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Stockholm Convention on Persistent Organic Pollutants

Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants Ninth meeting Geneva, 29 April–10 May 2019 Item 5 (e) of the provisional agenda*

Matters related to the implementation of the Convention: listing of chemicals in Annex A, B or C to the Convention

> Recommendation by the Persistent Organic Pollutants Review Committee to list perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex A to the Convention and draft text of the proposed amendment

Note by the Secretariat

I. Introduction

- 1. At its twelfth meeting, by its decision POPRC-12/2, the Persistent Organic Pollutants Review Committee adopted a risk profile for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds (UNEP/POPS/POPRC.12/11/Add.2) and decided, in accordance with paragraph 7 (a) of Article 8 of the Stockholm Convention on Persistent Organic Pollutants, that PFOA, its salts and PFOA-related compounds were likely, as a result of their long-range environmental transport, to lead to significant adverse human health and environmental effects such that global action was warranted.
- 2. At its thirteenth meeting, by its decision POPRC-13/2, the Committee adopted a risk management evaluation for 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 to the Stockholm Convention that it consider listing PFOA, its salts and PFOA-related compounds in Annex A or B to the Convention with specific exemptions as specified in paragraph 2 of that decision. In the same decision, the Committee decided to establish an intersessional working group to assess the information provided in accordance with paragraphs 3, 4 and 5 of the decision with the intention of strengthening the recommendation on the listing of the chemicals for consideration at its fourteenth meeting.
- 3. At its fourteenth meeting, by its decision POPRC-14/2, the Committee adopted an addendum to the risk management evaluation for PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.14/6/Add.2) and decided to further refine its recommendation 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 as specified in paragraph 2 of the decision.
- 4. In the same decision, the Committee recommended to the Conference of the Parties that it consider encouraging Parties not to replace fire-fighting foam that contained or may contain PFOA, its salts and PFOA-related compounds with short-chain per- and polyfluoroalkyl substances (PFASs) due

^{*} UNEP/POPS/COP.9/1.

to their persistency and mobility as well as potential negative environmental, human health and socioeconomic impacts.

- 5. Pursuant to paragraph 2 of Article 21 of the Convention, on 25 October 2018 the Secretariat communicated the Committee's recommendation on PFOA, its salts and PFOA-related compounds to the Parties and signatories to the Convention. The communication, which also invited Parties to provide comments, was circulated more than six months before the ninth meeting of the Conference of the Parties. A compilation of the comments received from Parties relating to the proposed listing of PFOA, its salts and PFOA-related compounds is set out in document UNEP/POPS/COP.9/INF/23. The executive summary of the risk management evaluation on PFOA, its salts and PFOA-related compounds and the decision of the Committee setting out its recommendation are reproduced in the annex to the present note. The executive summary is presented without formal editing.
- 6. As is indicated in paragraph 9 of Article 8 of the Convention, the Conference of the Parties, taking due account of the recommendations of the Committee, including any scientific uncertainty, is to decide, in a precautionary manner, whether to list those chemicals, and specify their related control measures, in Annexes A, B and/or C to the Convention. If the Conference of the Parties decides to list those chemicals in Annexes A, B and/or C, the respective annex or annexes will be amended in accordance with Articles 21 and 22 of the Convention.

II. Proposed action

- 7. The Conference of the Parties may wish to consider encouraging Parties not to replace fire-fighting foam that contains or may contain PFOA, its salts and PFOA-related compounds with short-chain per- and polyfluoroalkyl substances (PFASs) due to their persistency and mobility as well as potential negative environmental, human health and socioeconomic impacts.
- 8. The Conference of the Parties may also wish to adopt a decision along the following lines:

The Conference of the Parties,

Having considered the risk profile, the risk management evaluation and the addendum to the risk management evaluation for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds as transmitted by the Persistent Organic Pollutants Review Committee.¹

Taking note of the recommendation by the Persistent Organic Pollutants Review Committee that perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds be listed in Annex A to the Stockholm Convention on Persistent Organic Pollutants with specific exemptions,²

1. Decides to amend part I of Annex A to the Stockholm Convention to list therein perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, with specific exemptions for the production and use of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, by inserting the following rows:

Chemical	Activity	Specific exemption
Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds	Production	As allowed for the Parties listed in the Register in accordance with the provisions of part [X] of this Annex, with the exception of fire-fighting foam
	Use	In accordance with the provisions of part [X] of this Annex:
		 Manufacture of semiconductors or related electronic devices as listed in accordance with the provisions of paragraph 2 of part [X] of this Annex
		Photographic coatings applied to films

¹ UNEP/POPS/POPRC.12/11/Add.2; UNEP/POPS/POPRC.13/7/Add.2; UNEP/POPS/POPRC.14/6/Add.2.

