluate data that had already been validated by regulatory agencies. One member suggested that the main topics discussed by the Committee should be listed together with corresponding information on how they had been or were to be addressed, which would be a helpful document for delegates attending meetings of the Conference of the Parties who had not followed the discussions of the Committee. Another member highlighted the need for more information on the chemicals being listed, such as a fact sheet for each chemical outlining the salient details.

63. In response to a query from a member on whether the recommendations presented at the current meeting could be taken on board by the intersessional working group established at the meeting, the Chair replied that the group might find it useful to examine information on related chemicals by use or by application in preparing the draft risk management evaluation.

### B. From science to action

64. Introducing the item, the representative of the Secretariat said that updates to the work on “From science to action”, including revisions to the draft road map for science to action, were presented in document UNEP/POPS/POPRC.14/INF/11. The goal of the road map was to strengthen the science–policy interface by engaging Parties and others in informed dialogue for enhanced science-based action in the implementation of the Basel, Rotterdam and Stockholm conventions at the national and regional levels.

65. During the ensuing discussion, several members emphasized the importance of ensuring that policy formulation on chemicals was properly informed by scientific knowledge. One member, supported by others, noted the imbalance between developed and developing countries with regard to the generation of information, the accessibility of data, and the technical capacity and human resources to process the data. In that regard, knowledge sharing to fill information gaps was necessary. He added that gaps at the country level also needed to be addressed, including between researchers working in isolation, and between scientists and policymakers. Another member said that greater efforts should be made to ensure conformity in the methods applied when gathering, processing and presenting data to ensure comparability of data sets. Another member said that the road map would help in emphasizing the responsibility and accountability of national authorities in supporting science-related activities.

66. The Committee took note of the information provided.

### C. Preparations for the ninth meeting of the Conference of the Parties

67. The representative of the Secretariat provided information on the ninth meeting of the Conference of the Parties to the Stockholm Convention, which would be held back to back with the next meetings of the conferences of the Parties to the Basel and Rotterdam conventions, in Geneva, from 29 April to 10 May 2019. As decided by the conferences of the Parties in 2017, the 2019 meetings would not include a high-level segment. Within available resources, regional preparatory meetings for the conferences of the Parties would be held in March 2019.

68. The Committee took note of the information provided.

## IX. Adoption of the report

69. The Committee adopted the present report on the basis of the draft report (UNEP/POPS/POPRC.14/L.1) on the understanding that the finalization of the report would be entrusted to the Rapporteur, working in consultation with the Secretariat.

## X. Closure of the meeting

70. Following the customary exchange of courtesies, the meeting was declared closed at 4.15 p.m. on Friday, 21 September 2018.

# Annex I

## Decisions adopted by the Persistent Organic Pollutants Review Committee at its fourteenth meeting

POPRC-14/1: Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds

POPRC-14/2: Perfluorooctanoic acid (PFOA) its salts and PFOA-related compounds

POPRC-14/3: Evaluation of perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) pursuant to paragraphs 5 and 6 of part III of Annex B to the Stockholm Convention

## POPRC-14/1: Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds

*The Persistent Organic Pollutants Review Committee,*

*Having completed* an evaluation of the proposal by Norway to list perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds, defined as any substance that contains the chemical moiety $C_6F_{13}SO_2$- as one of its structural elements and that potentially degrades to PFHxS, in Annexes A, B and/or C to the Stockholm Convention and having decided at its thirteenth meeting, in its decision POPRC-13/3, that the proposal meets the criteria set out in Annex D to the Convention,

*Having also completed* the risk profile for perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds in accordance with paragraph 6 of Article 8 of the Convention,

1. *Adopts* the risk profile for perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds;[1]

2. *Decides*, in accordance with paragraph 7 (a) of Article 8 of the Convention, that perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds are likely as a result of their long-range environmental transport to lead to significant adverse human health and environmental effects such that global action is warranted;

3. *Also decides,* in accordance with paragraph 7 (a) of Article 8 of the Convention and paragraph 29 of the annex to decision SC-1/7 of the Conference of the Parties, to establish an intersessional working group to prepare a risk management evaluation that includes an analysis of possible control measures for perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds in accordance with Annex F to the Convention;

4. *Invites,* in accordance with paragraph 7 (a) of Article 8 of the Convention, Parties and observers to submit to the Secretariat the information specified in Annex F bye 26 November 2018.

## POPRC-14/2: Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

*The Persistent Organic Pollutants Review Committee,*

*Recalling* its decision POPRC-13/2, by which it recommended to the Conference of the Parties that it consider listing perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds[2] in Annex A or B to the Convention with specific exemptions as specified in paragraph 2 (a)–(c) of that decision;

*Having* assessed the information provided in accordance with paragraphs 3 to 5 of decision POPRC-13/2, [3]

*Recognizing* that a transition to the use of short-chain per- and polyfluoroalkyl substances (PFASs) for dispersive applications such as fire-fighting foams is not a suitable option from an environmental and human health point of view and that some time may be needed for a transition to alternatives without PFASs,

1. *Adopts* the addendum to the risk management evaluation for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds;[4]

2. *Decides,* in accordance with paragraph 9 of Article 8 of the Convention, to recommend to the Conference of the Parties that it consider listing perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex A to the Convention with specific exemptions for the following:

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[1] UNEP/POPS/POPRC.14/6/Add.1.

[2] The titles of decisions POPRC-12/2 and POPRC-13/2 refer to “pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds”, consistent with the proposal for the listing of the chemicals submitted by the European Union (UNEP/POPS/POPRC.11/5). During the intersessional period, however, the chemicals that are the subject of these decisions were referred to as “perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds”. Both terms designate the same group of chemicals, but the phrase “perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds” is more consistent with other references to these chemicals. As noted above, the Committee has used the latter name in the present decision. The latter name will therefore be used henceforth to refer to the chemicals covered by decisions POPRC-12/2 and POPRC-13/2 in documents prepared under the auspices of the Stockholm Convention.

[3] UNEP/POPS/POPRC.14/3.

[4] UNEP/POPS/POPRC.14/6/Add.2.

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

- (i) Manufacture of semiconductors or related electronic devices:
    - a. Equipment or fabrication plant-related infrastructure containing fluoropolymers and/or fluoroelastomers with PFOA residues;
    - b. Legacy equipment or legacy fabrication plant-related infrastructure: maintenance;
    - c. Photo-lithography or etch processes;
- (ii) Photographic coatings applied to films;
- (iii) Textiles for oil and water repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety;
- (iv) Invasive and implantable medical devices;
- (v) Fire-fighting foam for liquid fuel vapour suppression and liquid fuel fires (Class B fires) already in installed systems, including both mobile and fixed systems, taking due account of the possible related control measures specified in the annex to the present decision;

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

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

3. *Recommends* to the Conference of the Parties that it consider encouraging Parties not to replace fire-fighting foam that contains or may contain PFOA, its salts and PFOA-related compounds with short-chain PFASs due to their persistency and mobility as well as potential negative environmental, human health and socioeconomic impacts.

# Annex to decision POPRC-14/2

# Possible related control measures for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

### Part [X]

### PFOA, its salts and PFOA-related compounds

1. The use of PFOA, its salts and PFOA-related compounds shall be eliminated except for Parties that have notified the Secretariat of their intention to use them in accordance with Article 4.

2. Each Party that has registered for an exemption pursuant to Article 4 for the use of PFOA, its salts and PFOA-related compounds for fire-fighting foam shall:

(a) Notwithstanding paragraph 2 of Article 3, ensure that fire-fighting foam that contains or may contain PFOA, its salts and PFOA-related compounds shall not be exported or imported except for the purpose of environmentally sound disposal as set forth in paragraph 1 (d) of Article 6;

(b) Not use fire-fighting foam that contains or may contain PFOA, its salts and PFOA-related compounds for training or testing purposes;

(c) By the end of 2022, restrict uses of fire-fighting foam that contains or may contain PFOA, its salts and PFOA-related compounds to sites where all releases can be contained. Containment measures, such as bunds and ponds, shall be controlled, impervious and not allow firewater, wastewater, run-off and other wastes to be released to the environment (e.g., to soils, groundwater, waterways and storm water);

(d) Ensure that all firewater, wastewater, run-off, foam and other wastes are managed in accordance with paragraph 1 of Article 6;

3. Make determined efforts designed to lead to the environmentally sound management of fire-fighting foam stockpiles and wastes that contain or may contain PFOA, its salts and PFOA-related compounds, in accordance with paragraph 1 of Article 6, as soon as possible.

## POPRC-14/3: Evaluation of perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) pursuant to paragraphs 5 and 6 of part III of Annex B to the Stockholm Convention

*The Persistent Organic Pollutants Review Committee,*

*Recalling* decision SC-6/4, by which the Conference of the Parties adopted a process, set out in the annex to that decision, for the evaluation of perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) pursuant to paragraphs 5 and 6 of part III of Annex B to the Stockholm Convention,

*Having completed* the second assessment of alternatives to PFOS, its salts and PFOSF in accordance with paragraph 3 of decision SC-6/4[5] and having reviewed the draft report of the Secretariat on the evaluation of information on PFOS, its salts and PFOSF[6] in accordance with the terms of reference for the assessment,[7]

1. *Decides* to submit the report on the assessment of alternatives to PFOS, its salts and PFOSF [8] to the Conference of the Parties for consideration at its ninth meeting;

2. *Requests* the Secretariat to finalize its report on the evaluation of information on PFOS, its salts and PFOSF[9] on the basis of comments and suggestions provided by the Committee taking into account the discussions at the fourteenth meeting of the Committee and to submit it to the Conference of the Parties for consideration at its ninth meeting;

3. *Recommends* that the Conference of the Parties consider amending Annex B to the Convention taking into account the recommendations set out in the annex to the present decision;

4. *Also recommends* that the Conference of the Parties encourage Parties that are using sulfluramid as insect bait for the control of leaf-cutting ants from *Atta* spp. and *Acromyrmex* spp. to register for an acceptable purpose by notifying the Secretariat in accordance with Annex B to the Convention;

5. *Requests* the Secretariat to revise, by 31 October 2018, the report on the assessment of alternatives to PFOS, its salts and PFOSF set out in the respective annexes to documents UNEP/POPS/POPRC.14/INF/8 and UNEP/POPS/POPRC.14/INF/8/Add.1, taking into account the discussions at the fourteenth meeting;

6. *Invites* Parties and observers to provide, by 30 November 2018, comments on the revised report;

7. *Requests* the Secretariat to further revise the report on the assessment of alternatives to PFOS, its salts and PFOSF, taking into account the comments received in accordance with paragraph 6 above for submission to the ninth meeting of the Conference of the Parties.

## Annex to decision POPRC-14/3

## Recommendations on the continued need for perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) for various the various acceptable purposes and specific exemptions

### A. Acceptable purposes

#### (a) Photo-imaging:

Based on the assessment of the use of alternatives to perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) for photographic coatings applied to film, paper

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[5] UNEP/POPS/POPRC.14/INF/8, UNEP/POPS/POPRC.14/INF/8/Add.1.

[6] UNEP/POPS/POPRC.14/INF/9.

[7] UNEP/POPS/POPRC.13/INF/9.

[8] UNEP/POPS/POPRC.14/INF/13.

[9] UNEP/POPS/POPRC.14/INF/9.

and printing plates, the Committee recommends that the acceptable purpose for the use of PFOS, its salts and PFOSF for photo-imaging no longer be available under the Convention.

**(b) Photo-resist and anti-reflective coatings for semi-conductors; etching agent for compound semi-conductors and ceramic filters:**

Based on the steadily declining use of PFOS, its salts and PFOSF for semi-conductors (photo-resist and anti-reflective coatings for semi-conductors; etching agent for compound semi-conductors and ceramic filters) and the commercial availability of alternatives, the Committee recommends that the acceptable purpose for the use of PFOS, its salts and PFOSF for photo-resist and anti-reflective coatings for semi-conductors and as etching agent for compound semi-conductors and ceramic filters no longer be available under the Convention.

**(c) Aviation hydraulic fluids:**

Based on the assessment and the availability of alternatives and the withdrawal of a number of Parties from the Register of acceptable purposes, the Committee recommends that the acceptable purpose for the use of PFOS, its salts and PFOSF for aviation hydraulic fluids no longer be available under the Convention.

**(d) Metal plating (hard metal plating) only in closed-loop systems:**

Based on the availability of alternatives for PFOS, its salts and PFOSF for metal plating (hard metal plating) only in closed-loop systems and their assessment, the fact that some Parties have indicated that the use of PFOS is either declining or has been completely phased out, while others have indicated a continued need for the use of PFOS, the Committee recommends that the use of PFOS, its salts and PFOSF for metal plating (hard metal plating) only in closed-loop systems be amended from an acceptable purpose to a specific exemption.

**(e) Certain medical devices (such as ethylene tetrafluoroethylene copolymer (ETFE) layers and radio-opaque ETFE production, in vitro diagnostic medical devices, and CCD colour filters):**

Based on its assessment, the Committee concluded that alternatives for the use of PFOS, its salts and PFOSF for certain medical devices are available and therefore recommends that the use of PFOS, its salts and PFOSF for certain medical devices (such as ethylene tetrafluoroethylene copolymer (ETFE) layers and radio-opaque ETFE production, in vitro diagnostic medical devices, and CCD colour filters) no longer be available under the Convention.

**(f) Fire-fighting foam:**

The assessment indicated that alternatives to PFOS-based fire-fighting foam are readily available in many countries and have been demonstrated to be technically feasible and economically viable but some have potential negative environmental and health impacts. On that basis, the Committee recommends that the acceptable purposes for the production and use of PFOS, its salts and PFOSF for fire-fighting foam be amended to a specific exemption for the use of fire-fighting foam for liquid fuel vapour suppression and liquid fuel fires (Class B fires) already in installed systems, including both mobile and fixed systems, and with the same conditions specified in paragraphs 2 (a)-(d) and 3 of the annex to decision POPRC-14/2 on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds;

The Committee recognized that a transition to the use of short-chain per- and polyfluoroalkyl substances (PFASs) for dispersive applications such as fire-fighting foam is not a suitable option from an environmental and human health point of view and that some time may be needed for a transition to alternatives without PFASs.

**(g) Insect bait for control of leaf-cutting ants from *Atta* spp. and *Acromyrmex* spp.:**

The assessment of the use of alternatives to PFOS, its salts and PFOSF showed dissenting views on the need to use sulfluramid for combating leaf-cutting ants, the availability of alternatives, technical and economic feasibility and operational effectiveness of those alternatives;

The Committee discussed both the lack of clarity in the text of Annex B listing PFOS, its salts and PFOSF (as sulfluramid is not explicitly mentioned in the use entry) and the current widespread use of sulfluramid. Based on those discussions, the Committee suggests including “sulfluramid (CAS No: 4151-50-2)” in the entry for the listed acceptable purpose and specifying that the current acceptable purpose is meant for agricultural use only;

The Committee therefore recommends that the acceptable purpose be maintained and that the text of the use entry in the Annex be clarified as follows: “Insect baits with sulfluramid (CAS No:

4151-50-2) as an active ingredient for control of leaf-cutting ants from *Atta* spp. and *Acromyrmex* spp. for agricultural use only";

The Committee encourages additional research and development of alternatives and, where alternatives are available, that they be used;

The Committee further encourages Parties to consider monitoring activities for sulfluramid, PFOS and other relevant degradation products in the different environmental compartments (soil, groundwater, surface water) of the application sites.

## B. Specific exemptions

### (a) Photo masks in the semiconductor and liquid crystal display (LCD) industries:

The industry has largely phased out the use of PFOS, its salts and PFOSF from this use. Therefore, the Committee recommends that the specific exemption for the use of PFOS, its salts and PFOSF for photo masks in the semiconductor and liquid crystal display (LCD) industries no longer be available under the Convention.

### (b) Metal plating (hard metal plating) and metal plating (decorative metal plating):

For metal plating (hard metal plating) and metal plating (decorative plating), it is noted that for a number of Parties, the notification has expired or been withdrawn. While there is uncertainty over the potential for conversion of Cr(VI) to Cr(III), based on the availability of viable alternatives, and the use of Cr(III) techniques in the case of decorative plating, the Committee recommends that the specific exemptions for the use of PFOS its salts and PFOSF for metal plating (hard metal plating) and metal plating (decorative metal plating) no longer be available under the Convention.

### (c) Electric and electronic parts for some colour printers and colour copy machines:

PFOS, its salts and PFOSF for these uses has been largely phased out. This indicates that alternatives to PFOS are available and widely used. Therefore, the Committee recommends that the specific exemption for the use of PFOS, its salts and PFOSF for electric and electronic parts for some colour printers and colour copy machines no longer be available under the Convention.

### (d) Insecticides for control of red imported fire ants and termites:

A range of chemical and non-chemical alternatives have been identified and it is indicated that these are widely available and technically feasible. These alternatives have been widely used. The Committee recommends that the specific exemption for the use of PFOS, its salts and PFOSF for insecticides for the control of red imported fire ants and termites no longer be available under the Convention.

### (e) Chemically driven oil production:

The assessment showed that alternatives are widely available. Given the use of alternatives to PFOS, its salts and PFOSF in most oil-producing areas, the Committee recommends that the specific exemption for the use of PFOS, its salts and PFOSF for chemically driven oil production no longer be available under the Convention.

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Ms. Ajeng Arum Sari (Indonesia)

Mr. Akihiko Ikegawa (Japan)

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Mr. Luiz Carlos Forti (Leaf-Cutting Ant Baits Industries Association (ABRAISCA))

Mr. Ricardo Edson Merino (Leaf-Cutting Ant Baits Industries Association (ABRAISCA))

# Annex III

## Workplan for the preparation of a risk management evaluation during the intersessional period between the fourteenth and fifteenth meetings of the Committee

| *Scheduled date* | *Interval between activities (weeks)* | *Activity (for each chemical under review)* |
|---|---|---|
| 21 September 2018 | – | The Committee establishes an intersessional working group |
| 28 September 2018 | 1 | The Secretariat requests Parties and observers to provide the information specified in Annex F for a risk management evaluation |
| 26 November 2018 | 8 | Parties and observers submit the information specified in Annex F for a risk management evaluation to the Secretariat |
| 14 January 2019 | 7 | The working group chair and the drafter complete the first draft |
| 28 January 2019 | 2 | The members of the working group submit comments on the first draft to the chair and the drafter |
| 11 February 2019 | 2 | The working group chair and the drafter finish their review of the comments from the working group and complete the second draft and a compilation of responses to those comments |
| 18 February 2019 | 1 | The Secretariat distributes the second draft to Parties and observers for comments |
| 1 April 2019 | 6 | Parties and observers submit their comments to the Secretariat |
| 6 May 2019 | 5 | The working group chair and the drafter review the comments from Parties and observers and complete the third draft and a compilation of responses to those comments |
| 13 May 2019 | 1 | The Secretariat sends the third draft to the working group |
| 29 May 2019 | 2 | The members of the working group submit their final comments on the third draft to the chair and the drafter |
| 12 June 2019 | 2 | The working group chair and the drafter review the final comments and complete the fourth (final) draft and a compilation of responses to those comments |
| 17 June 2019 | <1 | The Secretariat sends the final draft to the Division of Conference Services, United Nations Office at Nairobi, for editing and translation |
| 12 August 2019 | 8 | The Division of Conference Services completes the editing and translation of the final draft |
| 19 August 2019 | 1 | The Secretariat distributes the final draft in the six official languages of the United Nations |
| 30 September – 4 October 2019 | 6 | Fifteenth meeting of the Committee |

# 附錄二、全氟己烷磺酸(PFHxS)風險資訊

UNITED
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UNEP/POPS/POPRC.14/6/Add.1

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Stockholm Convention
on Persistent Organic
Pollutants

**Persistent Organic Pollutants Review Committee**
**Fourteenth meeting**
Rome, 17–21 September 2018

# Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting

## Addendum

## Risk profile on perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds

### Note by the Secretariat

At its fourteenth meeting, by its decision POPRC-14/1, the Persistent Organic Pollutants Review Committee adopted a risk profile on perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds on the basis of the draft contained in the note by the Secretariat (UNEP/POPS/POPRC.14/2), as revised during the meeting. The text of the risk profile as adopted is set out in the annex to the present addendum. It has not been formally edited.

**Annex**

# Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds

# RISK PROFILE

**September 2018**

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# Executive summary

1. The POPs Review Committee at its thirteenth meeting concluded that perfluorohexane sulfonic acid (PFHxS) fulfilled the screening criteria in Annex D and decided that issues related to the inclusion of PFHxS salts and PFHxS-related compounds that potentially degrade to PFHxS should be dealt with in developing the draft risk profile (decision POPRC-13/3). The substances covered in this risk profile include PFHxS (CAS No: 355-46-4), its salts and PFHxS-related compounds, defined as any substances that contain the chemical moiety $C_6F_{13}SO_2$ as one of their structural elements and that potentially degrade to PFHxS.

2. PFHxS, its salts and PFHxS-related compounds are or have been widely used in fire-fighting foams, as surfactants, in metal plating as well as in cleaning, waxing, polish and other surface treatment products, and/or water- and stain-protective coatings for carpets, paper, leather and textiles, in many cases as a replacement for PFOS. In addition, PFHxS, its salts and related compounds have been used in certain per- and poly-fluoroalkyl substances (PFASs) based consumer products. PFHxS are and have been unintentionally produced during the electrochemical fluorination (ECF) processes of some other PFASs.

3. Historically, 3M was most likely the main manufacturer of PFHxS, its salts and PFHxS-related compounds with an annual production of about 227 tonnes of the parent compound perfluorohexane sulfonyl fluoride (PFHxSF) in the US in 1997. Current manufacturers of PFHxS, its salts and PFHxS related compounds include at least one producer in Italy and a few producers located in China. Information in the public domain on the current production and historic volumes of PFHxS, its salts and PFHxS-related compounds is very limited.

4. Limited research has been conducted on releases of PFHxS, its salts and PFHxS-related compounds to the environment. In general terms, releases to the environment occur from the production of the parent compound (i.e. PFHxSF) and its derivatives (i.e. PFHxS, its salts and PFHxS-related compounds), during processing, use and disposal, as well as from consumer products containing the derivatives. Release of PFHxS and perfluorohexane sulfonamides (FHxSA) from consumer products is documented by their detection in indoor dust and in wastewater, sludge and leachate from landfills and releases due to use of aqueous film-forming foams (AFFFs) containing PFHxS and PFHxS-related compounds such as FHxSA.

5. PFHxS is extremely persistent in the environment. Numerous studies have reported elevated levels of PFHxS in soil, water and a variety of biota. Contamination with PFHxS is especially apparent in the vicinity of fire-fighting training areas as a result of the historical (and ongoing) use of PFHxS-containing foams. The perfluoroalkyl moiety $C_nF_{2n+1}$- in general is very resistant to chemical, thermal and biological degradation due to its strong carbon-fluorine (C-F) bonds. Based on a read-across approach from the conclusions applied to the persistence of perfluorobutansulfonic acid (PFBS), PFOS and PFOA, it can be concluded that PFHxS is not degradable under natural conditions and is very persistent in water, soil and sediment. Due to the combined hydrophilic and hydrophobic properties as well as the high acid dissociation of PFHxS (pKa ≈ -5.8 to -3.3), it is very challenging to experimentally measure log $K_{ow}$ of the undissociated acid. It should be noted that PFHxS is present in its anionic form under environmental conditions due to its low pKa. Furthermore, the PFHxS ion is relatively water-soluble and it binds to proteins in target organisms. In fish, the substance is not expected to be accumulated by the organism but excreted rather rapidly via the gills, resulting in bioaccumulation factors (BAFs)/bioconcentration factors (BCFs) under the Annex D criteria of 5000. Based on the identified protein-binding associated bioaccumulation, standard BCF/BAF in aquatic organisms are less meaningful descriptors for bioaccumulation for PFASs including PFHxS. However, biomagnification does occur, with biomagnification factors (BMFs) and trophic magnification factors (TMFs) $>1$ (BMF range 1.4–48 and TMF range 0.1–4.3) available for PFHxS, including from the organisms in the Arctic food chains. The estimated serum elimination half-life of PFHxS in humans is higher than other PFASs with an average of 8.5 (range 2.2-27 years).

6. PFHxS is distributed in the environment including in urban cities, rural areas and in regions that produce or use PFHxS or its precursors in the processing or manufacture of commercial products. It is also found in Arctic regions far away from any sources of release. Worldwide monitoring of water, air, sediment and biota (including humans) at remote locations have detected the presence of PFHxS. At Svalbard, Norway, an annual change has been observed in PFHxS levels in polar bears most likely due to transport through water and air to the Arctic. The highest levels of PFHxS measures in biota, are found in polar bears. Direct transport through ocean currents is likely the main mechanism of transport to remote regions, in addition to atmospheric transport of PFHxS and its precursors.

PFHxS has been detected in air, snow, meltwater, rainwater and lichen, indicating that atmospheric transport of precursors that may degrade to PFHxS locally, has occurred. Furthermore, PFHxS as well as FHxSA have been detected in leachates from landfills receiving waste from many sources, indicating possible uses of PFHxS precursors in consumer products.

7. Exposure of the general population takes place by consumption of food, drinking water, by inhalation of indoor air and respiratory and oral uptake of dust containing PFHxS, its salts and PFHxS-related compounds. PFHxS has been detected in human blood and breast milk in many regions, and is together with perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA) and perfluorononanoic acid (PFNA) one of the most frequently detected and predominant PFASs in human blood. The foetus is exposed to PFHxS via the umbilical cord blood, and breast milk may be an important source of exposure for the infant. In women post-menarche and males, PFHxS levels increase with age, and in general, the highest levels have been observed in men.

8. In regions where regulations and phase-outs have been implemented, human concentrations of PFOS, perfluorodecane sulfonic acid (PFDS), and PFOA are generally declining, while previously increasing concentrations of PFHxS have begun to level off. However, there are also observations of no decline or increasing levels of PFHxS in the same regions, most often connected to households receiving PFHxS contaminated drinking water, but in a few cases also in individuals that get their exposure from unknown sources. Limited data are available on levels and trends of PFHxS in humans in Asia where production continued after the 3M phase out.

9. PFHxS affects liver function, lipid and lipoprotein metabolism and activates the peroxisome proliferating receptor (PPAR)-alpha. In studies on rodents, increased liver weight as well as marked hepatocellular hypertrophy, steatosis and necrosis have been observed. Furthermore, alterations in serum cholesterol, lipoproteins, triglycerides, and alkaline phosphatase have been observed in rodents after PFHxS exposure. Effects on lipid metabolism and serum enzymes has been observed in human epidemiology studies. Effects on reproduction (decreased live litter size) have been observed in mice after PFHxS exposure. PFHxS binds to the thyroid transport protein, and has been associated with changes in serum thyroid hormones across species. Some evidence suggests that exposure to PFHxS may affect the developing brain and immune system. Effect on the antibody response to vaccination has been shown in epidemiology studies.

10. PFHxS is ubiquitous in environmental compartments such as surface water, deep-sea water, drinking water, waste-water treatment plants and leachates from landfills, sediment, groundwater, soil, the atmosphere, dust, as well as biota (including wildlife), and humans globally. PFHxS is persistent, bioaccumulative, toxic to animals including humans and transported to locations far from its production and use. Therefore, it is concluded that PFHxS, its salts and PFHxS-related compounds are likely, as a result of their long-range environmental transport, to lead to adverse human health and/or environmental effects such that global action is warranted.

## 1. Introduction

11. In May 2017, Norway submitted a proposal to list perfluorohexane sulfonic acid (PFHxS), its salts and related compounds in Annexes A, B and/or C to the Convention. The proposal (UNEP/POPS/POPRC.13/4) was submitted in accordance with Article 8 of the Convention, and reviewed by the POPs Review Committee (POPRC) at its thirteenth meeting in October 2017.

12. PFHxS, its salts and PFHxS-related compounds belong to the per- and poly-fluoroalkyl substances (PFAS) group. PFASs consist of carbon chains of different chain length, where the hydrogen atoms are completely (perfluorinated) or partly (polyfluorinated) substituted by fluorine atoms (Buck et al., 2011). The very stable bond between carbon and fluorine is only breakable with high energy input (see also 2.2.1 Persistence). Therefore, substances like PFHxS are not degradable in the environment. However, PFHxS-related compounds can degrade to PFHxS under environmental conditions and are therefore known as precursors. A number of PFHxS-related substances including some polymers, have been identified (See section 2.1.1 and 2.1.2; Norwegian Environment Agency, 2017a, M-792/2017; OECD 2018; http://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/) and included in the proposal submitted by Norway (UNEP/POPS/POPRC.13/4).

13. The read-across approach has been applied mainly for the persistence criteria in this document. Guidance from the European Chemical Agency (ECHA, 2017c) and from the Organisation for Economic Co-operation and Development (OECD, 2014) has been used in terms of the definition of grouping of substances and use of the approach. In general, the read-across approach can be applied for substances of which physico-chemical and/or toxicological and/or ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity. PFHxS belongs to a group of PFASs of which several similar substances already have been assessed with respect to their

POP- or persistent, bioaccumulation and toxicity properties. The substances in this group have a highly similar chemical structure with a perfluorinated carbon chain and a terminal acid group, sulfonic acid (PFSA) or carboxylic acid (PFCA), which justifies the use of read-across. It is clearly stated in the present document when the read-across approach has been applied.

## 1.1 Chemical Identity

14. The proposed compounds included in the nomination of PFHxS, its salts and PFHxS-related compounds were defined in document UNEP/POPS/POPRC.13/4 and in decision POPRC-13/3 (UNEP/POPS/POPRC.13/7). In line with decision POPRC-13/3, the following apply:

(a) Perfluorohexane sulfonic acid (CAS No: 355-46-4, PFHxS);

(b) Any substance that contains the chemical moiety $C_6F_{13}SO_2$- as one of its structural elements and that potentially degrades to PFHxS.

15. A number of chemicals are included in the group of PFHxS, its salts and PFHxS-related compounds including isomers. Some examples are given in Figure 1. The OECD has identified 72 PFHxS-related/precursor/polymer substances including PFHxS (CAS No: 355-46-4) (see Appendix 1 in UNEP/POPS/POPRC.14/INF/4) which all contain the fluorinated alkyl moiety $C_6F_{13}SO_2$ (OECD 2018; http://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/). A study published by the Norwegian Environment Agency identified 79 commercially available compounds, including PFHxS and PFHxSF, based on a literature study and a theoretical assessment of abiotic degradation pathways leading to PFHxS (Norwegian Environment Agency, 2017a, M-792/2017; Appendix 2 in UNEP/POPS/POPRC.14/INF/4).

a) Perfluorohexanesulfonic acid (CAS No:

b) Perfluorohexanesulfonyl fluoride (CAS No: 423-50-7)

c) Perfluorohexanesulfonate ammonium salt (CAS No: 68259-08-5)

d) Potassium N-ethyl-N-[(tridecafluorohexyl)sulfonyl] glycinate (CAS No: 67584-53-6)

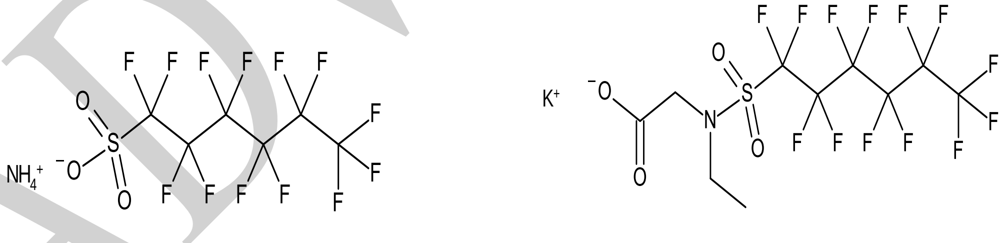

**Figure 1.** Structural formula for PFHxS (a), its raw material PFHxSF (b), and examples of its related compounds PFHxSNH$_4$ (c) and potassium N-ethyl-N-[(tridecafluorohexyl) sulfonyl] glycinate (d). Non-exhaustive lists of compounds are given in UNEP/POPS/POPRC.14/INF/4.

16. PFHxS is a strong acid with six fully fluorinated carbons, having both hydrophobic- and hydrophilic properties (Kissa, 2001). Experimental data on the physicochemical properties of PFHxS are limited (Kim et al., 2015), however, some studies (Wang et al., 2011; Ding and Peijnenburg, 2013; Kim et al., 2015) have reported some empirical and estimated physicochemical properties of PFHxS and its related compounds

17. Table 1 below lists the chemical identity of PFHxS, and Table 2 lists selected modelled and experimental physico-chemical properties for PFHxS.

**Table 1. Chemical identity of PFHxS**

| | |
|---|---|
| CAS number: | 355-46-4 |
| IUPAC name: | 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexane-1-sulfonic acid |
| EC number: | 206-587-1 |
| EC name: | Perfluorohexane-1-sulfonic acid |
| Molecular formula: | $C_6F_{13}SO_3H$ |
| Molecular weight: | 400.11 |
| Synonyms: | PFHxS<br>PFHS<br>Perfluorohexanesulfonic acid;<br>1,1,2,2,3,3,4,4,5,5,6,6,6-Tridecafluorohexane-1-sulfonic acid;<br>Tridecafluorohexane-1-sulfonic acid;<br>1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-;<br>1,1,2,2,3,3,4,4,5,5,6,6,6-Tridecafluoro-1-hexanesulfonic acid;<br>Tridecafluorohexanesulfonic acid |
| Trade names | RM70 (CAS No: 423-50-7), RM75 (3871-99-6), and RM570 (CAS No: 41997-13-1) (PFHxS-related substances produced by Miteni SpA, Italy).<br>FC-95 Fluorad brand fluorochemical surfactant (CAS No: 3871-99-6). Contains PFHxS-K produced by 3M. |

**Table 2. Overview of selected physicochemical properties for PFHxS**

| **Property** | **Value** | **Reference** |
|---|---|---|
| Physical state at 20°C and 101.3 kPa | Solid white powder for PFHxSK | As referenced in ECHA, 2017a (Company provided) |
| Melting point | 320 K (41°C) | Kim et al., 2015 |
| Boiling point | 238–239°C | Kosswig, 2000 (measured) |
| p$K_a$ | -3.45<br>-3.3±0.5<br>-5.8±1.3 | Wang et al., 2011 (COSMOtherm)<br>ACD/Percepta 14.2.0 (Classic)<br>ACD/Percepta 14.2.0 (GALAS) |
| Vapour pressure | 58.9 Pa (0.0046 mmHg) | Wang et al., 2011(COSMOtherm)* |
| Water solubility | 1.4 g/L (PFHxSK; 20–25°C)<br>2.3 g/L (non-dissociated) | Campbell et al., 2009 (measured)<br>Wang et al., 2011 (COSMOtherm)* |
| Air/water partition coefficient, $K_{aw}$ (log value) | -2.38 | Wang et al., 2011 (COSMOtherm)* |
| n-Octanol/water partition coefficient, $K_{ow}$ (log value) | 5.17 | Wang et al., 2011 (COSMOtherm)* |
| Octanol-air partition coefficient $K_{oa}$ (log value) | 7.55 | Wang et al., 2011 (COSMOtherm)* |
| Organic carbon/water partition coefficient $K_{oc}$ (log value) (mobility) | 2.05<br>2.40<br>2.31 (range 1.8–2.76) | Guelfo and Higgins, 2013 (measured)<br>D'Augostino & Mabury, 2017 (measured)<br>Chen et al., 2018 field-based |

* Estimates from Wang et al. (2011) refer to the neutral form of PFHxS only. It should be noted that PFHxS is present in its anionic form under environmental conditions due to its low pKa. Therefore, to describe partitioning of both the neutral and ionized species of PFHxS in the environment, estimated partition coefficients of the neutral form need to be converted to respective distribution ratios, as suggested in Schwarzenbach et al. (2002) and Wang et al. (2011).

18. As discussed in ECHA 2017a, the experimental determination of partition coefficients is difficult because of the surface-active properties of the ionic PFSAs. The presence of ionic PFSAs depends on the dissociation of PFSAs in aqueous media. There are models available, e.g. COSMOtherm that are used to calculate partition coefficients of neutral PFASs. COSMOtherm is a quantum chemistry-based method that requires no specific calibration and is the method used in Wang et al., 2011. Therefore, COSMOtherm is expected to be able to estimate properties for PFSAs and PFCAs. Studies have shown that properties estimated with COSMOtherm showed good agreement with the experimental data for a number of PFASs (Arp et al., 2006; Wang et al., 2011).

## 1.2 Conclusion of the POPs Review Committee regarding Annex D information

19. The POPs Review Committee evaluated the proposal by Norway to list PFHxS, its salts and PFHxS-related compounds under the Convention as well as additional scientific information provided by members and observers at its thirteenth meeting. The committee concluded that PFHxS met the screening criteria specified in Annex D (decision POPRC-13/3). It was decided to review the proposal further and to prepare a draft risk profile in accordance with Annex E to the Convention and that issues related to the inclusion of PFHxS salts and PFHxS-related compounds that potentially degrade to PFHxS should be dealt with in developing the draft risk profile.

## 1.3 Data sources

20. The draft risk profile is based on the following data sources:

(a) The proposal to list perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds submitted by Norway (UNEP/POPS/POPRC.13/4);

(b) Information submitted by the following Parties and observers according to Annex E to the Convention: Australia, Canada, Denmark, Ecuador, Germany, Japan, Monaco, The Netherlands, Sweden, The United Kingdom, The United States, Alaska Community Action on Toxics and International POPs Elimination Network (ACAT/IPEN), Council of Chemists of the Province of Treviso, FluoroCouncil, Basel and Stockholm Conventions Regional Centre in China;

(c) The supporting documents for the identification of PFHxS as a Substance of Very High Concern (SVHC) in the European Union prepared by Sweden, where PFHxS was recently identified as very persistent and very bioaccumulative (vPvB) (ECHA, 2017a, b);

(d) Peer-reviewed scientific journals, as well as information from reports and other grey literature;

(e) The Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) various tier II assessments for perfluoroalkane sulfonates ($C_5$–$C_7$) (NICNAS, 2017a, b, c, d);

(f) AMAP, 2017. AMAP Assessment 2016: Chemicals of Emerging Arctic Concern. Arctic Monitoring and Assessment Programme (AMAP), Oslo, Norway. xvi+353pp.

## 1.4 Status of the chemical under national regulations and international forums

21. In 2017, PFHxS and its salts were identified as Substances of Very High Concern (SVHC) and added to the REACH Candidate List due to their persistent and bioaccumulative properties (ECHA, 2017a). Toxicity and ecotoxicity have not been evaluated in the SVHC evaluation process. Inclusion on this list means that the substances can be subject to an authorization procedure under which the substances can only be used for specific authorized purposes under strictly controlled conditions. Moreover, upon request industry is obliged to inform consumers on the occurrence of the listed substances in consumer articles above a concentration of 0.1%.

22. In Norway, PFHxS, its salts and PFHxS-related compounds was recently added to the national list of priority substances (Prioritetslista http://www.miljostatus.no/prioritetslisten) with a national goal to phase out the use by 2020. Some PFHxS-related substances are listed on the Canadian Domestic Substances List (DSL) (Environment Canada, 2013), an inventory of substances manufactured in, imported into or used in Canada on a commercial scale. Any person who intends to import or manufacture a substance in Canada that is not listed on the DSL (such as PFHxS or PFHxSF) must submit a notification required under the New Substances Notification Regulations. These regulations ensure that new substances are not introduced into the Canadian marketplace before undergoing ecological and human health assessments. Management measures may be imposed under this process to mitigate any risks to the environment or human health. In the United States new uses of the chemicals in this group are prohibited without prior approval from the United States Environmental Protection Agency (US EPA) (United States Government, 2002; 2007). The US EPA published an action plan on long-chain PFASs, including PFHxS, and their salts and precursors in 2009. All chemicals were identified as persistent, bioaccumulative and toxic (US EPA, 2009). In Australia NICNAS has developed an action plan for assessment and management of chemicals which may degrade to PFCAs, PFASs, and similar chemicals. The primary assumption outlined in this action plan is that chemicals with a perfluorinated chain terminated by a sulfonyl group will degrade to the perfluoroalkyl sulfonate (of the same chain length) (NICNAS 2017, a, b, c or d).

23. Perfluorinated chemicals were identified under the Strategic Approach to International Chemicals Management (SAICM) as an issue of concern. Efforts are focused on gathering and

exchanging information on perfluorinated chemicals and to support the transition to safer alternatives (http://www.saicm.org/tabid/5478/Default.aspx).

24. OECD provided a recent overview on risk reduction approaches for PFASs across countries (OECD, 2015). Responses from participating countries indicated that risk reduction approaches for PFASs are mainly covered under existing national and/or regional regulatory frameworks and cover principally long chain PFASs and their precursors and salts. The type of risk reduction approaches implemented across countries varies, but there is often a combination of voluntary and regulatory approaches that are used.

