CRC-14/5: Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

The Chemical Review Committee,

Recalling Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

1. *Concludes* that the notifications of final regulatory action for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds submitted by Norway and Canada[1] meet the criteria set out in Annex II to the Convention;

2. *Adopts* the rationale for the Committee's conclusion set out in the annex to the present decision;

3. *Recommends*, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex III to the Convention as industrial chemicals;

4. *Decides*, in accordance with paragraph 1 of Article 7 of the Convention, to prepare a draft decision guidance document for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds;

5. *Also decides*, in accordance with the process for drafting decision guidance documents set out in decision RC-2/2 and amended by decision RC-6/3, that the composition of the intersessional drafting group to prepare the draft decision guidance document for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds and the workplan of the group shall be as set out in annexes II and III, respectively, to the report of the Committee on the work of its fourteenth meeting.

Annex to decision CRC-14/5

Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Norway and Canada in respect of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in the industrial category meet the criteria of Annex II to the Rotterdam Convention

1. The notifications on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds from Norway and Canada have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether or not the notifications appeared to meet the requirements of the Convention.

2. The notifications, the supporting documentation and the results of the preliminary review were made available to the Chemical Review Committee for their consideration (documents UNEP/FAO/RC/CRC.14/8, UNEP/FAO/RC/CRC.14/INF/13, UNEP/FAO/RC/CRC.14/INF/14).

[1] See UNEP/FAO/RC/CRC.14/8.

I. Norway

(a) Scope of the regulatory action notified by Norway

3. The regulatory action notified by Norway relates to perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds (collectively referred to hereafter as PFOA) as an industrial chemical. Since 1 June 2014, it has been prohibited to manufacture, import, export, and sell consumer products that contain PFOA and individual salts and esters of PFOA (CAS Nos. 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 pure substance or in a mixture when the mixture contains 0.001 per cent or more by weight of the substance. Furthermore, since 1 June 2014, it has been prohibited to manufacture, import, export or sell textiles, carpets and other coated consumer products that contain PFOA when the content of the substance in the product's individual parts is greater than or equal to 1 $\mu g/m^2$. Since 1 June 2014 it has also been prohibited to manufacture, import, export or sell consumer products that contain PFOA when the content of the substance in the product's individual parts is greater than or equal to 0.1 per cent by weight. The prohibitions do not apply to food packaging, food contact materials and medical devices, or spare parts for consumer products made available for sale prior to 1 June 2014.

(b) Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

4. The Committee confirms that the regulatory action was taken to protect human health and the environment. The notification states that PFOA is a substance of very high concern with respect to its health and environmental properties. PFOA is harmful to the reproductive system, is carcinogenic, toxic and harmful to human health through repeated exposure, and is also an irritant. PFOA does not degrade in the environment. The notification describes the specific risks and concludes that it is impossible to establish an acceptable level for substances with such properties in the environment, and that emissions and exposure should be limited to the greatest extent possible.

5. In Norway, PFOA has been used in coating agents for carpets, textiles, furniture, shoes, paper, food wraps, printing plates, paint, floor wax, glue and photographic film. It is also present in products as a chemical impurity or as trace amounts of remaining starting materials from the production of other perfluorinated compounds. PFOA has been found in imported products such as textiles treated with perfluorinated compounds as well as in food contact materials with non-stick properties. PFOA was previously often present in small amounts in ski wax as a chemical impurity of the perfluorinated constituents in the wax.

6. The notification refers to a wide range of regulatory agency reviews: the impact assessment of regulating perfluorooctanoic acid (PFOA) and individual PFOA salts and esters in consumer products (UNEP/FAO/RC/CRC.14/INF/13); European Food and Safety Agency (EFSA) document "Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts: scientific opinion of the Panel on Contaminants in the Food Chain" (*EFSA Journal* 2008, 653, 1–131); European Chemicals Agency document "Pentadecafluorooctanoic acid (PFOA) as a substance of very high concern because of its CMR and PBT properties", 14 June 2013.