² UNEP/POPS/COP.9/14.

- Textiles for oil- and waterrepellency for the protection of workers from dangerous liquids that comprise risks to their health and safety
- Invasive and implantable medical devices
- 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, in accordance with paragraph 3 of part [X] of this Annex
- Use of perfluorooctyl iodide for the production of perfluorooctyl bromide for the purpose of producing pharmaceutical products, in accordance with the provisions of paragraph 4 of part [X] of this Annex
- 2. Also decides to insert a definition for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in part III of Annex A as follows:
 - "(d) "Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds" means the following:
 - (i) Perfluorooctanoic acid (PFOA; CAS No: 335-67-1) including any of its branched isomers;
 - (ii) Its salts; and
 - (iii) PFOA-related compounds which, for the purposes of this Convention, are any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety (C₇F₁₅)C as one of the structural elements, for example:
 - a. Polymers with $\geq C_8$ based perfluoroalkyl side chains;
 - b. 8:2 fluorotelomer compounds;
 - c. 10:2 fluorotelomer compounds.
 - (iv) The compounds below do not degrade to PFOA and are therefore not included as PFOA-related compounds:
 - a. C_8F_{17} -X, where X= F, Cl, Br;
 - b. Fluoropolymers that are covered by $CF_3[CF_2]n-R'$, where R'=any group, n>16;
 - c. Perfluoroalkyl carboxylic and phosphonic acids (including their salts, esters, halides and anhydrides) with ≥8 perfluorinated carbons;
 - d. Perfluoroalkane sulfonic acids (including their salts, esters, halides and anhydrides) with ≥9 perfluorinated carbons;
 - e. Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF), as listed in Annex B to the Stockholm Convention."

3. Further decides to insert a new part [X] in Annex A as follows:

Part [X]

Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

- 1. The production and use of perfluorooctanoic acid (PFOA), its salts and PFOA- related compounds shall be eliminated except for Parties that have notified the Secretariat of their intention to produce and/or use them in accordance with Article 4 of the Convention.
- 2. Specific exemptions for the manufacture of semiconductors or related electronic devices may be available for the production and use of PFOA, its salts and PFOA-related compounds limited to the following:
 - (a) For five years from the date of entry into force of the amendment in accordance with Article 4:
 - (i) Equipment or fabrication plant-related infrastructure containing fluoropolymers and/or fluoroelastomers with PFOA residues;
 - (ii) Legacy equipment or legacy fabrication plant-related infrastructure for maintenance;
 - (iii) Photo-lithography or etch processes;
 - (b) For ten years from the date of entry into force of the amendment: refurbishment parts containing fluoropolymers and/or fluoroelastomers with PFOA residues for legacy equipment or legacy refurbishment parts.
- 3. Each Party that has registered for a specific 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;
- (e) 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.
- 4. With regard to the specific exemption for the use of perfluorooctyl iodide for the production of perfluorooctyl bromide for the purpose of producing pharmaceutical products, at its eleventh ordinary meeting and at every second ordinary meeting thereafter, the Conference of the Parties shall review the continued need for this specific exemption. This specific exemption shall in any case expire at the latest in 2036.

Annex

Risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds¹ and the recommendation of the **Persistent Organic Pollutants Review Committee**

I. Executive summary of the risk management evaluation²

- 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 compounds³ 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).
- The scope of the chemicals covered is defined in paragraph 21 of the risk management evaluation (UNEP/POPS/POPRC.13/7/Add.2) and a comprehensive list of substances is available in document UNEP/POPS/POPRC.13/INF/6/Add.1.
- PFOA, its salts and PFOA-related compounds are used in a wide variety of applications and consumer products across many sectors (details see UNEP/POPS/POPRC.12/11/Add.2). PFOA and its salts are, or were, most widely used as processing aids in the production of fluoroelastomers and fluoropolymers, with polytetrafluoroethylene (PTFE) being an important fluoropolymer used in producing, e.g. non-stick kitchen ware. PFOA-related compounds, including side-chain fluorinated polymers, are used as surfactants and surface treatment agents, e.g. in textiles, paper, paints, firefighting foams. Based on the available information in the risk management evaluation, these were the uses with the highest amount of PFOA.
- Releases occur from past and ongoing production, use and disposal. Direct releases to the environment of PFOA and/or related compounds occur from the production of the raw substances (including PFOA as impurity in the manufacturing of PFOA-related compounds and some alternatives) during the processing, use and disposal of the chemical, from treated articles and from products contaminated with PFOA. Main emission vectors of PFOA and its salts are wastewater and particles/aerosols. Indirect releases of PFOA occur from the biotic and abiotic (photo-) degradation or transformation of precursors. PFOA-related compounds, as defined in para 21, are released to air, water, soil and solid waste, and will, to a greater or lesser degree, degrade to PFOA in the environment and in organisms. Releases of PFOA from degradation contribute a major share to the releases of PFOA in some local environment, e.g. remote inland environments (details see UNEP/POPS/POPRC.12/11/Add.2).
- The activities of the Strategic Approach to International Chemicals Management (SAICM) at the global level focus on gathering and exchanging information on perfluorinated chemicals and to support the transition to safer alternatives. Voluntary efforts to phase out PFOA and related substances