25. No harmonized classification or labelling is available for PFHxS in EU or globally. However, in Australia PFHxS-related compounds are included in the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, which includes both human health and environmental assessments (NICNAS 2017c). Based on the NICNAS action plan to assess and manage chemicals which may degrade to perfluorinated carboxylic acids, perfluoroalkyl sulfonates and similar chemicals, where chemical specific data was not available, the perfluorooctane sulfonate (PFOS) hazard information was used to estimate the systemic health hazard of potassium PFHxS, ammonium PFHxS, diethanolammonium PFHxS and PFHxSF. In relation to human health risks, potassium PFHxS, ammonium PFHxS, diethanolammonium PFHxS and PFHxSF were identified as: toxic if swallowed - Cat. 3 (H301), causes serious eye irritation - Cat. 2A (H319), causes damage to organs through prolonged or repeated exposure if swallowed - Cat. 1 (H372), suspected of causing cancer - Cat. 2 (H351) using the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). In EU, self-classifications have been submitted by industry with the notification to the C&L inventory under the EU legislation, for PFHxS and several PFHxS-related substances for acute Tox. 4 and Skin Corr. 1B, STOT SE 3 (inhalation, lung), Skin Irrit.2, Eye Irrit. 2 (https://www.echa.europa.eu/en/information-on-chemicals/cl-inventory-database).

# 2. Summary of the information relevant to the risk profile

## 2.1 Sources

### 2.1.1 Production, trade, stockpiles

26. As with PFOS, its salts and PFOS-related compounds, PFHxS, its salts and PFHxS-related compounds have been produced from a common parent compound, perfluorohexane sulfonyl fluoride (PFHxSF). PFHxSF may be intentionally produced from the ECF of hexanesulfonyl chloride ($C_6H_{13}SO_2Cl + 14\ HF \rightarrow C_6F_{13}SO_2F + HCl$ + byproducts) with a yield of about 36% (Gramstad and Haszeldine, 1957).

27. In addition, PFHxSF may be unintentionally produced as a byproduct from the ECF of octanesulfonyl fluoride or chloride, the process to produce perfluorooctane sulfonyl fluoride (POSF) (Gramstad and Haszeldine, 1957; Jiang et al., 2015). Unless manufacturers remove PFHxSF from POSF, it would stay in POSF and also react with reactants to form PFHxS, its salts and/or PFHxS-related compounds as byproducts in PFOS and its related compounds, as shown in, e.g., 3M, 2015; Herzke et al., 2012; Huang et al., 2015. It is likely that the ratios of PHxSF yields to POSF yields in the production of POSF are between 4% (Gramstad and Haszeldine, 1957) and 14.2% (reported by a Chinese manufacturer; Ren, 2016). This is supported by measured ratios of PFHxS to PFOS in commercial PFOS product, namely 3.5%–9.8% in 3M's FC-95 (3M, 2015) and 11.2%–14.2% in three products from China (Jiang et al., 2015). Of the PFHxS impurities from the 3M ECF production process for PFOS also branched isomers of PFHxS were detected e.g. 18% branched from 4.7% PFHxS impurity in one lot (Benskin et al., 2010).

28. PFHxS and its salts may be produced after the hydrolysis of PFHxSF (Gramstad and Haszeldine, 1957). As with POSF (3M, 1999), PFHxSF may be further reacted with methyl- or ethylamine to form N-methyl or N-ethyl perfluorohexane sulfonamide (N-MeFHxSA or N-EtFHxSA), which may subsequently react with ethylene carbonate to yield N-methyl or N-ethyl perfluorhexane sulfonamido ethanols (N-MeFHxSE or N-EtFHxSE). N-MeFHxSA, N-EtFHxSA, N-MeFHxSE and N-EtFHxSE may be used as the building blocks of PFHxS-related compounds (3M, 1999).

29. The information on the production of PFHxS, its salts and PFHxS-related compounds is scarce in the public domain and mostly qualitative rather than quantitative. However, the substances are produced- and available on the world market and some of the substances (CAS Nos: 423-50-7; 355-46-4; 3871-99-6; 68259-08-5; 41997-13-1; 68259-15-4; 34455-03-3) are reported to the EU classification and labelling inventory notification system (C & L Inventory, https://echa.europa.eu/information-on-chemicals), which shows that substances are produced, used and/or imported to the European market. However, after the final deadline for registration of

substances exceeding a 1000 kg under REACH, no PFHxS related substances are registered (ECHA database) i.e. are not produced or used in the EU above 1 tonne. Furthermore, it is noted that PFHxS, its salts and many PFHxS-related compounds have been listed on multiple national chemical registration inventories (see UNEP/POPS/POPRC.14/INF/4, Table 2 and Annex 1), indicating historical production, importation and/or uses of products containing these substances, historically and/or ongoing. Historically, 3M was likely the biggest global manufacturer of PFHxS, its salts and PFHxS-related compounds, with an annual production of about 227 tonnes of PFHxSF in the US in 1997 (3M, 2000a); in 2000–2002, 3M ceased its production of PFHxS, its salts and PFHxS-related compounds (3M, 2000a). Further historical and/or current manufacturers or suppliers of PFHxS, its salts and PFHxS-related compounds include at least Miteni from Italy (Miteni, 2018) as well as Hubei Hengxin (Hengxin, 2018), Wuhan Defu (Defu, 2018), Wuhan Yangtze River (Yangtze River, 2018), Wuhan Fengfan (Huang et al., 2015), Shanghai Vatten (Vatten, 2018; Huang et al., 2015) and Time Chemical (Time, 2018) from China.

30. In 2016 Fu et al. reported that the annual productions of PFOS and PFHxS at Hengxin Chemical Plant (Yingcheng, Hubei province, China) were approximately 60 and 0 tonnes in 2008, respectively. The production of PFOS was considerably reduced after PFOS was restricted in 2009 by the Stockholm Convention, and PFHxS then became a new product of the plant. The annual production volumes of PFOS from 2009 to 2011 were 30, 10, and 10 tonnes, respectively, whereas those of PFHxS were 10, 10 and 30 tonnes, respectively. Furthermore, it was reported that in 2012, the plant expanded the annual production of PFOS to 65 tonnes and ceased PFHxS production in light of changing market requirements. Simultaneously, the synthesis of PFHxS-based fabric finishing agent continued in 2012 using the PFHxS in stock (Fu et al., 2016).

31. Using market research reports for PFHxS (CAS No: 355-46-4) and PFHxSF (CAS No: 423-50-7), review of peer-reviewed literature and other information sources in the public domain, and stakeholder consultations, the Norwegian Environment Agency (Report M-961/2018) performed a project to shed light on the sources to PFHxS in the environment. Information on the global production and use of PFHxS, its salts and related compounds and content in consumer products were collected. Across all evaluated sources of information as well as from consultation of stakeholders, such as possible manufacturers and producers of consumer products, it was found that there is a lack of publicly available information on the quantitative production levels and descriptions of product-specific uses of PFHxS and PFHxS-related compounds. There was also a lack of willingness from stakeholders to release such information. In addition, the quality of the market research reports is questionable and did not cover the global producers since only two producers in China were reflected in the reports. Historical production or import of PFHxS, its salts and PFHxS-related compounds in the United States is extracted from the US Toxic Substances Control Act (TSCA) Inventory Update Reporting Database and summarized in Table 3 below. In addition, an OECD survey in 2004 reported that <4000 kg of PFHxSF, <1500 kg of PFHxS, and <600 kg of FHxSA were produced in 2003 in Italy (OECD, 2005). Similarly, the subsequent two OECD surveys reported the production of some PFHxS, its salts and PFHxS-related compounds, but with no information on their respective production volumes and locations (OECD, 2006, 2010).

**Table 3. Overview of PFHxS salts and PFHxS-related compounds manufactured or imported in the US (source: US TSCA Inventory Update Reporting)**

| **CAS number** | **Chemical** | **Reporting years (in tonnes)** | | | | |
|---|---|---|---|---|---|---|
| | | **1986** | **1990** | **1994** | **1998** | **2002** |
| 423-50-7 | PFHxSF | 4.5–226 | 4.5–226 | No Reports | 4.5–226 | No Reports |
| 3871-99-6 | PFHxSK | No Reports | 4.5–226 | No Reports | No Reports | No Reports |
| 34455-03-3 | EtFHxSE | 4.5–226 | 4.5–226 | 4.5–226 | 4.5–226 | No Reports |
| 50598-28-2 | FHxSA-derivative | No Reports | 4.5–226 | 4.5–226 | 4.5–226 | 10–500 |
| 68555-75-9 | MeFHxSE | 4.5–226 | 4.5–226 | 4.5–226 | 4.5–226 | No Reports |
| 67584-57-0 | MeFHxSE-acrylate | 4.5–226 | 4.5–226 | 4.5–226 | 4.5–226 | No Reports |
| 38850-58-7 | FHxSA-derivative | 4.5–226 | > 226–450 | 4.5–226 | No Reports | No Reports |
| 73772-32-4 | FHxSA-derivative | No Reports | No Reports | No Reports | 4.5–226 | No Reports |
| 68815-72-5 | PFHxS-ester | 4.5–226 | 4.5–226 | 4.5–226 | 4.5–226 | No Reports |

32. Despite being manufactured in a limited number of countries, PFHxS, its salts and PFHxS-related compounds have been distributed globally through the trade of products containing these substances, particularly some old generations of aqueous film-forming foams (AFFFs) that are previously known as "PFOS-based AFFFs" (for more details on such products, see the next section).

### 2.1.2 Uses

33. Due to the thermal and chemical stability as well as the hydro- and oleophobicity of the perfluoroalkyl moiety ($C_nF_{2n+1}$-), PFHxS, its salts and PFHxS-related compounds can be used as effective surfactants and/or surface protectors. PFHxS is found in elevated amounts in the environment and is used as one replacement for PFOS (Swedish Chemicals Agency, KEMI 2015; Chen et al., 2018a). In the light of information identified recently by the Norwegian Environment Agency (M-961/2018) and in other public sources, PFHxS, its salts and PFHxS-related compounds have been intentionally used at least in the following applications: (1) AFFFs for firefighting; (2) metal plating; (3) textiles, leather and upholstery; (4) polishing agents and cleaning/washing agents; (5) coatings, impregnation/proofing (for protection from damp, fungus, etc.); and (6) within the manufacturing of electronics and semiconductors. In addition, other potential use may include pesticides and flame retardants. Details on these identified uses and potential uses are elaborated below. Furthermore, it should be noted that information on the volumes and uses of many PFHxS, its salts and PFHxS-related compounds has been reported to the competent authorities in Denmark, Sweden and Norway, but most of such information has been claimed as confidential business information (SPIN, 2018; Norwegian Environment Agency M-961/2018).

**AFFFs for firefighting**

34. Historically, 3M used PFHxS in the production of its AFFF formulations (Olsen et al., 2005). According to Olsen et al., 3M produced PFHxS (or PFHS) as a building block for compounds incorporated in firefighting foams and this information is in accordance with patents from 3M (3M, 1972, 1973, 1992) and from another potential historical producer (reviewed in Norwegian Environment Agency M-961/2018). In particular, 3M (1992) indicates that PFHxS-related compounds and PFOS were likely used in the same AFFF formulations, i.e. previously known as “PFOS-based AFFFs” (e.g. FC-600). This is in good agreement with investigations of AFFF formulations, some of which were legacy formulations, where PFHxS-related compounds were identified (D’Agostino et al., 2014; Barzen-Hanson et al., 2017; Place and Field, 2012; Backe et al., 2013) and PFHxS was detected at 820 ± 140 mg/kg (Vecitis et al., 2010), 370 mg/L (Herzke et al., 2012), 500−1400 mg/L (Houtz et al., 2013), 20.0–1330 mg/L (Weiner et al., 2013), 760–1700 mg/L (Backe et al., 2013 and 0.2–1025.5 mg/kg (Favreau et al., 2017). It is also well supported by measurements of environmental media at AFFF-impact sites (Backe et al., 2013; Houtz et al., 2013; Baduel et al., 2017; Barzen-Hanson et al., 2017; Bräunig et al., 2017; Lanza et al., 2017) and by measurements of firefighters’ serum levels (Jin et al., 2011; Rotander et al., 2015), where similar or higher levels of PFHxS than that of PFOS were detected, and in some cases, elevated levels of PFHxS-related compounds were identified. It is possible that such “PFOS-based AFFFs” containing PFHxS-related compounds have been discontinued after 3M ceased its global production in 2000–2002 (3M, 2000a), however, production by companies other than 3M cannot be excluded. Furthermore, there may still be substantial stockpiles of such legacy AFFF formulations around the world (UN Environment, 2011; Zushi et al., 2017). Furthermore, Shanghai Vatten has recently developed and commercialized at least one new PFHxS-related amphoteric surfactant for foam fire-extinguishers (Vatten, 2018; Huang et al., 2015).

**Metal plating**

35. A number of patents (Dainippon, 1979, 1988; 3M, 1981; Hengxin, 2015) were identified for the use of PFHxS, its salts and various PFHxS-related compounds in metal plating as mist suppressants, suggesting that such use may have occurred. It is likely that at least Hubei Hengxin from China has marketed the potassium salt of PFHxS for metal plating (Hengxin, 2018). Furthermore, it should be noted that the manufacturing (including importing) or processing of one salt of PFHxS (tridecafluorohexanesulfonic acid, compound with 2,2'-iminodiethanol (1:1); CAS No: 70225-16-0) for use as a component of an etchant, including a surfactant or fume suppressant, used in the plating process to produce electronic devices shall not be considered a significant new use subject to reporting under the US EPA Significant New Use Rule on perfluoroalkyl sulfonates and long-chain perfluoroalkyl carboxylate chemical substances (US EPA, 2013).

**Textiles, leather and upholstery**

36. Historically, 3M used PFHxS-related compounds in some of its aftermarket (post-production) carpet protection products (Olsen et al., 2005), e.g., those carpet and upholstery protector containing FC-228 (ITEM, 2004). This is in accordance with the measured higher serum PFHxS concentrations (range 27.5–423 ng/mL) than that of PFOS (15.2–108 ng/mL), as well as highly elevated levels of PFHxS in household dust and carpets of a Canadian family, whose household carpets were treated 8 times with Scotchgard formulations over 15 years (Beesoon et al., 2012). It is possible that such aftermarket carpet and upholstery protector products produced by 3M have been discontinued after the company ceased its global production in 2000–2002 (3M, 2000a). However, it is reported that

water-proofing textile finishes based on PFHxS-related compounds have recently been developed by at least Hubei Hengxin Chemical Co., Ltd. (CAS No: 68259-15-4, (tridecafluoro-N-methylhexanesulfonamide); CAS No: 68555-75-9 (tridecafluoro-N-(2-hydroxyethyl)-N-methylhexanesulfonamide); and CAS No: 67584-57-0, (2-[methyl[(tridecafluorohexyl) sulfonyl]amino]ethyl acrylate)) and Wuhan Fengfan Surface Engineering Co., Ltd. from China (Huang et al., 2015; Hengxin, 2018), as alternatives to PFOS-based compounds (Huang et al., 2015). The industrial activities with C-6 waterproofing agent for textiles in the Taihu Lake region in China might be a potential source of PFHxS where recent production and use of PFHxS as an alternative to PFOS and PFOA has been reported (Ma et al., 2017).

**Polishing agents and cleaning/washing agents**

37. One PFHxS-related compound (CAS No: 67584-53-6, [N-Ethyl-N-(tridecafluorohexyl) sulfonyl]glycine, potassium salt) was reportedly used in polishing agents and cleaning/washing agents at least between 2000 and 2015 in Denmark, Norway and Sweden with the use volumes claimed as confidential business information (SPIN, 2018). For example, the FCP102 Floor Sealer and FCP300 Duro Gloss Floor Sealer & Finish from Fritztile contain this compound (Fritztile, 2018a,b).

**Coating and impregnation/proofing**

38. One PFHxS-related compound (CAS No: 67584-61-6, 2-[Methyl[(Tridecafluorohexyl) Sulfonyl]Amino]Ethyl Methacrylate) was reportedly used in impregnation/proofing for protection from damp, fungus, etc. at least in four products between 2003 and 2009 in Denmark (SPIN, 2018).

**Manufacturing of semiconductors**

39. During the POPRC-13 meeting in 2017, an industry representative noted that PFHxS, its salts and PFHxS-related compounds are currently being used as replacements to PFOS, PFOA and their related compounds in the semiconductor industry. This information is further strengthened by published information that indicates that PFHxS is used in the semiconductor industry in Taiwan province of China (Lin et al., 2010). PFHxS (133,330 ng/L), together with PFOS (128,670 ng/L), was one of the primary contaminants at a semiconductor fabrication plant waste water effluent site. Both PFSAs are present in the effluent in similar amounts showing that PFHxS is a primary substance in this process and are not unintentionally present at this site.

**Other potential uses**

40. Hubei Hengxin has marketed the potassium salt of PFHxS and PFHxS-related compounds (CAS No: 68259-15-4, tridecafluoro-N-methylhexanesulfonamide) for potential uses as a flame retardant and in pesticides, respectively (Hengxin, 2018). PFHxS has been detected in food packaging materials (Schaider et al., 2017). Information regarding use of PFHxS in a company that develops, manufactures, and distributes analogue and digital imaging products has been reported (The Netherlands submission to PFOA intersessional work, 2018).

### 2.1.3. Releases to the environment

41. To date, limited research has been conducted to specifically study the releases of PFHxS, its salts and PFHxS-related compounds in the environment, resulting in a lack of quantitative information on releases, although various studies have detected the ubiquitous presence of PFHxS in the environment (for details, see section Environmental levels and trends below). The occurrence of PFHxS and its related compounds in the environment is a result of anthropogenic production, use and disposal, since they are not naturally occurring substances. Unintentionally produced PFHxS, its salts and PFHxS-related compounds that are byproducts contained in PFOS, its salts and PFOS-related compounds are likely to have the same release pathways as the respective PFOS, its salts and PFOS-related compounds, which have been described in detail previously (3M, 2000b; UN Environment, 2006). This is in line with recent studies on source identification for PFHxS in groundwater samples (n=102) from non-industrial areas in China and drinking water in the U.S. (n=36977), showing that PFHxS clustered/occurred together with PFOS. Thus, for these sites, PFHxS may have originated from similar sources as PFOS such as AFFFs, pesticide applications, landfill leachates and WWTP effluents (Wei et al., 2018; Guelfo and Adamson et al., 2018). However, this was not the case in a study by Ma et al., (2018) where levels of PFHxS exceeded PFOS levels in Taihu Lake
(Ma et al., 2018). This increase of PFHxS was linked to production and use of PFHxS as an alternative due to recent regulation of PFOS (and PFOA and related compounds) (Ma et al., 2018). A recent paper reports concentrations in rivers in China. The estimated load of PFHxS to these rivers were 21.6 tonnes in 2016, up from 0.09 tonnes in 2013 (Pan et al., 2018).

42. In addition, as with PFOA, PFOS and their related compounds (3M, 2000b; UN Environment, 2006, 2016), intentionally produced PFHxS and its related compounds may be released during their whole life cycle: they can be released at their production, at their assembly into a commercial product, during the distribution and industrial or consumer use, as well as from waste treatment facilities such as landfills and wastewater treatment plants (Shafique et al., 2017), including from land treatment using contaminated sludge from wastewater treatment plants. Studies indicate that PFHxS remains relatively unchanged throughout the successive treatment steps (Kunacheva et al., 2011, Thompson et al., 2011). Furthermore, PFHxS-related compounds may be transformed to PFHxS in the environment and biota (for details, see section on PFHxS precursors and degradation below).

43. Investigations revealed that PFHxS was the main PFAS constituent in the final waste effluent from a semiconductor fabrication plant and that the amount of waste effluent was estimated to be >5000 tonnes/day. The corresponding mass of PFHxS generated each day from the manufacturing process was estimated to be >0.67 kg (Lin et al., 2009). In the same study, raw waste effluent from an electronic/optoelectronic fabrication plant was analysed for content of PFASs. However, in this effluent the main constituent was PFOA, and PFHxS was found at low levels.

44. The contributions of individual stages to overall releases throughout the life cycle, and receiving environmental media, may vary across compounds and applications. In general, manufacturing processes constitute a major source of PFHxS, its salts and PFHxS-related compounds to the local environment, e.g., in elevated levels of PFHxS in water and the population close to a production plant in Minnesota, the United States (Oliaei et al., 2012). In addition, some uses of PFHxS, its salts and PFHxS-related compounds may result in direct environmental releases. For example, the use of relevant AFFFs in fire-fighting training and real incidences, as well as accidental releases, contribute a substantial amount of PFHxS, its salts and PFHxS-related compounds in the environment (e.g., Backe et al., 2013; Houtz et al., 2013; Ahrens et al., 2015; Baduel et al., 2017; Barzen-Hanson et al., 2017; Bräunig et al., 2017; Lanza et al., 2017). In contrast, some other uses of PFHxS, its salts and PFHxS-related compounds may lead to releases to indoor environments such as from dust (Norwegian Environment Agency, Report M-806/2017c). One example is releases of PFHxS, its salts and PFHxS-related compounds from treated carpets to household dusts (Beesoon et al., 2012).

## 2.2. Environmental fate

### 2.2.1 Persistence

45. There are some characteristics which are valid for the whole group of PFASs, and therefore also for PFHxS; high electronegativity, low polarizability, and high bond energies make highly fluorinated alkanes extremely stable organic compounds. Based on the persistency of all other PFASs it can be assumed that PFHxS is persistent as well, and this was concluded in the EU when PFHxS was identified as very persistent and very bioaccumulative substance. This conclusion was made based on the knowledge of the stability of the C-F bonds and the read-across approach (ECHA, 2017c) with PFOS and PFOA (ECHA, 2017a, b).

46. PFASs are very resistant to chemical, thermal and biological degradation due to their strong C-F bonds (Kissa, 2001) and resistance to degradation makes them persistent in the environment. The stability of PFASs has been described in detail (Siegemund et al., 2000 as referenced in ECHA, 2017a). When all valences of a carbon chain are saturated by fluorine, the carbon skeleton is twisted out of its plane in the form of a helix and this structure shields it from chemical attack. Several other properties of the carbon fluorine bond contribute to the fact that highly fluorinated alkanes are the most stable organic compounds. These include low polarizability and high bond energies, which increase with increasing substitution by fluorine. The influence of fluorine is greatest in highly fluorinated and perfluorinated compounds (Siegemund et al., 2000 as referenced in ECHA, 2017a).

47. Experimental data on the persistence of PFHxS are very sparse. However, in a field study on photolysis of PFHxS in water conducted at high altitude in Mt. Mauna and Mt. Tateyama, no photolysis was observed for PFHxS following, respectively, 106 and 20.5 days of exposure (Taniyasu et al., 2013; Wang et al., 2015a).

48. PFHxS is found in soil, water and a variety of biota (see UNEP/POPS/POPRC.14/INF/4, Tables 1.1–1.5) in the vicinity of fire-fighting training areas following historical (and ongoing) use of PFHxS-containing foams (Braunig et al., 2017; Filipovic et al., 2015). Although no degradation studies were performed, results show that PFHxS is persistent and does not undergo significant abiotic or biotic degradation under normal environmental conditions after use of AFFF.

49. There are no available experimental biodegradation data in water or soil for PFHxS. Biodegradation of the structural analogue PFOS has been evaluated in a number of tests in several

studies. Aerobic biodegradation has been tested in activated sewage sludge, sediment cultures and soil cultures (ECHA, 2017a). Anaerobic biodegradation has been tested in sewage sludge. PFOS did not in any of these tests show any sign of biodegradation (UNEP/POPS/POPRC.2/17/Add.5). The very Persistence (vP) classification (vP; persistence criteria under REACH (https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf) are similar to the criteria for persistence in Annex D under the Stockholm Convention) of PFOA in water, sediment and soil has also been confirmed (ECHA, 2013). Furthermore, Quinete et al. (2010) demonstrated that PFBS is not biodegradable and expected to be a highly stable transformation product which several precursors ultimately degrade into (Quinete et al., 2010; D'Agostino and Mabury, 2017; Wang et al., 2013). In addition, the results of a ready biodegradability test of perfluorobutane sulfonate in compliance with Good Laboratory Practice provided in a conference room paper from Japan showed that PFBS is not readily biodegradable. Measurements of BOD and chemical analysis of the parent substance indicated zero biodegradation occurred in the study. Since the stability of PFSAs is in general based on the stability of the fluorinated carbon chain, it can also be concluded for PFHxS that no biodegradation can be expected in water, soil or sediment (ECHA, 2017a).

50. In Australian assessments, multiple studies conducted on a range of PFASs, including the $C_4$ and $C_8$ homologues of PFHxS, have found no evidence of potential for biodegradation, hydrolysis or aqueous photolysis under environmental conditions (NICNAS, 2017a; 2017b; 2017c).

51. PFHxS is not expected to undergo hydrolysis or photolysis, and biodegradation and, like other PFASs, is found to be poorly removed in waste water treatment plants (Danish Ministry of Environment, 2015). Based on a read-across approach from the conclusions applied to the persistence of PFBS, PFOS and PFOA, it can be concluded that PFHxS is not degradable under natural conditions and is very persistent in water, soil and sediment.

### 2.2.2 Occurrence of PFHxS related compounds and degradation

52. A theoretical assessment of abiotic degradation pathways to PFHxS has been performed (Norwegian Environment Agency, 2017a, M-792/2017). Based on available data on the degradation of PFBS- and PFOS-precursors, PFHxS precursors are anticipated to degrade to PFHxS in the environment. Results from this study indicated that substances containing the moiety $C_6F_{13}SO_2$ may undergo abiotic degradation resulting in the release of PFHxS and $C_6$ PFCA. However, comparing with PFOS degradation studies, one may expect that major products from abiotic degradation would rather be PFCA (PFHxA) than PFHxS (10:1) (Norwegian Environment Agency, 2017a, M-792/2017 and references within), whereas major products from biotic degradation would be almost solely PFHxS (Wang et al., 2014).

53. Analytical methods for identifying and quantifying PFHxS-related compounds (e.g. perfluorohexane sulfonamides (FHxSA)) are at present very limited. Two studies using non-target analysis detected FHxSA in AFFF-impacted groundwater, 3M historical AFFF, and consumer products as well as in drinking water (Barzen-Hanson et al., 2017; Kabore et al., 2018). Although the data are not quantitative, they do show that PFHxS precursors have been used and that they are present in the environment and that human exposure can occur via drinking water. A recent study by D'Agostino and Mabury, 2017, reported that precursors of PFHxS are broadly present in urban- and AFFF-impacted Canadian surface waters. FHxSA was detected in surface water from sites with AFFF-impact and from sites without known FHxSA sources (D'Agostino and Mabury, 2017). FHxSA was found ubiquitously in all urban waters but at significantly lower levels than in AFFF-impacted waters. The study does not reveal whether the detected FHxSA was a result of direct use of FHxSA or indirect unintentional use due to contamination, but the authors conclude that these precursors are present in Canadian urban- and AFFF-impacted surface water and that they so far have been rarely considered (D'Agostino and Mabury, 2017). However, FHxSA has previously been detected in AFFF as well as AFFF-impacted water, soil, and aquifer solids (Houtz et al., 2013; McGuire et al., 2014) and in tapwater from Canada, EU, Ivory Coast and China (Kabore et al., 2018).

54. A study from the north of Sweden showed that the concentration of PFHxS increased over a time-period of 1–14 days in a snowpack during seasonal melt. Furthermore, the PFHxS detected at different depths of the snowpack showed the highest concentration in the deepest layer (Codling et al., 2014). The reason for this increase during melting is unknown but one possible explanation is that PFHxS precursors transported through air precipitate locally and photodegrade to PFHxS during snowmelt (Codling et al., 2014). Meyer et al., 2011, also observed this phenomenon of enrichment in the melting snowpack of an urban watershed in Toronto, Canada. The fate of PFHxS and/or its precursors during snowpack ageing and the release during periods of melt could therefore influence their loading to both surface and ground waters. Furthermore, in a Dutch study, PFHxS was detected in infiltrated rainwater and the authors suggested that the presence of PFHxS could be due to

degradation of precursors in the atmosphere (Eschauzier et al., 2010).

55. A variety of consumer products (e.g., textiles, paper, and carpets) and packaging containing PFASs and PFAS precursors are sent to municipal landfills at the end-of-life. In a recent review, it was reported that PFASs are routinely detected in landfill leachate with PFASs ($C_4$–$C_7$) being most abundant, possibly an indication of their greater mobility, and reflecting the shift toward usage of shorter-chain substances (Hamid et al., 2018). Furthermore, PFAS ($C_4$–$C_7$) substances are more easily released and prone to leach from landfills due to their higher water solubility and lower log Koc relative to longer-chain PFASs (Guelfo & Higgins, 2013). Following disposal, PFASs are released from the waste through both biological and abiotic leaching either from precursor degradation (biological or abiotic) or from direct use of PFASs such as PFHxS or PFOS (Allred et al., 2015). In a study by Allred et al., 2014, several PFHxS precursors (FHxSAA, MeFHxSAA, EtFHxSAA) were detected in leachates from landfills indicating that these PFHxS precursors and/or their parent compounds may be used in a variety of applications since the landfills had received residential and commercial waste, construction and demolition waste, biosolids from waste water treatment plants as well as non-hazardous industrial waste. The detection of PFHxS precursors is in line with what has been detected for precursors of PFBS and PFOS in other matrixes (see section 2.2.4; Stock et al., 2007; Del Vento et al., 2012; Dreyer et al., 2009). A study of influent and effluent sewage water and sludge from waste water treatment plants found a net mass increase in PFHxS content between influent and effluent at 3 different waste water treatment plants in Sweden suggesting that degradation of precursor compounds during waste water treatment can be contributing to PFHxS contamination in the environment (Eriksson et al., 2017).

56. Applying the read-across approach (see Section 1) and results from studies on other PFASs, indicates that PFHxS-related compounds may have the potential to degrade to PFHxS in the environment. Biodegradation data available for the $C_8$N-ethylperfluorooctanesulfonamidoethyl alcohol (CAS No: 1691-99-2) demonstrate conversion with the ultimate biodegradation product being PFOS (Hekster, et al., 2002; Martin, et al., 2010). Other chemicals containing the perfluorooctyl sulfonate group are expected to be susceptible to a similar biotransformation process (Martin, et al., 2010). Further, data available for the $C_4$N-methylperfluorobutanesulfonamidoethyl alcohol (CAS No: 34454-97-2) indicate potential for atmospheric degradation to PFBS through oxidation by hydroxyl radicals (D'eon, et al., 2006; Martin, et al., 2010). Moreover, PFBS is expected to be a highly stable transformation product in which several precursors ultimately degrade into (Quinete et al., 2010; D'Agostino and Mabury, 2017; Wang et al., 2013; Norwegian Environment Agency, 2017a, M-792/2017).

### 2.2.3 Bioaccumulation and toxicokinetics

57. Due to the surface-active properties of PFHxS it is not possible to experimentally measure log Kow since the substance is expected to form multiple layers in an octanol-water mixture (OECD, 2002; 2006; Conder et al., 2008). In addition, PFHxS is relatively water soluble and has been shown to preferentially bind to proteins in liver and blood (Jones et al., 2003; Ahrens et al., 2009; Martin et al., 2003; Goeritz et al., 2013) and therefore the log Kow as descriptor for the bioaccumulation potential is not appropriate for PFHxS and related compounds. Even if the reported BCF and BAF for PFHxS are below the numerical criteria of 5000 (Martin et al., 2003; Yeung and Mabury, 2013; Kwadijk et al., 2010; Casal et al., 2017; Ng and Hungerbuhler, 2014; Naile et al., 2013), the numerical criterion for BCF or BAF are not appropriate for PFHxS since PFHxS does not follow the behaviour of traditional hydrophobic compounds by partitioning into fatty tissues (UNEP/POPS/POPRC.3/INF/8). As mentioned above, PFHxS preferentially binds to proteins in the organism and due to its water solubility is expected to quickly be excreted through gill permeation in gill-breathing organisms such as fish (Martin et al., 2003; Goeritz et al., 2013).

58. Studies on uptake of PFHxS from soil to earthworms have also been performed. In these studies, low bioaccumulation in earthworms were reported by biota-to-soil accumulation factors (BSAF) (Zhao et al., 2013; 2014). Furthermore, PFSAs have also been reported to be taken up by plant roots from spiked soil in the order PFOS>PFHxS>PFBS (Felizeter et al., 2012).

59. Factors such as high bioaccumulation in other species and monitoring data indicating a bioaccumulation potential of the chemical is sufficient to justify consideration of PFHxS within the Stockholm Convention. BMFs and TMFs explicitly account for biomagnification resulting from trophic transfer where the chemical concentration in one organism exceeds that of the organism at a lower level of the food chain (reviewed by Conder et al., 2012). As reviewed in the nomination dossier (UNEP/POPS/POPRC.13/4) a number of studies have reported BMFs over 1. Investigation of biomagnification in selected species from different Arctic regions, including the European- and Canadian Arctic, showed BMFs in the range 6.9 to 22 (Haukås et al., 2007; Routti et al., 2016; Tartu et

al., 2017). Furthermore, Houde et al., 2006, investigated the accumulation of PFHxS in the Bottlenose dolphins prey food web at two different locations in the United States and BMFs ranged from 1.8 to 14. In addition, in the SVHC dossier (ECHA, 2017a) authors have calculated from Riget et al., 2013, the BMFs for polar bear/ringed seal food chain to 16.7. Monitoring data also reveal that polar bears contain the highest levels of PFHxS of any investigated animal (see Table 1.3 UNEP/POPS/POPRC.14/INF/4).

60. A study on pigs fed a diet contaminated with known concentrations of PFHxS, calculated dietary BMFs for whole pig, meat and liver for PFHxS were 20.1, 13.1 and 48, respectively (Numata et al., 2014).

61. An overview of the BMFs from the above-mentioned studies are shown in Table 4. Limitation of these BMF/TMF studies was discussed in the nomination dossier (UNEP/POPS/POPRC.13/4) and the SVHC dossier also reviews some of the bioaccumulation studies listed in Table 4 in detail (ECHA, 2017a).

**Table 4. Available BMFs and TMFs from different food chains and diet studies**

| Specie/Food web | Tissue | BMF | TMF | Reference |
|---|---|---|---|---|
| Bird/Fish (Arctic) | Liver | 6.0–8.5 | | Haukås et al., 2007 |
| Polar bear/Ringed seal (Arctic) | Plasma | 22 | | As calculated from Routti et al., 2016 and Tartu et al., 2017 |
| Dolphin/Fish | Plasma/whole | 1.8–14 | Dolphin 0.2 ± 0.9 (plasma)<br>Dolphin 0.1 ± 0.4 (whole) | Houde et al., 2006 |
| Fish/Zoo plankton | Whole | 9.1–10 | | Houde et al., 2006 |
| Polar bear/Ringed seal (Arctic) | Liver | 16.7 | | Riget et al., 2013<br>(as reported in ECHA 2017a) |
| Fish/Chironomids (Lake fly) | Fillet/whole | 1.43–4.70 | | Babut et al., 2017 |
| Pig diet study | Whole/meat/liver | 13.1–48 | | Numata et al., 2014 |
| Benthic (Sole/flat fish/crab/clams and polychaetes) | Whole | | 4.3 | Munoz et al., 2017 |
| Bentho-pelagic (demersal; top predators seabass and meagre) | Whole | | 1.5 | Munoz et al., 2017 |

62. Studies investigating trophic magnification of PFHxS in food webs are limited. TMFs were estimated, using both plasma-based and whole-body-estimate based calculations, in a marine food web (Houde et al., 2006). The reported TMFs ranged from 0.2 ± 0.9 to 0.1 ± 0.4. However, there are large variations in the TMFs, reflected in standard errors being larger than their corresponding TMFs. A number of factors such as temperature, time of sampling, reproduction status, migration, age and tissue versus whole body calculations may affect the calculation of TMF (Borgå et al., 2012; Franklin, 2016). In a recent study, two estuary intertwined sub-food web were investigated. TMFs for PFHxS were reported to be 4.3 for the benthic food web and 1.5 for the bentho-pelagic food web (Munoz et al., 2017; see Table 4 above).

63. The use of the elimination half-life is a useful addition to the use of BMF and TMF as an indicator of bioaccumulation potential that should be considered in a weight-of-evidence bioaccumulation assessment (Franklin, 2016). Average half-lives for PFHxS, PFOS and PFOA in humans were 8.5, 5.4, and 3.8 years, respectively. Hence, the half-life of PFHxS is approximately 1.5 times longer than for PFOS. Elimination half-life in other species has also been reported (Sundstrom et al., 2012). The reported half-life of PFHxS in men is on average 8.5 years (range 2.2–27 years) (Olsen et al., 2007) but estimates up to 35 years have been made (see Table 3 in UNEP/POPS/POPRC.14/INF.4), which is the longest of all PFASs for which data are available. The half-life of PFHxS is comparable to the longest human elimination half-lives recorded for known PBT/vPvB- and POP-substances such as some PCBs (ECHA, 2017a). The elimination half-life of PFHxS, PFOS and PFOA in serum of 26 retired fluorochemical production workers (22 males and 2 females) has been reported (Olsen et al., 2007). However, pharmacokinetic studies in non-humans have demonstrated that serum elimination half-lives of PFHxS can vary considerably between species (Sundstrom et al., 2012; Numata et al., 2014) and, in some cases, between genders within species (Hundley et al., 2006; Sundstrom et al., 2012), but are generally much shorter than the reported human serum elimination half-lives. Furthermore, serum elimination times in humans are affected by female menstruation as well as child-birth (Gomis et al., 2017).

64. The species-specific and sex-specific elimination of PFHxS is highly expressed in the study by Sundstrom et al., 2012. Male and female rats were investigated in terms of serum elimination and

results showed that females much more efficiently eliminated PFHxS than male rats. Furthermore, rats and mice appeared to be more effective at eliminating PFHxS than monkeys (Sundstrom et al., 2012). See Table 3 UNEP/POPS/POPRC.14/INF/4) for comparison of half-lives. PFHxS is highly bound to plasma proteins (Kim et al., 2017; Jones et al., 2003) and pharmacokinetic studies have revealed that certain PFASs interact with proteins (e.g. albumin, liver fatty acid binding proteins, organic anion transporters) and that their clearance is species-, gender- and chain length-dependent (Andersen et al., 2008; Ng & Hungerbuhler, 2014).

65. The ability to strongly bind to blood proteins and the low clearance and slow excretion in the urine were recently proposed as the best predictors for a chemical's bioaccumulation potential and long half-life (Tonnelier et al., 2012). In a study of pigs fed a diet contaminated with PFASs, PFHxS was found to have the slowest urinary excretion as well as the highest serum half-life among the investigated PFASs (Numata et al., 2014). In addition, blood plasma contained the largest amount of unexcreted PFHxS. Interestingly, studies on cows revealed a different pattern of PFHxS with regard to partitioning to blood, liver and edible tissues (Kowalczyk et al., 2013). In dairy cows, muscle tissue contained the highest concentration of PFHxS indicating a lower tendency for PFHxS to accumulate in plasma than was seen for pigs (Numata et al., 2014). Furthermore, in the dairy cow study, PFHxS was detected in urine as well as milk during the experimental period showing a higher rate of elimination in cows than in pigs. These studies indicate that both elimination and tissue distribution is species-specific for PFHxS and other PFASs.

66. In a Spanish human autopsy study PFHxS was found in all studied human (general public) organs/tissues: liver, kidneys, bone, brain and lungs, with highest levels observed in lungs and kidney, and was most frequently detected in lungs (43%) (Perez et al., 2013). The highest concentrations of PFHxS are found in blood, liver, kidney and lung. Transfer to breast milk appears to be a significant route of elimination during breastfeeding. Time-trend studies indicate that the human bioaccumulation potential of PFHxS may be larger than that of PFOS (ECHA, 2017a).

### 2.2.4 Potential for long-range transport

67. The potential for long-range transport of PFHxS was reviewed in the nomination dossier (UNEP/POPS/POPRC.13/4). In support of the long-range transport, data show that PFHxS is found in various environmental compartments in the remote regions of the Arctic including in air, snow, soil, sediment as well as in biota (including humans). In the Antarctica PFHxS was found in biota and snow, strengthening the evidence that PFHxS can be transported over long distances far from the primary source. For monitoring data from both the Arctic and Antarctica see UNEP/POPS/POPRC.14/INF/4, Tables 1.1, 1.2 and 1.3 for biota and Table 1.4 for abiota.