7. The Committee therefore confirms that the criterion in paragraph (a) of Annex II is met.

(c) Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

8. The government and agency reviews (UNEP/FAO/RC/CRC.14/INF/13) provided are considered to be scientifically sound, generated according to scientifically recognized methods and reported according to generally recognized scientific principles and procedures.

9. The notification refers to a number of articles published in scientific peer-reviewed journals or government agency reports.

10. The Committee confirms that the criteria in paragraph (b) (i) and (ii) of Annex II are met.

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

11. The notification from Norway and the supporting material provide a large amount of data relating to human exposure, as well as information from European Food and Safety Agency document "Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts: scientific opinion of the Panel on Contaminants in the Food Chain" and European Chemicals Agency document "Pentadecafluorooctanoic acid (PFOA) as a substance of very high concern because of its CMR and PBT properties". The Norwegian studies show that PFOA is transferred from the mother to the foetus, and that relatively high plasma concentrations are detected in blood samples from small children. Information on occupational exposure of professional Norwegian ski-waxers, leading to higher PFOA concentrations in blood serum, is also provided. Information in the risk evaluation points to widespread occurrence and concentrations of PFOA in the Norwegian environment (air, water and sediment). Persistence, bioaccumulation, temporal trends in some Arctic species (e.g., the polar bear) and evidence of long-range transport warrant concern.

12. The notification indicates that PFOA is a substance of very high concern with respect to its health and environmental properties. PFOA is harmful to the reproductive system, is carcinogenic, toxic and harmful to human health through repeated exposure, and is also an irritant. PFOA does not degrade in the environment. PFOA is a persistent, bio-accumulating and toxic (PBT) substance.

13. The notification concludes it is impossible to establish an acceptable level for substances with such properties in the environment, and that emissions and exposure should be limited to the greatest extent possible.

14. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

15. The Committee confirms that the criteria of paragraph (b) of Annex II are met.

(d) Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

16. The notification does not provide information on amounts of actual use, but provides information on the uses in Norway. The regulatory action reported by Norway is a prohibition on the manufacture, import, export and selling of consumer products that contain PFOA as a pure substance or in a mixture when the mixture contains 0.001 per cent by weight or more of the substance. In addition, it is prohibited to manufacture, import, export and sell textiles, carpets and other coated consumer products that contain PFOA when the content of the substance in the product's individual parts is greater than or equal to 1 $\mu g/m^2$. Individual parts comprise the materials of which the product is manufactured and the product's individual components.

17. Furthermore, it is prohibited to manufacture, import, export and sell consumer products that contain PFOA when the content of the substance in the product's individual parts is greater than or equal to 0.1 per cent by weight. The prohibitions on manufacture and export are applied to adhesives, foil and tape in semiconductors, and photographic coatings for film, paper and printing plates.

18. Although the restrictions are not applied to food packaging, food contact materials and medical devices, or spare parts for consumer products made available for sale prior to 1 June 2014, considering the information on earlier PFOA applications in Norway, it can be concluded that the restrictions have led to a significant decrease in the quantity of the chemical used in Norway.

19. The Committee therefore confirms that the criterion in paragraph (c) (i) is met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

20. The notification notes that it is impossible to establish an acceptable level for substances with such properties in the environment, and that emissions and exposure should be limited to the greatest extent possible. Therefore, reduction of exposure of humans and the environment is expected to result in a significant risk reduction, especially considering the carcinogenic, mutagenic or reprotoxic (CMR) as well as PBT properties of PFOA.

21. The Committee confirms that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

22. The notification notes that concerns similar to those identified in Norway are likely to be encountered in other countries where the substance is used. PFOA is present in various globally distributed products. Adaptation of manufacturing methods to meet the Norwegian requirements may lead to reduced levels of PFOA in products in other countries as well. Several textile brands have phased out the use of perfluorinated compounds for water repellence treatment because of the negative attention directed at such compounds by various stakeholders.