¹ 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 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. The Committee has used the latter name in the latest decision POPRC-14/2, which will 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.

² UNEP/POPS/POPRC.13/7/Add.2.

³ PFOA-related compounds are differently defined according to the chemical scope in different approaches. In the risk management evaluation, the term "PFOA-related compounds" is used as defined in section 1.1 to that document. 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.

have been implemented, such as the United States Environment Protection Agency (USEPA) PFOA Stewardship Program and work by industry. In 2006, the eight main manufacturers of fluoropolymers and fluorotelomers in the US, Europe and Japan agreed on a phase-out of their production and use of PFOA and related long-chain substances by the end of 2015. A similar program existed with manufacturers in Canada. All Stewardship Program participants were successful at virtually eliminating those chemicals from facility emissions and product content. The voluntary phase out did not include manufacturers using PFOA in countries who were not part of the voluntary efforts, i.e. including those having large manufacturers and/or users of PFOA like China, India and Russia (details see UNEP/POPS/POPRC.12/11/Add.2).

- 6. Regulatory risk management approaches are implemented or underway in several national legislative control actions i.e. Norway, EU (existing restriction) and in Canada. These actions prohibit manufacture, making available on the market and use of PFOA, its salts and PFOA-related compounds with exemptions (time-limited or not). Based on technical and socio-economic assessments, these risk management approaches are considered technically and economically feasible. In 2016 Canada published legislation which prohibits PFOA, its salts and precursors as well as products containing them, unless present in manufactured items, and with a limited number of exemptions. Norway bans the use of PFOA in consumer products and textiles since 2014 with certain exemptions. The EU restricts the manufacture, placing on the market and use (including import) of PFOA, its salts and PFOA-related compounds as well as articles containing these substances. The EU risk management approach considers exemptions for certain uses; however, it does not cover the degradation to PFOA from long-chain perfluoroalkyl and polyfluoroalkyl substances (PFASs). In the US a rule proposed in 2015 would require manufacturers of PFOA and PFOA-related chemicals to notify new uses of these chemicals to USEPA in order to allow the evaluation of new uses and, if necessary, take action to prohibit or limit the activity.
- 7. In the processes of developing the regulatory risk management approaches for PFOA, its salts and PFOA-related compounds in Canada, the EU and Norway, technical and socio-economic information has been included in the decision-making process to allow for certain exemptions. In general, these risk management approaches are considered technically and economically feasible. Information received from industry stakeholders during these regulatory processes indicates that exemptions with or without time limitation were needed for certain uses where stakeholders asserted and scientific committees concluded that alternatives were not economically and/or technically feasible. A prohibition of PFOA, its salts and PFOA-related compounds with possible specific exemptions for certain uses is also considered to be technically and economically feasible under the Stockholm Convention.
- 8. The information on the availability of alternatives considering efficacy and efficiency indicates that appropriate alternatives may currently not be available for several uses, namely: (1) equipment used to manufacture semiconductors and related infrastructure; (2) latex printing inks; (3) textiles for the protection of workers from risks to their health and safety; (4) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment; (5) plasma nano-coatings; (6) medical devices; (7) production of implantable medical devices; (8) photographic coatings applied to films, papers or printing plates; (9) photo-lithography processes for semiconductors or in etching processes for compound semiconductors; (10) certain pharmaceutical chemicals; and (11) use of sulfluramid. However, for most of these uses, the development of alternatives is underway. In restricting or banning PFOA, its salts and PFOA-related compounds under the Stockholm Convention, this could be considered with specific exemptions with time limits or acceptable purposes without time limits.
- 9. Similarly, as expected for the Canadian, Norwegian and the EU approaches, globally restricting or prohibiting PFOA, its salts and PFOA-related compounds will positively impact human health, the environment including biota, and agriculture by decreasing emissions and subsequently exposure. The full magnitude and extent of the risks of PFOA, its salts and PFOA-related compounds cannot be quantified. The risk management of these substances is driven by scientific data and precautionary actions to avoid the potentially severe and irreversible adverse impacts resulting from continued unrestricted emissions. The available alternatives are expected to pose lower health risks than an unrestricted use of PFOA, its salts and PFOA-related compounds.
- 10. The EU, Norwegian and the Canadian risk management approaches are considered to have moderate cost impacts because the market is already replacing PFOA, its salts and PFOA-related compounds and because the risk management approaches provide exemptions for certain uses with or without time limits. The same can be expected for the combined regulatory and voluntary approaches taken in the US and Australia. Cost competitive alternatives to PFOA, its salts and PFOA-related compounds that do not exhibit persistent organic pollutants (POPs) characteristics have already been