68. While there is scientific consensus that PFASs are subject to long-range environmental transport, the pathway governing the long-range environmental transport of individual PFASs are dependent on the substance's physiochemical properties and on geographical locations (Butt et al., 2010; Ahrens et al., 2011; Rankin et al., 2016). Processes that transport PFHxS, its salts and PFHxS-related compounds to the Arctic include direct transport of compounds in air or water and/or indirect transport of neutral volatile and semivolatile precursor compounds that can undergo degradation by atmospheric oxidation or by biological degradation (Butt et al., 2010; Ahrens et al., 2011; Alava et al., 2015, Wang et al., 2015; Rauert et al., 2018a,b). The PFHxS detected in environmental samples in remote regions may thus partially result from biological or abiotic degradation of such precursors prior to or after deposition (D'Eon et al., 2006; Xu et al., 2004; Tomy et al., 2004). Furthermore, local inputs from anthropogenic activities may be another source to PFHxS in the Arctic regions (reviewed in Butt et al., 2010). A recent study measured PFASs (including PFHxS) in a number of matrixes, at local and remote locations at Svalbard in the Norwegian Arctic and found that the amount of PFHxS detected was dependent on whether the sampling site was close to local sources such as firefighting training sites. Levels at background sites were found to be low and seawater along harbours was also low in contamination (<0.005 ng/L PFHxS), hence the authors concluded that potential local PFAS sources do not yet contribute significantly to the local marine and terrestrial pollution (Skaar et al., 2018).

69. Recent data from Svalbard indicate that levels of PFASs detected in polar bears are most likely not due to local sources, but is rather a result of global emissions. PFAS concentrations in polar bears were higher (30–35%) in animals that have a wider home range (offshore bears) than animals that live in coastal areas close to Svalbard (Tartu et al., 2018). Furthermore, using isotope analysis it was shown that polar bears with a wider home range eat more marine food than animals living close to the coast that have a large proportion of terrestrial food in their diet (Tartu et al., 2017b; 2018). In areas with more sea ice, such as those used by offshore bears, environmental PFAS levels were likely higher than in areas with less sea ice such as the coast of Svalbard. The positive relationship between PFAS

concentrations and home range longitude position in polar bears accords with a study that showed that PFAS concentrations in ivory gull eggs from more eastern colonies at Franz Josef Land were slightly higher than concentrations in eggs from Svalbard (Miljeteig et al., 2009).

70. PFHxS is water soluble and transported through water to remote areas. Yamashita et al., 2005, first described global occurrence of PFHxS and other PFASs in open ocean water. Since then, a number of studies have reported frequent detection of PFHxS in open ocean and coastal water world-wide (reviewed in Butt et al., 2010; González-Gaya et al., 2014; Rosenberg et al., 2008; Busch et al., 2010; Benskin et al., 2012; Zhao et al., 2012; Ahrens et al., 2010; Wei et al., 2007; Brumovský et al., 2016). A number of studies reported the detection of PFHxS in Arctic seawater (Caliebe et al., 2005 as cited González-Gaya et al., 2014; Rosenberg et al., 2008; Busch et al., 2010; Cai et al., 2012; Benskin et al., 2012; Zhao et al., 2012; Yeung et al., 2017). In contrast, it has been suggested that oceanic long-range transport of PFHxS and other PFASs to the Antarctic has been more limited. Ocean currents and related dilution effects cause a decreasing concentration gradient from Northern Europe to the South Atlantic Ocean (Ahrens et al., 2010) explaining the lower concentrations detected in the Southern Ocean. Long distance from important source regions in the northern hemisphere, limited chemical manufacture of PFASs in the southern hemisphere, low effectiveness of delivery to the Antarctic via the atmospheric route and low yield of ionic PFASs produced from atmospheric oxidation are indicated as other possible explanations (Bengtsson Nash et al., 2010; Alava et al., 2015).

71. The higher frequency and levels of PFHxS detected in ocean waters compared to what has been detected in air, as well as its relatively high water solubility, gives an indication that one of the major transportation pathways for PFHxS to remote regions is through water currents (discussed in UNEP/POPS/POPRC.13/4). The ocean acts as a long-term reservoir of PFASs. Hence the input of PFHxS to the Arctic will likely continue over the long-term, particularly as the volume of Atlantic water masses transported northwards has increased during the last two decades (Hansen et al., 2015; Routti et al., 2017; UNEP/POPS/POPRC.13/4). In addition, Llorca et al., 2012, predicted that PFHxS, like most other perfluoroalkyl acids, is a “swimmer”, i.e., a chemical that is anticipated to undergo long-range environmental transport in water, by using the modelling result from Lohmann et al., 2007.

72. Due to detection of PFHxS in Arctic air and snow, long-range transport of PFHxS and/or PFHxS-related compounds through the atmosphere occurs (Theobald et al., 2007 as cited in Butt et al., 2010; Stock et al., 2007; Genualdi et al., 2010; Butt et al., 2010; Wong et al., 2018; Norwegian Environment Agency M-757, 2017b). A recent study reporting a significant increase in concentrations of PFHxS ($p<0.006$) during the period 2009–2015 in Arctic air both in Canada and Norway indicating that an increase in long-range transport has occurred (Rauert et al., 2018a). PFHxS was also recently detected in air at remote locations in the Latin American and Caribbean region (Rauert et al., 2018b). Furthermore, higher PFHxS levels were detected in coastal water of Greenland compared to seawater, a finding that was attributed to precipitation in the form of rain, snow and/or ice melting at the Greenlandic mainland (Busch et al., 2010). An atmospheric source could involve neutral PFHxS related compounds as with those reported for PFBS and PFOS (Martin et al., 2006; D'Eon et al., 2006). A number of studies show evidence that PFSA precursors are transported through air and degrade to e.g. PFBS, PFOS (Stock et al., 2007; Dreyer et al., 2009; Del Vento et al., 2012) and most likely also PFHxS. The potential for PFHxS to undergo long-range environmental transport via air is further supported by the detection of PFHxS in lichen from the Antarctic Peninsula. Lichen accumulates pollutants from air and is used as bioindicators for air pollution (Augusto et al., 2013). PFHxS has also been detected in the feathers of an accipiter bird in rural areas of Tibet (Li et al., 2017). This argument is strengthened by the detection of increasing amounts of PFHxS during snow melt (Codling et al., 2014; Meyer et al., 2011) and detection of PFHxS in rain water (Eschauzier et al., 2010). See section 2.2.2 for further details.

73. Recent studies of polar bears from Norwegian Arctic showed that plasma levels of PFSA ($\Sigma_2$PFSA; PFHxS and PFOS) were found in the highest concentration compared to other already regulated POPs. Total concentration (ng/g ww) of $\Sigma_2$PFSA were 264.35±12.45 (PFHxS 30 ng/g ww; PFOS 233 ng/g ww), ΣPCB were 39.98±3.84 ng/g ww while ΣPBDE were 0.18±0.01 ng/g ww (Bourgeon et al., 2017). Hence in these studies the concentration of PFHxS is similar to the total PCB concentrations. In general, it is between 2–18 times more PFOS than PFHxS detected in animals from the Norwegian Arctic, and the amount of PFHxS is 2–7 times higher compared to PFOA (Miljeteig et al., 2009; Bytningsvik et al., 2012; Aas et al., 2014; Routti et al., 2017).

74. In summary, there is strong evidence that PFHxS is transported to remote regions through water and ocean currents and there is indication of long-range transport also through atmospheric transport of PFHxS and
PFHxS-precursors.

## 2.3 Exposure

### 2.3.1 Environmental levels and trends

75. Environmental monitoring shows that PFHxS is ubiquitous in the environment. Numerous studies have reported detection of PFHxS in compartments such as surface water, deep-sea water, drinking water, wastewater treatment plant effluent, sediment, groundwater, soil, atmosphere, dust, as well as biota, and humans globally (ECHA 2017a, annex II, Table 13; Tables 1.1–1.12 in UNEP/POPS/POPRC.14/INF/4). Degradation of PFHxS-related substances may add to the total exposure. There are likely to be many precursors, many of which are unknown. Quantification of these substances is challenging as commercial analytical standards are seldom available.

76. The highest environmental levels of PFHxS measured are found in urban and/or industrial areas both in terms of biotic- and abiotic matrices (Gewurst et al., 2013; Ma et al., 2018). In China, PFHxS (ranging between 45.9–351 ng/L) was found to be the predominant PFAS in the water of Taihu Lake and its in-flow rivers (Ma et al., 2018). The rivers were considered the main input of PFHxS to the lake since some of the rivers mainly collect discharge water from bigger cities with local PFAS-related plants. The level of PFHxS in the lake has increased in the period 2009–2014 while levels of PFOA and PFOS have remained more or less the same, which may be an indication of increased direct use of PFHxS and/or PFHxS-related compounds (Ma et al., 2018).

77. Numerous studies have reported environmental contamination due to use of AFFF based on fluorosurfactants (reviewed in Dauchy et al., 2017). PFHxS and/or PFHxS related compounds may be found in these foams either as an unintentional contamination due to the use of PFOS or as an intentionally added ingredient most likely in the form of perfluorohexane sulfonamide (FHxSA) derivatives (Barzen-Hanson et al., 2017; D'Agostino & Mabury, 2017). In Canada, PFHxS has been found in variety of matrixes including urban and rural surface water, air, Arctic ocean water and sediment (low frequency) at sites impacted- and not impacted by contamination from AFFF (D' Agostino and Mabury 2017; Lescord et al., 2015; Wong et al., 2018; Genualdi et al., 2010; Gewurtz et al., 2013). PFHxS has been detected in ground- and surface waters close to airports and metal plating facilities, in surface water in the vicinity of waste water treatment plant, and in sludge and effluent/influent water from waste management facilities in Sweden (Ericson Jogsten and Yeung, 2017; Eriksson et al., 2017; Norwegian Environment Agency M-806, 2017c; Swedish EPA, 2016; Hu et al., 2016). In the Netherlands PFHxS (0.3–25 pg/L) has been detected in infiltrated rainwater likely originating from atmospheric transport of precursors (Eschauzier et al., 2010).

78. For a number of studies, exposure in limited areas (such as snowpack, melt water) can be attributed to long-range environmental transport (Zhao et al., 2012; Routti et al., 2017; Codling et al., 2014; Kwok et al., 2013; Yeung et al., 2017; Li et al., 2017). For example, PFHxS has been detected in snowpack in a remote area of northern Sweden (Codling et al., 2014), in surface- snow and water at Svalbard, Norway (Kwok et al., 2013) and in marine Arctic and Antarctic surface waters (Zhao et al., 2012). In a study by Yeung et al., 2017, PFHxS was detected in Arctic snow/meltpond water as well as in ocean water.

79. Furthermore, recent studies report that PFHxS is found at the highest concentration among species- and is the third most abundant PFAS in polar bears (Tartu et al., 2017a; Routti et al., 2017; Norwegian Environment Agency 2017d, M-817/2017; Table 1.3 in UNEP/POPS/POPRC.14/INF/4). Similarly, for polar bears from Hudson Bay, Canada, PFHxS was second only to PFOS in concentration in the liver (Letcher et al., 2018). In plasma from polar bears at Svalbard (Norway), PFHxS levels were in the range 4.9–70 ng/g wet weight (ww) for the time period 2000-2014 (Routti et al., 2017). The concentrations in polar bears from Svalbard are similar to those reported for humans living at the proximity of a fluorochemical manufacturing plant in China (which in turn are an order of magnitude higher than in general populations in China) (Fu et al., 2015). Concentration of PFHxS in polar significantly decreased during the period 2003–2009 (-8.8%, range from 12.5% to -4.8% within 95% confidence interval), whereas the annual change during the period 2009-2014 was +5%, although not significant within 95% of the confidence interval. The annual change varied between -1% per year to +11% per year within 95% confidence interval (Routti et al., 2017). Furthermore, the authors propose that the fast drop in PFAS concentration following the phase out of $C_{6-8}$ perfluoroalkyl sulfonates was due to decreased air transport of volatile precursors, while the recent increase in PFHxS levels is most likely due to the much slower oceanic transport of PFASs (Routti et al., 2017). However, a study of PFHxS levels in Norwegian Arctic air recently revealed that significant increasing amounts (<0.007–2.2 pg/m$^3$; p<0.006) has been detected during the period 2009–2015 (Rauert et al., 2018a) and these results correspond with the observed increase in polar bears levels described in Routti et al. (2017) above. In the Routti study, levels of PFHxS in liver from Arctic foxes collected during 1997–2014 were in the range <0.05–139 ng/g ww. PFHxS

concentrations in Arctic foxes decreased 11% per year from 2002 to 2014, and the annual change with 95% probability was between -17% to -5%. PFHxS trends for both polar bears and Arctic foxes were similar prior and after they were corrected to the climate-related variation in feeding habits and food availability, the first reflecting the actual trends in the animals and the latter one reflecting the trends in their food web.

80. The results indicate that PFAS concentrations in polar bears and Arctic foxes are mainly affected by emissions. In a previous study, polar bears from five locations in the North American Arctic and two locations in the European Arctic as well as Greenland were studied and PFHxS was detected in polar bears at all locations (Smithwick et al., 2005a,b). At the Svalbard location in the European Arctic, a mean concentration of 2940 ng/g (range 2260–4430 ng/g wt) was detected in polar bear liver, which to our knowledge is the highest concentration of PFHxS reported in polar bears. In polar bears from East Greenland and in samples collected in 2006, a tissue distribution study showed that levels of PFHxS were highest in the liver followed by blood > brain ≈ muscle ≈ adipose but consistently 2 orders of magnitude lower than PFOS. For PFHxS, concentrations were by far the highest in liver (30.9 ± 2.1 ng/g) and blood (18.0 ± 1.1 ng/g), and concentrations in brain, muscle and adipose tissues were of similar levels (1.37 ± 0.10; 1.87 ± 0.1; 1.55 ± 0.20 ng/g, respectively). In the liver, PFHxS was found to be significantly higher in females which the authors indicate may be due to uneven sex distribution (14 male and 6 females) and the limited number of females' studies (Greaves et al., 2012). In a complementary study in various brain regions of the same polar bears, PFHxS concentrations were consistently the same throughout the brain (Greaves et al., 2013). Other studies have also detected PFHxS in marine mammals (Fair et al., 2012). See Table 1.1–1.4 in UNEP/POPS/POPRC.14/INF/4 for additional data on exposure levels in remote- and other regions.

81. A number of studies have reported time-trends for PFHxS in various species and matrixes. However, there are some discrepancies in these data and trends are increasing (Rauert et al., 2018a; Holmstrom et al., 2010), decreasing (Lam et al., 2016; Huber et al., 2012), and without any significant trend (Routti et al., 2017; Ullah et al., 2014; Roos et al., 2013). In a systematic review of trend studies most data on PFHxS showed no significant change, while an increasing or decreasing trends were observed in a few matrices and regions (Land et al., 2018). However, as mentioned above, the trend of PFHxS in polar bears in the European Arctic (Svalbard, Norway) has an annual change of 5% (although not significant within 95% of the confidence interval) in the time-period 2010–2014, while the trend in the Arctic fox from the same area is decreasing (Routti et al., 2017). The observed trend in polar bears (Routti et al., 2017) corresponds with a recent study reporting increasing trends in Arctic air during the same time-period (Rauert et al., 2018a). Hence, the temporal trend in each case is most likely dependent of emission sources, food choices (terrestrial, marine) and location (urban versus rural) among other factors.

### 2.3.2 Human exposure

82. Exposure pathways for PFASs, including PFHxS, include indoor dust, diet, drinking water and indoor/outdoor air (ECHA 2017a; Table 1.4 and 1.6 to 1.8 in UNEP/POPS/POPRC.14/INF/4). PFHxS, along with PFOS and PFOA, is the most frequently detected PFAS in blood-based samples from the general population world wide (ECHA 2017a, annex II, Table 14; Table 1.10 in UNEP/POPS/POPRC.14/INF/4) and present in the umbilical cord blood and breast milk (Kärrman et al., 2007; Gützkow et al., 2012). PFHxS is transferred to the foetus through the placenta in humans and is excreted via lactation. Breast milk may therefore be an important source of exposure to breast-fed infants. Lifestyle factors contribute to the exposure; microwavable food intake and low frequency of indoor dust removal by vacuuming are connected to higher serum levels of PFHxS and other PFASs (Siebenaler et al., 2017), as well as frequent use of stovetop PTFE cookware and preheated packaged foods, and increased use of carpet for floor covering (Hu et al., 2018) and use of stain repellents (Kingsley et al., 2018).

83. A number of studies have reported presence of PFHxS in food items (EFSA 2012; Gebbink et al., 2015a; Noorlander et al., 2011¸ Food Standards Australia New Zealand, 2016; Table 1.7 in UNEP/POPS/POPRC.14/INF/4). In a Swedish study, decreasing human dietary exposure in the period 1999–2010 from food stuff was observed (from 55 to 20 pg/kg bw/day), with egg and fish contributing most to human dietary exposure of PFHxS (Gebbink et al., 2015a). In a Dutch study, crustaceans, lean fish, flour and butter (44, 23, 18 and 16 pg/g dw, respectively) had highest levels of PFHxS, low levels (<10 pg/g dw) were also found in fatty fish, industrial oil, bakery products and chicken (Noorlander et al., 2011). Levels of PFHxS in 2948 human food samples on the European marked quantified PFHxS in samples from vegetables (2%), fruits (21%), meat (1%), fish and other seafood (2%) and drinking water (12%) (EFSA, 2012). The PERFOOD Project developed robust and reliable analytical tools including reference materials for the determination of PFAS including PFHxS in food items and calculated upper bound dietary intake for different European countries that range from 35 to 105 pg/kg

bw per day for adults and 69 to 329 pg/kg bw per day (mean estimates) for children (https://ibed.fnwi.uva.nl/perfood/). A study from Northern-Norway Mother-Child Contaminant Cohort Study (2007–2009) determined that high consumers of game had elevated levels of PFHxS, with “a 20% difference between the highest and lowest intake group” (Berg et al., 2014). A study using data from the US National Health and Nutrition Examination Survey (NHANES) 2013–2014 for children aged 3–11 years-old found that higher levels of PFHxS in serum were associated with consumption of fruits and juices (Jain 2018). There is data indicating that food packaging materials constitute a source of human PFHxS exposure (Hu et al., 2018) as well as canned food (Averina et al., 2018).

84. A study from Australia of PFHxS in food and water environmental samples mainly from contaminated sites, found highest mean upper bound PFHxS amounts in cattle meat (13.31 µg/kg), rabbit meat (4.94 µg/kg) and eggs (4.27 µg/kg). Other foods with high concentrations were crustaceans, fish liver and sheep meat (Food Standards Australia New Zealand, 2016).

85. It is estimated that drinking water consumption from sources near or in contaminated areas is one of the most important exposure pathways of PFASs for humans. Human biomonitoring studies concluded that exposure to PFHxS (and other PFASs) via drinking water can lead to much higher blood serum levels compared to unexposed groups, as observed in USA, Germany, Sweden and Italy (Hu et al., 2016; Wilhelm et al., 2009; Li et al., 2018; Annex E submission by Council of Chemists of the Province of Treviso, Italy). In Sweden exposure to PFHxS via drinking water lead to 180-times higher blood serum level compared to reference group (Li et al., 2018). Starting February 2014, the Swedish National Food Agency (NFA) conducted a survey of the drinking water in Sweden. The results indicate that just over one-third, or 3.6 million of the Swedish population, gets their drinking water from a water source that is affected by PFASs including PFHxS (Banzhaf et al., 2017). In 2010– 2015, PFHxS was detected in drinking water in 23 US States among 134 water utilities serving 5.5 million people (EWG's Tap Water Database). PFHxS was detected in more than 200 samples from >5000 public watersystems screened for PFASs in the USA (Guelfo and Adamson, 2018). Contamination of tapwater with PFHxS at low levels has been observed world wide (Mak et al., 2009; Kabore et al., 2018; Zafeiraki et al., 2015; Boiteux et al., 2012; Ericson et al., 2009, see Table 1.6 in UNEP/POPS/POPRC.14/INF/4 for details).

86. Exposure may also occur via indoor air, mainly through particulate matter. In a Canadian household with carpets treated with Scotchgard$^{TM}$ regularly for the last 20 years, the carpet in the family room contained ~3000 ng/g PFHxS and blood levels in the family varied from 27.3–423 ng/mL, with the youngest child having the highest levels (Beesoon et al., 2012). Hu et al., also reported that PFHxS in a study from the USA that fully or partially carpet covered floors were associated with 37.2% increase in serum PFHxS concentrations in children (Hu et al., 2018). Furthermore, serum PFHxS concentrations in children enrolled in the Health Outcomes and Measures of the Environment (HOME) Study at the 8-year visit were 33% higher among those who reported having ever used stain repellents compared with those who reported never using stain repellents (Kingsley et al., 2018). A Canadian study (Kubwabo et al., 2005) shows a median of 23.1 ng/g in dust from the indoor environment while 45.5 ng/g was detected in US homes and day care centres (Strynar and Lindstrom 2008). Recently, PFHxS levels in dust from a furniture centre and a hotel in Norway ranged from 1600 to 2300 ng/g. PFHxS was the predominant PFAS in the sample together with 6:2 diPAP, which was found at equally high levels in the range 330–3300 ng/g (Norwegian Environment Agency, Report M-806/2017c). See also Table 1.9 in UNEP/POPS/POPRC.14/INF/4 for details on PFHxS detection in products.

87. PFHxS has been detected in humans globally with high levels (1790 µg/L in blood serum) detected in people consuming PFHxS contaminated drinking water (Li et al., 2018). Levels in serum range from <1–1790 µg/L, (ECHA 2017a, annex II, Table 14; Table 1.10 in UNEP/POPS/POPRC.14/INF/4). The PFHxS detection rate was above 98% in pregnant women in birth cohorts from Shanghai, Northern Norway, Greenland and two from Denmark (Bjerregaard-Olesen et al., 2017). PFHxS was detected in every sample of maternal and umbilical cord whole blood and plasma in a study of women and their newborn children (n=7) from Arctic Russia (Hanssen et al., 2013). A marked gender difference for elimination has been observed, with women aged between 15 and 50 years being more efficient than men in excreting PFHxS, with half-lives of 4.7 and 7.4 years, respectively (Li et al., 2018).

88. Furthermore, PFHxS was detected in umbilical cord blood (ECHA 2017a, annex II, Table 14; Table 1.11 in UNEP/POPS/POPRC.14/INF/4) and seems to be transmitted to the embryo to a larger extent than what was reported for PFOS (Kim et al., 2011; Gützkow et al., 2012; Pan et al., 2017). Cord serum albumin was a positive factor for higher transfer efficiency, while maternal plasma albumin was a negative factor (Pan et al., 2017).

89. Infants are also exposed to PFHxS through breast milk, however, PFHxS seems to be less efficiently transferred from mothers' blood to breast milk compared to PFOS (Kim et al., 2011; Mogensen et al., 2015). After the first six months infants' serum concentrations increased 4- to 3.5-fold for PFOS and PFHxS, respectively, in relation to cord blood (Fromme et al., 2010, Winkens et al., 2017). PFHxS was detected in more than 70% of breast milk samples analysed from Japan, Malaysia, Philippines, and Vietnam at mean concentrations ranging from 6.45 (Malaysia) to 15.8 (Philippines) pg/mL (Tao et al., 2008). Other studies report levels ranging from <0.005 to 0.3 ug/L (ECHA 2017a, annex II, Table 14; Table 1.12 in UNEP/POPS/POPRC.14/INF/4). Breastfeeding can be an efficient route of PFHxS elimination from the maternal blood. Comparisons of serum concentrations of women who did or did not breastfeed their infants showed that breastfeeding significantly decreases maternal serum concentrations of PFHxS, PFOS, and PFOA (Bjermo et al., 2013; Brandtsæter et al., 2013; Papadopoulou et al., 2015). Commonly a reduction of 3% in the mother's serum for PFOS and PFOA and 1% for PFHxS per month of breastfeeding has been observed (Kim et al., 2011). In a Swedish monitoring study, PFHxS was analysed in breast milk samples from Stockholm and Gothenburg. In Stockholm, the concentrations of PFHxS, (low pg/mL range), have increased over the whole time-period (1972–2015), although if only considering the last 10 years there seemed to be a decrease during the last 10 years both in Stockholm and Gothenburg (Nyberg et al., 2017). PFHxS were detected in all children age 3–11 from NHANES 2013–2014, at concentrations similar to those of NHANES 2013–2014 adolescents and adults. This suggest prevalent exposure to PFHxS or its precursors among U.S. population and 3-11 years old children, most of whom were born after the phase out of PFOS in the United States in 2002 (Ye et al., 2018).

90. In a temporal trend study of different PFASs in serum of primiparous women in Uppsala, Sweden, there was a significant increase in PFHxS serum levels between 1996 and 2010 (8.3%/year), with the concentrations in 2010 being approximately 6.5 ng/mL, reaching the same level as PFOS (Glynn et al., 2012 and supporting info). A doubling time of 11.7 years was found for the same sample group with samples from 1997-2012 for PFHxS (Gebbink et al., 2015b). A significant reducing trend for linear vs linear + branched PFOS was observed for the time period, but only a non-significant reduction was observed for PFHxS (Gebbink et al., 2015b). It was later discovered to be due to drinking water contamination coming from historical use of AFFF at a closed military airport (Gyllenhammar et al., 2015). The levels of PFHxS in ground/drinking water varied from 16 ng/L (upstream of the airport) to 690 ng/L (downstream of the airport). The concentration in the communal water well was 83 ng/L.

91. In the area of Arnsberg, Germany, there was a large environmental contamination incident of PFASs in 2006. Wilhelm and co-workers, 2009, evaluated the levels of some PFASs, including PFHxS, in human blood sampled before the contamination (during the period 1977–2004), and the PFHxS plasma levels had increased steadily ($p<0.001$) from 1977 to 2004. This was in contrast to PFOS and PFOA which remained fairly stable with a small increase during the first 10–15 years followed by a decrease from about 1990–1995. The total median concentration of PFHxS for the entire time period was 1.7 µg/L (range 0.5–4.6 µg/L).

92. In a recent human biomonitoring study in the city of Ronneby in Sweden people have been exposed to high levels of PFASs via drinking water, including PFHxS (1700 ng/L in 2013) from a nearby military airport. The levels of PFHxS were the highest ever reported in Sweden, (277 ng/mL, range 12–1660) (Li et al., 2018).

93. Increasing trend of PFHxS was also observed in archived serum samples from Norway (Haug et al., 2009); Serum levels in men (age 40–50 years) for PFHxS increased from 1976 to the early 1990s where the levels stabilised until 2006. The concentrations for PFHxS ranged from a minimum of 0.1 µg/L in 1977 to a maximum of 3.4 µg/L (2000) and the concentration was 1.4 µg/L in 2006. No temporal patterns were observed for PFHxS in archived serum samples from two German cities from 1980–2010 (Yeung et al., 2013). A decline of 61% was seen for PFHxS age- and sex-adjusted geometric mean concentrations from 2000–2001 to 2015 in American Red Cross adult blood donors (Olsen et al., 2017). No decline in PFHxS serum levels were observed in Californian women age 50–80 years in the period 2011 to 2015 in contrast to other PFASs which significantly declined (Hurley et al., 2018), this was also evident after removing participants with known drinking water exposure. In a longitudinal study of men conducted in Northern Norway, concentrations of PFOS and PFOA were highest during 1994–2001 and 2001, respectively, whereas PFHxS levels increased to 2001, however did not decrease between 2001 and 2007 (Nøst et al., 2014). In a study of blood spots from newborn in New York, USA from 1997 to 2007, PFHxS levels (and PFOS and PFOSA) increased and peaked around year 2000 and then declined. Levels of PFOS and PFOSA declined well below 1997 levels, but PFHxS levels were only slightly lower than 1997 levels (Spliethoff et al., 2008). In pooled human sera from the Australian population, PFHxS levels ranged from 1.2 to 5.7 ng/mL (08/09) and from 1.4 to 5.4 ng/mL (10/11) but overall the median levels of PFHxS have not

significantly changed from 2002 (Toms et al., 2014). In a systematic review excluding data from occupational exposure and or populations exposed to point sources such as contaminated drinking water, the concentrations of PFOS, PFDS, and PFOA in humans are generally declining, and increasing concentrations of PFHxS have started to level off in recent years (Land et al., 2018). However, in a study reconstructing past human exposure by using serum biomonitoring data from USA and Australia using a population based pharmacokinetic model, significant declines were observed for PFOS and PFOA but no trend was observed for PFHxS (Gomis et al., 2017). Furthermore, the concentrations of PFHxS in serum followed a different age pattern than PFOS indicating that global exposure to PFHxS is still ongoing and has not significantly declined since the early 2000s.

94. Occupational exposure can lead to high serum levels of PFHxS. In firefighters' serum levels of PFOS and PFHxS were in the range of 92–343 and 49–326 ng/mL, respectively (whereas the control group had 1–40 and 0.2–22 ng/mL of PFOS and PFHxS, respectively) (Rotander et al., 2015). At a Chinese fluorochemical manufacturing plant for PFOS-related compounds, indoor dust (67.3%) and diet (31.6%) was found to be the largest sources to human PFHxS exposure (Gao et al., 2015). The drinking water PFHxS average concentration was 0.80 ng/L in that study. Serum concentrations of PFHxS were in the range 12.8–10546 ng/mL, and indoor dust levels rang from nd-257201 ng/g (mean = 15726) (Gao et al., 2015). In another study from a fluorochemical manufacturing plant in the same district, serum concentrations of PFHxS in family members of occupational workers were in the range 4.33-3164 ng/mL, dust in residences connected to the plant had PFHxS in the range 0.44 to 708 ng/g, both significantly higher than in ordinary residents in the plant area, diet PFHxS was in the range 0.067–0.448 ng/g ww and drinking water PFHxS from n.d to 3.2 ng/L (Fu et al., 2015). In the Fu et al., 2016 study serum concentrations of PFHxS in occupational workers were in the ranges of <LOD to 19,837 ng/mL (median=764 ng/mL). The serum levels of PFHxS in the exposed workers showed an obviously increasing trend with length of service. Concentrations in urine ranged from <LOD–77.1 ng/mL (median=1.7 ng/mL).

## 2.4 Hazard assessment for endpoints of concern

### 2.4.1 Toxicity to aquatic organisms and birds

95. Ecotoxicity data for PFHxS are limited, and fish toxicity studies are lacking for PFHxS. The findings available for other perfluorinated acids indicate that toxicity increases with increasing carbon length, and sulfonates are more potent than carboxylates (Giesy et al., 2010, Hagenaars, et al., 2011; Ulhaq, et al., 2013). The findings available for perfluorinated acids other than PFHxS indicate that the primary toxicity concern for these substances is chronic, intergenerational toxicity. Read-across from the $C_4$ and $C_8$-homologes (PFBS and PFOS) could indicate potential effects from exposure to PFHxS. Fish toxicity data available for the $C_8$ homologue, PFOS, indicate potential for increased mortality in offspring when the parent generation is exposed to concentrations as low as 0.01 mg/L (Ji et al., 2008). Although PFBS has been shown to cause low acute toxicity to fish (reviewed in Giesy et al., 2010), PFBS was recently shown to induce multi-generational disturbance of the thyroid system in marine medaka in a life-cycle exposure at environmentally relevant levels (Chen et al., 2018c). Exposure to PFBS (0, 1.0, 2.9 and 9.5 μg/L) was from F0 egg until sexual maturity, while F1 and F2 was not exposed. Bodyweight was significantly reduced for both female and male F0 fish exposed to 2.9 μg/L and 9.5 μg/L for 6 months, and in female F0 plasma T3 level was significantly reduced (41%) in the 9.5 μg/L group. In the F1 larvae a significant increase in T3 was observed in 1 μg/L group. Delayed hatching was coupled to elevated T3 levels in F1 larvae. Also, the F2 larvae TH disruption was exhibited with increased T4 levels (significantly increased in the 9.5 μg/L group) observation was strengthened by alteration in gene expression of TH-related genes (deiodinase 1 and thyroid binding globulin) was increased (Chen et al., 2018c).

96. In a chronic life-cycle test using a nominal concentration of PFOS in the range of 1 to 100 μg/L, the chironomid *Chironomus tentans* EC 50 values were ~95 μg/L for the endpoints survival, growth and emergence, 2-3 orders of magnitude lower than those reported for other aquatic organisms (MacDonald et al., 2004). This might reflect effects on haemoglobin as the larvae gradually became pale losing the colour associated with haemoglobin. Microorganisms and algae in an aquatic ecosystem could be affected by membrane effect from PFASs in their environment. Fitzgerald et al (2018) observed increased membrane permeability and quorum sensing response (which is important for initiating bacterial responses such as biofilm, toxin or antibiotic production) in a model bacterium exposed to PFBS, PFHxS or PFOS. A pattern for increasing potency with increasing chain length was observed, significant changes were observed at 50 mg/L for PFHxS but PFOS showed significant effects at 0.3 mg/L.

97. Sub lethal effects of PFHxS on amphibian at current environmental levels have been observed in one study (Hoover et al., 2017). Northern leopard frog (Rana pipiens) tadpoles (n=36 x 2 replicates) were exposed to 0, 10, 100 or 1000 μg/L PFHxS, PFOS, PFOA or 6:2 fluorotelomer sulfonate (6:2 FTS) for 40 days. Survival for all treatments was above 90%. Although PFOS showed a higher BCF (2 orders of magnitude higher) than other test compounds in this study, PFHxS was more potent for the endpoints (gosner stage (development) and snout-vent length) at day 40. Statistical significance was observed for all doses of PFHxS tested and the two highest doses of PFOS. However, all tested PFASs showed the same tendency in delaying frog development.

98. A study on the African clawed frog (*Xenopus laevis*) tadpoles, indicates possible endocrine-disrupting potential when testing PFBS and PFOS at 0, 0.1, 1, 100 and 1000 μg/L from stage 46/47 to 2 months post metamorphosis. The PFOS used in this study was 98% pure, and detectable levels of PFHxS in the range of 3.4–4.8 and 18.1–42.6 µg/L were observed in the water with PFOS 100 and 1000 µg/L, respectively. However, it should be anticipated that effects observed are caused by the PFOS. Survival exceeded 85% for all treatments and no reduction in body weight was observed after 4 months of exposure. Both PFOS and PFBS promoted expression of estrogen and androgen receptors in the brain, and estrogen receptor in the liver, from exposure levels of 0.1 µg/L for 2 months.
Hepato-histology impairments (hepatocyte degeneration, hepatocyte hypertrophy and increase in blood sinusoids) were observed at high concentrations (100–1000 µg/L) for both PFOS and PFBS, however, no change in hepatosomatic index was observed. PFOS at concentration at 1, 100 and 1000 µg/L induced degenerative spermatogonia while no such effect was observed for PFBS (Lou et al., 2013). Read-across from the $C_4$ and $C_8$-homologes (PFBS and PFOS) could indicate potential effects from exposure to PFHxS.

99. Studies in birds have shown that PFHxS affects thyroid hormone pathways and genes related to neuronal development at 8.9 to 38,000 ng/g (Cassone et al., 2012 a,b). Based on egg injection, the lowest observed effect concentration (LOEC) was 890 ng PFHxS/g ww for developing leghorn chicken embryos (plasma free T4) (Cassone et al., 2012b). Plasma free T4 levels were reduced in a dose-dependent manner in embryos exposed to PFHxS from 8.9 ng/g with statistically significant changes occurring at 890 ng/g (Cassone et al., 2012b). Effect on gene expression was observed in avian primary neuronal culture in the concentration range 0.1-10 µM (Vongphachan et al., 2011). Furthermore, negative correlations between plasma PFHxS and ratio total T3/ free T3 thyroid hormones have been observed in Arctic seabird (Rissa tridactyla) (Nøst et al., 2012).

### 2.4.2 Toxicity in rodents relevant for humans

100. Experimental studies in rodents exposed to PFHxS consistently show adverse effects to the liver (Butenhoff et al., 2009; Bijland et al., 2011; Chang et al., 2018; Das et al., 2016), and associated metabolic effects, such as effects on serum levels of cholesterol, lipoproteins, triglycerides and free fatty acids (Butenhoff et al., 2009; Das et al., 2016; Bijland et al., 2011). Effects on the liver include a dose-dependent increase in hepatocellular hypertrophy associated with a significant enlargement of the liver (56% increase in absolute liver weight) in male rats following 42 days of exposure at 10 mg/kg bw/d, and significant increase in relative liver weight at doses of 3 and 10 mg/kg/d (Butenhoff et al., 2009). In another study, 110% increase in absolute liver weight was observed following 28 days of PFHxS exposure at 6 mg/kg/d in genetically modified male mice (APO3*-Leiden.CETP (E3L.CETP), which has an increased clearance of apoB-containing lipoproteins (Bijland et al., 2011). The exposure caused hepatomegaly with steatosis as well as reduced serum total cholesterol and triglycerides. The authors hypothesis that the PFHxS-impaired lipoprotein secretion from the liver is the underlying mechanism, leading to accumulation of lipoproteins and triglycerides in the liver, causing hepatomegaly and steatosis and reduced serum lipoproteins and triglycerides (Bijland et al., 2011). In a reproductive/developmental toxicity study in mice, significantly increased liver weights were observed in F0 males and females from 1 mg/kg bw/day dosed for 42 days (Chang et al., 2018). At the highest dose, 3 mg/kg bw/day, the 70% increased liver weight was associated with moderate to marked hepatocellular hypertrophy, steatosis, single-cell necrosis and increased alkaline phosphatase (ALP) as well as significantly reduced serum cholesterol. A LOAEL of 0.3 mg/kg bw/day based on reductions of total serum cholesterol at all doses was derived from the Butenhoff et al., 2009. Significantly increased absolute and relative liver weight in male rats and hepatocellular hypertrophy in this study was seen from 3 mg/kg bw/d.

101. The effect of PFHxS on the liver is believed to be, at least partly, mediated via activation of nuclear receptors. Several studies have explored the mechanistic effects of PFHxS on liver function, gene expression and peroxisome proliferator-activated receptor (PPAR)-alpha activation. In a study by Wolf et al., 2008, PFHxS was found to activate both mouse and human PPAR-alpha-receptor *in vitro* with LOECs of 8.76 and 4.38 µg/mL, respectively, (equals 20 and 10 µM) in transiently transfected

African green monkey kidney cells (COS-1 cells). PFHxS also activated PPAR-alpha receptors from Baikal seals in a transactivation assay in a dose dependent manner (Ishibashi et al., 2011). In a study on wild type and PPAR-alpha null mice exposed orally to 10 mg/kg/d PFHxS for 7 days, liver effects (significant increase in liver weight, steatosis) was observed in both strains, whereas exposure to the PPAR-alpha agonist WY-14643 did not induce this effect in the PPAR-alpha null mice, indicating that the effects on the liver by PFHxS occur also independent of PPAR-alpha (Das et al., 2017; Rosen et al., 2017). Gene expression profile also indicate that certain PFASs have the potential to activate constitutive activated receptor (CAR) and PPAR-gamma (Rosen et al., 2017). PFHxS also affected hepatic expression of genes involved in lipid and cholesterol metabolism in mice (Bijland et al., 2011; Das et al., 2017; Rosen et al., 2017). In a pre-adipocyte culture PFHxS was more potent than PFOS in inducing triglyceride accumulation, and both PFSAs produced strong changes in gene expression with similarities to those observed with PPAR-gamma agonist (Watkins et al., 2015). In another study, PFHxS was found to rapidly inhibit gap junctional intercellular communication (GJIC) in a dose-dependent and reversible manner (Hu et al., 2002).

102. Exposure to PFHxS has also been shown to alter haematological parameters in male rats exposed for 42 days (Butenhoff et al., 2009). Hematocrit and red blood cell counts were significantly reduced at 3 mg/kg bw/d, haemoglobin concentration significantly reduced from the 1 mg/kg/d group and prothrombin time was altered at all doses tested except for 1 mg/kg bw/d. However, no alteration of haematology parameters was observed in male mice exposed to PFHxS for 3 mg/kg bw for 42 days (Chang et al., 2018).

103. Thyroid organ toxicity has been observed following exposure to PFHxS. In F0 male rats exposed to PFHxS at 0, 0.1, 1.0, 3.0 or 10 mg/kg for 42 days, a dose-dependent increase in thyroid hypertrophy/hyperplasia of the follicular epithelium was observed, no effect was observed in F0 females, however, serum concentrations in female rats were approximately 8 times lower than in males (Butenhoff et al., 2009). The underlying mechanism for the thyroid effects were believed to be due to increased plasma turnover of thyroxine (T4) resulting in a stimulation in thyroid stimulating hormone (TSH) and a compensatory hypertrophy/hyperplasia. A LOAEL of 3 mg/kg bw/d could be determined for hyperplasia of thyroid follicular epithelial cells (not reported in the paper). Some mechanistic studies have explored the effect of PFHxS on the thyroid hormone pathway. PFHxS competed with thyroxine (T4) for binding to the human thyroid hormone transport protein transthyretin (TTR) (Weiss et al., 2009; Ren et al., 2016), which is the main T4 carrier in cerebrospinal fluid, and expressed at high levels during prenatal and early postnatal life (Larsen and Delallo, 1989). PFHxS did also dose-dependently inhibit triiodothyronine (T3)-dependent cell growth in vitro at low concentrations ($10^{-8}$ to $10^{-5}$ Molar (M)) but increased cell proliferation at higher concentrations ($10^{-4}$ M) (Long et al., 2013).