23. The notification also cites Norway's "Evaluation of consequences of regulating PFOA and selected salts and esters of PFOA in consumer products", according to which PFOA is transported long distances via air and sea currents, and its presence has been detected in the Arctic in a variety of species, including sea birds, seals and polar bears. The substance has also been identified as CMR and PBT, which are relevant concerns for any state or region in which PFOA may be released.

24. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

25. There is no information on trade of PFOA in Norway. However, the notification notes that, while PFOA is not produced in Norway, it is still used or imported either as a chemical impurity or in articles.

26. Information from ongoing discussions in the Persistent Organic Pollutants Review Committee of the Stockholm Convention indicates ongoing international trade (UNEP/POPS/POPRC.12/11/Add.2 and UNEP/POPS/POPRC.13/7/Add.2).

27. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

28. The Committee confirms that the criteria of paragraph (c) of Annex II are met.

(e) Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

29. There is no indication in the notification that concerns about intentional misuse prompted the regulatory action.

30. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

(f) Conclusion

31. The Committee concludes that the notification of final regulatory action by Norway meets the criteria set out in Annex II to the Convention.

II. Canada

(a) Scope of the regulatory action notified by Canada

32. The regulatory action notified by Canada relates to perfluorooctanoic acid, which has the molecular formula $C_7F_{15}CO_2H$, and its salts, as well as 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. The chemicals are collectively referred to as PFOA.

33. The notification specifies the following CAS numbers: PFOA: 335-67-1; PFO: 45285-51-6; PFOA salts: PFOA (NH4+): 3825-26-1, PFOA linear/branched (NH4+): 90480-56-1, PFOA (Na+): 335-95-5, PFOA (K+): 2395-00-8, PFOA (Ag+): 335-93-3. PFOA potential precursors are listed in Table A-1 of Annex A to the notification.

34. Under the Canadian Environmental Protection Act, 1999 (CEPA), the final regulatory action (The Prohibition of Certain Toxic Substances Regulations, 2012, (SOR/2012-285) as amended 2016 (SOR/2016-252)) prohibits the import, manufacture, use, sale and offer for sale of PFOA and products containing PFOA, with a limited number of exemptions (http://gazette.gc.ca/rp-pr/p2/2016/2016-10-05/html/sor-dors252-eng.html as of 23 December 2016).

(b) Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

35. The Committee confirms that the regulatory action was taken to protect the environment. The notification concluded that PFOA, its salts and its precursors are entering or may be 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.

36. PFOA and long-chain perfluorocarboxylic acids (LC-PFCAs) are primarily used in Canada as water, oil and grease repellents; as surfactants; and as spreading and wetting agents. While PFOA and LC-PFCAs are not manufactured in Canada, they were historically imported and may have been imported for use in the following manufacturing sectors: textile mills, paper and packaging, paints and coatings, inks and photo media, chemical manufacturing, electrical and electronics, cleaning products, plastic and rubber products.

37. The Committee therefore confirms that the criterion in paragraph (a) of Annex II is met.

(c) Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

38. The available government and agency reviews are considered to be scientifically sound, generated according to scientifically recognized methods and reported according to generally recognized scientific principles and procedures.

39. The Committee therefore confirms that the criteria in paragraphs (b) (i) and (b) (ii) of Annex II are met.

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

40. The notification from Canada states that the final regulatory action was based on a risk or hazard evaluation and that it was relevant to the environment. The notification refers to the ecological assessment that is based on a weight-of-evidence approach regarding persistence, bioaccumulation, temporal trends in some species (e.g., the polar bear), long-range transport and the widespread occurrence and concentrations of PFOA in the environment and biota (including remote areas of Canada).

41. The notification indicates that, on the basis of the available information, it is concluded that PFOA, its salts and its precursors pose a risk to the environment. The risk quotient for Canadian mammalian wildlife (i.e., polar bears) is less than 1; however, owing to the persistence of the substance, its tendency to accumulate and biomagnify in a variety of terrestrial and marine mammals, its hepatotoxicity, and the upward temporal trend of PFOA concentrations in polar bears and some other species, PFOA concentrations in polar bears may approach exposures resulting in harm.