implemented in many countries. This indicates partial economic and technical feasibility of alternatives. Substituting these compounds with appropriate alternatives leads to savings of health and environmental costs resulting from decreased exposure. Furthermore, a restriction or prohibition would prevent further contamination of surface water, groundwater and soil and would thus reduce costs for identification and remediation of contaminated sites.

- 11. PFOA is unintentionally formed from incomplete combustion of fluoropolymers.
- 12. The Committee recommends, in accordance with paragraph 9 of Article 8 of the Convention, that the Conference of the Parties to the Stockholm Convention consider listing and specifying the related control measures of PFOA, its salts and PFOA-related compounds:
- 13. Based on the evaluation of uses and the efficiency and efficacy of possible control measures, the Committee recommends to the Conference of the Parties that it consider listing pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annex A or B to the Convention with specific exemptions for the following:
- (a) For five years from the date of entry into force of the amendment in accordance with Article 4:
 - (i) Manufacture of semiconductors or related electronic devices:
 - a. Equipment or fabrication plant related infrastructure containing fluoropolymers and/or fluoroelastomers with PFOA residues;
 - b. Legacy equipment or legacy fabrication plant related infrastructure: maintenance;
 - c. Photo-lithography or etch processes;
 - (ii) Photographic coatings applied to films;
 - (iii) Textiles for oil and water repellency for the protection from dangerous liquids for the protection of workers from risks to their health and safety;
- (b) For ten years from the date of entry into force of the amendment for manufacture of semiconductors or related electronic devices: refurbishment parts containing fluoropolymers and/or fluoroelastomers with PFOA residues for legacy equipment or legacy refurbishment parts;
- (c) For use of perfluorooctyl iodide, production of perfluorooctyl bromide for the purpose of producing pharmaceutical products with a review of continued need for exemptions. The specific exemption should expire in any case at the latest in 2036.
- 14. The Committee invites Parties and observers, including the relevant industries, to provide information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds in particular in the following applications:
- (a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment: information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects;
- (b) Transported isolated intermediates in order to enable reprocessing in another site than the production site: information on the quantities used, extent of transport and risks, and use;
- (c) Medical devices: information on specific applications/uses and timelines foreseen as needed for potential related exemptions;
- (d) Implantable medical devices: information on the quantities used, extent of transport and risks, and use;
- (e) Photo imaging sector: information on paper and printing, and information relevant for developing countries;
 - (f) Automotive industry: information on spare parts;
- (g) Firefighting foams: information on chemical composition of mixtures and the volumes of pre-installed amount of firefighting foam mixtures.

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

II. Executive summary of the addendum to the risk management evaluation⁴

- 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 compounds⁵ 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 compounds⁶ (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;

⁴ UNEP/POPS/POPRC.14/6/Add.2.

⁵ 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.

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.

- (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.
- 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

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 CF₄ and C₂F₆, which are unrelated to PFOA. From the currently available information it is not possible to conclude that aluminium production represents a relevant source of PFOA releases to the environment. 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.

<u>Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment</u>

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 perfluorooctyl 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

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)⁷ 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

⁷ PFOA can used as an emulsifier in the manufacture of PTFE, and would be present as a by-product of the finished product.

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 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 C₆-fluorotelomers.⁸ 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

⁸ 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.

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.

III. Decision setting out the recommendation of the Committee

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 compounds⁹ 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, 10

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;¹¹
- 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:
- (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;

⁹ 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.

¹⁰ UNEP/POPS/POPRC.14/3.

¹¹ UNEP/POPS/POPRC.14/6/Add.2.

- (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 perfluorooctyl iodide, production of perfluorooctyl 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;
- (e) 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.

13