104. In a reproductive/developmental toxicity screening study in CD-1 mice exposed to PFHxS at 0, 0.3, 1.0 or 3.0 mg/kg bw/day, significantly decreased mean live litter size were observed from 1.0 mg/kg bw/day and reduced fertility index was observed at 3.0 mg/kg bw/day, although not significantly different from control (Chang et al., 2018). However, a clear dose-response relationship was lacking for these responses and the highest dose is considered low. For comparison, PFOS has been shown to reduce litter size by perinatal mortality at 2 mg/kg for rats and 10 mg/kg for mice (Lau et al., 2003). Adverse effect on reproductive or developmental parameters in dams or offspring in rats was not shown (Butenhoff et al., 2009, Ramhøj et al., 2018). However, a marked reduction in T4 was observed both in dams and offspring, with a significant reduction from 5 mg/kg/day, when dams were orally exposed from gestation day 7 (Ramhøj et al., 2018).

105. Adult dose-dependent behaviour and cognitive disturbance was observed in mice after a single neonatal dose of PFHxS in the vulnerable brain developmental period (9.2 mg/kg bw, oral single dose at postnatal day 10) (Viberg et al., 2013). PFHxS affected the cholinergic system, manifested as altered nicotine-induced behaviour in adult animals, which is in agreement with previous findings for PFOA and PFOS (Viberg et al., 2013). Levels of several proteins important in the brain growth spurt indicative of normal brain development and cognitive function were affected 24 h after exposure, and taurine levels in the cerebral cortex were different from control at 4 months in males (Lee and Viberg, 2013). In another study on developmental effects in rats, no effect on motoric activity was observed for rats exposed in utero and through lactation to 0.3–10 mg/kg/d (Butenhoff et al., 2009) or mice dosed from 0-3 mg/kg bw/d (Chang et al., 2018). However, the difference in elimination time between female rats and mice (2 vs 30 days) may contribute to the diverging results on neurodevelopment effects observed between rats and mice.

106. Neurotoxic effects of PFHxS have been further explored, and PFHxS was found to reduce neuronal activity involved in learning and memory. PFHxS (100 µM) decreased the long-term potentiation in hippocampus CA1 region in adult rats with comparable potency as PFOS (Zhang et al.,

2016). Furthermore, increased frequencies of spontaneous miniature postsynaptic currents as well as increased voltage dependent calcium influx were observed after exposure of hippocampal primary neuronal cultures to 100 µM PFHxS (Liao et al., 2009). PFHxS was also shown to induce apoptosis in vitro in the dopaminergic neuronal cell line (PC12) and glutamatergic primary cells (cerebellar granule cells). Doses tested corresponded to the Butenhoff et al., 2009, in vivo study (0.3–10 mg/kg/d) which gave serum concentrations of 111–505 µM (Lee et al., 2014a, 2014b and 2016).

107. Endocrine modalities have been investigated for PFHxS in vitro. PFHxS inhibits 11-beta-dehydrogenase isozyme 2 (11b-HSD2) involved in corticosteroid hormone metabolism in human and rat kidney microsomes. The half-maximal inhibitory concentrations (IC50s) of human and rat 11b-HSD2 activities were 18.97 and 62.87 µM PFHxS, respectively (Zhao et al., 2011). PFHxS was shown to have anti-androgenic activity and weak estrogenic effect in vitro (Kjeldsen and Bonefeld-Jørgensen 2013). PFHxS antagonize androgen induced androgen receptor (AR) transactivation in vitro ($IC_{50}$=30 µM), and induced estrogen receptor (ER) transactivation between $10^{-5}$ and $10^{-4}$ M (20% of E2 activation). However, in co-exposure with E2 (25 pM), PFHxS further enhanced E2-induced ER response up to 187% (~similar enhancement was observed with PFOA and PFOS) (Kjeldsen and Bonefeld-Jørgensen 2013). PFHxS had weak inhibitory effect on aromatase activity (CYP19) $IC_{50}$=298 µM (human placental carcinoma cells JEG-3) (Gorrochategui et al., 2014), and displace corticosterone hormone from serum binding proteins isolated from chicks and bald eagle (Jones et al., 2003).

108. The immunotoxic effect of PFHxS has not been investigated in vitro or in vivo experiments. However, in an in vitro study, a range of related PFASs (PFBS, PFOS, perfluorooctane sulfonamide (PFOSA), PFOA, perfluorodecanoic acid (PFDA) and 8:2 fluorotelomer alcohol (8:2 FTOH)) showed immunosuppressive potential (Corsini et al., 2012), suggesting this might occur for PFHxS through the same mechanisms as observed for PFBS and PFOS.

### 2.4.3 Human epidemiology

109. Most epidemiology studies investigating the association between PFHxS levels and health effects are cross-sectional (measuring effect and exposure at the same time) with the limitations typical for those studies. Although the long half-life of PFHxS (8.5 years, with a range from 2.2 to 27 years) increases the likelihood that current serum measurements represent past exposure that would be biologically relevant for the observed effect, there is likely to be some exposure misclassification. Prospective studies that evaluate effects in children relative to early childhood exposures could increase confidence in this body of evidence. The study design and covariates do also differ between the studies, and in some studies levels of PFHxS are highly correlated with other serum PFASs and thus weakening the results observed for PFHxS. An overview of outcome and study design from identified studies on serum lipids and thyroid effects are shown in Tables 4.1 and 4.2, respectively, in UNEP/POPS/POPRC.14/INF/4. Please also notice the difference in elimination time between species and gender summarized in Table 3, UNEP/POPS/POPRC.14/INF/4.

110. Epidemiological studies have shown the association between serum levels of PFASs and PFHxS and serum levels of cholesterol, lipoproteins, triglycerides and free fatty acids (Fisher et al., 2013; Steenland et al., 2009; Starling et al., 2014). In an evaluation of the epidemiological studies on PFASs, increases in serum enzymes and increases in serum bilirubin were observed in the studies of PFOA PFOS and PFHxS, suggestive of liver damage (ATSDR 2018). In a cross-sectional analysis of adults in Canada a significant association between PFHxS and cholesterol outcomes (total cholesterol (TC), low density lipoprotein cholesterol (LDL), TC/high density lipoprotein (HDL) ratio and non-HDL cholesterol) were observed after weighting for sampling strategy (Fisher et al., 2013). No evidence to support the association between PFOA and PFOS with the cholesterol outcomes was observed. A positive monotonic increase in cholesterol with increasing decile of PFHxS, as well as for PFOA and PFOS, were observed in a study from the $C_8$ Health project of a population living near a chemical plant (Steenland et al., 2009). However, Nelson et al., 2010 found a negative association with PFHxS and TC, non-HDL and LDL in the general US population (NHANES 2002-3), while positive associations were observed for PFOA, PFOS and PFNA. In pregnant women in Norway a positive association with HDL-cholesterol was observed for 5 PFASs including PFHxS (Starling et al., 2014). A study of pregnant women from the Spain found that PFOS and PFHxS were positively associated with impaired glucose tolerance and gestational diabetes mellitus (Matilla-Santander et al., 2017).

111. Effects on the thyroid hormone pathway have been shown for PFHxS in epidemiological studies. Levels of total T4 levels were found to increase with increasing PFHxS levels in the general U.S population, positive but non-significant associations were also seen with total T4, PFOS and PFOA (Jain, 2013). In another study of the same population higher serum levels of PFHxS were

associated with increase in total T3 and total T4 in women (Wen et al., 2013). In men, a negative association was observed for serum PFHxS and free T4 of the U.S. general population (Wen et al., 2013). The authors also found that the risk of subclinical hyperthyroidism among women increased with increased serum PFHxS (Wen et al., 2013). No causal link between serum PFHxS, PFOA or PFOS levels and the risk of hypothyroxinemia was observed in pregnant women in a case control study from Canada (Chan et al., 2011). In a retrospective birth cohort study in the Republic of Korea the association of certain PFASs and thyroid hormones in cord blood was explored. Gender-specific analysis showed that prenatal PFHxS exposure was positively associated with T3 in girls and PFOS was not associated with any thyroid-related parameter (Shah-Kulkarni et al., 2016). T4 level in male neonates were negatively correlated with increasing prenatal exposure to PFHxS in a birth cohort study from USA (Preston et al., 2018). Webster (et al., 2016) used data from the general U.S population and found that two indicator stressors, thyroid-peroxidase antibody (TPOAb) and iodine status, did not modify the association between certain PFASs and TH alone. However, PFHxS and PFOS were negatively associated with free T4. In the small group with joint exposure to high TPOAb and low iodine, PFHxS, PFOA, PFOS and PFNA were positively associated with free T3, free T3/freeT4, TSH and TT3 (Webster et al., 2016). A systematic review of certain PFASs effects in pregnant women and children found some evidence of positive association of PFHxS and PFOS exposure and TSH levels in maternal blood, but no significant association with T3 and T4 (Ballesteros et al., 2017).

112. Human epidemiological studies have looked at the correlation between serum PFASs including PFHxS and neurotoxic or neuro developmental effects in children. From the $C_8$-health project Stein and Stavitz (2011) examined the cross-sectional association in children (age 5–18 years; n=10,456) between serum PFOS, PFOA PFNA and PFHxS concentrations and parent or self-report of doctor-diagnosed ADHD with and without current ADHD medication. Although this population had highest exposure for PFOA, the strongest association between exposure and outcome was observed for PFHxS, with elevated odds ratio (OR)s for quartiles 2–4 compared with the lowest quartile, ranging from 1.44 to 1.59 (PFHxS levels ranged from 0.25–276.4 ng/mL). No strong association with ADHD was observed with PFOS, PFOA and PFNA (Stein and Stavitz 2011). Significant increased odds for ADHD was also found in another study from U.S. using data from NHANES 1999–2000 and 2003–2004, with 1 ug/mL increase in PFHxS serum level, n=571 (Hoffman et al., 2010). However, in this study both PFOA, PFOS and PFNA were also positively associated with parental reported ADHD. In a study, investigating blood levels of various perfluoro- compounds in children and associations with behavioural inhibition, the results showed that blood levels of PFHxS were significantly associated with behavioural inhibition deficits in children (n=83) (Gump et al., 2011). High compared to low prenatal exposure to PFHxS was also associated with problematic behaviour assessed using the Strength and Difficulties Questionnaire in a prospective study of children age 5–9 years from both Greenland and Ukraine (n=1023) (Høyer et al., 2018). In Voung et al (2016) increased tendency but no significant association was observed between prenatal PFHxS levels (as well as PFOS) and behavioural regulation in children at 5 and 8 years in a cohort from the USA (n=256).

113. Epidemiological studies indicate immunotoxic or modulative effects caused by certain PFASs and PFHxS exposure prenatal and in childhood. The relationship between prenatal exposure to certain PFASs and prevalence of infectious diseases up to 4 years of life were investigated in 1558 mother-child pairs in Japan. Prenatal exposure to PFOS and PFHxS were found to be associated with occurrence of infectious diseases (such as ottis media, pneumonia, RS virus and varicella) in early life. For PFHxS the association was observed only among girls (OR: 1.55, (95% CI: 0.976, 2.45); p for trend=0.045) (Goudarzi et al., 2017). An inverse association was observed between maternal PFHxS serum levels and the level of anti-rubella antibodies (also observed for PFOA, PFOS and PFNA) (n=50). A positive association was observed between serum levels of PFHxS and number of episodes of gastroenteritis at age 3 (also observed for PFOA) (n=66) (Granum et al., 2013). Grandjean et al., 2012, observed odds ratios in a well conducted cohort study of 1.78 (95% CI: 1.08; 2.93) for inadequate antibody concentrations at age 7 for tetanus vaccine with doubling of the PFHxS serum concentration at age 5. In a follow-up study combining two birth cohorts from Faroe Island, 1997–2000 and 2007–2009, a significant reduction of pre-boost serum antibodies to tetanus vaccine at age 5 years was associated with doubling of serum concentrations at birth for PFHxS. A similar reduction was seen for PFOA (Grandjean et al., 2017a). Structural equation models showed that a doubling in PFAS exposure at 7 y was associated with losses in diphtheria antibody concentrations at 13 y of 10–30% for the five PFASs. The present study extends the previous findings of deficient antibody responses in this cohort at younger ages and therefore adds support to the notion that substantially strengthened prevention of PFAS exposure is indicated (Grandjean et al., 2017b). Furthermore, increased incidence of asthma has been indicated in children exposed to PFHxS (Dong et al., 2013; Zhu et al., 2016; Qin et al., 2017). In asthmatic children (n=132), a significant association between increasing PFHxS serum level and decreases in pulmonary function was observed (Qin et al.,

2017). PFAS (PFHxS, PFOS and PFCA $C_{8-10}$) exposure at age 5 was associated with increased risk of asthma among a small subgroup of measles, mumps and rubella (MMR)-unvaccinated children. The association was reversed in the MMR vaccinated group, but a doubling of serum PFHxS at age 5 was associated with elevated odds of non-atopic asthma and atopic eczema at age 13, but this could be chance findings (Timmermann et al., 2017). However, no associations were observed between serum PFHxS and asthma or wheezing in a cross-sectional study of children age 12-19 in the United States (n=1877) (Humblet et al., 2014). A Canadian study (n=1242) of prenatal exposure to PFHxS and cord blood immune markers (IgE, IL-33, TSLP) reported no significant associations (Ashley-Martin et al., 2015). A prospective birth cohort study of 1056 woman found that prenatal exposure to PFOA, PFDA, PFDOA and PFHxS significantly increased the risk of childhood atopic dermatitis in female children during the first 24 months of life (Chen et al., 2018b).

114. Some studies indicate that PFHxS and certain PFASs might impact reproduction in humans. Both epidemiological and in vitro studies suggest that perfluoroalkyl acids might influence ovarian cell signalling and measures of overall reproductive health. In a recent study, blood and follicular fluid was collected from 36 subjects undergoing in vitro fertilization in the United States. Results showed that baseline follicle count was inversely related to plasma PFHxS concentrations, flagging this particular PFAS as a potential compound of interest in the context of ovarian pathology (McCoy et al., 2017). In a case control study from Denmark a strong significant association between serum PFAS levels (PFDA and PFNA) and miscarriage and an almost significant association with PFHxS was observed with adjusted odds ratio 1.53 (95% CI:0.99, 2.38) while no association was observed for PFOA and PFOS (n=56 cases (miscarriage) and 336 controls (birth)) (Jensen et al., 2016). In a birth cohort study from Canada between 2008–2011, n=1625, increased concentrations of PFOA and PFHxS in the female plasma were associated with decreased fecundability as measured by a longer time-to-pregnancy and increased odds of infertility, while no significant association was observed for PFOS (Velez et al., 2015).

115. In the U.S. population in NHANES 2009–2010 (n=1566) prevalence of osteoporosis was significantly higher in the high versus lowest quartiles of serum PFHxS with OR 13.2 (95% CI: 2.72–64.15), significant ORs were also observed for PFOA and PFNA (Khalil et al., 2016). In a case-control study (n=77 cases and 81 controls) of the relationship between serum levels of certain POPs and risk for breast cancer in Greenlandic Inuit women, Wielsøe et al. found a significant positive association between breast cancer risk and PFHxS (Wielsøe et al., 2017).

### 2.4.4 Mixture toxicity and combined effects of multiple stressors

116. The following section summarizes a number of published studies, both experimental laboratory- and field studies, where combined effects of chemicals (including PFHxS) has been revealed. The compounds have been studied in combination and the effect observed can not necessarily be attributed to a specific substance rather to the mixtures of substances tested. As shown throughout many of the references cited in this Risk Profile, PFHxS is almost always detected together with a range of other PFAS (e.g. PFOS and PFOA) in the blood samples from children and others. Therefore, the multiple pathways of exposure as well as the multiple pathways of adverse effects must be taken into account, especially for developing children (Winkens et al., 2017). Little is known about the mixture toxicity of PFASs at environmental relevant conditions, but some studies have investigated the mixture effects of the most commonly detected PFASs in human serum. More than additive effect was observed for a mixture of PFHxS, PFOS, PFOA, PFNA, and PFDA, when tested for anti-androgen activity in vitro at concentration corresponding to 1 μM of each single component in the mixture (Kjeldsen and Bonefeld-Jørgensen, 2013). Binary combinations of PFOA + either PFNA, PFHxA, PFOS or PFHxS tested for activation of PPAR-alpha in vitro produced concentration-response curves that were closely aligned with predicted curves for both response addition and concentration addition at low concentration (1–32 μM) (Wolf et al., 2014). A mixture of 10 PFASs (PFHxS included) at equimolar doses (final concentrations of each PFAS: 1.56–50 μM) acted in an additive manner when tested for transactivation of PPAR-alpha from baikal seal (Ishibashi et al., 2011). Viability studies of individual and mixtures of PFASs ($C_4$–$C_{11}$) had an obvious non-monotonic concentration-response relationship on human liver cells. Results of the three binary mixtures of PFASs, one with the combination PFHxA/PFHxS, showed that synergistic effects occurred under effective concentrations of $IC_0$, $IC_{10}$, and $IC_{50}$ in mixtures while under $IC_{-20}$ the synergistic effect only occurred under a higher proportion of PFSA (Hu et al., 2014).

117. In a recent developmental toxicity study in rats, a more marked effect on serum T4 levels, antiandrogenic endpoints and liver weight were observed in the group co-exposed to PFHxS and an endocrine disruption mix (EDmix) than observed for PFHxS or EDmix alone indicating that PFHxS and the EDmix potentiate the effect of each other on various endpoints, despite their different modes of action (Ramhøj et al., 2018).

118. Studies from East Greenlandic polar bears (n=10) found significant correlations between PFCAs and PFSAs and neuro transmitter enzyme activity and neuro transmitter receptor density (Pedersen et al., 2015). Average brain sum PFSAs ($C_4$-$C_{10}$) was 28.8 ng/g ww, where PFOS accounted for 91% (PFHxS average 1.1 ng/g ww ~3.81%). Both PFCAs and PFSAs showed negative association with density of muscarine acetylcholinesterase receptor. The cholinergic-system was also affected in the mice study of Viberg et al., 2013. Furthermore, the concentrations of eleven steroid hormones were determined in eight brain regions, and levels could not be explained by concentrations in serum. Correlative analysis showed positive association between both sum PFCAs and sum PFSAs and 17-alpha- hydroxypregnenolone (OH-PRE) and several steroids were significantly correlated with the sum of PFCAs. The results indicate that an increase in the concentration of bioaccumulative PFASs concurs with an increase in brain steroid hormones (Pedersen et al., 2016). These studies indicate that the concentration of certain PFASs in polar bears from East Greenland have exceeded the threshold limit for neuro-chemical and hormonal alterations (Pedersen et al., 2015; 2016).

119. A recent study on polar bear from Svalbard found a negative relationship between $\Sigma_8$PFASs (including PFHxS) plasma levels and some thyroid hormones, and indicate that PFASs contribute to possible alteration of the thyroid hormone homeostasis in polar bears by altering the levels of free T3 (Bourgeon et al., 2017). For all studied substances (PCB, chlorinated pesticides and ΣPFAS), T3 levels were negatively related to the pollutants indicating that T3 could be more sensitive than other THs. In a study of polar bear mothers and cubs from Svalbard, there was no significant change in PFHxS levels between 1998 and 2008, with levels exceeding those associated with health effects in humans, including neurobehavioral effects and alterations in serum cholesterol (Bytingsvik et al., 2012).

120. There is evidence from experimental studies and indications from human epidemiology studies that PFHxS can affect lipid metabolism (see section 2.4.2 and 2.4.3). Tartu et al., 2017a, reported that diet and metabolic state were the main factors determining the amount of PFASs in female polar bears from Svalbard and that factors such as fasting affect the levels of PFHxS accumulated by female polar bears (Tartu et al., 2017a). In this study, levels of PFHxS were significantly negative related to urea: creatine ratios indicating a fasting state. Certain PFASs ($\Sigma_6$PFCA with carbon chain 8 to 13 and $\Sigma_2$PFSA with 6 and 8 carbons) contribute to the multiple-stressor effects observed in polar bears from Svalbard. A recent study by Tartu et al., 2017b, showed that PFAS exposure was related to biomarkers of energy metabolism (lipid-related genes, and plasma cholesterol, HDL and triglycerides). The relationship between PFASs and cholesterol as well as HDL was more pronounced when combined with reduced sea ice extent and thickness suggesting that climate driven sea ice decline and PFASs (and other organohalogenated compounds) have a synergistic negative effect on polar bears (Tartu et al., 2017b).

121. Arctic top predators such as polar bears are among the most polluted species in the world (Letcher et al., 2010) and undergo seasonal energy-demanding periods due to variation in temperature, food availability, reproduction and hibernation. As described in section 2.2.3, it is well known that certain PFASs including PFHxS will bioaccumulate in protein rich compartments (kidney, liver and blood etc) but it is not clear how body condition (such as starvation) affect tissue concentration and distribution of PFASs and a possible alteration of the toxic potential. Cocktail effects due to increased concentration of traditional POPs in fat storage as well as climate changes will also affect these periods. PFHxS has high affinity to proteins and are not subject to biotransformation (Jones et al., 2003). In Arctic fox, adipose tissue was the only tissue affected by body condition, with lean foxes having three times (95% CI: 1.1, 12) higher concentrations of PFHxS than fat foxes (Aas et al., 2014). The large seasonal variability in fat content in Arctic mammals may thus affect tissue concentrations of certain PFASs including PFHxS and increase their potential effects during seasonal emaciation. The effects are not only related to the increased concentration of PFASs, but also to increased concentration of other POPs in target organs during decreased body condition which may further increase toxicity (discussed in Aas et al., 2014).

122. Cumulative limits for PFASs in drinking water and ground water have been set in Sweden and Denmark, when PFASs are believed to act together in a mixture. In Sweden, a concentration limit of 90 ng/L is set for $PFAS_{11}$ (PFBS, PFHxS, PFOS, 6:2 FTS, PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA) and above this concentration risk reducing action is to be taken (https://www.livsmedelsverket.se/en/food-and-content/oonskade-amnen/miljogifter/pfas-in-drinking-water-fish-risk-management#Action levels). A similar approach is enforced in Denmark (http://mst.dk/media/91517/pfas-administrative-graensevaerdier-27-april-2015-final.pdf). The United States (https://www.epa.gov/sites/production/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf) and Germany (https://www.umweltbundesamt.de/sites/default/files/medien/pdfs/pft-in-drinking-water.pdf) have made recommendations for content of PFOS and PFOA in drinking water. Furthermore, in the proposal for a new European Drinking Water Directive, which

is under discussion, a limit value is proposed for the group of PFASs. Values of 0.1 µg/L for each individual PFAS and 0.5 µg/L for PFASs in total in as been suggested (http://ec.europa.eu/environment/water/water-drink/pdf/revised_drinking_water_directive_annex.pdf).

# 3. Synthesis of information

123. PFHxS, its salts and PFHxS-related compounds belong to the PFAS group and have been used as surfactants, water- and stain protective coatings for carpets, paper, leather and textiles and in fire-fighting foams among other applications, often as a replacement for PFOS. It is also known that PFHxS has been unintentionally produced during the electrochemical fluorination processes used in production of other PFASs e.g. PFOS. These compounds have provided surfactant, water- and stain protective functions in various products due to their thermal stabilities and hydrophobic and lipophobic nature.

124. Information about current global manufacture of PFHxS, its salts and PFHxS-related compounds are limited. Historical production was mainly carried out by 3M. One European manufacturer with production of less than 1 tonne per year and a few producers located in China have been identified in respect of on-going production, however, quantitative production data are not publically available. PFHxS, its salts and many PFHxS-related compounds have been listed on national chemical inventories (US, Canada, Japan, Australia, EU, Nordic countries and China) indicating historical/present production, importation and/or uses of products containing these substances. Possible direct and indirect sources of PFHxS to environmental releases are many and emissions may take place through air, dust, water, waste, wastewater and sludge.

125. While analytical methods for detection of PFHxS are well established, it is presently a challenge to qualify and analytically quantify PFHxS precursors due to the lack of established methods. However, precursors such as perfluorohexane sulfonamides were detected/identified in leachates from landfills indicating that these PFHxS precursors may be used in a variety of applications since the landfills received waste from a number of sources. FHxSAs has also been detected in historical AFFF manufactured by 3M.

126. PFHxS has been detected in numerous environmental matrixes worldwide including in the Arctic and Antarctica. Due to historical use of AFFF containing PFHxS and PFHxS-related compounds, high levels of PFHxS has been detected in the vicinity of fire-fighting training fields, both at commercial airports and at military facilities. Based on the persistence of PFASs in general, the known extreme stability of the C-F bond and the monitoring data showing the ubiquitous presence of PFHxS in the environment, it is concluded that PFHxS is persistent to abiotic and biotic degradation. Based on physical properties, PFHxS is known to undergo protein-binding associated bioaccumulation rather than lipid partitioning, which makes standard BCF/BAF analysis less meaningful. Thus, as with PFOA and PFOS, the use of log Kow and BCF have been demonstrated to be inappropriate measures of bioaccumulation. Several studies have reported bioaccumulation and biomagnification of PFHxS with field based BMFs and TMFs > 1 for different food chains, including from the Arctic. PFHxS binds strongly to proteins and this phenomenon is observed across species. The reported half-lives of PFHxS in human serum, which is in general known to be a good indicator of bioaccumulation, is very high 8.5 (range 2.2-27 years).

127. PFHxS is found ubiquitously spread throughout the environment and in biota globally. A number of studies have reported exposure in remote areas that can be attributed to long-range environmental transport. PFHxS is detected in water, snow, air and biota (including humans) at remote locations. Increasing trends, most likely due to increased emissions, have recently been detected in polar bears at Svalbard (Norway) and in air in the Canadian- and Norwegian Arctics. In polar bears, PFHxS was the third most abundant PFAS measured in the plasma of these animals. The main mechanism of transport to remote regions like the Arctic is presently most likely through ocean currents, supported by detection in a number of studies of PFHxS in waters worldwide. However, transport of PFHxS and PFHxS-related compound via the atmosphere cannot be excluded since PFHxS has been measured in snow, rainwater and air as well as in lichen. It is likely that both PFHxS and PFHxS-related compounds are transported through air to remote regions and that PFHxS-related compounds degraded to PFHxS locally.

128. Environmental trend data of PFHxS levels are not conclusive, in most regions and matrices no obvious trend has been observed, while a few matrices show a declining or increasing trend. Limited data are available on levels of PFHxS in humans in Asia where production continued after the 3M phase out.

129. Humans are exposed to PFHxS mainly through intake of food and drinking water but also through the indoor environment via exposure to dust or consumer products containing PFHxS or its precursors. Exposure to PFHxS through dust from carpeting is a prominent source of exposure to toddlers. Following PFOS and PFOA, PFHxS is the most frequently detected PFAS in blood-based samples from the general population worldwide. PFHxS is present in the umbilical cord blood and breast milk. Breast milk may be an important source of exposure to breast-fed infants since it is documented that PFHxS is excreted via lactation. Contamination of drinking water can result in highly increased PFHxS serum levels due to the long elimination-time in humans.

130. In rodents, liver effects such as increased liver weight, marked hepatocellular hypertrophy, steatosis, necrosis, increased serum alkaline phosphatase have been observed from PFHxS exposure. Effect on liver lipid and lipoprotein metabolism and altered serum cholesterol, triglycerides and lipoproteins has been observed in both rodents and humans. PFHxS activates peroxisome proliferating receptor (PPAR)-alpha, however, effects on liver are also observed in mice without PPAR-alpha, showing mechanisms of action independent of PPAR-alpha. In addition, effect on reproduction (significantly decreased live litter size) has been observed in mice following PFHxS exposure.

131. Neurotoxic and neurodevelopmental effects have been observed in controlled laboratory experiments in mice and rats, and some studies indicate association between behavioural inhibition in children and certain PFASs (and PFHxS) exposure prenatally and in childhood. Effects on the thyroid hormone system have been reported cross-species (bird, rat, polar bear and human). Furthermore, several epidemiology studies indicate that the naïve and developing immunesystem might be vulnerable to certain PFASs and PFHxS exposure, observed associations between serum PFHxS levels and reduced effect of vaccines and higher incidences of infections and asthma in children.

132. Certain PFASs, including PFHxS, contribute to the multiple-stressor effects observed in Arctic animals. Studies indicate that the level of certain PFASs in polar bear brain exceeded the threshold limit for neurochemical and hormonal alterations, and can affect the thyroid homeostasis. PFHxS bioaccumulate in protein-rich tissue, but during seasonal emaciation PFHxS levels increased in fat tissue. Combined exposure of PFASs with other POPs have unknown consequences and may cause increased toxicity for heavily stressed species.

**Table 5. POP characteristics of PFHxS**

| Criterion | Meets the criterion (Yes/No) | Remarks |
|---|---|---|
| Persistence | Yes | • No photolysis in water was observed for PFHxS following, respectively, 106 and 20.5 days of exposure in a field study of PFHxS conducted at high altitude in (Taniyasu et al., 2013).<br>• PFHxS is found in soil, water and a variety of biota in the vicinity of fire-fighting training areas following the historical use of PFHxS-containing foams, showing that it is persistent and does not undergo any abiotic or biotic degradation under normal environmental conditions (Bräunig et al., 2017; Filipovic et al., 2015).<br>• Read-across from experimental degradation data for PFBS, PFOS and PFOA demonstrate that these substances are very persistent (Quinete et al., 2010, ECHA 2017a; ECHA 2013), and based on the stability of PFASs in general (Siegemund et al., 2000) one can expect that PFHxS have the same persistent characteristics. |
| Bio-accumulation | Yes | • Found in elevated concentrations in top predators in the Arctic (Routti et al., 2017; Tartu et al., 2017b; Smithwick et al., 2005b).<br>• BMFs>1 in aquatic organisms (Haukås et al., 2007; Houde et al., 2006; Babut et al., 2017)<br>• BMFs >1 in terrestrial organisms (Riget et al., 2013 as reported in ECHA 2017a).<br>• TMFs> 1 in aquatic organisms (Munoz et al., 2017).<br>• Highest levels of PFHxS in biota are detected in polar bears (Smithwick et al., 2005 a, b; Routti et al., 2017)<br>• Half-life of PFHxS in humans are the highest reported for any PFAS. An average of 8.5 years (range 2.2-27 years) have been reported (Olsen et al., 2007) |

| Criterion | Meets the criterion (Yes/No) | Remarks |
|---|---|---|
| Potential for Long-Range Environmental Transport | Yes | • PFHxS is found in air and snow in the Arctic (Theobald et al., 2007 as cited in Butt et al., 2010; Stock et al., 2007; Genualdi et al., 2010; Butt et al., 2010; Wong et al., 2018; Norwegian Environment Agency M-757, 2017b, Rauert et al., 2018a)<br>• Detection of PFHxS in Arctic seawater (Caliebe et al., 2005 as cited González-Gaya et al., 2014; Rosenberg et al., 2008; Busch et al., 2010; Cai et al., 2012; Benskin et al., 2012; Zhao et al., 2012¸ Yeung et al., 2017).<br>• Transport pathways are most likely both through water and air (reviewed in Butt et al., 2010; Rauert et al., 2018 a,b).<br>• Transport of PFHxS-related compounds through air indicated by detection of increasing amounts of PFHxS in snowmelt (Codling et al., 2014; Meyer et al., 2011) and in rain water (Eschauzier et al., 2010).<br>• Detection in top predators in Arctic with increasing levels far away from local sources (Routti et al., 2017; Tartu et al., 2017b; 2018). |
| Adverse effects | Yes | PFHxS exerts effects on liver, serum lipids and cholesterol, and affects serum thyroid hormones and may impair neuro development. Key data include:<br>• Effects on liver; increased liver weight, marked hepatocellular hypertrophy, steatosis, necrosis and altered serum cholesterol, triglycerides, lipoproteins and alkaline phosphatase in rodents (Butenhoff et al., 2009; Bijland et al., 2011; Das et al., 2017, Chang et al., 2018). A LOAEL of 0.3 mg/kg bw/day based on reductions of total serum cholesterol at all doses was derived from the Butenhoff et al., (2009). Significantly increased absolute and relative liver weight in male rats and hepatocellular hypertrophy in this study was seen from 3 mg/kg bw/d.<br>• Effects on reproduction (decreased live litter size) was observed in mice from 1.0 mg/kg bw/day (Chang et al., 2018).<br>• Epidemiology studies show association between PFHxS exposure level and serum concentration of cholesterol, lipoproteins (Fisher et al., 2013: Steenland et al., 2009).<br>• Thyroid organ effects were observed in male rats exposed to PFHxS at 10 mg/kg for 42 days, a dose-dependent increase in thyroid hypertrophy/hyperplasia was observed (Butenhoff et al., 2009). Some epidemiology studies show association between PFHxS serum levels and thyroid hormones (Jain 2013; Wen et al., 2013; Webster et al., 2016).<br>• Developmental neurotoxicity observed in mice (Viberg et al., 2013; Lee and Viberg, 2013). Epidemiological indications for cognitive developmental effects in humans (Stein and Stavitz 2011; Høyer et al., 2018).<br>• Effect on the immune system has been shown in epidemiology studies, both reduced effects to vaccination (Granum et al., 2013; Grandjean et al., 2012; 2017a,b), increased incidence of asthma (Dong et al., 2013; Zhu et al., 2016; Qin et al., 2017; Timmermann et al., 2017) and higher risk of infection in children has been observed in correlation with PFHxS serum levels (Goudarzi et al., 2017; Grannum et al., 2013). |

# 4. Concluding statement

133. PFHxS is released into the environment, including from degradation of PFHxS related substances, and human activities e.g. from manufacturing processes, product use and disposal and management of waste. PFHxS is persistent, bioaccumulative and has the potential to undergo long-range environmental transport, making emissions of this substance a transboundary pollution problem including in remote areas. Globally, the occurrence and distribution of PFHxS is shown for humans, wildlife and the environment. Detections include measurements in the Arctic and Antarctic.

134. PFHxS is one of the most frequently detected PFAS in human blood in the general population and has a very long half-life in humans of 8.5 years (range 2.2-27 years). Furthermore, PFHxS has been detected in human umbilical blood, serum and breast milk. High concentrations of PFHxS have

been detected in soil, ground and drinking water near airports or fire-fighting training sites, sludge and wastewater from waste water treatment plants, as well as in the vicinity of PFAS/PFHxS production/usage plants and in leachate from landfills.

135. Available scientific literature suggests that there is a risk for adverse effects on the general population, in particular for children and population groups that are exposed to elevated levels of PFHxS and other PFASs through drinking water.

136. The concern for adverse effects relates to observed effects on the liver, thyroid hormone system, reproduction, and immune modulating effects, as well as indications of neurotoxic and neurodevelopmental effects have been shown. Furthermore, effects on lipid and lipoprotein metabolism add to the concern both for humans and Arctic animals.

137. Recent data from polar bear studies at Svalbard (Norway) revealed increasing levels of PFHxS in plasma. PFASs, including PFHxS, contribute to the multiple-stressor effects observed in polar bears from Svalbard indicating a risk for adverse effects in wildlife.

138. Based on the persistence, bioaccumulation, toxicity in mammals including humans and the widespread occurrence in environmental compartments including at remote regions, it is concluded that PFHxS, its salts and PFHxS related compounds are likely, as a result of their long-range environmental transport, to lead to significant adverse human health and environmental effects such that global action is warranted.

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# 附錄三、全氟辛酸(**PFOA**)及其鹽類和相關化合物之風險管理評估

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**Persistent Organic Pollutants Review Committee**
**Fourteenth meeting**
Rome, 17–21 September 2018

# Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting

## Addendum

## Addendum to the risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

### Note by the Secretariat

At its fourteenth meeting, by its decision POPRC-14/2, the Committee adopted an addendum to the risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds on the basis of the draft contained in the note by the Secretariat (UNEP/POPS/POPRC.14/3), as revised during the meeting. The text of the addendum to the risk management evaluation as adopted is set out in the annex to the present addendum. It has not been formally edited.

## Annex

# FURTHER ASSESSMENT OF INFORMATION ON PFOA, ITS SALTS AND PFOA-RELATED COMPOUNDS

## Addendum to the risk management evaluation on PFOA, its salts and PFOA-related compounds[1]

September 2018

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[1] UNEP/POPS/POPRC.13/7/Add.2.

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## Executive Summary

1. In June 2015, the European Union (EU) and its member States submitted a proposal to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds[2] in Annexes A, B, and/or C to the Stockholm Convention (UNEP/POPS/POPRC.11/5). At its twelfth meeting in September 2016, the Persistent Organic Pollutants Review Committee (POPRC) concluded that PFOA is persistent, bioaccumulative and toxic to animals including humans. There is widespread occurrence of PFOA and a number of PFOA-related compounds in environmental compartments and in biota and humans. Therefore, PFOA, its salts and PFOA-related compounds that degrade to PFOA are likely, as a result of their long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action is warranted (UNEP/POPS/POPRC.12/11/Add.2).

2. At its thirteenth meeting in October 2017, the POPRC adopted the risk management evaluation (RME) on PFOA, its salts and PFOA-related compounds[3] (UNEP/POPS/POPRC.13/7/Add.2) and recommended to the COP that it consider listing the chemicals in Annex A or B to the Convention with specific exemptions specified in decision POPRC-13/2 (also in UNEP/POPS/POPRC.13/7/Add.2, para 13). However, the Committee was unable to reach conclusions on whether exemptions may be needed for specific uses. Furthermore, additional work was needed to consider the possibility of unintentional releases and specific issues related to substance identity.

3. The Committee established an intersessional work group to assess additional information to help further the discussion at the fourteenth meeting to define the need for possible specific exemptions and/or acceptable purposes for certain additional applications and to evaluate their unintentional releases in the view of strengthening its recommendation to the COP. The Committee invited Parties and observers, including the relevant industries, to provide information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds in particular in the following applications:

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

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

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

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

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

(f) Automotive industry: information on spare parts;

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

4. For the applications above, information regarding socio-economic aspects as well as other relevant information was also requested.

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

[3] The title of decision POPRC-13/2 refers to “pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds”, consistent with the proposal for the listing of the chemicals submitted by the European Union (UNEP/POPS/POPRC.11/5). During the intersessional period, however, the chemicals that are the subject of the decision were referred to as “perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds”. Both terms designate the same group of chemicals, but the phrase “perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds” is more consistent with other references to these chemicals. As noted above, the Committee has used the latter name in the present decision. The latter name will therefore be used henceforth to refer to the chemicals covered by decisions POPRC-12/2 and POPRC-13/2 in documents prepared under the auspices of the Stockholm Convention.

5. In addition, the Committee invited Parties and observers to submit information that would assist the further evaluation by the Committee of PFOA, its salts and PFOA-related compounds in relation to its unintentional formation and release, in particular from primary aluminium production and from incomplete combustion.

6. The Committee also invited Parties and observers to provide information that would assist the Committee to further evaluate the chemical identity of the PFOA-related compounds chemical list; in particular in relation to sulfluramid and 1-hydroperfluorooctane (1-H-PFO). Sulfluramid is manufactured by using perfluorooctane sulfonyl fluoride (PFOSF) as an intermediate and its structure is related to perfluorooctane sulfonic acid (PFOS). In the environment, it degrades in significant yields to PFOS although it also has the potential to degrade to PFOA under certain conditions. Since sulfluramid (N-ethyl perfluorooctane sulfonamide, CAS No: 4151-50-2) is produced from PFOSF, it is already covered, although not explicitly mentioned, under the listing of PFOS, its salts and PFOSF. However, sulfluramid production is already covered by an acceptable purpose under the PFOS listing and it should then not be included under the PFOA listing to avoid double regulation. Based on the further information submitted, 1-H-PFO should not be excluded from the scope of PFOA-related compounds since studies suggest that a transformation to PFOA is possible. 8:2 fluorotelomer methacrylate, polymer with methyl methacrylate (CAS No: 93705-98-7) is included in the non-exhaustive list of PFOA-related compounds.

Unintentional formation and release

7. The RME identified that PFOA, its salts and PFOA-related compounds could potentially be unintentionally formed from incomplete combustion and primary aluminium production but that further information was needed on this topic. Additional information on unintentional formation and release of PFOA, its salts and PFOA-related compounds was provided by Austria (2018), the Netherlands (2018a) and International POPs Elimination Network (IPEN) and Alaska Community Action on Toxics (ACAT) (2018). 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, open combustion and other sources of unintentional formation would be desirable. It is also noted that in developing and transition countries there is greater prevalence of open combustion and other uncontrolled combustion processes, and these should also be considered. The Netherlands (2018a) highlighted that an addition to Annex C would need to not only be justified but proportionate, highlighting that the emission is negligible compared to all the other sources.  No new information on unintentional releases of PFOA linked to aluminium production were provided. Most of the information identified in literature and detailed in the RME relates to emissions of $CF_4$ and $C_2F_6$, which are unrelated to PFOA. From the currently available information it is not possible to conclude that aluminium production represents a relevant source of PFOA releases to the environment. Concerns were raised that presence of PFOA may not be from incineration but from previous presence in products. Based on the information assessed, the Committee does not recommend listing PFOA, its salts and PFOA-related compounds in Annex C to the Convention. Additional information and preferably also further measurements/quantitative data from other waste incinerators, open burning, and other sources of unintentionally produced POPs, in particular from developing countries, would be useful for future consideration.

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

8. The RME for PFOA highlighted a potential need for more information about a possible exemption for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. Several potential alternatives for use in textiles such as short-chain fluorinated alternatives, non-fluorine containing alternatives and non-chemical alternatives have been identified in the RME, including those that meet regulatory requirements and are in current use. In addition, no specific application has been identified that requires $C_8$ chemistry. Based on the evaluation of available information a specific exemption for use in membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment is not recommended.

Transported isolated intermediates

9. The RME for PFOA highlighted a potential need for more information about a possible exemption for transported isolated intermediates. The Committee requested information related to the quantities used, extent of transport and possible risks, and use. Archroma reported about the risk management measures in place. Based on the evaluation of available information a specific exemption is not recommended for the use of perfluorooctane iodide (PFOI) generated as an unintentional

by-product and used as an isolated intermediate to enable reprocessing to tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) in another site than the production site.

Medical devices

10. For medical devices, 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. However, on the other hand the RME (UNEP/POPS/POPRC.13/7/Add.2) highlights that alternatives to PFOA for manufacture of PTFE exist and have been commercialised. A report by ECHA (2015a) as part of the European restriction estimated European usage of PFOA within medical devices as <1kg per year. An extrapolation from the EU estimate would result into a corresponding global usage of <5kg per year based on a 20% global market share. MedTech (2018) and Euromed (2015) both highlighted the difficulty in producing detailed lists of specific applications within healthcare due to the diverse ways in which polytetrafluoroethylene (PTFE)[4] is used, though alternatives for PFOA and PFOA-related compounds in medical devices have passed stringent regulatory requirements in some geographies and are already in use. However, MedTech (2018) highlighted that due to the stringent regulations for substitution in the healthcare sector, if changes are made to articles this can trigger the need for a new round of clinical trials (taking years to complete). Based on the information compiled and discussed within the RME and further elaborated upon within the current addendum, examples exist cases where medical devices made without PFOA are available on the market and in use. However, the evidence reviewed suggests that phase-out is still ongoing for some uses. Based on the information compiled and discussed within the RME and further elaborated upon within the current document, the Committee recommends a specific exemption only for invasive medical devices.

Implantable medical devices

11. The RME for PFOA highlighted a need for more information about a potential exemption for medical implantable devices due to possible presence as a by-product in PTFE. Quantities of PFOA and PFOA-related compounds used in the production of PTFE found in implantable medical devices are small. As an indicative estimate for order of magnitude a manufacturer commented that the EU total is 20g in all devices put on the market during the period 2018–2025. This would lead to and estimation of 100g worldwide (ECHA, 2014a). ECHA (2015b) reported during the EU REACH restriction that during the manufacture of PTFE, concentrations of PFOA as a by-product range from 0.0001 to 0.5% wt/wt PTFE. Alternatives such as PFOA free PTFE products have undergone clinical testing, and been approved for use in some geographies. Limited additional information has been provided on the extent of transport, risks and socio-economic impacts of a possible restriction however the low quantities presently being used in implantable medical devices would also mean low potential for exposure. Similarly, additional information on the use of PFOA in medical implants in developing countries is unknown. The Committee recommends a specific exemption for implantable medical devices.

Photo imaging sector

12. At POPRC-13, representatives of the European photographic industry provided information for the RME that suggested specific exemptions for photographic coatings applied to paper and for use in printing plates are no longer needed. Non-fluorinated alternatives and the move to digital imaging have successfully replaced these uses in the imaging and printing industry. Only limited critical applications (limited to photographic coatings applied to films only) still use PFOA. However, it was also noted that for developing countries, such information was lacking. New information indicates that analogue printing is being phased out and replaced rapidly by digital, including in developing and transition countries. Based on the existing and rapid transition towards digital imaging, the wide use of digital techniques in developing and transitional countries, and the further reduction in use of PFOA in this sector, the Committee does not recommend specific exemptions for photographic coatings applied to paper and printing plates.

Automotive industry

13. The RME for PFOA highlighted a need for more information about a potential PFOA exemption for automotive service and replacement parts. Specification of relevant automotive service and replacement parts as well as sound justification for any exemption is required. No conclusive information was provided on specific relevant service and replacement parts and on the quantities of relevant substances used in different applications. In addition, no conclusive information was provided

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[4] PFOA can used as an emulsifier in the manufacture of PTFE, and would be present as a by-product of the finished product.

on time required for phase-out, estimation of economic impacts, and alternatives in place, and retrofitting capacity. Based on the insufficient information and lack of an appropriate justification, the Committee does not recommend a specific exemption.

Fire-fighting foams

14. Fire-fighting foams were identified as a dispersive use of PFOA in the RME resulting in direct release to the environment. Perfluorinated compounds within fire-fighting foams have been used because they proved effective against liquid fuel fires (Class B) (ECHA, 2014a).

15. Only limited information on the existing stockpiles of fire-fighting foams containing PFOA and PFOA-related compounds was available. A global inventory of APFO (the ammonium salt of PFOA, which was the main species used intentionally for fire-fighting foams) indicates a production of 3,600–5,700 tonnes between 1951 and 2004 (Norway, 2007). This can be back calculated to between 309 million and 4901 million litres of ammonium salt (APFO) based aqueous film forming foam (AFFF) concentrate within existing stockpiles depending on the assumed shelf-life of the goods.

16. Alternatives to all uses of PFOA in fire-fighting foams exist and include fluorine-free solutions as well as fluorosurfactants with $C_6$-fluorotelomers.[5] Fluorine-free foams are comparable to fluorine-based AFFFs and fire-fighting foams with PFOA in their performance and in meeting relevant certifications for almost all uses. Based on current data, prices of fluorine-free and fluorine containing AFFFs are comparable.

17. Overall the costs associated with destruction and replacement of fire-fighting foams containing PFOA and PFOA-related compounds can be perceived to be significant. One estimate by Seow (2013) quotes 1.5 Euro per litre of concentrate. However, costs associated with clean-up for sites contaminated by perfluorinated compounds are also significant, with examples quoted in the RME and the present document as millions of euros per site.

18. Based on the information compiled and reviewed within the RME, the size of in-use stockpiles of fire-fighting foams containing PFOA and PFOA-related compounds may be significant and socio-economic impacts of an immediate ban may be equally significant, potentially justifying a specific exemption. However, the impacts of release to ground water and socio-economic costs of clean-up are equally if not more significant, and the continued dispersive use of a POP is not consistent with the objectives of the Convention. On the other hand, the use of fluorinated alternatives could lead to contamination of water from short-chain per-and polyfluoroalkyl substances (PFASs) due to their mobility and persistence. This contamination is even more difficult to remediate than the contamination from the long-chain PFASs.

19. Some concerns were expressed about the importance of effective fire-fighting foams for liquid fuel fires, the potential unavailability of suitable alternatives and the cost of their use and implementation, considering that some time to move to alternatives without PFASs may be needed. The Committee does not recommend an exemption for the production of fire-fighting foams that may contain PFOA as impurities and PFOA-related compounds as constituents.

20. The Committee further concludes that there is a need for a specific exemption for use of fire-fighting foams containing PFOA and PFOA-related compounds already installed in systems including both mobile and fixed systems with specific conditions.

Listing to Annex A

21. Based on the review of information within the RME and elaborated on in the current document, only specific exemptions are envisaged. Furthermore, within the European restriction (EU 2017/1000) only one non-time limited exemption exists (implantable medical devices). MedTech (2018) commented that a transition period up to 2030 would be needed for implantable medical devices, suggesting that a specific exemption would be sufficient. Therefore, in accordance with paragraph 9 of Article 8 of the Convention, the Conference of the Parties to the Stockholm Convention should consider listing and specifying the related control measures of PFOA, its salts and PFOA-related compounds in Annex A, with specific exemptions accompanied if needed with a specific part of Annex A that details actions.

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[5] Note that perfluorohexane sulfonic acid (CAS No: 355-46-4) (PFHxS)), its salts and PFHxS-related compounds have been nominated as POPs and are currently under review by the Committee.

# 1 Introduction

## 1.1 Overview of actions to date

22. In June 2015, the European Union (EU) and its member States submitted a proposal to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annex A, B, and/or C of the Stockholm Convention (UNEP/POPS/POPRC.11/5). This proposal was considered by the Persistent Organic Pollutants Review Committee (POPRC) at its eleventh meeting held in October 2015, where the Committee concluded that PFOA fulfilled the screening criteria in Annex D and that issues related to the inclusion of PFOA-related compounds that potentially degrade to PFOA and the inclusion of PFOA salts should be addressed in the draft risk profile (see decision POPRC-11/4).

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

24. By decision POPRC-13/2,[6] the Committee adopted the RME on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2) and decided, in accordance with paragraph 9 of Article 8 of the Convention, to recommend to the Conference of the Parties that it consider listing PFOA, its salts and PFOA-related compounds in Annex A or B to the Convention with specific exemptions for the following:

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

- (i) Manufacture of semiconductors or related electronic devices:
    - a. Equipment or fabrication plant related infrastructure containing fluoropolymers and/or fluoroelastomers with PFOA residues;
    - b. Legacy equipment or legacy fabrication plant related infrastructure: maintenance;
    - c. Photo-lithography or etch processes;
- (ii) Photographic coatings applied to films;
- (iii) Textiles for oil and water repellency for the protection from dangerous liquids for the protection of workers from risks to their health and safety;

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

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

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

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[6] The title of decision POPRC-13/2 refers to “pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds”, consistent with the proposal for the listing of the chemicals submitted by the European Union (UNEP/POPS/POPRC.11/5). During the intersessional period, however, the chemicals that are the subject of the decision were referred to as “perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds”. Both terms designate the same group of chemicals, but the phrase “perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds” is more consistent with other references to these chemicals. As noted above, the Committee has used the latter name in the present decision. The latter name will therefore be used henceforth to refer to the chemicals covered by decisions POPRC-12/2 and POPRC-13/2 in documents prepared under the auspices of the Stockholm Convention.

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

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

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

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

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

(f) Automotive industry: information on spare parts;

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

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

27. Furthermore, the Committee invited Parties and observers to provide, information that would assist the Committee to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds, in particular from primary aluminium production and from incomplete combustion. Finally, the Committee invited Parties and observers to provide information that would assist the Committee to further evaluate the chemical identity of PFOA-related compounds chemical list.

28. This document represents an *addendum* to the adopted RME of PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2; considering the information received from Parties and observers. The RME will not be re-opened. To aid readers, the present document contains references to the RME and repeats selected essential details from the RME (in italics) in order to enable a good understanding for an informed discussion at the fourteenth meeting of the Committee.

## 1.2 Structure of this document

29. For ease of reference this document has been set out in a chronological fashion to answer the questions set out by the Committee’s invitation for additional information. Section 2 will provide an overview of information on substance identity. Section 3 will provide information on unintentional releases, and section 4 will provide information on each of the seven uses identified in paragraph 3 of decision POPRC-13/2. To provide as complete a narrative as possible and for ease of reference, where necessary sections of the RME have been included in the current document. Where this is the case, text will be marked in italics to clearly denote the text taken directly from the RME.

## 1.3 Data sources

30. The current document is primarily based on information that has been provided by Parties to the Convention and observers. Information was submitted by the following Parties:

(a) Parties: Belarus, Brazil, Canada, Ecuador, Monaco, Netherlands, Philippines, Sweden and United Kingdom of Great Britain and Northern Ireland (UK);

(b) Observers: Associação brasileira dos fabricantes de iscas inseticidas (ABRAISCA), FluoroCouncil (including Archroma), Canadian Vehicles Manufacturers’ Association (CVMA), Fire-fighting Foam Coalition (FFFC), Health Care Without Harm (HCWH), MedTech Europe, and joint submission by International POPs Elimination Network (IPEN), and Alaska Community Action on Toxics (IPEN/ACAT).

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

(a) RME on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2);

(b) Supporting information related to the RME on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/INF/6);

(c) Additional information in relation to the RME of PFOA, its Salts, and Related compounds; Prepared by ETH Zurich on behalf of the Swiss Federal Office for the Environment (FOEN), 2017;

(d) Non-exhaustive list of substances covered or not covered by the RME. (UNEP/POPS/POPRC.13/INF/6/Add.1).

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

32. The Committee invited Parties and observers to provide information that would assist its further evaluation of the chemical identity of PFOA-related compounds chemical list. Relevant information has been submitted by The Brazilian Ministry of Agriculture (Brazil, 2018) and ABRAISCA (2018) (Brazilian association of manufacturer of insecticides), Norway (2018), Mexico (2018), Austria (2018), Japan (2018), Canada (2018) Fluoro Council (FluoroCouncil, 2018a, 2018b), and IPEN/ACAT (IPEN/ACT, 2018). No additional information is available for submission from Canada on the chemical identity of PFOA except from the information already presented in the risk profile and RME (Canada, 2018).

## 2.1 Chemical identity according to the RME

33. The chemical identity and related details are outlined in section 1.1 of the RME.[7] The following paragraphs in italics are copied from the RME:

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

35. The RME covers:

*(a) PFOA (pentadecafluorooctanoic acid, CAS No: 335-67-1, EC No: 206-397-9) including any of its branched isomers;*

*(b) Its salts; and*

*(c) PFOA-related compounds which, for the purposes of this risk management evaluation, are any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety ($C_7F_{15}$)C as one of the structural elements, for example:*

- *(i) Polymers with ≥$C_8$ based perfluoroalkyl side chains;*[8]
- *(ii) 8:2 fluorotelomer compounds;*
- *(iii) 10:2 fluorotelomer compounds.*

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

- *(i) $C_8F_{17}$-X, where X= F, Cl, Br;*
- *(ii) Fluoropolymers*[9] *that are covered by $CF_3(CF_2)n$-R', where R'=any group, n>16;*[10]
- *(iii) Perfluoroalkyl carboxylic and phosphonic acids (including their salts, esters, halides and anhydrides) with ≥8 perfluorinated carbons;*
- *(iv) Perfluoroalkane sulfonic acids (including their salts, esters, halides and anhydrides) with ≥9 perfluorinated carbons;*

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[7] UNEP/POPS/POPRC.13/7/Add.2.

[8] DuPont, 1998. Technical information: Zonyl fluorochemical intermediates.

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

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

*(v) Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) as listed in Annex B to the Stockholm Convention.*

Since sulfluramid (N-ethyl perfluorooctane sulfonamide, CAS No: 4151-50-2) is produced from PFOSF, it is already covered, although not explicitly mentioned, under the listing of PFOS, its salts and PFOSF.

36. 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. Sulfluramid is listed, but is explicitly excluded from the scope of the RME.

## 2.2 Possible exclusion of sulfluramid from the scope of the RME

37. Sulfluramid is manufactured by using PFOSF as an intermediate and is the active ingredient in the manufacture of ant baits and ready-to-use formulations. The use of sulfluramid represents a direct release of PFOS to the environment. Sulfluramid is identified as a (potential) precursor of PFOAs in the OECD New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs). Brazil has notified the production and use of PFOSF for the acceptable purpose "insect baits for the control of leaf-cutting ants from *Atta* spp. and *Acromyrmex* spp.*"*.[11] Regarding baits used in Brazil, baits with sulfluramid represent more than 95% of the total use (UNEP/POP/POPRC.4/15/Add.6).

38. According to Brazil (2018), sulfluramid should be excluded from the list of PFOA-related compounds until conclusive information has been obtained. The main concern expressed is that sulfluramid is a compound related to PFOS, it salts and PFOSF and the use of this substance is already covered by the Stockholm Convention as acceptable purpose in Annex B (decision SC-4/17). 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 sulfluramid or provide its CAS number. Brazil states that, the information regarding sulfluramid is consolidated as part of the process for evaluation of the continued need of PFOS, it salts and PFOSF for the various acceptable purposes and specific exemptions in accordance with paragraphs 5–6 of part III of Annex B to the Convention. Further, Brazil (2018) states that the inclusion of the substance in the PFOA list took place without extensive discussion and with no technical justification and that papers were cited as justification for the inclusion, which would not be conclusive and would not reflect the conditions that occur in the environment. It would therefore not be possible to conclude, based on this information only, that sulfluramid degrades to PFOA, nor that sulfluramid is a PFOA-related compound (Brazil, 2018).

39. The exclusion of sulfluramid from the non-exhaustive list of substances is also supported by ABRAISCA (2018), stating that sulfluramid is a perfluoalkyl sulfonate compound, and not a perfluoroalkyl carboxylate such as PFOA. Thus, according to ABRAISCA, sulfluramid should be in the list of compounds that do not degrade to PFOA. It is known that sulfluramid could be a PFOS-related compound and that the production of sulfluramid is obtained from PFOSF.

40. Martin et al. (2006) investigated the possibility that perfluorooctane sulfonamides which are present in the atmosphere 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, results from Martin et al. (2006) do not represent atmospheric conditions. In addition, ABRAISCA criticised that *N*-ethyl perfluorobutane sulfonamide was used as target material to investigate the gas phase reactivity of perfluoroalkane sulfonamides in the presence of radicals, and not the relevant substance, which has a different volatility (see ABRAISCA, 2018). However, the butane analogue, *N*-ethyl perfluorobutane sulfonamide, was used because *N*-ethyl perfluorooctane sulfonamide is not volatile enough for their in vitro system, but is an appropriate model because the perfluorinated chain length is not expected to have an effect on the reactivity. Even if the experimental conditions were not representative for environmental conditions, Martin et al. (2006) provide scientific evidence that the degradation of perfluorooctane sulfonamides to PFOA cannot be excluded. The results of D´eon et al. (2006) indicate that *N*-methyl perfluorobutane sulfonamidoethanol may contribute to the burden of perfluorinated contamination in remote locations. It appears that anthropogenic production of *N*-methyl perfluorooctane sulfonamidoethanol contributes to the ubiquity of perfluoroalkyl sulfonate and carboxylate compounds in the environment (D´eon et al., 2006). According to ABRAISCA, the results from this study investigating the formation of PFCAs from *N*-methyl perfluorobutane

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[11] See register of acceptable purposes available at http://chm.pops.int/Implementation/Exemptions/AcceptablePurposes/AcceptablePurposesPFOSandPFOSF/tabid/794/Default.aspx.

sulfonamidoethanol cannot be transferred to perfluoroalkane sulfonamides (such as sulfluramid), which have no hydroxyethyl group attached to a nitrogen atom. According to ABRAISCA this hydroxyethyl group leads to a higher reactivity compared to *N*-alkyl perfluoro sulfonamides (ABRAISCA, 2018). Even if the hydroxyethyl group in *N*-methyl perfluorobutane sulfonamidoethanol leads to a higher reactivity compared to *N*-alkyl perfluoro sulfonamides, it cannot be excluded that PFCAs are formed from *N*-alkyl perfluoro sulfonamides.

41. Plumlee et al. (2009) irradiated selected perfluorinated surfactants in aqueous hydrogen peroxide solutions using artificial sunlight to study transformation under aquatic environmental conditions, 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. Indirect photolysis mediated by hydroxyl radical was among others observed for sulfluramid. ABRAISCA noted with regard to the study by Plumlee et al. (2009), that the conditions used in the study do not represent environmental conditions. Further, ABRAISCA stated that the formation of perfluorooctane sulfonamide from sulfluramid is by far more favourable than the formation of PFOA (see ABRAISCA, 2018). Moreover, ABRAISCA argues that sulfluramid molecules are not identical to *N*-methyl perfluorobutane sulfonamidoethanol. Even if the experimental conditions were not representative for environmental conditions, Plumlee et al. (2009) provide scientific evidence that the degradation of sulfluramid to PFOA cannot be excluded.

42. Liu et al. (2017) analysed PFOS and PFOA release into the environment in the central and eastern region of China, which accounts for the vast majority of national emissions. According to the authors, sulfluramid likely resulted in the release of PFOS and PFOA to the environment. The environmental release of PFOS has been estimated to be 2.6 t/a while the release of PFOA from this source was calculated to be 1.4 t/a based on the annual consumption of sulfluramid, and the transformation rate to PFOA and PFOA content as impurities in sulfluramid (Liu et al., 2017). Regarding this study, ABRAISCA 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 ABRAISCA stated that no new experimental scientific evidence is presented and that the study should be seen as a modeling paper to estimate emissions (see ABRAISCA, 2018). 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 (Lehmler et al., 2007). The Liu et al. study also notes the possibility that the active ingredient in 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.

43. Regarding the comments from ABRAISCA (2018) with respect to the question whether sulfluramid is a PFOA-related compound, it can be stated that two in vitro studies (Martin et al., 2006 and Plumlee et al., 2009) provide scientific evidence that indicates that sulfluramid can degrade to PFOA and could thus be considered a PFOA-related compound. Moreover, abiotic degradation to PFOA via photo-oxidation may occur given that volatilization of sulfluramid from moist soil surfaces is expected to be an important fate process (HSDB database) Austria added that in a recent report by the Norwegian environment Agency it was concluded that photooxidation of perfluorobutane sulfonic acid (PFBS) and perfluorohexane sulfonic acid (PFHxS) sulfonamides will also result in the release of $C_2$–$C_6$ PFCAs and concluded that the same mechanism can be anticipated for *N*-ethyl perfluorooctane sulfonamide. These studies and information sources suggest that a transformation of sulfluramid to PFOA is possible. However, the question whether sulfluramid can degrade to PFOA under environmental conditions is not conclusively clarified.

44. Sulfluramid is more structurally related to PFOS (both consist of a $C_8F_{17}SO_2$-unit) than to PFOA, thus degradation of sulfluramid to PFOS is more likely. Zabaleta et al. (2018) investigate the importance of sulfluramid as a source of environmental PFOS. The authors conclude on the one hand, that observed formation of PFOA may be due to the presence of *N*-ethyl perfluorooctanamide, which is known to occur as an impurity in sulfluramid. Zabaleta et al. (2018) performed experiments in the presence of carrot that produced PFOS yields of up to 34 % using a technical sulfluramid standard and up to 277% using a commercial sulfluramid formulation used in Brazil. The authors note that a significant fraction appears to be associated with one or more unidentified PFOS-precursors in the commercial bait. 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%. Avendaño and Liu (2015) reported 4% PFOS yields from degradation of EtFOSA from soil biodegradation experiments.

45. ABRAISCA (2018) 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 2018). 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, 2018).

46. 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 (Nguyen et al., 2013, Avendano and Liu, 2015, Benskin et al., 2009, Gilljam et al., 2015). Based on the available information sulfluramid can also be considered a PFOA-related compound. 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 *Atta* spp. and *Acromyrmex* spp., as well as insecticides for control of imported red fire ants and termites. Sulfluramid is not explicitly included in Annex B in the scope of the listing of PFOS, its salts and PFOSF. However, sulfluramid production is already covered by an acceptable purpose under the PFOS listing and it should then not be included under the PFOA listing to avoid double regulation.

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

47. The status of 1-H-PFO (1-hydroperfluorooctane, PFOH, CAS No: 335-65-9) as a PFOA-related compound is questioned by FluoroCouncil (FluoroCouncil, 2018a). Currently, substances with the formula $C_8F_{17}$–X are considered PFOA-related compounds except if the X consists in either fluorine, chlorine or bromine (i.e. $C_8F_{17}$-F, $C_8F_{17}$-Cl or $C_8F_{17}$-Br) ending or they are specifically excluded from the scope (e.g. PFOS) As a result, 1-H-PFO is considered a PFOA-related compound. FluoroCouncil (2018) argues that $C_8F_{17}$-H (1-H-PFO) is even less accessible to biological and chemical degradation compared to the exempted molecules $C_8F_{17}$-Cl and $C_8F_{17}$-Br. FluoroCouncil further states that 1-H-PFO has comparable temperature and chemical inertness to the fully fluorinated perfluorooctane $C_8F_{18}$ and that the $C_8F_{17}$-H structure and excellent thermal stability which shows no evidence of degradation to PFOA under foreseeable conditions. 1-H-PFO's transformation into PFOA would require the loss of the hydrogen as well as two Fluor atoms on the carbon (see Figure 2.1). FluoroCouncil states that this has never been observed considering the remarkable stability of the C-F bond and the fact that the hydrogen is surrounded by 3 large atoms of Fluor (FluoroCouncil, 2018a).

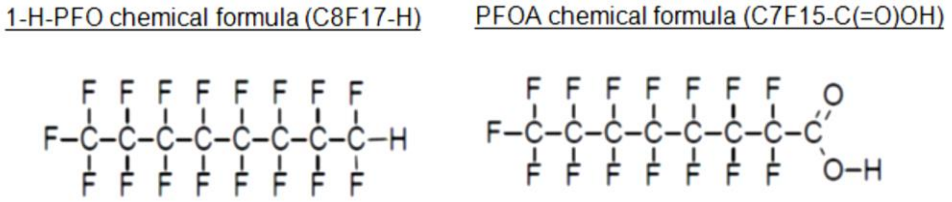

**Figure 2.1 chemical structure of 1-H-PFO and PFOA**

48. FluoroCouncil argues that 1-H-PFO should not be considered a PFOA-related compound. FluoroCouncil believes that the scientific basis for the status of 1-H-PFO as PFOA-related compound should be further investigated (FluoroCouncil, 2018a). Japan brought forward that it would be an overstatement to conclude that 1-H-PFO is among PFOA-related compounds because the reaction rate with OH radicals is negligibly small at the order of 10E(-15)$cm^3$ molec-1 s-1 (Japan, 2018).There is some evidence that 1-H-PFO is relatively stable. 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).[12] However, Chen et al. (2003) showed that $CF_3CF_2CF_2CF_2CF_2CHF_2$ can react with OH radicals over the temperature range -23 to 156°C (reported in Chen et al. as Kelvin: 250-430 K). This shows for a shorter-chained hydrofluorocarbon (HFC) compound with a -$CHF_2$ moiety that a H-abstraction reaction by OH radicals takes place and the carbon-oxygen bond degrades. Young et al. (2009) showed that PFCAs

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[12] Luo, Y.R 2007 Comprehensive Handbook of Chemical Bond Energies, CRC Press, Boca Raton, FL, USA.

can be formed from atmospheric reactions of $CF_3CF_2H$ and $CF_3CF_2CF_2CF_2H$ in absence of NOx. Accordingly, HFCs with the –$CHF_2$ moiety (e.g., HFC-329ccb and HFC 52-13p) can react with OH radicals and form a perfluoroalkyl radical ($CF_3(CF_2)n\bullet$),which can further react to form PFCAs (under low $NO_x$ conditions) (see Wang et al., 2014). Chen et al. (2011)[13] propose a mechanism for the oxidation of 1-H-PFO to PFOA in the atmosphere through reaction with OH radicals. They report that molar yields of PFOA range between 0.07-0.12. 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. The FluoroCouncil argues that the intramolecular shielding of the H-C bond makes degradation extremely unlikely and that, in atmospheric conditions, the probability of a reaction with OH radicals is further reduced by the existence of a competing reaction with NOx that does not result in PFOA. However, Switzerland notes that 1-H-PFO remains in the atmosphere (> 99 % based on EPI Suite Level III Fugacity Model with emissions to air only) until transformed and 1-H-PFO may be transformed to PFOA over long time scales (Switzerland 2018). Chen et al. (2011) estimated an atmospheric lifetime of 24 year.

49. 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 compounds. In addition, 1-H-PFO is identified as a (potential) precursor of PFAAs in the OECD New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs).

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

50. Based on information submitted by Australia (2018), 8:2 fluorotelomer methacrylate (CAS No: 93705-98-7), polymer with methyl methacrylate should be included in the non-exhaustive list of PFOA-related compounds. Australia’s National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework concluded that PFOA is expected to be the major product of environmental biodegradation for the following five long-chain fluorinated chemicals on the Australian Inventory of Chemical Substances (AICS) (NICNAS undated): 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-$C_{4-10}$-alkyl)thio] derivatives (CAS No: 68187-42-8); and 7:1 fluoroalcohol methacrylate, polymer with acrylic acid (CAS No: 53515-73-4). The remaining 4 chemicals indicated are already included in the list of non-exhaustive substances.

51. In conclusion, 8:2 fluorotelomer methacrylate polymer with methyl methacrylate (CAS No: 93705-98-7) is included in the non-exhaustive list of PFOA-related compounds.

## 3 Information on unintentional formation and release

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

### 3.1 Unintentional formation and release from incomplete combustion

53. During the development of the RME, Switzerland supplied information on unintentional formation of PFOA from incineration of fluoropolymers with inappropriate incineration or open combustion facilities at moderate temperatures. Recent studies have been summarized, *showing measurable amounts of PFOA and a wide range of other PFCA homologues that can be generated during the thermolysis of PTFE (polytetrafluoroethylene) at temperatures between 250 and 600°C. It has been concluded that this may be particularly relevant for developing countries and countries in*

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[13] Chen, L., Uchimaru, T., Kutsuna, S., Tokuhashi, K., Sekiya, A. and Okamoto, H. (2011). Kinetics and mechanism of gas-phase reaction of CF3CF2CF2CF2CF2CF2CF2CF2H with OH radicals in an environmental reaction chamber at 253–328K. Chemical Physics Letters, 501(4-6), pp.263-266.

*transition, where wastes are often not incinerated to sufficiently high temperatures and without proper treatment of flue gases* (FOEN, 2017).

54. High temperature incineration (e.g., at 1000°C) can be effective to destroy PFOA and to prevent the formation of PFOA from the thermolysis of highly fluorinated polymers. It is however, currently unclear to what extent formation of PFOA may occur in municipal waste incinerators where (1) flue gases may reach temperatures of 850°C or greater and may result in different degradation products; (2) other substances coexist and may interfere with the thermolysis of fluoropolymers (e.g., thermolysis of PTFE is inhibited by a hydrogen or chlorine atmosphere in contrast to steam, oxygen or sulfur dioxide, which accelerate decomposition; and (3) technologies such as activated carbon injection (ACI) coupled with baghouse filtration (BF) may be installed to remove dioxin or mercury and may also trap PFCAs. A laboratory-scale study from the US concluded that waste incineration of fluorotelomer-based polymers does not lead to formation of detectable levels of PFOA under conditions representative of typical municipal waste incineration in the US. However, a recent study found PFOA in flue gases from a state of the art incinerator of Harlingen, the Netherlands (see the RME). Currently (as of 2018) PFOA is not regulated as an air pollutant from waste incineration under the Industrial Emission Directive (Directive 2010/75/EU) on European level (Austria, 2018). In Europe, the state of the art (best available technique, BAT) in waste incineration is defined in the European BAT Reference Document on Waste Incineration (BREF WI 2006), issued by the European IPPC Bureau (EIPPCB) in 2006. The document has been subject to a review process since July 2014 and is supposed to be published and set into force in 2019. In contrary to for instance polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) and PCBs, PFOA and other fluorinated organic compounds are not addressed by the BREF WI so far (POPRC Member, 2018). During the Final Meeting of the BREF WI Review process, the monitoring of brominated dibenzodioxins and dibenzofurans (PBDD/F) was first proposed for the incineration of waste containing brominated flame retardants as well as for plants using continuous bromine injection into the boiler as a mercury abatement technique.

55. Information provided by IPEN and ACAT (2018) in their current submissions mainly supports information provided by Switzerland which has already been considered in the RME, and further includes additional information on PFOA detected in a state of the art incineration facility in the Netherlands (Harlingen). According to information provided by IPEN and ACAT (2018), PFOA can be unintentionally generated as a product of incomplete combustion arising from open combustion and waste incineration processes. In laboratory experiments, high temperature incineration is effective to destroy PFOA and prevent formation of PFOA, however, in practise PFOA may be formed in currently operating incinerators (a link to raw data from the above-mentioned incinerator in Harlingen has been provided as reference).[14] IPEN and ACAT (2018) conclude that stringent adherence to best available techniques and best environmental practices (BAT/BEP) is needed to avoid PFOA generation and release and that PFOA should be listed in Annex C as an unintentional POP to capture potential formation and unintentional release from anthropogenic sources (IPEN and ACAT, 2018). Further, according to information provided by Austria (2018), there is evidence given in literature from the Netherlands 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.[14] There is also evidence from laboratory experiments that fluoropolymers have to be regarded as possible sources of halogenated organic compounds generated during waste incineration.[15]

56. According to the recent submission by the Netherlands (2018a), listing PFOA in Annex C to the Convention is not recommended due to the following reasons. Firstly, the data from the Harlingen municipal waste incinerator (with capacity of 230,000 tonnes) from the Netherlands indicates that PFOA emissions are negligible. Estimating a yearly emission, using the flow rate of this installation, the total PFOA emitted at a particular site is shown to be 0.057 g/yr (at concentrations about 0.01–0.04 ng/m$^3$). Furthermore, emissions of other POPs such as decabromodiphenyl ether (decaBDE) are in a similar order of magnitude and indicate that all POPs may be expected in all kinds of incineration processes, which is also related to the fact that measurement techniques have improved considerably in recent decades. According to the Netherlands, these reasons need to be considered to enable the COP to properly evaluate the pros and cons of a possible Annex C listing (Netherlands, 2018).

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[14] www.harlingen.nl/recloket and https://www.harlingen.nl/recloket/monitoring-in-de-schoorsteen_42638/.

[15] Ellis et al. (2001): Ellis, D.A., et al.: Thermolysis of fluoropolymers as a potential source of halogenated organic acids in the environment. Nature Vol. 142, 19 July 2001, www.nature.com (2001).

## 3.2 Unintentional formation and release from primary aluminium production

57. According to the RME, referring to a study from the EU Parliament from 2008, perfluorocarbons (PFCs) are widely used in aluminium production and emissions of PFCs (possibly including PFOA; not specified in the study) occur during specific electrolysis processes in aluminium manufacturing.[16] This can be reconfirmed by several information sources, for instance Gibbs et al. (2001) stating that the primary aluminium production process has been identified as the largest anthropogenic source of emissions of two PFCs: tetrafluoromethane ($CF_4$) and hexafluoroethane ($C_2F_6$). It is further explained that primary aluminium is produced using the Hall-Héroult electrolytic process, where the smelting pot itself acts as the electrolysis cell during the reduction process. When the alumina ore content of the electrolytic bath falls below critical levels required for electrolysis, rapid voltage increases occur, termed "anode effects". Anode effects cause carbon from the anode and fluorine from the dissociated molten cryolite bath to combine, producing $CF_4$ and $C_2F_6$. Further, the International Aluminium Institute provides among other statistics, information on global PFCs emissions from aluminium production. The available data refers to emissions of gases containing $CF_4$ and $C_2F_6$.[17] It was not possible to identify relevant information indicating that also PFOA may be released from aluminium production. It seems that most of the available information relates to emissions of $CF_4$ and $C_2F_6$ from aluminium production. No additional information has been submitted by Parties and observers on potential releases of PFOA from aluminium production.

## 3.3 Summary and conclusion related to unintentional formation and release

58. In summary, the Committee invited Parties and observers to provide additional information to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds from incomplete combustion and primary aluminium production. New information was provided by IPEN and ACAT (2018), the Netherlands (2018a) and Austria (2018). The UK (2018) stated that PFOA is not a substance that is reported within the UK's Pollution Inventories, and therefore no relevant data on its releases is available. The same also applies to emissions from primary aluminium production (UK, 2018).

59. Information from the RME indicates that *PFOA may be unintentionally formed and released from inadequate incineration or open burning at moderate temperatures*. Switzerland provided recent studies (FOEN, 2017), showing small, but measurable amounts of PFOA detected at incineration temperatures between 250 °C and 600 °C. Therefore, it has been concluded that this may be particularly critical for developing countries and countries in transition, where wastes are often not incinerated at sufficiently high temperatures and without proper flue gas treatment. The submissions from IPEN and ACAT (2018) are in line with information submitted by Switzerland and further include information on PFOA detected in a state of the art incineration facility in the Netherlands (at concentrations about 0.01–0.04 $ng/m^3$). IPEN and ACAT (2018) conclude that stringent adherence to BAT/BEP techniques is needed to avoid PFOA generation and release and that PFOA should be listed in Annex C as an unintentional POP. The Netherlands (2018a), in contrast, indicates that adding PFOA to Annex C is not the right way forward as estimated yearly emissions, appear to be negligible, and costs to reduce the emission are disproportionate. Further, it is pointed out by the Netherlands (2018a) that other POPs (such as decaBDE) are detected in a similar order of magnitude as PFOA, without currently being listed under Annex C.

60. No information has been submitted by Parties and observers on potential releases of PFOA, its salts and PFOA-related compounds from primary aluminium production.

61. In conclusion, available information to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds from incomplete combustion and primary aluminium production is limited. For potential PFOA releases from aluminium production, most of the information identified in literature relates to emissions of $CF_4$ and $C_2F_6$ during aluminium production. From the currently available information it is not possible to conclude that primary aluminium production represents a relevant source of PFOA releases to the environment. Concerns were raised that presence of PFOA may not be from incineration but from previous presence in products. Based on the information assessed, the Committee does not recommend listing PFOA, its salts and PFOA-related compounds in Annex C to the Convention. Additional information and preferably also further measurements/quantitative data from other waste incinerators, open burning, and other sources

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[16] http://www.europarl.europa.eu/RegData/etudes/etudes/join/2008/393524/IPOL-ENVI_ET(2008)393524_EN.pdf.

[17] http://www.world-aluminium.org/statistics/perfluorocarbon-pfc-emissions/.

of unintentionally produced POPs, in particular from developing countries, would be useful for future consideration.

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

## 4.1 Introduction

62. The RME identified a range of uses[18] covering applications for production of fluoropolymers (primarily polytetrafluoroethylene (PTFE)), use as surfactants and one use involving the generation of intermediates for further processing. All seven of the uses documented in the RME have the potential to generate releases during production, use and end of life for articles. During POPRC-13 in October 2017, the Committee discussed each of these uses and whether an exemption was necessary, but were unable to reach a conclusion. The Committee invited Parties and observers to provide further information around specific aspects of each use (see section 1.1) which are presented in the current document.

63. Existing national and regional control actions differ with regard to their chemical scope and exemptions. Appendix I to this document (Table 3 of the RME) gives an overview of the regulatory risk management approaches and exemptions in Canada, the EU and Norway. Section 3 of the background document (UNEP/POPS/POPRC.13/INF/6) provides further details on the legislative approaches in these countries.

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

### 4.2.1 Introduction

64. The RME highlights the need for more information about a possible exemption for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. Additional information to clarify the scope of the applications, used amounts, availability of alternatives and socio-economic aspects is needed to allow for an exemption.

65. The Committee invited Parties and observers to submit further information on the scope of the applications, used amounts, availability of alternatives, socio-economic aspects and other relevant information. Information on membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment has been provided by Canada (2018), China (2018), Mexico (2018) and IPEN and ACAT (2018). Furthermore, additional information has been identified in the submissions from HealthCare Without Harm Europe (HCWH, 2018) and MedTech Europe (2018), providing information related to medical devices.

### 4.2.2 Efficacy and efficiency of possible control measures

66. According to IPEN and ACAT (2018), 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 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).

67. A possible presence of PFOA in surgical drapes was confirmed by MedTech: “The presence of PFOA is mainly related to the use of fluoropolymers such as PTFE” (MedTech Europe, 2018). According to information submitted by HCWH (2018), PFOA can be found in several products in health care including textiles. A complete picture on PFOA use in the sector is however not yet available. For this reason, HCWH believes that it is crucial as a first step to collect further information and determine which fluorinated compounds are present in products used in the healthcare sector (HCWH, 2018).

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[18] A number of the uses covered have applications in healthcare. The RME disaggregates healthcare uses based on different applications, for example membranes covers all uses of PFOA within membranes, some of which will include medical applications. To maintain this distinction uses relating to healthcare can be found under the following headings by application, section 4.2 for membranes, section 4.6 for photo-imaging, section 4.5 for implantable medical devices and section 4.4 for all other medical devices.

68. According to information submitted by Canada (2018), commercial filter membranes can be made of different materials, some based upon fluorochemicals such as polyvinylidene fluoride (PVDF), poly(ether sulfone) (PES) and polytetrafluoroethylene (PTFE). PFOA can be used as a surfactant in the emulsion polymerization of PTFE. Further, according to Canada, PTFE membranes are among others used in manufacture of purified water and special need water, beverage and dairy, chemical regent, biochemical regent, air filtration of fermentation tank, purification and filtration in microelectronic plants, filtration and separation of antibacterial fluid, production of medicine, air conditioning of hospitals and commercial buildings (Canada, 2018).

### 4.2.3 Information on alternatives

69. The companies Arkema, Asahi, BASF Corporation, Clariant, Daikin, 3M/Dyneon, DuPont and Solvay Solexis have agreed under the US EPA 2010/15 Stewardship program to manufacture fluoropolymers without using PFOA (as processing aid) by the end of 2015. The objective of the proposal is to restrict the placing on the market, import, and use of fluoropolymers manufactured with PFOA, while allowing the use of the same fluoropolymers when they are not manufactured with PFOA. The substitution was reportedly being carried out by around 70% of the global market for fluoropolymers in 2015 (ECHA, 2014a).

70. According to the RME, *for filter materials for oil and fuel filtration some companies claim that no alternatives are available*. This has been also stated in a recent submission from China (2018). However, it is also further stated that several strategies are being developed to use potentially non-bioaccumulable alternatives of PFOS and PFOA (China, 2018).

71. Several alternatives for use in textiles such as short-chain fluorinated alternatives, non-fluorine containing alternatives and non-chemical alternatives have been identified in the RME. In the following paragraphs, relevant alternatives are briefly summarised (see the RME for full details, not for discussion).

*Short-chain fluorinated alternatives*

72. Information on short-chain fluorinated alternatives was identified in the RME. For the fluorotelomer products based on 8:2 fluorotelomer alcohol (8:2 FTOH), short-chain 6:2 FTOH are used as alternatives for a variety of uses including textiles. This substance will not degrade to PFOA, but rather to other acids, such as perfluorobutanoic acid (PFBA), perfluoropentanoic acid (PFPeA), perfluorohexanoic acid (PFHxA), and 2H,2H,3H,3H-undecafluoro octanoic acid (5:3 fluorotelomer acid). The fluorinated chemical alternatives to PFOA (6:2 FTOH, PFHxA, 6:2 methacrylate and 6:2 acrylate) have not been evaluated under the Stockholm Convention. However, IPEN and ACAT highlight that there are several related scientific literature sources and conclude that these alternatives raise various concerns including persistence, long range transport, high mobility in water and soil and potential toxic properties. For instance, 6:2 FTOH is found in the Artic 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). Besides, PFHxS is currently nominated and under review by the Committee (Canada, 2018). Concerns that short-chain fluorinated alternatives meet POP criteria are further addressed in the RME for instance in paragraph 179.

73. *During the development of the RME, industry associations noted that especially in the field of professional, technical and protective textiles and other advanced textiles, no alternatives meeting the high demand by legal requirements and by customers are currently available. However, those textile products that must only fulfil low-performance requirements, which were formerly treated with PFOA-related compounds, may be treated by* $C_6$*-products or even fluorine-free alternatives (*see the RME*).*

74. *The European Apparel and Textile Confederation states that over the life-cycle, technical textiles treated with 6:2 fluorotelomer-based finishes often exhibit 4–8 times higher total PFAS emissions compared to the observed emissions using the* $C_8$*-chemistry (*see the RME*).*

*Non-fluorine-containing alternatives*

75. According to the RME, *non-fluorine containing alternatives in the textile industry include paraffins, alpha olefin modified siloxanes, fatty-acid modified melamine resins and fatty-acid modified polyurethanes exist for textiles with low required levels of water repellency. In some cases, when applying fluorine-free alternatives, quality requirements of technical textiles cannot be fulfilled due to, for example, decreased chemical-, oil- and/or dirt-repellent properties, inadequate abrasion and/or wash resistance. Available alternatives for grease- and dirt-repellent agents are limited. Most*

*prominent water-repellent alternatives are reported to be silicone-based agents. These include high molecular weight polydimethylsiloxanes (PDMS), mixtures of silicones and stearamide methyl pryriden chloride (sometimes in combination with carbamide (urea) and melamine resins), waxes and paraffins (usually consisting of modified melamine-based resins) and dendrimers that are being developed to imitate the ability of the lotus blossom to repel water. Alternatives to provide similar stain- and water-repellency are available and include textile surface treatment applications based on acrylate, methacrylate adipate and urethane polymers* (see the RME).

76. According to the RME, *a range of fluorocarbon-free, water-repellent finishing agents for textiles include commercial products such as BIONIC-FINISH®ECO and RUCO-DRY® ECO marketed by Rudolf Chemie Ltd., Geretsried/ Germany; Purtex® WR, Purtex® WA, Purtex® AP marketed by the Freudenberg Group, Weinheim/Germany; and ecorepel® marketed by SchoellerTechologies AG, Sevelen/Switzerland* (see the RME).

77. According to the RME, *paraffin repellents are liquid emulsions that should not be classified as hazardous to health according to the producers. However, some of the identified ingredients seem to be harmful. The main ingredient in most products is paraffin oil/wax (mixtures of long chain alkanes), which is considered harmless in pure form. Some products also contain isocyanates, dipropylene glycol, metal salts, which may be harmful* (see the RME).

78. According to the RME, PDMS are inert and have in general no adverse effects. Various siloxanes, especially the cyclic siloxanes known as D4, D5 and D6 and specific linear siloxanes are intermediates for the synthesis of silicone polymers used for textile impregnation. Certain siloxanes are persistent and widespread in the environment. Mostly, they are detected in urban areas and in the aquatic environment. High levels have been found in livers of fish, which were caught close to outlets of sewage treatment plants. Siloxanes are generally removed from the aqueous phase by sedimentation, and exhibit a long half-life in sediments. In soils, siloxanes are transformed depending on the conditions into hydroxylated forms, which still may be persistent. In Canada, it is concluded that D4 is entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity (see the RME). In Europe, D4, D5 and D6 are identified as Substances of Very High Concern (SVHCs) under the REACH regulation based on their PBT and/or vPvB properties.[19] The ecological risks arising from industrial uses of cyclic siloxanes in Australia have recently been assessed. This assessment concluded that D4, D5 and D6 are persistent in the air and sediment compartments, and that D4 and D5 can bioconcentrate in fish. According to National Industrial Chemicals Notification and Assessment Scheme (NICNAS), although a small fraction of cyclic siloxanes in use are emitted to the aquatic environment these emissions are not currently considered to pose a direct risk to aquatic life (NICNAS 2018).

79. IPEN and ACAT (2018) submitted information that technically feasible alternatives that meet regulatory requirements but do not contain PFOA are available. These include surgical gowns and drapes.[20] [21] [22] [23] According to Wang et al. (2015) and Rudolf Group (2018), "non-fluorinated water-repellent textile finishes that are based on high molecular weight and highly branched polymers known as dendrimers have been commercialized" for use in textile pre-treatment, coating, sizing, and finishing and may have application for medical textiles.

80. According to the RME, *there are no data on health properties of the active substances and other components of dendrimer-based repellents, but producers of commercial products have provided health data in the material safety data sheets and made some proposals for classification of the product. According to information from producers these products should not be classified as harmful for the environment, but it is not possible to evaluate these statements on the basis of available information. The compositions of the products were not specified sufficiently for an assessment, but some of the products include unknown siloxanes, cationic polymers, isocyanates, or irritating organic*

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[19] https://echa.europa.eu/documents/10162/23843530/msc-60_minutes_en.pdf/f407b9e7-78a4-966d-cc51-9d36b8c7ee3e; https://echa.europa.eu/de/candidate-list-table/-/dislist/details/0b0236e18263bf5e; https://echa.europa.eu/de/candidate-list-table/-/dislist/details/0b0236e1826466a3; https://echa.europa.eu/de/candidate-list-table/-/dislist/details/0b0236e18263c05e

[20] http://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSu9n_zu8l00xm8mBl8t94v70k17zHvu9lxtD7xt1evSSSSSS-

[21] https://www.daikinchem.de/products-and-performance/water-oil-repellency.

[22] https://products.halyardhealth.com/surgical-solutions/surgical-gowns/breathable-high-performance-gowns/halyard-microcool-breathable-high-performance-surgical-gown-with-secure-fit-technology.html .

[23] https://www.agcchem.com/news/2016/june-1-2016-asahiguard-ag-e600-repellent-provides-sustainable-solution-for-nonwoven-medical-textiles.

*acids. In summary, the available information for this group of chemicals is insufficient for an assessment of the possible health effects of the impregnation agents* (see the RME).

81. *The RME identified alternatives to PFOA for use in reverse osmosis membranes for water and effluent treatment. It notes that for membranes an alternative to PTFE is a composite of a hydrophobic polyester and a hydrophilic polymer forming a microstructure, which allows the fabric to breathe* (see the RME).

82. Syndar Filtration manufactures membranes for a wide variety of purposes, including water filtration, effluent treatment, production processes, and medical applications. They use fluorine-free materials for these applications including: polyacrylonitrile (PAN), most often used for oil/water separations and similar applications; polyethersulfone (PES), most often used for protein concentration and purification; and thin film composite (TFC), these membranes use PES with polyamide coatings that are used for various concentrating and purifying applications (IPEN and ACAT, 2018).[24]

*Non-chemical alternatives*

83. Considering information provided by IPEN and ACAT (2018), bioinspired slippery liquid-infused porous surfaces, based on substances found in the Nepenthes plant, although still in the development phase, have a broad application that includes biomedical devices, optical sensing, fluid/fuel handling, and anti-fouling; and provide a viable alternative for surface treatments.[25]

### 4.2.4 Information on impacts on society

84. According to the textile industry submissions, *the technical textile sector has to fulfil many different performance standards in particular medical, chemical and environmental protection. Textiles have to be certified in long procedures, which could take years and several textiles are regulated by various other EU- and national laws* (see the RME).

85. According to ECHA (2014), the introduction of alternatives in the fluoropolymers production industry has been carried out by around 70% of the global market which took place with a moderate price increase (see the RME).

86. 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.

87. Mexico (2018) would support a specific exemption for the membranes used in medical practices to prevent impact upon patients. However, no further information / justification has been given.

### 4.2.5 Synthesis of Information

88. According to HCWH (2018), membranes intended for use in medical textiles could include products that function as a barrier to exposure to blood or fluids such as surgical drapes, in which the presence of PFOA is mainly related to the use of fluoropolymers. However, they indicate that there are technically feasible alternatives available that meet regulatory requirements but which do not contain PFOA. These include surgical gowns and drapes.[26] [27] [28] [29]

89. According to information submitted by Canada (2018), PFOA can be used as a surfactant in the emulsion polymerization of PTFE. PTFE membranes are reported to be used in various applications (see e.g. Canada, 2018).

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[24] http://synderfiltration.com/ and personal communication with Kevin Donohue, Global Sales Manager, Syndar Filtration 9 January 2017.

[25] Wong, T-S et al., 2011. Bioinspired self-repairing slippery surfaces with pressure-stable omniphobicity. Nature 477:443-447.

[26] http://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSu9n_zu8l00xm8mBl8t94v70k17zHvu9lxtD7xt1evSSSSSS-

[27] https://www.daikinchem.de/products-and-performance/water-oil-repellency.

[28] https://products.halyardhealth.com/surgical-solutions/surgical-gowns/breathable-high-performance-gowns/halyard-microcool-breathable-high-performance-surgical-gown-with-secure-fit-technology.html.

[29] https://www.agcchem.com/news/2016/june-1-2016-asahiguard-ag-e600-repellent-provides-sustainable-solution-for-nonwoven-medical-textiles.

90. According to the RME, *for filter materials for oil and fuel filtration some companies claim that no alternatives are available.* Specific information is, however, not available.

91. According to the information available, technical and/or economically feasible alternatives exist for membranes intended for use in medical textiles and filtration in water treatment, production processes and effluent treatment. No specific application has been identified that requires $C_8$-chemistry.

92. IPEN and ACAT (2018) state that a prohibition on PFOA use for these applications would benefit companies making alternatives, particularly non-fluorinated alternatives. 70% of the fluoropolymer producing market has already replaced the use of PFOA by the end of 2015 at a moderate price increase (ECHA, 2014a). This indicates that membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment can possibly be produced without PFOA.

93. The Committee requested information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects. Information was submitted on the scope of the applications and the availability of alternatives by HCWH (2018), Canada (2018) and IPEN and ACAT (2018). IPEN and ACAT (2018) suggest that the socio-economic impacts of not allowing PFOA for these uses should be more limited given that feasible alternatives exist and are in use. 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.

### 4.2.6 Conclusion

94. 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 is not recommended.

## 4.3 (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

95. The RME for PFOA highlighted a potential need for more information about a possible exemption for transported isolated intermediates. An exemption without time limit is included in the EU restriction, paragraph 4(c) (EU 2017/1000 amending EC 1907/2006), provided that the use complies with the REACH definition of strictly controlled conditions according to Art. 18(4) (described further below). 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, as quoted in the RME: *"(1) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage; (2) procedural and control technologies shall be used that minimise emission and any resulting exposure; (3) only properly trained and authorised personnel handle the substance; (4) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered; (5) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures; (6) substance-handling procedures are well documented and strictly supervised by the site operator".*

96. The Committee invited Parties and observers to provide information that would assist the possible defining of specific exemptions, in particular for transported isolated intermediates, in order to enable reprocessing at a different site than the production site. The Committee requested information related to the quantities used, extent of transport and possible risks, and use.

97. Relevant information was submitted by IPEN and ACAT (2018), by the FluoroCouncil (2018), Norway (2018), and the Netherlands (2018a).

### 4.3.1 Efficacy and efficiency of possible control measures

98. An exemption should be considered under the Stockholm Convention with similar conditions to those established under the EU restriction (EU 2017/1000) approach. IPEN and ACAT (2018) note that the proposal to exempt transport of isolated intermediates at the global level undermines the integrity of the Stockholm Convention. The Convention limits generic exemptions relating to intermediates to strictly closed-system site-limited intermediates that are chemically transformed in the manufacture of other chemicals that, taking into consideration the criteria in paragraph 1 of Annex D, do not exhibit the characteristics of POPs.[30] However, exemptions for the transport of intermediates can still be requested.

99. 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).

100. The FluoroCouncil (2018) submitted a request for an exemption for the "use of PFOI as intermediate in the production of TFE (tetrafluoroethylene, CAS No: 116-14-3) and HFP (hexafluoropropylene, CAS No: 116-15-4)". The FluoroCouncil provides information on the processes from their member, Archroma, on the research and development (R&D) activities, as well as the strict conditions of use of PFOI from its generation as an unintended side chain fraction (by-product) of $C_6$ fluorotelomer production to its reprocessing into TFE.

101. Brown et al (2008) completed studies suggesting that PFOI is a PFOA-related compound (amongst 120 substances) predicted to become an Arctic contaminant based on modelling studies. Brown et al (2008) go on to claim that PFOI 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 has endocrine effects (Wang et al., 2011). Wang et al. (2015) showed that 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).

102. Archroma (a member of the FluoroCouncil), produces $C_6$ fluorotelomers at one single site, located in Germany. During the $C_6$ telomerisation, PFOI, is generated as an unintended side fraction of $C_8$/ long-chain fluorotelomers, the residual fraction includes some longer-chain substances such as $C_{10}F_{21}$-I and possibly $C_{12}F_{25}$-I and other non-fluorinated substances. The composition of the residual fraction is projected to shift further from $C_{12}$ and $C_{10}$ towards $C_8$ as of 2020 as a result of the reduction effort. This fraction that also consists of $C_{10}F_{21}$-I and possibly $C_{12}F_{25}$-I is sent in closed barrels to a facility in the Republic of Korea where the company claims that iodine recovery and reprocessing to TFE and HFP take place under closed system conditions. TFE and HFP are used as raw materials for the production of fluoropolymers and $C_6$ fluorotelomers. With respect to this matter, the Korean company informed the Korean government that the facility will stop importing the PFOI intermediate by the end of 2019.

103. In the EU, PFOI is registered as a transported isolated intermediate under REACH[31] for the purpose of its off-site reprocessing and is exempted from the REACH restriction on PFOA (FluoroCouncil, 2018a). According to the FluoroCouncil, PFOI cannot be directly reprocessed via pyrolysis to obtain the desired products TFE and HFP due to iodine contamination which prevents use in downstream polymerisation reactions (FluoroCouncil, 2018a).

104. The FluoroCouncil did not report the current volume of the PFOI fraction to be covered by their proposed exemption, but stated that an R&D project is ongoing with the aim to further reduce this fraction (by a factor 3 to 6). By 2020, Archroma estimates that the volume of PFOI generated as unintended side fraction (by-product) in the production of $C_6$ fluorotelomers at their manufacturing sites will range between 50 and 100 tonnes per year (FluoroCouncil, 2018a).

105. According to the submission of the FluoroCouncil, reprocessing of PFOI to TFE and HFP takes place via iodine recovery and subsequent pyrolysis (FluoroCouncil, 2018a). TFE and HFP are both gases and can be used as raw material for the production of fluoropolymers and $C_6$ fluorotelomers. No significant additional releases of PFOI are expected from this process compared to PFOI incineration, particularly as transport would be required in the absence of on-site iodine recovery

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

[31] EU regulation EC 1906/2006 on the Registration, Evaluation, Authorisation and restriction of Chemicals.

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).

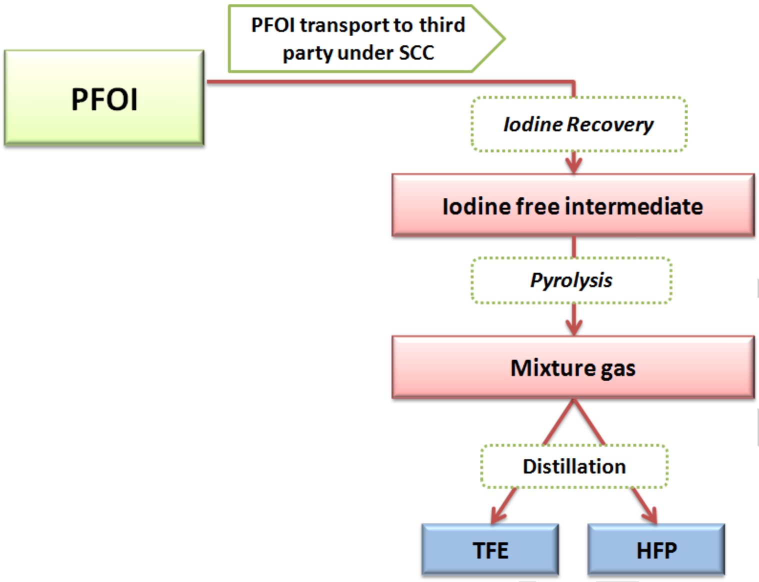


**Figure 4.1 PFOI closed-system reprocessing (FluoroCouncil, 2018a)**

106. 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 compound. 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 compound, 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). The viability of on-site iodine extraction will depend on the status of the substance, 1-H-PFO. 1-H-PFO, not PFOI, would then need to be transported for reprocessing. Additional information on the status of 1-H-PFO as a PFOA-related compound can be found in the section on the chemical identity (see section 2 on chemical identity).

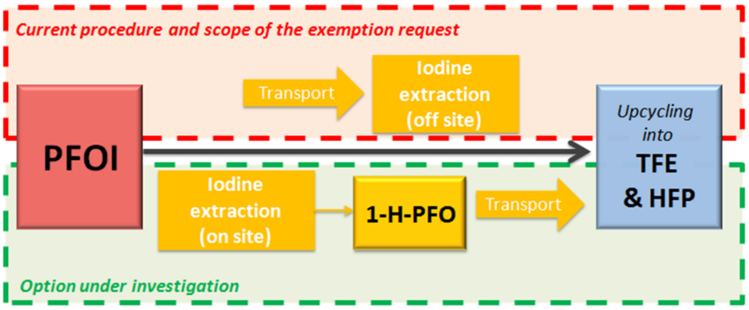


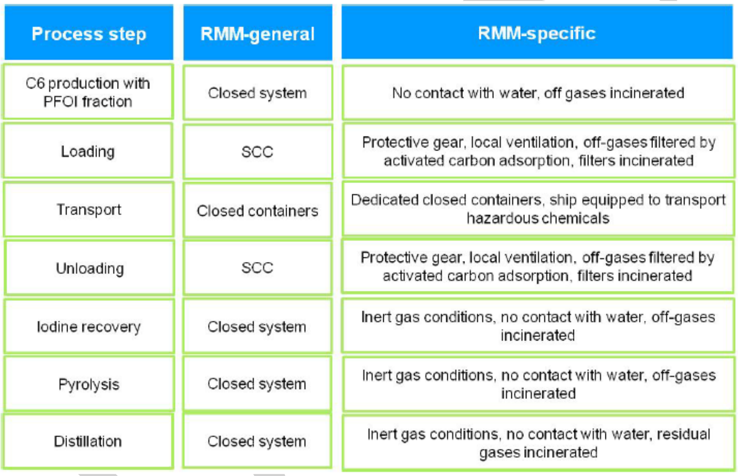
**Figure 4.2 Current off-site reprocessing procedure (red dotted line) and on-site processing option (green dotted line) (FluoroCouncil, 2018a)**

107. 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 claims that all steps of the process covered by the exemption request apply the best available techniques and 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 they claim that strictly controlled conditions are in place (FluoroCouncil, 2018b). Independent verification of these processes was not provided.

108. Archroma indicated that the production personnel are supervised and trained, that all procedures are well documented and most of them are controlled by a process control system.

Maintenance operations, (typically unclogging), are conducted with products which are incinerated after use. The $C_6$ 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. In 2016, Archroma made significant investments which have terminated any contact with water during production, thereby preventing any presence of fluorinated chemistry in waste water (FluoroCouncil, 2018b). They report that the only possible emissions are in the off-gases which are incinerated. The loading and unloading steps for transport in containers take place with local ventilation. Archroma claims 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. Archroma claims that the transport of the entire unintentional side fraction takes place in dedicated containers and with an experienced specialised shipment company for chemicals. The 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 and that the process is water free. Archroma claims that the only possible emissions are in the residual off-gases which are incinerated (2018). The estimated emissions from the process are around 10 kg/year for 100 tonnes/year of PFOI. These emissions are limited to the air, since there is no contact with water in the process. Emissions are limited to the loading and unloading steps and will further decrease as a result of a reduction of the PFOI fraction. Independent verification of these processes was not provided.

109. A summary of Archroma's risk-management measures in place are displayed below (SCC=strictly controlled conditions):



| Process step | RMM-general | RMM-specific |
|---|---|---|
| C6 production with PFOI fraction | Closed system | No contact with water, off gases incinerated |
| Loading | SCC | Protective gear, local ventilation, off-gases filtered by activated carbon adsorption, filters incinerated |
| Transport | Closed containers | Dedicated closed containers, ship equipped to transport hazardous chemicals |
| Unloading | SCC | Protective gear, local ventilation, off-gases filtered by activated carbon adsorption, filters incinerated |
| Iodine recovery | Closed system | Inert gas conditions, no contact with water, off-gases incinerated |
| Pyrolysis | Closed system | Inert gas conditions, no contact with water, off-gases incinerated |
| Distillation | Closed system | Inert gas conditions, no contact with water, residual gases incinerated |

**Figure 4.3 Risk-management measures for the handling of the PFOI fraction (Flurocouncil, 2018b)**

110. IPEN and ACAT provided information indicating that that TFE does not readily biodegrade in water, sediment, or soil and is reasonably anticipated to be a human carcinogen[32] and HFP is persistent with an atmospheric half-life of 21-95 days.[33] An HFP derivative damages the liver, bioaccumulates in carp and is found in humans.[34] The data that do exist for commonly manufactured $C_6$ fluorotelomers indicates that these substances have properties that raise concerns for POPs properties (IPEN and ACAT, 2018a; Brendel et al., 2018; Ritscher et al., 2018). As an example, IPEN and ACAT provided information from peer-reviewed publications on the properties of 6:2 fluorotelomer alcohol (6:2 FTOH) (IPEN and ACAT, 2018a). In addition, China raised concerns about an increased use of 6:2 PFAS that can lead to an increased concentration of 6:2 FTCA in the environment (China, 2018).

111. In conclusion, IPEN and ACAT (2018) suggest that the Committee should not recommend an exemption for non-site-limited isolated intermediates. The proposed exemption would, according to IPEN and ACAT, also open the door to waste dumping in developing and transition countries under the guise of "reprocessing". IPEN and ACAT argue that this exemption could result in significant further releases of PFOA (IPEN and ACAT, 2018a). Archroma argues that the transport would be subject to the strict rules of Article 3 of the Convention.

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[32] https://monographs.iarc.fr/wp-content/uploads/2018/06/mono110-02.pdf; https://monographs.iarc.fr/wp-content/uploads/2018/06/mono71-54.pdf; http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s170tfe.pdf.

[33] https://pubchem.ncbi.nlm.nih.gov/compound/Hexafluoropropene#section=Ecological-Information.

[34] https://www.ncbi.nlm.nih.gov/pubmed/28780851.

### 4.3.2 Information on alternatives

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

### 4.3.3 Information on impacts on society

113. The FluoroCouncil argues that the need for on-site storage if an exemption is not granted might lead to closure of the production site of their member company. A closure would lead to direct job losses and impact suppliers and downstream users. 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). When considering impacts on society, potential negative e.g. effects in case of a (accidental) release of PFOI have to be taken into account.

### 4.3.4 Synthesis of information

114. At sites of Archroma (a member of the FluoroCouncil) PFOI is generated as an unintended side fraction
(by-product) in the production of $C_6$ fluorotelomers. According to the FluoroCouncil, their member can currently not process PFOI on-site to TFE and HFP. Therefore, they are requesting an exemption for transporting PFOI as an isolated intermediate to another site for reprocessing to TFE and HFP. Brown et al (2008) completed modelling studies for 120 substances, which suggested that PFOI is a PFOA-related compound with potential to become an Arctic contaminant.

115. According to Archroma (2018), developing a technology to conduct the on-site iodine extraction would take several years after the entry into effect of the Convention’s provisions on PFOA and would lead to the production of 1-H-PFO which currently falls under the definition of a PFOA-related compound. If on-site iodine extraction were in place, 1-H-PFO would be transported for reprocessing. In summary, Archroma’s proposal requires an exemption for PFOI transport as an intermediate, as1-H-PFO is a PFOA-related compound (see paragraph 48 above).

### 4.3.5 Conclusion

116. During the discussion at the POPRC-14, the Korean company informed the Korean government that the facility will stop importing PFOI intermediate by the end of 2019. At the POPRC-14, Archroma also informed of plans to seek a new customer for PFOI. Given that this date comes before the probable date of entry into force of the amendment to list PFOA in Annex A to the Convention, and that there are no details provided on an expected pending use, therefore the Committee concluded that the need for the specific exemption could not be fully evaluated. Therefore, a specific exemption is not recommended for the use of perfluorooctane iodide (PFOI) generated as an unintentional by-product and used as an isolated intermediate to enable reprocessing to tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) in another site than the production site.

## 4.4 (c) Medical devices other than implantable devices

### 4.4.1 Introduction

117. The RME for PFOA highlighted a potential need for more information about a possible exemption for medical devices. The request for information specifically requested information on specific applications/uses and timelines foreseen as needed for potential related exemptions.

118. Relevant information was submitted by Canada (2018), IPEN and ACAT (2018) and MedTech Europe industry association (2018). Information related to medical devices including implantable medical devices was also provided by Healthcare Without Harm (HCWH, 2018)

119. MedTech Europe (2018) provided details in their submission stating that PFOA and PFOA-related compounds are used within medical settings as both non-polymeric substances and side-chain fluorinated polymers[35] (including PTFE). A report by ECHA (2015a) as part of the European

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[35] Polymeric Fluorotelomer-based Products are also known as “side-chain fluorinated polymers.” These products consist of hydrocarbon backbones with polyfluoroalkyl side chains that stick out like teeth on a comb. These

restriction estimated European usage of PFOA within medical devices as <1kg per year. An extrapolation from the EU estimate would result in a corresponding global usage of <5kg per year based on a 20% global market share.

120. Within the EU restriction (EU 2017/1000 amending EC 1907/2006), a time limited exemption (until 4 July 2032) is given for medical devices other than for certain implantable medical devices within the scope of Directive 93/42/EEC (EU Directive concerning medical devices). For the production of implantable medical devices, an exemption without time limitation is given in the EU. Norway has an exemption in place for medical devices (with no time limit). The import, use, sale and offer for sale of medical devices containing PFOA, its salts or PFOA-related compounds are not restricted in Canada. According to the information submitted by IPEN and ACAT (2018), in line with the provisions of the Convention clarity is needed over the specific use being exempted in order to allow ratified parties to easily enforce it. Limited data on specific uses within medical devices has been provided.

121. The RME for PFOA noted that an exemption (with or without time limit) could be considered for use of medical devices. However, a conclusion was not reached at POPRC-13 and the Committee invited Parties and observers to submit further information on specific applications/uses and timelines foreseen as needed for potential related exemptions.

### 4.4.2 Efficacy and efficiency of possible control measures

*Identification of uses of PFOA and PFOA-related compounds in medical devices*

122. MedTech (2018) and Euromed (2015) commented that medical device manufacturers encompass up to 11,000 suppliers, with supply chains up to five to seven tiers globally. They suggest that the global supply chain makes collection of information on specific applications difficult. MedTech (2018) further commented that the diverse set of applications and complexity of supply chains makes development of detailed lists of uses extremely challenging. However, MedTech (2018) noted that based on a survey of their members the presence of PFOA and PFOA-related compounds within medical devices will be present as a by-product of PTFE manufacture, where PFOA is used as an emulsifier. The use of PTFE within medical devices is selected based on its chemical resistance, heat resistance, lubrication and biocompatibility. However, it is also important to recognise that alternatives to the use of PFOA within PTFE, and PFOA-free PTFE products have been developed (discussed further in section 4.4.3 on information on alternatives) and have passed regulatory tests for commercialisation in some geographies.

123. The 2010/15 PFOA stewardship program (which is chaired by the US EPA) which includes eight major manufacturers of PFOA globally, has seen the manufacture of PFOA cease in the EU and decrease dramatically in the US and Japan.[36] However, MedTech (2018) also commented that the main component production is outside of Europe and may use PFOA (produced in China and India) as a raw material input for the production of the applied polymers (Euromed, 2015).

124. MedTech (2018) stated that when PFOA is used in PTFE production in generic components, trace quantities can end up in medical equipment such as:

(a) Cable and wiring;

(b) Electronics (insulators, solder sleeves, vapour phase soldering media);

(c) Photographic applications (see section 4.6); and

(d) Medical articles (non-woven medical garments; stain- and water-repellents for surgical drapes and gowns (see section 4.2); surgical patches; and vascular catheters).

125. The above-mentioned components result in applications within a wide range of medical devices including sensors, cardiovascular devices, vascular catheters, protection tubing, implants and orthopaedic devices. Invasive medical devices which may be manufactured with PTFE containing PFOA can include, but are not limited to, guidewires, balloon catheters and introducer sheets.

126. A report by ECHA for the European restriction (ECHA, 2015a) comments that the total usage of PTFE and quantities of PFOA or PFOA-related compounds in medical devices are unknown.

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polymers are used to treat textiles, carpets, nonwovens and paper to provide water, soil, oil and stain resistance. https://fluorocouncil.com/fluorotechnology/terminology/.

[36] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfass#tab-3.

However, based on the survey conducted with industry, ECHA (2015a) estimates that total quantities of PFOA in medical devices in use across Europe would not exceed 1kg. ECHA (2015a) estimates that the use within the EU makes up 20% of total global demand for PTFE, and therefore by extrapolation total quantities of PFOA in medical devices globally may not exceed 5 kg, based on the assumption that the use of PFOA would be similar in other non-EU geographies.

*Timescales foreseen for potential exemptions*

127. MedTech Europe (2018) noted that the substitution of substances within the medical sector is likely to differ from substitution in other sectors. This is because of the scrutiny and stringent regulatory requirements for medical equipment. MedTech Europe (2018) go on to state that a change in materials could be perceived as affecting the reliability of the device and would thus trigger the need for evaluation as if the device were a new piece of equipment, including the potential need for clinical trials which would delay the transition. MedTech Europe (2018) state that products that have already entered the supply chain would have a shelf-life of 3 to 5 years, mainly relating to product sterility and therefore an exemption would be needed for a similar period of time. It is not clear whether this relates only to implantable medical devices or to all medical devices.

128. The European restriction (EU 2017/1000) allows an exemption for all medical devices (excluding implantable medical devices) of 15 years and a non-time limited exemption for implantable medical devices. This is expected to expire on 4 July 2032. ECHA considered comment (within ECHA, 2015a) that the reason for the length of the exemption relates to the stringent regulatory requirements for medical equipment which can delay the substitution with alternatives and that a shorter exemption may mean certain critical applications would become unavailable to the healthcare sector.

### 4.4.3 Information on alternatives

129. Canada (2018) stated as part of the invitation for submissions that the main use of PFOA within medical devices is as a process aid in the emulsion polymerisation of PTFE; however, Canada states that Zero PFOA PTFE products are now available on the market. IPEN and ACAT (2018) also comment that PFOA-free PTFE products have been commercialised and are available on the market within the USA.

130. The RME provided an overview of the main PFOA-free PTFE goods available on the market. In absence of further new information and for ease of reading this information is provided from the RME in the following paragraph.

131. *Three PFOA-alternatives with ether moieties (GenX, ADONA and EEA-NH*$_4$*) that are generally shorter and/or less fluorinated were assessed in the EU restriction process (ECHA, 2015b, section C3). C*$_3$ *Dimer salt,*[37] *ADONA and EEA-NH*$_4$ *are applied as alternatives for the use of PFOA as polymerization processing agent where it is applied as emulsifying agent enabling reactants from the aqueous phase and reactants from the hydrophobic phase to get into contact in an emulsion and react with each other (ECHA, 2015b). According to ECHA most of the stakeholders stated that there are no technical differences between fluoropolymers produced with the alternatives and fluoropolymers produced with PFOA (or stakeholders do not know whether there are any differences) (ECHA, 2015b). Fluoropolymer manufacturers stated during the EU public consultation that the production costs varied from none to 20% increase when applying the alternatives (ECHA, 2015b). The increase is a result of higher costs of the alternatives as well as higher amounts of the alternatives needed to manufacture one unit of fluoropolymer. Some downstream users mentioned that no cost effects occurred after substitution from PFOA to alternatives.*

132. Further information around the persistent, bioaccumulative and toxic (PBT) properties of potential alternatives is detailed within the RME.

### 4.4.4 Information on impacts on society

133. MedTech Europe (2018) commented that health risks of medical devices are adequately assessed during regulatory procedures before the placing on the market. The European medical device industry commented that they fully supported a phase out of PFOA but requested a limited time exemption in order to avoid market disruption and allow for a substitution that is properly enforceable. Regarding waste implications, the amount of PFOA in question is considered to be small and it can be expected that most medical devices would be disposed of according to the stringent waste disposal

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

requirements applicable to hospitals. However, the stringency of medical waste disposal practices will vary.

### 4.4.5 Other considerations

134. None.

### 4.4.6 Syntheses of information

135. MedTech Europe (2018) noted that, based on a survey of its members, PFOA will mainly be present in medical devices as a by-product of PTFE manufacture. However, it is also important to recognise that alternatives to the use of PFOA within PTFE, and PFOA-free PTFE products have been developed (Nesbitt, 2017). MedTech Europe (2018) and Euromed (2015) both highlighted the difficulty in producing detailed lists of specific applications within healthcare due to the diverse ways in which PTFE is used. However, in line with the provisions of the Convention, a use of PFOA should be specifically identified to enable consideration of an exemption. Generic uses of PTFE in medical devices include cables and wiring, electronics (such as insulators, solder sleeves, and vapour phase soldering media), photographic applications, medical articles (such as non-woven garments, stain and water repellents for surgical drapes and gowns, and vascular catheters. ECHA (2015) made estimates to quantify PFOA and PFOA-related compounds in medical devices, estimating that these are at or below 1kg for Europe and below 5kg globally.

136. ECHA (2015a) noted that substitution to alternative substances may be more challenging in the healthcare sector due to the stringent regulations applied, which can include the need for clinical trials. This was a point also made by MedTech (2018) and Euromed (2015). The European restriction includes a 15-year exemption for medical devices due to expire on 4 July 2032. ECHA commented (ECHA, 2015a) that such an exemption was needed to aid transition and prevent critical applications becoming unavailable.

137. The RME states that alternatives have been developed and commercialised, including Zero PFOA PTFE.

138. The RME indicates that three key alternative products exist with ether moieties (GenX, ADONA and EEA-$NH_4$) that are generally shorter and/or less fluorinated than what was assessed in the EU restriction process (ECHA, 2015a, section C3). $C_3$ Dimer salt, ADONA and EEA-$NH_4$ are applied as alternatives for the use of PFOA as a polymerisation processing agent where it is applied as an emulsifying agent enabling reactants from the aqueous phase and reactants from the hydrophobic phase to get into contact in an emulsion and react with each other (ECHA, 2015b). According to ECHA most of the stakeholders stated that there are no technical differences between fluoropolymers produced with the alternatives and fluoropolymers produced with PFOA (or stakeholders cannot recognise any differences) (ECHA, 2015b). Fluoropolymer manufacturers stated during the EU public consultation that the production costs varied from zero to a 20% increase when applying the alternatives (ECHA, 2015b). The increase is a result of higher prices of the alternatives as well as higher quantities of the alternatives needed to manufacture one unit of fluoropolymer. However, some downstream users mentioned that no cost effects occurred after substitution from PFOA to alternatives (ECHA, 2015b).

139. 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 (MedTech Europe, 2018). MedTech Europe (2018) and Euromed (2015) both highlight that regulations within the healthcare sector are stringent, and that alteration of substances within devices can mean the need for retesting, including potentially clinical trials. This reportedly delays the transition to alternative products. However, alternatives that do not use or contain PFOA have already passed medical regulations in at least some geographies, and are commercially available.

### 4.4.7 Conclusion

140. Based on the information compiled and discussed within the RME and further elaborated upon within the current document, the Committee recommends a specific exemption only for invasive medical devices.

## 4.5 (d) Implantable medical devices

141. The RME for PFOA highlighted a potential need for more information about a possible exemption for implantable medical devices. The Committee invited Parties and observers to submit further information on the scope of the applications of use, used amounts, extent of transport and risks

and other relevant information on socio-economic aspects. Relevant information was submitted by Canada (2018), IPEN and ACAT (2018), Healthcare Without Harm (HCWH, 2018) and MedTech Europe (2018).

142. Within the EU restriction (EU 2017/1000), an exemption without time limit is currently given for the production of certain implantable devices.

### 4.5.1 Efficacy and efficiency of possible control measures

143. Information submitted to ECHA (2015a) indicates that amounts of PFOA and PFOA-related compounds related to this use are estimated to be extremely low. In implantable devices, one 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 compounds). This was extrapolated to 100g total worldwide by the industry assuming that the EU occupies 20% of the market assuming similar usage in other non-EU geographies (MedTech Europe, 2018). The concentration of PFOA in PTFE is stated to range from 0.001 to 0.5% for emulsion route material (ECHA, 2015b), with a comment from ECHA that confidential information indicated that the working concentrations for implantable medical devices would be at the lowest concentration range (ECHA, 2018).

144. MedTech Europe (2018) commented that an exemption for implantable cardiovascular devices until 2030 would be sufficient to allow transition to alternatives without impacting the European healthcare sector. ECHA (2015a) commented that a derogation for implantable medical devices in the EU was needed given the very low amounts of PFOA and PFOA-related compounds involved and high costs reported for immediate transition.

145. Further information and data on quantities used, extent of transport and risks, and use of PFOA in implantable medical devices was not provided in response to the request for information.

### 4.5.2 Information on alternatives

146. Implantable medical devices, which may be manufactured with PTFE containing PFOA can include, but are not limited to, synthetic vascular grafts, endovascular and interventional devices, surgical meshes for hernia repair, to sutures for use in vascular, cardiac, and general surgery procedures. These can include PFOA residual levels at or below 1 ppm. However, PTFE can be made without PFOA (HCWH, 2018) and alternatives are reportedly now commercially available, approved by US Food and Drug Administration (FDA), and are a feasible and effective alternative to the use of PFOA (IPEN and ACAT, 2018). A number of commercialised PFOA-free PTFE medical devices are now available.[38] [39] [40] [41]

147. 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[42] due to problems with flaking and delamination in the body (Gupta et al., 2016). 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; Gupta et al., 2016). The second generation of PFOA-free PTFE products have resolved the bonding issue by changing manufacturing processes related to 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). Nesbitt (2017) also notes that processes following these altered practices have resulted in zero Class 1 FDA recalls.

148. Fluoropolymer manufacturers stated during the EU public consultation that the production costs varied from none to 20% increase when applying the alternatives (ECHA, 2015b). This increase arises from the higher costs and/or the higher amounts of alternatives that will be used, however

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[38] http://www.surfacesolutionsgroup.com/site/files/785/69121/273265/759549/no-pfoa-ptfe-coatings-guidewires-brochure.pdf.

[39] https://meritoem.com/composite-reinforced-coatings-the-future-of-medical-device-coatings/.

[40] http://store.tegramedical.com/zero-pfoa-green-ptfe-wire/.

[41] https://wytech.com/wire-components/.

[42] Nesbitt, 2017 comments that in October 2016 Medtronic a major supplier of guidewires used in medical implants had to recall 84,000 units after problems. Nesbitt notes that Medtronic was not the only supplier that needed to issue a recall as part of the US FDA recall.

during a previous request (in 2015) for information, EU Industry stated that there is no change in the quality of the PTFE manufactured with the alternatives (ECHA, 2015b).

149. In the EU public consultation, industry stakeholders indicated that substitution is ongoing but is a lengthy process given the complexity of the supply chains and the certification processes (ECHA, 2015a). In the specific case of implantable medical devices, one manufacturer requested a transition period of 15 years (ECHA, 2015c). This request was supported by a socio-economic analysis comparing the costs of not using the devices with the avoided emissions. ECHA found that, even if all costs were not clearly justified and might include some overestimation, this socio-economic analysis demonstrated that a shorter transition period than requested would not be cost-effective (ECHA, 2015a).

150. Further information on the alternatives to PTFE can be found in section 4.4.3 on medical devices.

### 4.5.3 Information on impacts on society

151. Implantable medical devices allow for example for minimally invasive insertion, and the innovative materials are biocompatible, homogenous and versatile. 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 (MedTech Europe, 2018). The RME and addendum notes that examples have been provided of cases where PFOA-free alternatives have been developed and are already in use for some geographies. However, it is unclear whether this is the case for all global geographies.

### 4.5.4 Syntheses of information

152. Quantities of PFOA and PFOA-related compounds used in implantable medical devices (largely for production of PTFE) are small (estimated to be 20g in the EU and 100g worldwide) and concentrations are low in the final product (PFOA in PTFE is stated to range from 0.001 to 0.5%; while personal communication with ECHA noted that based on engagement with industry and confidential data concentrations in implantable medical devices were lower than general PTFE). In addition, the development of alternatives for substitution is complex due to stringent regulatory requirements for material changes to medical devices but alternative PTFE coating methods are available and already in use. The past performance of PFOA-free PTFE alternatives has been subject to concern by the US-FDA (due to problems with flaking and delamination in the body) but improved manufacturing methods have resulted in zero Class 1 recalls. The RME indicates that the use of alternatives also induces a low to moderate increase in production costs (0–20%) and is paired with a net benefit to society in terms of human health impacts, through the reduced use of PFOA in human implants.

### 4.5.5 Conclusion

153. Cost competitive alternatives, such as PFOA free PTFE products have already undergone clinical testing, been approved and have been implemented for use in medical implants including cardiovascular devices in some geographic areas, such as North America (Nesbitt, 2017). However, it is unclear whether this transition has been made in all global geographies. 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. Therefore, the Committee recommends a specific exemption for implantable medical devices which can include, but are not limited to, synthetic vascular grafts, endovascular and interventional devices, surgical meshes for hernia repair, to sutures for use in vascular, cardiac, and general surgery procedures.

## 4.6 (e) Photo-imaging sector

### 4.6.1 Introduction

154. The RME recommends to the COP considering an exemption for five years (from the date of entry into force) for photographic coatings applied to films. However, the RME also highlighted the need for more information about a small number of relevant uses of PFOA in the photo-imaging sector more particularly in relation to photographic coatings applied to paper and in printing plates. Within the EU, an exemption from the REACH restriction is in place for photographic coatings applied to films, papers or printing plates without time limitation (EU 2017/1000). Exemptions applied in Norway and Canada until 2016 but are now ended (See Appendix I). The Norwegian risk management

approach only applies to consumer products and the Canadian approach does not apply to manufactured items.

155. At POPRC-13, representatives of the European photographic imaging industry provided information for the RME that suggested specific exemptions for photographic coatings applied to paper and for use in printing plates are no longer needed. Non-fluorinated alternatives and the move to digital imaging have successfully replaced these uses in the imaging and printing industry (I&P Europe). However, it was also noted that for developing countries, such information was lacking.

156. A conclusion on photographic coatings applied to paper and in printing plates was not reached at POPRC-13 and the Committee invited Parties and observers to provide information on photo imaging, specifically in relation to photographic coatings applied to paper and in printing plates and in developing countries.

157. Relevant information was submitted by the Netherlands (2018a), IPEN and ACAT (2018) and Healthcare Without Harm (HCWH, 2018).

### 4.6.2 Efficacy and efficiency of possible control measures

158. IPEN and ACAT (2018) provided multiple examples (from countries such as Gabon, Kazakhstan, Kenya, South Africa, Latin American region, and remote Arctic communities) where digital imaging has been adopted in developing countries in favour of hardcopy printing. 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” (IAEA & WHO, 2015)”.[43]

159. Further information on use of PFOA or PFOA-related compounds in developing countries in other industry sectors (other than healthcare) was not received in response to the call for information.

*Control measures*

160. Representatives of the European photographic industry provided information that PFOA or PFOA-related compounds are no longer used in photographic coatings applied to paper and in printing plates. This represents the situation in Europe (IPEN Comments on 1st draft RME). Information for other geographies has not been identified.

161. Due to lack of data, substitution costs in response to a restriction for photographic applications cannot be estimated and no further up to date information has been received in response to the call for information. This may be due to the extensive transition to digital technologies that has already occurred, however more information on cost of substitution would be useful.

162. Monitoring data linked directly to the photographic sector outside Europe is very limited and no additional data has been submitted in response to the recent call for information.

### 4.6.3 Information on alternatives

163. *According to I&P Europe, since 2000, European industry has reformulated/discontinued a large number of products, resulting in a world-wide reduction in the use of PFOA-related compounds of more than 95%. Although replacements do not currently exist for the remaining few applications, further reduction in use of PFOA-related compounds is anticipated as the transition continues towards digital imaging. I&P Europe believes that additional control measures for ongoing uses are not necessary (I&P Europe, 2016). A study by van der Putte et al. (2010) suggests that no alternative currently exists and the significant investment required in R&D to switch to an alternative means it is likely that manufacture and use of PFOA or PFOA-related compounds in the photo-imaging sector could cease (ECHA, 2014a). The largest barriers to development reportedly remain technical and cost of R&D. They suggest that substitution of PFOA typically amounts to 500–1,000,000 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,*

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[43] Note that the use of PFOA for film is already covered by an exemption stated in the RME. The current document covers the use for printing on paper and plates. The example is however included to evidence the transition towards digital technologies.

*2015).* For these reasons, the industry has shifted to digital technologies. According to information provided at POPRC-14, by the representatives of the European photographic industry, PFOA or PFOA-related compounds are no longer used in photographic coatings applied to paper and in printing plates.

164. The Netherlands (2018a) provided information stating that a European photographic company have created a replacement programme for PFOA. For substitution, the first option is to look at non-fluorine substances if applicable. The PFOA products concerned were replaced where possible by a combination of non-fluorinated products and/or degradable fluorinated compounds where no PFOA arises following degradation.

### 4.6.4 Information on impacts on society

165. According to I&P Europe Imaging and Printing Association, since 2000, the corresponding European industry has reformulated/discontinued a large number of products. As a result of which PFOA or PFOA-related compounds are no longer used in photographic coatings applied to paper and in printing plates manufactured by their members. Information from other geographies has not been made available.

### 4.6.5 Syntheses of information

166. According to I&P Europe, since 2000, European industry has reformulated/discontinued a large number of products, as a result of which PFOA or PFOA-related compounds are no longer used in photographic coatings applied to paper and in printing plates manufactured by their members. Analogue printing is being phased out and replaced rapidly by digital, including in developing and transition countries. IAEA and WHO note that the rapid adoption of digital technology results from "efficiencies inherent in digital capture, storage and display and the competitive cost structures of such systems when compared to alternatives involving film." 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.

### 4.6.6 Conclusion

167. Based on the existing and rapid transition towards digital imaging, the wide use of digital techniques in developing and transitional countries, and the further reduction in use of PFOA in this sector, the Committee does not recommend exemptions for photographic coatings applied to paper and printing plates.

## 4.7 (f) Automotive industry

### 4.7.1 Introduction

168. The RME highlighted the need for more information about the uses in automotive service and replacement parts. According to the RME, an exemption for automotive service and replacement parts could be considered under the Stockholm Convention. However, specification of relevant automotive service and replacement parts as well as sound justification for any exemption is required. No related exemptions have been given in the EU and Norway (see the RME) and no exemption is granted in the EU REACH restriction.

169. The Committee invited Parties and observers to submit further information on automotive spare parts and other relevant information. Information was submitted by the Canadian Vehicle Manufacturers` Association (CVMA, 2018), European Automobile Manufacturers Association (ACEA, 2018), Society of Indian Automobile Manufacturers (SIAM, 2018), Canada (2018) and IPEN and ACAT (2018).

### 4.7.2 Efficacy and efficiency of possible control measures

170. During the development of the RME, *the CVMA requested specific exemptions for automotive service and replacement parts. The request for exemption is also supported by the European (ACEA) and Indian (SIAM) automotive industry. According to the CVMA, the industry has been proactively phasing out PFOA use for some time, however, service and replacement parts might still contain PFOA. CVMA states that these parts represent a small percentage of PFOA use and will decrease naturally over time due to vehicle fleet turn-over. Automotive manufacturers indicated the need to*

*ensure the availability of Original Equipment (OE) and spare parts to satisfy customer demand* (see the RME).

171. In their recent submissions, CVMA requests an exemption 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 PFOA-related compounds that are not listed on the Global Automotive Declarable Substance List (GADSL) or listed on GADSL but used below the declaration concentration of 0.1%. 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. The issues and challenges would reportedly be similar (CVMA, 2018). IPEN and ACAT (2018) point out that the recommended exemption by POPRC is limited to parts used in legacy vehicles.

172. CVMA further explains that it is challenging to provide meaningful information in support of the required exemption for PFOAs used in the automotive industry. According to CVMA, this is in particular challenging as PFOA is unlike other substances examined under the Stockholm Convention identifiable by a single CAS number. The efforts have been focused so far on a selected number of PFOA-related compounds as information was not available on a broad number of PFOA-related compounds. 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). Further, CVMA points out that 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 (CVMA, 2018).

173. According to CVMA, the automotive industry has recognised the concerns with certain PFOA-related compounds and has taken proactive efforts to track and reduce those substances in products. Five (5) compounds were added to the GADSL (www.gadsl.org) in 2008, 3 substances in 2016 and another 4 in 2018 (see below). These substances tend to be used at very low levels and probably not all uses have been identified (CVMA, 2018).

**Table 4.1 list of PFOA-related compound on GADSL provided by CVMA (2018)**

| **Name** | **CAS Number** | **Addition Date to GADSL** |
|---|---|---|
| Ammonium salt of PFOA | 3825-26-1 | 1-Feb-2008 |
| Potassium salt of PFOA | 2395-00-8 | 1-Feb-2008 |
| Silver salt of PFOA | 335-93-3 | 1-Feb-2008 |
| Sodium salt of PFOA | 335-95-5 | 1-Feb-2008 |
| PFOA, perfluorooctanoic acid | 335-67-1 | 1-Feb-2008 |
| Ethylperfluorooctanoate | 3108-24-5 | 1-Feb-2016 |
| Methylperfluorooctanoate | 376-27-2 | 1-Feb-2016 |
| Pentadecafluorooctyl fluoride | 335-66-0 | 1-Feb-2016 |
| Poly(oxy-1,2-ethanediyl), α-(4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heptadecafluoro-2-hydroxyundecyl)-ω-[(4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heptadecafluoro-2-hydroxyundecyl)oxy]- | 122402-79-3 | Feb-2018 |
| 2-Propenoic acid, $C_{16-18}$-alkyl esters, polymers with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl acrylate | 160336-09-4 | Feb-2018 |
| Cyclotetrasiloxane, 2-(4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heptadecafluoroundecyl)-2,4,6,8-tetramethyl-, Si-[3-(oxiranylmethoxy)propyl] derivs | 206886-57-9 | Feb-2018 |
| Trisiloxane, 3,3'-(3,3,4,4,5,5,6,6,7,7,8,8-dodecafluoro-1,10-decanediyl)bis[3-[(dimethylsilyl)oxy]-1,1,5,5-tetramethyl-, reaction products with 4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heptadecafluoro-1-undecene | 185701-89-7 | Feb-2018 |

174. Only 12 PFOA salts and precursors are declarable under GADSL and therefore many of the other PFOA salts and precursors could potentially be present in production vehicles without the knowledge of the manufacturers. An initial evaluation of the non-exhaustive list of PFOA-related

compounds (i.e. UNEP/POPS/POPRC.13/INF/6/Add.1) shows that 24 individual CAS numbers have been identified by suppliers as potentially being used in the 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 also supports that there may be other PFOA used in service and replacement parts which the industry is unware of as the uses have not been declared according to CVMA. Further, it is important to highlight that the 12 PFOA and PFOA-related compounds are included in GADSL if they are used at a concentration above 0.1%. Consequently, all uses may not be known and sufficient lead time is required in the Canadian automotive industry to collect meaningful information. This process typically takes at least one full design cycle of approximately 5 years (CVMA, 2018).

175. Regarding service and replacement parts, CVMA has indicated that most likely service and replacement parts still contain PFOA, its salts and PFOA-related compounds. 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. Vehicle manufacturers normally ensure the availability of the OE service and replacement parts for a minimum of 15 years to satisfy consumer demand and potentially certification and quality requirements. Typically, parts may be built and stocked at the time of vehicle production or built to the original specifications, including compositions, in short production runs after the new vehicle production ends. The cost of replacing a class of substances in a small number of parts is according to CVMA prohibitive. However, no further information on costs has been disclosed. Further according to CVMA, it should be noted that repair parts need to meet the same performance specifications as the original parts. Based on replacement part availability obligations as noted above, the vehicle manufacturers are working to address the PFOA-related compounds listed from replacement parts by 2036 provided the effective date of the ban is 2021; for PFOAs substances not known, this would take much longer (CVMA, 2018).

176. CVMA further explains that each vehicle manufacturer in general carries over 250,000 active replacement parts, with roughly 20,000 new service parts added annually. The number of parts maintained in inventory and its location (Canada or US) depends on expected consumption and future ability to manufacture. To the extent that customers need replacement parts beyond what is initially stocked, there is a “production-on-demand market” whereby suppliers continue to produce replacement parts using original tools, materials and production processes. (CVMA, 2018).

177. Re-developed replacement parts must function identically to the original part to ensure the vehicle’s functionality and safety are not adversely impacted. 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).

178. Regarding the quantity of PFOA in spare parts (manufactured articles in finished vehicles), CVMA is not able to provide this information given the limited information and CAS numbers. Based on the typical function of PFOA-related compounds which is to repel dirt and water/moisture, it is typically found in areas such as vehicle safety restraint systems and air bag systems, as well as specialised gaskets, seals and weather -strippings, linings in engines, fuels and transmission systems, windshield washer arms, hoses, wirings, o-rings, cables and other areas not yet identified (subject to change). Concentrations tend to be less than 1% in the material and many are at concentrations less than 0.2%. 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 probed and exact PFOA-related compounds was not disclosed). The mass of PFOA in various components as a result of these low concentrations is also very small (CVMA, 2018). No specific information (e.g. quantities of the 12 PFOA-related compounds from the GADSL contained in spare parts) has been provided by CVMA. 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).

179. Regarding recycling activities of articles containing PFOA, no information is available (CVMA, 2018).

180. In contrast to the request for exemption information submitted by CVMA, IPEN and ACAT (2018) stipulate that key automotive industry associations have notified company members and suppliers that PFOA will be listed in the Stockholm Convention as well as being regulated in the EU and that “these substances should be substituted.”[44] CVMA (2018), however, indicates that they are unaware of key automotive associations notifying their members on a global basis and that this may have occurred on a regional basis rather than in a broader global context. The automotive industry also

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[44] http://www.acea.be/uploads/publications/20160704_INFORMATION_LETTER_TO_SUPPLIERS_ON_PFOA.pdf.

notes that, “most suppliers producing relevant articles, like waterproofed convertible roofs or PTFE-coated seals, no longer use PFOA or other long-chained perfluorinated chemicals.”[44] In the past PFOA has been used to make fluoropolymers used in automotive fuel systems but several companies have alternative emulsifiers so that PFOA has been eliminated in this class of automotive products.[45] 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). 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 therefore represents a significant challenge for data gathering compared to decaBDE which was based on a single substance. IPEN and ACAT advice that no exemption for PFOA use in the automotive industry should be recommended (IPEN and ACAT, 2018).

### 4.7.3 Information on alternatives

181. The information from the RME and the new submissions confirm that the phase-out of PFOA, its salts and PFOA-related compounds is ongoing in the automotive industry. Technical and/or economically feasible alternatives for PFOA exist at least in part for the automotive industry. The typical areas of application have been indicated by the automotive industry, however, a complete overview is not available, yet.

182. Information gathered indicates that the key obstacle towards a complete phase-out of PFOA in automotive service and spare parts by the entry does not appear to be the lack of alternatives but rather other obstacles such as costs, because additional costs arise for the certification of PFOA free alternative spare parts. These costs are considered prohibitive by the automotive industry; however, no further information has been provided by the industry related to associated costs.

### 4.7.4 Information on impacts on society

183. According to the RME, *general concerns of EU industry stakeholders are related to placing on the market and use of spare parts of various types already manufactured (e.g. in aviation, telecommunication, semiconductors, etc.). According to their comments, in the absence of derogation, those spare parts would have to be destroyed, which would represent an economic loss for EU manufacturers* (see the RME). However, this loss will not occur since spare parts containing PFOA, its salts and related compounds manufactured before the entry into force of a listing under the Stockholm Convention would not be covered by the listing (see Annex A, part I, note (ii) and Annex B, part I, note (ii) respectively).

184. CVMA and SIAM state, that vehicle manufacturers normally ensure the availability of the OE for service and replacement parts for a minimum of 15 years. According to CVMA, typically, parts may be built and stocked at the time of vehicle production or built to the original specifications, including compositions, in short production runs after the new vehicle production ends. It should be noted that repair parts need to meet the same performance specifications as the original parts.

185. Re-developed replacement parts must function identically to the original part to ensure the vehicle’s functionality and safety are not adversely impacted. The cost of replacing a class of substances in a small number of parts is prohibitive according to industry. It could also result in parts being purchased by consumers from jurisdictions where the original type part or an inferior performing variant could be obtained (CVMA, 2018). According to IPEN and ACAT, testing results can be applied to both new and old vehicles.

186. 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).

### 4.7.5 Syntheses of information

187. The information from the RME and the new submissions confirms that the phase-out of PFOA, its salts and PFOA-related compounds is well-advanced and ongoing in the automotive industries.

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[45] http://atozplastics.com/upload/literature/Fluoropolymers-application-automotive-fuel-engine-systems.asp.

188. In their recent submissions, CVMA requests an exemption for automotive vehicle service and replacement parts as well as for current production vehicles. 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. However, CVMA further stipulates that even with the mentioned provisions, an alternative timing for the phase-out of automotive service and replacement parts is still needed due to a number of reasons. Among others, the industry cannot assume that a substance is not present given disclosure thresholds and other limitations according to CVMA. Service and replacement parts for current and already produced vehicles are made available for a minimum of 15 years. Furthermore, CVMA highlights that due to the breadth or level of detail regarding all PFOA-related compounds used in the automotive sector comparisons to the data requirements used previously for decaBDE are unfair (CVMA, 2018).

189. According to CVMA, a key obstacle in a complete phase-out of PFOA in automotive service and spare parts by the entry into force of a possible amendment of Annex A appears to be the prohibitive costs. However, no information on possible cost implications has been submitted. In addition, the Canadian automotive industry has concerns regarding practical challenges related to the numerous CAS numbers of affected substances. This has also been expressed by automotive associations ACEA and SIAM.

190. According to CVMA, the level of PFOA usage in the sector is unknown but expected to be low as a result of reported concentrations. However, CVMA have declared 12 PFOA salts and precursors under GADSL. Given this, the industry has some information on 12 substances and at least 1 of the substances listed on GADSL is identified by CVMA as being used in the sector. Another PFOA-related compound, which is not been listed on GADSL has been identified by at least one OEM or a supplier as being used in the industry. No specific information (e.g. quantities of the eight PFOA substances from the GADSL) has been provided by CVMA so far.

191. For these identified PFOA-related compounds 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. Until now only a generic list of application areas is provided. This is especially the case if this exemption should take a similar approach as for decaBDE, as requested by CVMA in their recent submission. Based on specific information about relevant spare parts a list of relevant spare parts and categories could be established similar to the approach for decaBDE. The starting point for this could be the parts/categories already specified above, e.g. vehicle safety restraints and air bag systems, gaskets or seals in coatings or lubricants, gaskets, seals and linings in engine, fuel and transmission systems. This information could be supplemented with further information on available alternatives already commercially in use.

192. The Committee requested specification of relevant automotive service and replacement parts as well as sound justification as to why an exemption is required. The Committee invited Parties and observers to submit further information on automotive spare parts and other relevant information available. Limited information was submitted on socio-economic aspects and the availability of alternatives. 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 amounts used in different parts is considered necessary to justify a recommendation for an exemption.

### 4.7.6 Conclusion

193. Information submitted was insufficient to support an exemption. No conclusive information was provided on the specification of relevant automotive service and replacement parts (specific parts or categories of parts) and on the quantities of relevant substances used in different applications. In addition, no conclusive information was provided on time required for phase-out, estimation of economic impacts, alternatives in place and retrofitting capacity. Based on the insufficient information and lack of an appropriate justification, the Committee does not recommend an exemption.

## 4.8 (g) Fire-fighting foams

### 4.8.1 Introduction

194. The RME identified that aqueous film-foaming foams (AFFFs) may contain PFOA or PFOA-related compounds. This raised concerns at POPRC-13 due to the fact that the use of fire-fighting results in the dispersive and potential direct release to the environment.

195. Fluorinated compounds have been used in AFFF as they have proved effective at extinguishing liquid fuel fires. AFFF was reserved specifically for liquid fuel fires. (ECHA, 2014a). In the past industry has favoured the use of $C_8$ based perfluorinated compounds,[46] including PFOS (which has subsequently been added to the Stockholm Convention as a POP). These materials were largely produced using electrochemical fluorination (ECF), with hydrogen fluoride used as a feedstock alongside organic material (Swedish Chemicals Agency, 2015). PFOA was initially used as a component of AFFF in its ammonium salt form (Seow, 2013). AFFF were then developed as a mixture of $C_6$ and $C_8$ compounds and, over the years, foams were purified and $C_8$ components removed. The most recent formulations contain a very low level of $C_8$ impurities. However specific information on mixtures and formulations is limited in part because of the commercial sensitivities. 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. Barzen-Hanson et al, 2017, conducted analysis on AFFF foams (manufactured by both ECF and telomerisation) produced in the 1980s and 1990s which demonstrate the complexity of AFFF mixtures. The study indicated that more than 240 individual per and polyfluoroalkyl substances (PFAS) can be associated with AFFF, including discovery of forty novel classes of PFAS (30 associated with ECF and 10 associated with telomerisation) and detection of 17 previously reported PFAS. The authors stated that these newly discovered PFAS will pose challenges for effective remediation due to the presumed wide range of solubilities. Systems designed to capture PFOS and PFOA (such as granulated active carbon) will not be effective because shorter-chained substances will likely break through.

196. Following the concerns raised over human health and environment from the use of PFOS, industry largely moved towards $C_6$ fluorinated technology,[47] [48] although fluorine free alternatives were also developed. This transition is also commented on within the RME. The Swedish Chemicals Agency (2015) comments that $C_6$ technologies are not based on ECF but rather telomerisation, beginning with perfluoroalkyl iodide as the raw material. Where telomerisation reactions involve perfluorinated compounds it is possible to form $C_8$ perfluorinated compounds, including PFOA, as a contaminant within $C_6$ species. The Swedish Chemicals Agency (2015) comments that as much as 20% $C_8$ can end up within the final stages before clean-up, after which residual concentrations of 0.01% wt/wt may be present in the final commercial product. However, the Swedish Chemicals Agency (2015) also note that studies exist demonstrating that goods marketed as $C_6$ fluorotelomer products still contain concentrations of $C_8$ (including PFOA) significantly above trace residual concentrations, in some cases at concentrations with equal amounts of $C_6$ and $C_8$. ECHA (2014a) also comments that $C_8$ fluorotelomer alcohols (FTOHs) used within AFFF can degrade to form PFOA once in the natural environment.

197. Within the EU REACH restriction for PFOA (ECHA, 2015a), an exemption is given for foams mixtures already placed on the market.[49] It was considered that a full and quick replacement with AFFFs based on $C_6$ technology would not solve the problem of environmental contamination, because of the persistency and mobility of short chain fluorinated alternatives and the difficulty to remediate water contamination. In the EU, 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. Additionally, Queensland, the state in Australia, maintains a maximum concentration of 50,000 ppb as fluorine within fire-fighting foams (Queensland, 2016a), where this limit is exceeded goods must be

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[46] UNEP/POPS/POPRC.13/7/Add.2.

[47] http://www.chemguard.com/pdf/TFPP%20C8%20to%20C6%20Transition%20Bulletin.pdf.

[48] https://www.solbergfoam.com/Technical-Documentation/Foam-Concentrate-Data-Sheets/Arctic-Foam/Brochures/Transition-C8-C6-Foam-Spotlight_F-2017004.aspx.

[49] Under the EU REACH regulation PFOA based fire-fighting foams mixtures placed on the market by or before the 4th July 2020 would be permitted for use. Also concentrated fire-fighting foams mixtures placed on the market before 4 July 2020 to be used or used to produce other fire-fighting foams mixtures are exempted.

withdrawn and managed as regulated waste. In addition, Canada provides exemptions for trace quantities of PFOA within to fluorotelomer based AFFFs. Furthermore, in Europe the related compound PFOS had a time limited[50] exemption for foams that were already installed or placed on the market under the EU POPs Regulation.

198. Under the Stockholm Convention articles already placed on the market are exempt from the listing as detailed within item note (ii) of Part 1 of Annex A. However, where fire-fighting foams are marketed as concentrates which are mixed with water at the point of use, it is unclear if these materials can be considered as stockpiles as defined under the Convention.[51] Furthermore responses from industry suggested that an exemption for fire-fighting foams may be needed for stockpiles of in-use goods to aid phase-out. As a formal conclusion was not reached at POPRC-13, the Secretariat was tasked to prepare a document on note (ii) of part I of Annex A to the Convention and scope of the reference to stockpiles within Article 6 of the Convention and make it available to the Committee for consideration. The Committee invited Parties and observers to provide information on chemical composition of mixtures and the volumes of pre-installed fire-fighting foam mixtures in use. The Secretariat's report is set out in document UNEP/POPS/POPRC.14/INF/6.

199. Relevant information was submitted by Belarus (2018), Canada (2018), Netherlands (2018a), Sweden (2018), the Fire-Fighting Foams Coalition (FFFC, 2018) and IPEN and ACAT (2018).

### 4.8.2 Efficacy and efficiency of possible control measures

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

*Stockpiles already placed on the market*

201. The Fire-fighting Foam Coalition industry association (FFFC, 2004 and FFFC, 2011) provide 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-related compounds have been used within $C_8$ perfluorinated products. The inventory indicates that primary use of PFOS based fire-fighting foams was at installations where oil fires were possible, primarily military installations, petro-chemical facilities and oil refineries. In 2011 the USA PFOS based AFFF inventory records remaining stocks of in-use PFOS based AFFF concentrate as 3.3 million gallons (12.5 million litres) assuming similar quantities AFFF stockpiles containing PFOA and PFOA-related compounds. As an alternative estimate Norway (2007) provides commentary on a global inventory for the production of APFO, the primary ammonium salt of PFOA used within AFFF fire-fighting foams. The estimates by Prevedouros et al. (2006) which are quoted in Norway (2007) state that between 1951–2004 global production of APFO was between 3,600–5,700 tonnes. Prevedouros et al. (2006) further comments that the concentration of PFCAs within AFFF foams was between 0.1 and 1% wt/wt of the concentrate, with PFO making the largest proportion. As an alternate estimate, Sontake and Wagh (2014) commented that AFFF concentrates were mixed with water at point of use, with typical application rates of 1, 3 or 6% wt/wt concentrate, which meant that at the point of use (post mixing) surfactants concentration (fluorosurfactants, hydrocarbon surfactants) were at 0.03–0.45% wt/wt of the applied foam.

202. Taking a worst case scenario where all PFCA within the AFFF is PFOA/PFOA-related compound, based on active concentrations of 0.1 to 1% 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 309 million litres and 4901 million litres.[52] This would equate to an

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[50] Under EC 757/2010, fire-fighting foams containing PFOS placed on the market within the EU before 27 December 2006 were allowed to be used until 27 June 2011.

[51] Please note that under para 6 of decision POPRC-13/2: that, a request to the Secretariat has been made to prepare a document on note (ii) of part I of Annex A to the Convention and scope of the reference to stockpiles within Article 6 of the Convention and make it available to the Committee for consideration at its fourteenth meeting. This is intended to clarify the Convention scope for goods already placed to market.

[52] The global estimates for APFO manufacture (between 1951-2004) was 3,600–5,700 tonnes of APFO, equivalent to 3,600,000–5,700,000 kgs. Specific gravity of APFO is 1.163 g/cm (http://www.chemicalbook.com/ChemicalProductProperty_EN_CB7258194.htm) 3,600,000 kg / 1.163 specific gravity=3,095,442 litres. 5,700,000 kg / 1.163 specific gravity=4,901,117 litres. PFOS and APFO compounds are present at concentrations between 0.1–1% wt/wt in fire-fighting concentrates. Lowest estimate 309,544,282 litres of APFO as 0.1% Highest estimate 4,901,117,799 litres of APFO as 1% wt/wt.

average annual production of between 6 and 96 million litres of APFO based AFFF concentrate per annum. Assuming the shelf life of AFFF is between 10 and 25 years (FluoroCouncil, 2018), this would equate to remaining global stockpiles of between 60 and 2,400 million litres of APFO based concentrate.

203. Armitage et al. (2006) also quoted by Norway (2007) comments that the estimated environmental emissions of PFOA-related compounds from ECF based manufacture of $C_8$ perfluorinated AFFF between 1951 and 2004 was 50–100 tonnes, with the largest emissions linked to manufacture of APFO itself (2,060–4,090 tonnes of PFOA between 1951-2004).

204. ECHA (ECHA, 2014a) estimated that 50–100 tonnes of PFOA-related compounds (CAS No: 70969-47-0; $C_8$-$C_{20}$-ω-perfluoro telomer thiols with acrylamide) were in use for fire-fighting foams in 2014. This was based on data from the Norwegian product register and extrapolated to EU-wide quantities based on population, and provides an order of magnitude estimate due to uncertainties arising from the method. The EU report (ECHA, 2014a) assumes similar concentrations for PFOA in mixed foams. For means of comparison with the US inventory and APFO extrapolation, this quantity has been converted into US gallons[53] and litres based on the active concentration of 0.1–1% wt/wt in fire-fighting foam concentrates. This would equate to between 1.2–23.6 million gallons (4.5–89.3 million litres) of fire-fighting foams in Europe containing PFOA-related compounds.

205. Belarus (2018) noted that fluorinated surfactants are used for AFFF production. It was indicated, that PFOA and PFOA-related compounds are not used, and among the foaming agents perfluoroalkyl betaine and perfluoroalkylamide oxide are named. No detailed information on the composition of fluorinated surfactants currently and previous used has been provided by a manufacturer. According to the inventory, in 2017 about 130 t of AFFF were revealed at the enterprises in Belarus.

206. Australia (2018) comments that Australia has never manufactured PFOA or its precursor APFO. However, Australia has imported AFFF foams in the past that contained PFOA-related compounds. The import equated to approximately 48 grammes and 0.6 grammes of PFOA in 2002 and 2003 respectively. Import was discontinued after 2003. A letter from the Airservices Australia (Australia, 2016b) notes that some 260 airports and aerodromes exist across Australia. While efforts have been made to remove AFFF containing PFOS, PFOA and related compounds from service, Airservices Australia acknowledged that some tenants at hangars and fuel depots may still have such foams within fire suppression systems. Discussions were underway to best manage the disposal of these stockpiles. Seow (2013) further comments based on a 2009 NICNAS survey that while imports of new stocks had ceased, stockpiles of $C_8$ perfluorinated AFFF continue to exist in Australia (largely dominated by PFOS); however, Seow (2013) also noted there had been a shift by industry to make use of shorter chain ($C_4$–$C_6$) perfluorinated compounds (produced by telomerisation) or perfluorobutane sulfonates (PFBS) in fire-fighting foam.

207. 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 $C_{4\text{–}13}$ alkyl chains. In comparison, the mixtures commercially available in 2012 showed more frequently shorter-chain $C_{4\text{–}6}$ PFCAs, 4:2 and 6:2 FTS as well as 6:2 FTOH. The mean concentration of PFOA declined from 40 to 0.8 ppm (Favreau et al., 2017). Based on a 2005 estimate that quantified the amounts of AFFF stored in Switzerland to be 2,200–2,600 tonnes, the stockpile of PFOA in AFFF may be in the range of 2–100 kg. Queensland (Australia) has found that AFFF foams currently in use and claimed to be "$C_6$-based" contain significant levels of PFOA precursors in the form of 8:2 fluorotelomers that not only transform into PFOA but also are likely to result in a range of intermediate compounds of concern including ketone and aldehydes (Butt et al., 2013)

208. Alongside the issue of intentional use of PFOA as its ammonium salt (APFO) and PFOA-related compounds within existing stockpiles of AFFF, the Swedish Chemicals Agency (2015)

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[53] The EU proposal for restriction estimates 50–100 tonnes of PFOA-related compounds, equivalent to 50,000–100,000 kg. Specific gravity of $C_8$-$C_{20}$-ω-perfluoro telomer thiols with acrylamide is 1.12 g/cm (http://www.interstateproducts.com/fire_fighting/home/FS%20MSDS/FS-818-11.pdf) 50,000 kg / 1.12 specific gravity = 44,640 litres. 100,000 kg / 1.12 specific gravity = 89,300 litres. One US gallon is equivalent to 3.785 litres. 44,640 litres / 3.785 litres per gallon= 1,800 gallons of PFOA-related. 89,300 litres / 3.785 gallons per litre=23,600 US gallons.

Assuming that PFOA and PFOA-related compounds are used at between 0.1–1% wt/wt in fire-fighting concentrates. 11,890 gallons of PFOA-related=1.18–11.79 million US gallons of concentrate. 23,600 US gallons of PFOA-related=2.36–23.59 million US gallons of concentrate.

and European Chemicals Agency (ECHA, 2014a) highlight the possible continued presence of PFOA as an unintentional contaminant of $C_6$ fluorotelomers. While the manufacture of $C_6$ fluorotelomers does not use PFOA in the production process, the telomerisation of perfluorinated compounds can generate $C_8$ species including PFOA as a by-product. The Swedish Chemicals Agency (2015) comments that at the completion of the production process as much as 20% of the mixture can be $C_8$ perfluorinated species. After a clean-up phase the final commercial product is expected to contain trace residues at around 0.01%, although the Swedish Chemicals Agency (2015) highlight studies where concentrations found were far higher and could be as much as 50:50% wt/wt $C_6$:$C_8$ in some $C_6$ marketed products. The Netherlands (2018b) comments that data submitted by the Mineraloelwirtschaftsverband trade association, in the public commenting round for PFHxS under REACH, contains data from one PFOS containing AFFF and 14 other foams. The PFOS AFFF also contained PFOA at a concentration of 220 mg/L, approximately twenty times lower than PFOS. Two fluorotelomers based foams analysed as part of the same study (4:2 FTS, 6:2 FTS or 8:2 FTS) contained 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). Seow (2013) comments that industry have worked to refine production and reduce quantities of $C_8$ species within $C_6$ products; Seow (2013) however, also notes that many companies have also preferred to remain with their standard processes and mixture of $C_6$ and $C_8$. In particular Seow (2013) highlights the presence of acrylamide-based fluorosurfactant (CAS No: 70969-47-0) in some $C_6$ fluorotelomer products with a chain length of $C_8$–$C_{20}$ and capacity to act as a PFOA precursor.

209. The issue of concern for regulators is the presence of PFOA and PFOA-related substances in fluorinated foams. The product information and SDS provided by manufacturers and suppliers have not been informative of the PFAS content and it should be noted that the standard PFAS analyses do not detect a large proportion of the PFASs in the original formulation or transition compounds. This has necessitated the development of the total oxidisable precursor assay (TOP-Assay) to reveal the full extent of the PFAS types present.

*Control measures for environmental release linked to fire-fighting foam*

210. The Fire-fighting Foam Coalition (2016) provided details of best practice for use of Class B fire-fighting foams,[54] which includes both non-fluorinated and AFFF types of product. The guidance focuses on measures which can be grouped into one of three categories:

(a) Selection of when to make use of Class B fire-fighting foams. The FFFC (2016) comments that Class B fire-fighting foams should only be used when the most significant flammable liquid hazards are identified. For facilities that have potential liquid flammable risks, hazard assessments should be used in advance to investigate whether other non-fluorinated techniques can achieve the required extinguishment and burnback resistance. This includes consideration of the potential shortfalls that alternative methods may have. Furthermore, training exercises should not use fluorinated fire-fighting foams due to concerns over environmental pollution;

(b) Containment of environmental release during use of Class B fire-fighting foams for live incidents. The FFFC (2016) notes the variability of potential incidents and highlights that it is not possible to contain and collect fire runoff in all situations. However, the FFFC (2016) also highlight that runoff from liquid flammable fires will contain a mixture of water, residual hydrocarbon products, fire-fighting foam and therefore loss to environment should be avoided. For facilities that make use of flammable liquids (such as fuel farms and petroleum/chemical processing, airport operations, specific rail transportation, marine and military storage and industrial facilities) the FFFC (2016) best practice guidance states that a firewater collection plan should be developed in advance, and for fixed systems with automatic release triggers containment should be built into the system design. However, it is not clear how many facilities have done this in practice;

(c) Disposal of contaminated runoff and foam concentrate. The FFFC (2016) comments that Class B fire-fighting foam concentrates (which include PFOA based foams) do not carry expiry dates, but generally have a service life of 10–25 years. It is also possible to have testing completed routinely to assess whether the foam in stock still meets requirements. Destruction of Class B fire-fighting foam concentrate should be through thermal destruction. For contaminated fire-water from use of foams the FFFC (2016) guidance highlights that the solution will contain a mixture of chemicals and that thermal destruction is the preferable option. Other options include a combination of

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[54] Internationally fires are classified into groups based on the nature of the fire. This in turn defines what kind of fire-fighting media is most appropriate to be used. Class B fires relate to flammable liquids, where fire-fighting foams may be needed to suppress the fire (e.g. oil based fires). http://surreyfire.co.uk/types-of-fire-extinguisher/.

coagulation, flocculation, electro-flocculation, reverse osmosis, and adsorption on granular activated carbon (GAC).

211. Klein (2013) provides some further information on the likely costs incurred for the thermal destruction of perfluorinated fire-fighting foams (including PFOS and PFOA). This varies depending on technical approach with plasma-arc facilities likely more expensive than using cement kilns (noting that cement kilns operate at high temperatures).[55] Klein provides a general estimate of cost for Europe as €0.77 per litre of concentrate. For Australia costs within cement kilns ranged from $1–1.5 per litre and in plasma-arc $17–20 per litre. Klein (2013) also comments that the use of GAC, electrocoagulation, or reverse osmosis can be effective at reducing costs as these processes reduce the fluorochemical content. Capital costs for setting up treatment plants using these methodologies varies between €92,000–€230,000. Klein (2013) comments that the significantly high costs of managing disposal for perfluoro based fire-fighting foams had encouraged one major aviation industry operator to switch to fluorine free fire-fighting foams at all of its national airports. 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.

### 4.8.3 Information on alternatives

212. The RME highlighted that many viable chemical alternatives to AFFF containing PFOA and PFOA-related compounds are available and commercially in use globally. The paragraphs below are taken from the RME for ease of reference. New reference material is included where indicated.

*Short-chained fluorinated alternatives*

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

214. Chemical alternatives include $C_6$-fluorotelomers such as 6:2 fluorotelomer sulfonyl betaine, sometimes combined with hydrocarbons and the 3M product dodecafluoro-2-methylpentan-3-one. The direct release of substances to the environment and the detection of $C_6$ compounds in the environment including the Arctic, human and wildlife make this use of fluorinated alternatives undesirable (see UNEP/POPS/POPRC.13/INF/6) (IPEN, 2016). It should be noted that contamination of water from short-chain PFAS is very difficult, if not impossible, to remediate and, according to Holmes (2017), the belief that the alternative short-chain $C_6$ and lower PFASs are harmless if released is untrue. Significant evidence has emerged of potential health and environmental effects of short chain PFAS including enhanced mobility, uptake in crops, bioaccumulation, binding to proteins, increasing levels of exposure, difficulty to capture and to clean up once released into the environment (Brendel et al., 2018; Ritscher et al., 2018).

215. The EU Annex XV restriction report (ECHA, 2014a) highlighted that, while PFOA or PFOA-related compounds are not used in the manufacture of 6:2 fluorotelomer based fire-fighting foams, fluorotelomer based foams can contain trace quantities of PFOA as a by-product. The restriction implemented under the EU REACH regulation applies an exemption for fire-fighting foams containing PFOA and PFOA-related compounds placed on the market on or before 4 July 2020. However, after this date maximum concentrations of 25 ppb for PFOA or 1000 ppb for PFOA and PFOA-related compounds are imposed for fire-fighting foams placed to market in the EU.

216. In response to concerns over PFOS and PFOA, the United States Department of the Navy amended MIL-PRF-24385F (Mil Spec) in 2017. The amendment identifies United States Department of Defense's goal to develop and transition to a non-fluorinated agent and encourages AFFF manufacturers to minimize the levels of PFOS and PFOA in their products in the interim. The amendment established a maximum concentration for PFOS and PFOA at the limit of quantitation of current test methods (800 parts per billion (ppb) each).[56]

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[55] BREF, 2010, comments on the general operating conditions within European cement kilns with temperatures up to 2000 degrees Celsius. Materials within sintering zone reach temperatures of 1450 degrees Celsius and retention times of not less than eight seconds.

[56] Department of Defense Alternatives to Aqueous Film Forming Foam Report to Congress, June 2018.

*Non-fluorine containing alternatives*

217. However, Cousins (2016) and Hetzer (2014) comment that encouraging progress has been made, with some foam manufacturers stating that AFFF is no longer needed. Furthermore Norstrom (2011) comments that commercial airports in Sweden and Norway have replaced PFAS-based fire-fighting foams with fluorine-free foams because of environmental safety concerns. Since 2008 AFFF is no longer used at fire drills at the Swedavia airports in Sweden and in 2011 Swedavia started to use fluorine-free alcohol-resistant foam (Moussol FF 3/6)" (Nordstrom et al, 2015). *Moussoll-FF 3/6 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. The Swedish Armed Forces began phasing out the use of perfluorinated substances in fire-fighting foam in 2011 and currently use a fluorotelomer-based fire-fighting 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).*

218. The Solberg Company developed a high-performance fluorine-free foam concentrate for use on Class B hydrocarbon fuel fires. Recent independent test results published in 2017 (by the Southwest Research Institute) found that the Solberg fluorine-free foam Re-Healing RF3 met the Performance Level B Fire Test Standard of the International Civil Aviation Organization (ICAO). Furthermore, Solberg received the 2014 USEPA Presidential Green Chemistry Award[57] for the innovative development and commercialisation of its fluorine-free foam formulation "Re-Healing." Airservices Australia made the decision to use the Solberg Re-Healing RF6 6% foam as the preferred operational fire-fighting foam at the 23 capital and major regional city airports[58] throughout Australia that are under the auspices of Airservices Australia (Australian Parliament, 2017). When stored correctly, the Re-healing foam has a shelf-life of 20 years (Solberg, 2014). In Australia, the national aviation fire-fighting service (AirServices Australia) changed over to fluorine-free foam around 2010, other large users and industries in Australia and elsewhere including bulk fuel storages, ports, oil and gas platforms, and fire brigades have or are in the process of transitioning to fluorine-free foams.

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

220. Castro et al (2017) provides comments on the comparable performance between AFFF (telomer based) and FFF (fluorine free) products, which were based on 80 tests carried out by Auxquimia. For heptane and diesel based fires fluorine free foams were 6-7% slower than AFFF at bringing fires under control. For gasoline and jet A1 based fires, fluorine free foams were 50-60% slower than AFFF at bringing fires under control. However, where application rates were increased (from 2.31/min/$m^2$ to 3.75/min/$m^2$) for fluorine free based products similar levels of performance compared to AFFF were achieved. Castro et al (2017) goes on to hypothesis why this difference may be the case, noting that fluorinated compounds perform a variety of roles within the foam, one of which is oil repellence allowing foams to spread and control the fire for liquid fuels. Castro comments that fluorine free products lack this quality, but by increasing application rates the fluorine free foam can spread and cover liquid fires more quickly.

221. According to the Fire-fighting Foam Coalition (FFFC) AFFF agents containing fluorotelomer-based fluorosurfactants are the most effective foam agents currently available to fight flammable liquid fires in military, industrial, aviation and municipal applications. Test data provided by the United States Naval Research Laboratories (NRL, 2016) showed that, in pool fire tests, an AFFF agent achieved extinguishment in 18 seconds compared to 40 seconds for the fluorine-free foam. However, an alternate study from 2004 (Lerner, 2018) with the US Navy commented that based on testing of AFFF based foams from 3M and fluorine-free alternatives that similar rates were achieved for putting out fires. The fluorine-free alternative put out fires within 39 seconds, while AFFF ranged from 25 to 36 seconds. Modern development in fluorine-free foams has substantially

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[57] http://www.solbergfoam.com/getattachment/28194868-f365-4da5-ba40-860f1a3bd9eb/Presidential-Award-Bestowed-on-Solberg.aspx.

[58] Noting that 260 airports and aerodromes exist across Australia in total (Australia 2015).

decreased any difference in performance levels during POPRC-14 side event held on Monday, 17 September 2018.

222. In foam degradation tests, fluorine-free foam degraded after 1-2 minutes, while the AFFF lasted 35 minutes before it has been degraded. However, recent tests confirm that F3 foams are as effective or better and meet industry- established fire-fighting performance certifications. The FFFC does not support the opinion that AFFF agents are no longer needed and recommends the use of AFFF only in specific circumstances where a significant flammable liquid hazard occurs and that all available measures to minimize emissions to the lowest possible level should be implemented when using AFFF agents (FFFC, 2017). However, blockage factors (i.e. vapour suppression) were indistinguishable between a fluorine-free-foam and two AFFFs tested (Williams et al., 2011). Alternatively, information provided by The Solberg Company (Norway, 2018 personal communications) confirm that fluorosurfactant- and fluoropolymer-free fire-fighting foam used to effectively extinguish fuels with no environmental concerns for persistence, bioaccumulation or toxic breakdown have shown to perform the same ability to extinguish Class B fires as traditional AFFF.[59] Airports and offshore companies around the world have introduced fluorine-free foam and are satisfied by the performance.

223. Fluorine-free foams certified to different ICAO levels (required for use at civilian airports) are available on the market (see FFFC, 2017) and are already introduced at airports in practice. For example, the UK Civil Aviation Authority notes that fluorine-free foams are ICAO Level B approved and 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.[60] 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); and 3F (Freefor SF, Hyfex SF, Freedol SF).

224. 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). Solberg 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.[61]

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

226. Based on current data, prices of fluorine-free and fluorine containing AFFFs are comparable (information provided by Dr. Roger Klein at POPRC-14). The FFFC (2018) commented that short-chain fluorotelomer based AFFF has a shelf-life of 10-25 years, while a manufacturer of fluorine free alternatives (Solberg, 2014) quotes a shelf-life of 20 years. Comments from the Netherlands (2018b) note that, based on discussions with a fire brigade in the Netherlands, fires at private facilities are rare, and where AFFF should not be used for training, it can mean that stockpiles reach full life-expectancy without use, meaning shelf-life is an important consideration. An additional consideration is that non-fluorinated alternatives can also be used in firefighters training. Castro (2017) comments that for application of foams, particularly on petrol and jet A1 fuels that significantly more fluorine free foam (from 2.31/min/$m^2$ to 3.75/min/$m^2$) foam is needed to bring fires under control at an equivalent speed to AFFF fluorotelomer. IPEN commented in the RME however that when considering cost the wider environmental costs should also be taken into account. This would include *the internalized costs of continued reliance on fluorosurfactant foams, including the costs of groundwater remediation, contamination of aquatic environments, subsistence and commercial fisheries, and environmental and public health (IPEN Comments on 2nd draft RME). Lifetime costs for using AFFF, fluoroprotein (FP), or film forming fluoroproteins (FFFP) far outweigh those of fluorine-free foams because of legal and financial liabilities of using a fluorochemical based foam*

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[59] http://www.solbergfoam.com.

[60] https://www.solbergfoam.com/getattachment/b706ff4d-1f47-4030-bd7d-cc8762d3bfed/CAFS-FFF-In-ARFF.aspx.

[61] https://www.solbergfoam.com/getattachment/b706ff4d-1f47-4030-bd7d-cc8762d3bfed/CAFS-FFF-In-ARFF.aspx.

*(see Queensland Gov., 2016a and 2016b) as indicated above which include infringement of operating license conditions, reputational and brand image damage (see Klein 2013). Increasing evidence suggests that fluorochemical contamination of groundwater is an ongoing serious issue impacting agriculture, fisheries, property prices, with considerable political and public concern fallout resulting in hugely expensive and damaging and legal challenges. Remediation costs are still substantial, especially off-site, compounded by high analytical and consultancy costs in the case of environmental contamination with fluorinated breakdown products from an AFFF, FP or FFFP (see e.g. Klein 2013).*

227. During POPRC-14 meeting, a panel of experts discussed the use of fluorine-based and fluorine-free foams.

(a) According to the German Industrial Fire Protection Association the use of fluorine-free foams is viable for i) fires typical for municipal fire brigades including structural fires, car fires, solids fires, small to medium fuel spills, ii) fires of combustible materials like wood, paper, fabric, refuse (“Class A” fires), iii) fires of flammable liquids (“Class B” fires) < ~500$m^2$.

(b) To date, practical experience and/or scientific evidence is not sufficient to state that fluorine-free foam is an acceptable alternative for fires of flammable liquids (“Class B” fires) > ~500$m^2$ (typically expected at refineries, petrochemical plants and oil depots) and large fires of special chemicals (typically expected only at chemical plants).

(c) Fluorine-free foam has been in use in fire trucks at London Heathrow Airport without any operational deficiencies. The following advantages of using fluorine-free foam were described: The airport returned to full operations very quickly following two incidents, with no clean-up costs; Operational and environmental responsibilities met; Regular training built confidence in the new product.

(d) Socioeconomic effects were the drivers for developing the Queensland Foam Policy to phase out PFAS containing fire-fighting foams by 2019 including: Contaminated sites are numerous and increasing; Water and soil clean-up costs are very high (e.g. single airport spill 2017, €47M); Waste treatment, disposal and destruction are very expensive; Drinking water supplies are at risk; Seafood/fisheries can become restricted; Livestock and horticultural products can become unsaleable; Increasing number of legal actions and claims (against manufacturers and end users).

228. The evidence presented within the RME suggests that chemical alternatives to PFOA based AFFF exist and are actively in use globally. These include short-chain fluorinated foams as well as fluorine free alternatives. From the point of view of environmentally sound management, fluorine free products with proven efficacy should be the preferred option.

### 4.8.4 Information on impacts on society

229. The RME highlighted concerns related to the dispersive and direct way in which fire-fighting foams are used. The RME also noted that the continued use of PFOA in fire-fighting foams would result in the ongoing contamination of groundwater and soil surrounding facilities where AFFF containing PFOA and PFOA-related products was used (mainly military sites and airports). The RME provides examples of such cases with an indication of the magnitude of the contamination and remediation costs. As part of the request for information, the paragraphs below include further details on ground contamination linked to use of AFFF containing PFOA and PFOA-related compounds.

230. Military.com (2017) (quoted within IPEN, 2018) provides details of discussions held in the US senate regarding around 400 military facilities where fire-fighting foams containing PFOS, PFOA and PFOA-related compounds had been previously used and lost to the environment causing ground contamination such as that Fairchild Air Force base. Total estimated remediation costs for ground contamination are cited within the article as being as high as USD$2 billion dollars.

231. Klein (2013) provides examples of a number of cases of groundwater contamination at facilities (military, airports and petroleum refineries) where perfluoroalkyl-containing (chiefly PFOS) fire-fighting foams have been used for training or real cases of fire. In particularly Klein refers to a case study at US military fire training grounds where PFOS had been previously used, and even 10–15 years after the use had ceased monitoring found that groundwater would still contain high concentrations of fluorotelomer (14.6 mg/L fluorotelomer sulfonate). Another case study at Jersey Airport, Jersey Island, report that the use of PFOS-based AFFF on fire training grounds contaminated the island’s aquifer and drinking water. Remediation costs were estimated to be between £3.7 to £30 million pounds sterling (based on 1999–2000 prices) dependent on options selected. This included the potential removal and destruction of soil to a depth of 30 metres and reconstruction of the site.

Norway estimated that the costs of remediation of airport land contaminated with PFOS would be in the range of 4-40 million dollars per airport (Norway, 2018a).

232. Cousins (2016) (quoted within IPEN (2018)) further highlighted that the costs of cleaning up the contaminated site is only one of many costs associated with the legacy contamination from PFAS-containing fire-fighting foams (both long and short chain); Others include cost of analytical monitoring of PFAS, 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. Most of these costs will be borne by taxpayers, as it is challenging and often costly to identify the principal responsible party or parties in practice. However, in environmental law many countries have adopted the "polluter pays principle" to make the party responsible for the pollution responsible for cleaning it up. It is regarded as a regional custom because of the strong support it has received in most OECD countries and in the EU as well as in Norway. It is also a fundamental principle in US environmental law (Norway, 2018).

233. PFOS and PFOA containing foams have been used until recently in developing countries even with recent imports. Sites where PFOS and likely PFOA containing foams have been used for fire-fighting practice or sites of fire events are likely contaminated (Suriname 2017). Although such sites include areas of drinking water reservoirs, they are often not investigated due to the lack of monitoring capacity and available funding.

234. Recognizing the serious public health implications associated with contamination of drinking water sources by PFAS fire-fighting foams and the need to prevent further harm, policymakers in Washington State (USA)[62] recently enacted the first state legislation in the USA that prohibits the use of PFAS-containing fire-fighting foams for training purposes beginning on July 1, 2018 and prohibits the sale of PFAS-containing fire-fighting foams for use in Washington State beginning on July 1, 2020. Furthermore, Land et al. (2018) comment on temporal trends of perfluoroalkyl acids in humans and in the environment, stating: "In regions where regulations and phase-outs have been implemented, human concentrations of PFOS, PFDS, and PFOA are generally declining, while previously increasing concentrations of PFHxS have begun to level off".

235. The Swedish Chemicals Agency estimates the costs related to PFAS contamination of drinking water for two case examples amounting to 1 million € per year for charcoal filtering of water in Uppsala and to 3 million € for new water supply in Ronneby, which is a small city where approximately 5000 households were immediately affected when high levels of PFASs were discovered in 2013 (Swedish Chemicals Agency, 2016).

236. Patrick Breysse,[63] Director of the US Centers for Disease Control's National Center for Environmental Health, described the contamination of drinking water by perfluorinated chemicals in AFFF as "one of the most seminal public health challenges for the next decades." Unlike other persistent, bioaccumulative toxic chemicals such as PCBs and dioxins, PFAS are highly water soluble and do not break down in the environment. Of particular concern, perfluoroalkyl acids that reach groundwater "may remain there indefinitely, impacting drinking water sources for generations to come." In the United States alone, the drinking water of more than six million people in many communities throughout the country has been found to contain highly fluorinated chemicals at concentrations of concern. Cousins (2016) recommend a precautionary approach that respects the "design for degradation" principle of Green Chemistry, stating that "according to this reasoning, society should replace all PFAS-based fire-fighting foams with non-persistent fire-fighting products, given that they can lead to poorly reversible exposures." The precautionary approach is consistent with that mandated by the Stockholm Convention.

### 4.8.5 Other considerations

237. ECHA (ECHA, 2015a) allows a derogation for existing fire-fighting foams mixtures containing PFOA (including the concentrated ones) placed on the market on or before 4 July 2020, which allows further use for a period of 20 years, taking into account the shelf life. This derogation is consistent with the exemption for foams already in use, and will avoid the need for early replacement of exempted foams.[64] IPEN commented within the RME and discussions at POPRC-13 that the normal lifetime of fire-fighting foam varies considerably with temperature and storage conditions. According to them, 20 years is an inappropriate length of time for continued dispersive use of POPs, a use which

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[62] https://toxicfreefuture.org/new-law-protects-drinking-water-firefighters-toxic-perfluorinated-chemicals/.

[63] https://www.theguardian.com/australia-news/2017/oct/18/toxic-firefighting-chemicals-the-most-seminal-public-health-challenge.

[64] UNEP/POPS/POPRC.13/7/Add.2.

has led to massive contamination of groundwater in many countries. The FFFC (2016) best practice guidance commented that fire-fighting foam containing PFOA does not have an expiry date but will have a shelf life of 10–25 years. The Netherlands (2018b) noted from discussions with colleagues at the Bilthoven fire brigade, NL, the safety manager for the Gelderland region and their own experience that the active use of AFFF at private installations (e.g. airports, refineries, and military sites) is rare and that stockpiles of AFFF may be likely to reach the 25-year shelf life without use. Solberg (2012) comment that their fluorine-free fire-fighting foam has a shelf-life of 10 years. The Netherlands (2018b) further comment that where fires at private installations (e.g. airports, refineries, and military sites) are rare, the shelf-life of fire-fighting foams is an important consideration for costs.

### 4.8.6 Synthesis of information

238. Fluorinated fire-fighting foams have been used as an effective means of fighting Class B (oil) fires, with a preference in the past for $C_8$ technologies developed by ECF (Swedish Chemicals Agency, 2015). This included PFOS, which is now a POP under the Stockholm Convention, and PFOA, primarily used as the ammonium salt (APFO). Where human health and environmental concerns over $C_8$ perfluorinated compounds exist, industry moved to shorter chain $C_6$ technologies developed through telomerisation (Swedish Chemicals Agency, 2015). While $C_6$ fluorotelomers are not manufactured using PFOA, final goods can contain PFOA and PFOA-related compounds as unintentional by-products. The Swedish Chemicals Agency (2015) and Seow (2013) suggest that this is typically a trace residue but also highlight studies exist demonstrating that the quantity of $C_8$ species (including PFOA) within $C_6$ technologies can be present at greater concentrations, potentially up to 50:50% wt/wt and can contain PFOA precursors such as acrylamide-based fluorosurfactant (CAS No: 70969-47-0).

239. Only limited information exists to quantify the fire-fighting foams which may contain PFOA and PFOA-related compounds as impurities or constituents already placed on the marketECHA (ECHA, 2014a) estimated that 50-100 tonnes of PFOA-related compounds (CAS No: 70969-47-0) were in-use within fire-fighting foams in 2014 in Europe. After 2015 this volume was lower in the range from 15–30 t/a PFOA-related substances. This assumes that similar quantities of concentrates containing PFOA and PFOA-related compounds were in use. Alternatively estimates by Prevedouros et al. (2006) state that between 1951–2004 global production of APFO was between 3,600–5,700 tonnes, assuming all of this was used in fire-fighting foams equates to between 51–490 million litres of APFO concentrate manufactured globally between 1951– 2004.The FFFC (2016) developed a best practice guidance for use of Class B fire-fighting foams, which include fire-fighting foams containing PFOA and PFOA-related compounds. This included selection of fluorine-based foams only where most needed and avoiding the use of Class B fire-fighting foams for training due to concerns over environmental pollution. The best practice also included forward planning for facilities that use flammable liquids to put in place capture and containment systems for runoff. It is not clear how many facilities have implemented this part of the guidance. The FFFC (2016) guidance does also indicate the variability of incidents and that capture of runoff is not possible in every situation. The guidance also provides details on suitable destruction for fire-fighting runoff and foam concentrates; with thermal destruction as the preferred option. Klein (2013) provides indicative costs for destruction of foam concentrates at around €0.77 per litre or $1–1.5 Australian dollars per litre.

240. The RME details that multiple alternatives to fire-fighting foams containing PFOA and PFOA-related compounds are already commercialised and readily available. This includes fluorinated options based around fluorotelomers (C6:2) and fluorine free alternatives. ECHA (ECHA, 2014a) noted that the manufacture of fluorotelomer based fire-fighting foams can contain trace amounts of PFOA as a by-product. The restriction sets limits of 25ppb for PFOA and 1000ppb for PFOA and PFOA-related compounds.

241. The RME provided details regarding groundwater contamination with perfluorinated fire-fighting foams and their degradation products indicating the significant costs and efforts required to clean up contaminated sites and potential long-lasting effects of contamination. This included a case on the island of Jersey, where clean up options for contamination of an aquifer with PFOS based foams was in the order of £3.7–£30 million pounds. Other examples from the USA highlighted cases where groundwater contaminated with PFOS was still able to produce foam when extracted 10–5 years after contamination.

242. Finally, ECHA (ECHA, 2015a) discusses the length of the derogation needed for PFOA based fire-fighting foam placed on the market. Under the EU REACH restriction, a derogation was granted for fire-fighting foams (including concentrated solutions) placed on the market before 4 July 2020. Considering the shelf-life of fire-fighting foam mixtures, this means that they could be still used for

20 years manufacturers warrantee typically last 10 years. A similar exemption could be adopted for the Stockholm Convention, although the continued dispersive use of a POP would not be consistent with the objectives of the Convention. IPEN (2018) commented that the life span of foams varied depending on climate and storage and therefore a 20-year derogation would not be acceptable for the Stockholm Convention. The FFFC (2016) state that foams do not have an expiry date but have a shelf life of 10–25 years.

### 4.8.7 Conclusion

243. Based on the information compiled and reviewed within the RME, the size of in-use stockpiles for fire-fighting foams containing PFOA and PFOA-related compounds may be significant, considering that such compounds can also be present as an impurity in shorter chain $C_6$ telomer technologies. Concerns have been highlighted about the mobility and potential environmental impacts of shorter chain perfluorinated compounds in fire-fighting foams. Concerns have also been raised on the significant socioeconomic costs related to site decontamination and it is highly recommended not to use up stockpiles or installed fire-fighting foams containing PFOA and PFOA-related compounds for training purposes before the entry into force with the aim of avoiding disposal and decontamination costs. Fluorine-free foams are comparable to fluorine-based AFFFs and fire-fighting foams with PFOA in their performance and in meeting relevant certifications for almost all uses with some exceptions such as Mil Spec which has requirements for legacy AFFFs. Based on the information compiled and reviewed within the RME and its addendum, the Committee concludes that there are alternatives available for PFOA and PFOA-related compounds in fire-fighting foams. Therefore, the Committee does not recommend an exemption for the production of fire-fighting foams that may contain PFOA as impurities and PFOA-related compounds as constituents. However, some concerns were expressed about the importance of effective fire-fighting foams for liquid fuel fires and the potential unavailability of suitable alternatives and the cost of their use and implementation. One member indicated that an exemption would be needed for production of PFOA and PFOA-related compounds for fire-fighting foams such as for liquid fuel fires as he believes that transitioning to the production of short-chain PFASs is not a suitable option from an environmental point of view and that some time to move to alternatives without PFASs may be needed. The Committee further concludes that there is a need for an exemption for use of fire-fighting foams containing PFOA and PFOA-related compounds already installed in systems including both mobile and fixed systems with specific conditions.

# 5 Synthesis of information

## 5.1 Summary of information and concluding statement for uses

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

*Chemical Identity*

245. Since sulfluramid (*N*-ethyl perfluorooctane sulfonamide, CAS No: 4151-50-2) is produced from PFOSF, it is already covered, although not explicitly mentioned, under the listing of PFOS, its salts and PFOSF and it should then not be included under the PFOA listing to avoid double regulation. Based on the further information submitted, 1-H-PFO should not be excluded from the scope of PFOA-related compounds since studies suggest that a transformation to PFOA is possible.
8:2 fluorotelomer methacrylate, polymer with methyl methacrylate (CAS No: 93705-98-7) should be included in the non-exhaustive list of PFOA-related compounds.

*Annex C listing*

246. Based on the information assessed, the Committee does not recommend listing PFOA, its salts and PFOA-related compounds in Annex C to the Convention. Additional information and preferably also further measurements/quantitative data from other waste incinerators, open burning, and other sources of unintentionally produced POPs, in particular from developing countries, would be useful for future consideration.

*Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment*

247. Based on the evaluation of available information, a specific exemption for use in membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment is not recommended.

*Transported isolated intermediates*

248. Based on the evaluation of available information, a specific exemption is not recommended for the use of perfluorooctane iodide (PFOI) generated as an unintentional by-product and used as an isolated intermediate to enable reprocessing to tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) in another site than the production site.

*Medical devices*

249. The Committee recommends a specific exemption for invasive medical devices.

*Implantable medical devices*

250. The Committee recommends a specific exemption for implantable medical devices.

*Photo imaging sector*

251. Based on the existing and rapid transition towards digital imaging, the wide use of digital techniques in developing and transitional countries, and the further reduction in use of PFOA in this sector, the Committee does not recommend specific exemptions for photographic coatings applied to paper and printing plates.

*Automotive industry*

252. Based on the insufficient information and lack of an appropriate justification, the Committee does not recommend a specific exemption for the automotive industry.

*Fire-fighting foam*

253. Some concerns were expressed about the importance of effective fire-fighting foam for liquid fuel fires, the potential unavailability of suitable alternatives and the cost of their use and implementation, considering that some time to move to alternatives without PFASs may be needed. The Committee does not recommend an exemption for the production of fire-fighting foam that may contain PFOA as impurities and PFOA-related compounds as constituents.

254. The Committee further concludes that there is a need for a specific exemption for use of fire-fighting foam containing PFOA and PFOA-related compounds already installed in systems including both mobile and fixed systems with specific conditions.

# Appendix I

## Overview of regulatory risk management approaches, their chemical scope and exemptions for uses related to PFOA, its salts and PFOA-related compounds in Canada, the EU and Norway

**(for details see Canada, 2016c, European Commission, 2017 and Norway, 2016)**

**Table 3 of the RME set out in document UNEP/POPS/POPRC.13/7/Add.2**

| | **Canada** | **EU** | **Norway** |
|---|---|---|---|
| | Prohibit manufacture, use, sale, offer for sale or import of the substances and products containing these substances | Prohibit manufacturing, use or placing on the market (1) as substances, as constituents of other substances and (2) articles or any parts thereof containing one of the substances | Prohibit to manufacture, import, export and make available on the market (1) textiles, carpets and other coated consumer products that contain the substances and (2) consumer products that contain the substances |
| Chemical scope | PFOA and its salts;<br>Compounds that consist of a perfluorinated alkyl group that has the molecular formula $C_nF_{2n+1}$ in which n=7 or 8 and that is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom;<br>Perfluorocarboxylic acids that have the molecular formula $C_nF_{2n+1}CO_2H$ in which $8 \le n \le 20$, and their salts;<br>Compounds that consist of a perfluorinated alkyl group that has the molecular formula $C_nF_{2n+1}$ in which $8 \le n \le 20$ and that is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom.<br>(see Canada, 2016c) | PFOA and its salts;<br>Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula $C_7F_{15}$- directly attached to another carbon atom, as one of the structural elements.<br>Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula $C_8F_{17}$- as one of the structural elements.<br>Exclusions:<br>$C_8F_{17}$-X, where X= F, Cl, Br;<br>$C_8F_{17}$-C(=O)OH, $C_8F_{17}$-C(=O)O-X' or $C_8F_{17}$-$CF_2$-X' (where X'=any group, including salts).<br>Does not apply to PFOS and its derivatives, which are listed in Part A of Annex I to Commission Regulation (EC) No 850/2004<br>(see European Commission, 2017)<br>PFOA<25ppb, related compounds <1,000 ppb | PFOA and individual salts and esters of PFOA (CAS No: 335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5) as a pure substance or in a mixture, when the mixture contains 0.001 weight percent or more of the substance.<br>(See Norway, 2016) |
| Exemptions for photo-imaging | Photo media coatings until 31 December 2016<br>Since then partially captured under exemptions for manufactured items | Photographic coatings applied to films, papers or printing plates | Photographic coatings for film, paper or printing plate until 2016 |
| Exemptions for semiconductor industry | Partially captured under exemptions for manufactured items | - Equipment used to manufacture semiconductors (until 4 July 2022);<br>- Photo-lithography processes for semiconductors or in etching processes for compound semiconductors;<br>- Semiconductors or compound semiconductors. | Adhesives, foil or tape in semiconductors until 2016 |

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

The scope of the regulatory actions presented in the Table above differ in scope compared to each other and the scope set out in the RME based on the principles of the Stockholm Convention. The RME covers degradation to PFOA from long-chain PFASs with more than eight perfluorinated carbon atoms except for those explicitly excluded in the definition of PFOA-related compounds as they do not degrade to PFOA under natural conditions. This goes beyond the EU risk management approach which does not cover the degradation to PFOA from long-chain PFASs. The degradation from long-chain PFASs is also not considered in the Norwegian risk management approach. The Canadian risk management approach also applies to long-chain PFCAs, their salts, and their precursors. However, long-chain PFASs have been included on Norway's priority list of substances whose release to the environment should be eliminated by 2020, and they are included in the US Stewardship Program (IPEN Comments on 2nd draft RME).

A general definition of "long-chain PFCAs" (CnF2n+1COOH, n≥7) is provided by the OECD (OECD, 2017). As a result of the existing production processes, fluorotelomer-based substances have been generally manufactured as mixtures of homologues with a range of perfluoroalkyl chain lengths (for examples, see DuPont, 1998), including those that have more than eight perfluorinated carbon atoms.[65] Therefore, the information provided in the RME covers to a certain extent also those fluorotelomer-based substances with longer chain PFAS (longer than 8:2).

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

# Appendix II

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

**Table 5.1 Summary of evaluation of uses and conclusions regarding specific exemptions for PFOA, its salts and PFOA-related compounds**

| Use | Requested information | Estimated tonnages for PFOA and PFOA-related compounds per use globally | Summary of key points | Conclusion |
|---|---|---|---|---|
| Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment | Information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects | Unknown | The RME for PFOA highlights the need for further information to justify a possible exemption for these uses. In particular, the Committee requested additional information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects.<br>Limited information on the scope of the applications and the availability of alternatives has been submitted. However, alternatives including non-fluorinated alternatives for these uses are in current use. No relevant information has been provided or could be identified on used amounts in relevant applications. Used amounts in specific applications and related information which would also enable the socio-economic aspects and information on the possible non-availability of alternatives to be further evaluated would be required to justify exemptions.<br>In summary, there is a lack of information about specific uses and amounts but indication that alternatives are available for a variety of uses. | Based on the evaluation of available information a specific exemption for use in membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment is not recommended. |
| Transported isolated intermediates in order to enable reprocessing in another site than the production site | Information on the quantities used, extent of transport and risks, and use | 50–100 tonnes | IPEN and ACAT and the FluoroCouncil provided relevant information in response to the current information request. Both submitters and Norway commented on the first draft. IPEN and ACAT also expressed concerns that an exemption for transported isolated intermediates could “open the door to waste dumping in developing and transition countries under the guise of “reprocessing”.”<br>The FluoroCouncil requests an exemption on behalf of its member, Archroma for the transport of PFOI, an unintended side fraction in the production of $C_6$ fluorotelomers, as a transported isolated intermediate.<br>Archroma argues that they cannot reprocess PFOI, a PFOA-related compound, on-site as a closed-system site-limited intermediate. PFOI is currently transported in closed barrels to a facility in South Korea where iodine recovery and reprocessing to TFE and HFP, take place under closed system conditions. The Korean company informed the Korean government | Based on the evaluation of available information, a specific exemption is not recommended for the use of perfluorooctane iodide (PFOI) generated as an unintentional by-product and used as an isolated intermediate to enable reprocessing to tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) in another site than the production site. |

| **Use** | **Requested information** | **Estimated tonnages for PFOA and PFOA-related compounds per use globally** | **Summary of key points** | **Conclusion** |
|---|---|---|---|---|
| | | | that the facility will stop importing the PFOI intermediate by the end of 2019.<br>Archroma is developing a method for on-site iodine extraction, a prerequisite for reprocessing PFOI. A transitional exemption for the transport of PFOI as a transported isolated intermediate would be necessary, since the process will not be available on-site before the entry into effect of the Convention’s provisions on PFOA. Moreover, the process leads to the production of 1-H-PFO, that also falls under the definition of a PFOA-related compound (questioned by the FluoroCouncil) and is therefore not a viable solution.<br>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 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.<br>IPEN and ACAT (2018) note that the proposal to exempt transport of isolated intermediates at the global level undermines the integrity of the Stockholm Convention. The Convention limits generic exemptions relating to intermediates to strictly closed-system site-limited intermediates that are chemically transformed in the manufacture of other chemicals that, taking into consideration the criteria in paragraph 1 of Annex D, do not exhibit the characteristics of POP. IPEN and ACAT (2018) add that 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. | |
| Medical devices | Information on specific applications/uses and timelines foreseen as needed for potential related exemptions | Unknown | MedTech (2018) and Euromed (2015) commented that gathering information on specific applications was challenging and indicated that PFOA would chiefly be present as a by-product of PTFE manufacture, PFOA has been used as an emulsifier. MedTech (2018) also provided a summary of generic potential uses.<br>To ease the decision at the COP, IPEN and ACAT (2018) commented that a specific list of applications is needed to help maintain clarity and enforcement of the Convention. | The Committee recommends a specific exemption for invasive medical devices. |

| Use | Requested information | Estimated tonnages for PFOA and PFOA-related compounds per use globally | Summary of key points | Conclusion |
|---|---|---|---|---|
| | | | ECHA (ECHA, 2015) estimated in use quantities of <1kg in the EU extrapolated to <5kg globally. ECHA (ECHA, 2015). As part of the REACH restriction process an exemption was granted for non-implantable medical devices of 15 years to allow phase-out and development of alternatives.<br>The RME noted that PFOA free PTFE options have already been developed, passed stringent regulatory requirements and have been commercialised in some geographies. The ECHA Annex XV restriction report comments that 70% of global PTFE production is now PFOA free under the PFOA product stewardship programme chaired by the US EPA which covers Japan, Europe and the USA. However, many medical devices are manufactured outside of these areas (MedTech, 2018). | |
| Implantable medical devices | Information on the quantities used, extent of transport and risks, and use; | 20g for EU extrapolated to 100g globally | ECHA (ECHA, 2015a) indicates that amounts of PFOA and PFOA-related compounds related to this use are extremely low.<br>Further information and data on quantities used, extent of transport and risks, and use of PFOA in implantable medical devices was not provided in response to the request for information.<br>Implantable medical devices, which may be manufactured with PTFE containing PFOA can include but are not limited to synthetic vascular grafts, endovascular and interventional devices, surgical meshes for hernia repair, to sutures for use in vascular, cardiac, and general surgery procedures. These can include PFOA residual levels at or below 1 ppm (MedTech 2018). However, PTFE can be made without PFOA and alternatives are reportedly now commercially available, approved by US FDA, and are a feasible and effective alternative to the use of PFOA. | The Committee recommends a specific exemption for implantable medical devices. |
| Photo imaging sector | Information relevant for paper and printing sector and use in developing countries; | Unknown | I&P Europe (2018) state that non-fluorinated alternatives and the move to digital imaging have successfully replaced most uses in the imaging and printing industry.<br>Indeed, digital imaging has been adopted in developing countries in favour of hardcopy printing (IPEN and ACAT, 2018). The IAEA and WHO provided a further example of the transition to digital technologies within developing and transition countries, noting in particular 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.” | Based on the existing and rapid transition towards digital imaging, the wide use of digital techniques in developing and transitional countries, and the further reduction in use of PFOA in this sector, the Committee does not recommend specific exemptions for photographic coatings applied to paper and printing plates. |

| Use | Requested information | Estimated tonnages for PFOA and PFOA-related compounds per use globally | Summary of key points | Conclusion |
|---|---|---|---|---|
| | | | Further information on use of PFOA or PFOA-related compounds in other industry sectors was not received in response to the call for information.<br>According to I&P Europe, since 2000, European industry has reformulated/discontinued a large number of products, as a result of which PFOA or PFOA-related compounds are no longer used in photographic coatings applied to paper and in printing plates manufactured by their members. | |
| Automotive industry | Information on spare parts | Unknown | The Canadian automotive association, CVMA, requested specific exemptions for automotive service and replacement parts as well as for current production vehicles. The request for exemption is also supported by industry associations ACEA (Europe) and SIAM (India). According to CVMA, the industry has been proactively phasing out PFOA use for some time. However, service and replacement parts might still contain PFOA. According to CVMA, these parts represent a small percentage of PFOA use and will decrease naturally over time as the vehicle fleet turns-over. Automotive manufacturers reportedly need to ensure the availability of original equipment and spare parts to satisfy customer demand.<br>Further, according to the Canadian automotive industry, a key obstacle in a complete phase-out of PFOA in automotive service and spare parts appears to be the prohibitive costs. However, no information on possible cost implications has been submitted. In addition, the Canadian automotive industry has concerns regarding practical challenges related to numerous CAS numbers of affected substances. This has also been expressed by ACEA and SIAM, stating that a considerable amount of time would be required to collect relevant data.<br>In contrast to the request for exemption, IPEN and ACAT stipulate that key automotive industry associations have notified company members and suppliers that PFOA will be listed under the Stockholm Convention as well as being regulated in the EU and that these substances should be substituted. The automotive industry also notes that, most suppliers producing relevant articles no longer use PFOA or other long-chained perfluorinated chemicals. In the past PFOA has been used to make fluoropolymers used in automotive applications but several companies have alternative emulsifiers so that PFOA has been eliminated in this class of automotive products.<br>In summary, the Committee requested specification of relevant automotive service and replacement parts as well as sound justification as to why an | Based on the insufficient information and lack of an appropriate justification, the Committee does not recommend a specific exemption. |

| Use | Requested information | Estimated tonnages for PFOA and PFOA-related compounds per use globally | Summary of key points | Conclusion |
|---|---|---|---|---|
| | | | exemption is required. 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. CVMA indicates in their recent submission that they are currently working to see if any further information can be provided. | |
| Fire-fighting foams | Information on chemical composition of mixtures and the volumes of pre-installed amount of fire-fighting foam mixtures | APFO potentially between 10–230 million litres of AFFF concentrate.<br>PFOA and PFOA-related compounds as by-product in $C_6$ assumed as 50–100 tonnes of concentrate for EU. | Perfluorinated compounds have been used within fire-fighting foams as they prove effective against liquid fuel fires (Class B) (ECHA, 2014a). In the past $C_8$ based perfluorinated compounds have been used including PFOS and PFOA. PFOA was initially used as a component of AFFF in its ammonium salt form (Seow 2013).<br>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 AFFF stockpiles containing PFOA and PFOA-related compounds 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. Prevedouros (2006) further comments that the concentration of PFCAs within AFFF foams was between 0.1 and 1% wt/wt of the concentrate. Assuming a worst case that all of the 0.1–1% wt/wt was APFO would equate to between 309 and 4,901 million litres of concentrate produced between 1951 and 2004. Based on annual average production and shelf-life of 10–25 years, would estimate remaining stockpiles of 60–2,400 million litres of concentrate.<br>Industry moved away from $C_8$ based perfluoro technologies over concerns for health and environment, with preference towards shorter chain $C_6$ perfluorinated compounds produced through telomerisation. The Swedish Chemicals Agency (2015) comments that while $C_6$ fluorotelomers are not manufactured using PFOA, it can be created as a by-product of the process. At the concluding step around 20% $C_8$ can be present in $C_6$ mixtures (including PFOA), which then undergoes a clean-up process to reduce $C_8$ species down to trace residues. However, studies exist suggesting that the concentration of $C_8$ within $C_6$ products can be much higher than a trace (Swedish Chemicals Agency, 2015; Seow, 2013). Seow (2013) further | Some concerns were expressed about the importance of effective fire-fighting foams for liquid fuel fires, the potential unavailability of suitable alternatives and the cost of their use and implementation, considering that some time to move to alternatives without PFASs may be needed. The Committee does not recommend an exemption for the production of fire-fighting foams that may contain PFOA as impurities and PFOA-related compounds as constituents.<br>The Committee further concludes that there is a need for a specific exemption for use of fire-fighting foams containing PFOA and PFOA-related compounds already installed in systems including both mobile and fixed systems with specific conditions. |

| Use | Requested information | Estimated tonnages for PFOA and PFOA-related compounds per use globally | Summary of key points | Conclusion |
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| | | | comments that remaining $C_8$ perfluoro compounds in $C_6$ products can also degrade to PFOA in the environment.<br>ECHA (ECHA, 2015) estimates 50–100 tonnes of PFOA-related compounds (CAS No: 70969-47-0) were in use in 2014 in Europe, calculated to be between 1.18–23.6 million US gallons of concentrate (assuming 0.1–1% wt/wt active ingredient in concentrates). The FFFC (2018) provided details of best practice for class B fire-fighting foams including non-fluorinated and AFFF based products which included selective use, containment of runoff and appropriate destruction. The guidance did however note that runoff cannot be contained in all incidents due to variability<br>The RME provided details of clean-up costs for contaminated ground water where PFOS based foams had been used. Similar costs can be expected for PFOA based fire-fighting foams. For one example, this amounted to between £3.7–£30 million pounds (Klein, 2013). The Swedish Chemicals Agency estimates the costs related to PFAS contamination of drinking water for two case examples amounting to 1 million € per year for charcoal filtering of water in Uppsala and to 3 million € for new water supply in Ronneby. Norway also estimated that the costs of remediation of airport land contaminated with PFOAS would be in the range of 4-40 million dollars per airport | |

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| ABRAISCA | 2018 | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| Australia | 2018 | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| Belarus | 2018 | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| Brazil | 2018 | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| Canada | 2018 | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| CVMA | 2018 | Submission from Canadian Vehicle Manufacturer's Association of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| FFFC | 2018 | Submission from the Fire-Fighting Foam Coalition of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| FluoroCouncil | 2018a | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| FluoroCouncil | 2018b | Comment received on PFOA first draft. |
| HCWH | 2018 | Submission from Healthcare Without Harm of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| IPEN and ACAT | 2018 | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| MedTech Europe | 2018 | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
| Netherlands | 2018a | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |
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| UK | 2018 | Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention. |

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