42. The screening assessment performed in Canada (http://www.ec.gc.ca/ese-ees/default.asp?lanq=En&n=370AB133-1) makes use of the extensive information on uses, releases and environmental levels of PFOA in Canada, including the Canadian Arctic.

43. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

44. The Committee confirms that the criteria of paragraph (b) of Annex II are met.

(d) Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

45. The notification from Canada notes that PFOA and long-chain perfluorocarboxylic acids (LC-PFCAs) are primarily used as water, oil and grease repellents, as surfactants, and as spreading and wetting agents.

46. While PFOA and LC-PFCAs are not manufactured in Canada, they were historically imported and may have been imported for use in the following manufacturing sectors: textile mills, paper and packaging, paints and coatings, inks and photo media, chemical manufacturing, electrical and electronics, cleaning products, plastic and rubber products. A study conducted for Environment Canada estimated that approximately 308 tonnes of PFOA and LC-PFCAs were imported into Canada in 2010.

47. The regulations prohibit the manufacture, use, sale, offer for sale or import of PFOA and products containing PFOA, unless the substance is incidentally present, with a limited number of exemptions (UNEP/FAO/RC/CRC.14/8).

48. The Committee therefore confirms that the criterion in paragraph (c) (i) is met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

49. The notification states that the substance PFOA and its salts and the substances LC-PFCAs and their salts are persistent and that they accumulate and biomagnify in terrestrial and marine animals. The ongoing release of PFOA and LC-PFCAs may result in harm to the Canadian environment. The risk management objective for the regulatory action is to achieve the lowest technically or economically feasible level of releases of PFOA into the Canadian environment. The prohibition of its use in manufacturing minimizes further releases to the environment and can be expected to result in a significant reduction of risk for the environment.

50. The Committee therefore confirms that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

51. The notification states that, once in the environment, PFOA is extremely persistent and not known to undergo significant abiotic or biotic degradation under relevant environmental conditions. PFOA is highly soluble in water and typically present as an anion (conjugate base) in solution. It has low vapour pressure; therefore, the aquatic environment is expected to be its primary sink, with some additional partitioning to sediment. The presence of PFOA in the Canadian Arctic is likely attributable to the long-range transport of PFOA (e.g., via ocean currents) and/or volatile precursors to PFOA (e.g., via atmospheric transport).

52. PFOA has been detected at trace levels in the northern hemisphere. The notification states that a number of countries and organizations (including the European Union, Norway, the United States of America, the Stockholm Convention on Persistent Organic Pollutants and the Protocol to the United Nations Economic Commission for Europe Convention on Long-Range Transboundary Air Pollution of 1979) either have put in place or are proposing management measures to control the manufacture, import, use and releases of perfluoroalkyl substances (PFAS) and manufactured products containing PFAS.

53. Given the hazards and long-range transport of this substance as described in the screening assessment on which the regulatory action is based, any state or region in which exposure or release is possible may find the regulatory action relevant.

54. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

55. The notification states that PFOA is not produced in Canada but has been imported for manufacturing (now prohibited). The import of certain products and articles (such as aqueous film forming foams) containing PFOA is allowed.

56. Information from ongoing discussions in the Persistent Organic Pollutants Review Committee of the Stockholm Convention indicates ongoing international trade (UNEP/POPS/POPRC.12/11/Add.2 and UNEP/POPS/POPRC.13/7/Add.2).

57. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

58. The Committee confirms that the criteria of paragraph (c) of Annex II are met.

(e) Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

59. There is no indication in the notification or the supporting documentation that concerns about the intentional misuse prompted the regulatory action.

60. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

(f) Conclusion

61. The Committee concludes that the notification of final regulatory action submitted by Canada meets the criteria set out in Annex II to the Convention.

III. Conclusion

62. The Committee concludes that the notifications of final regulatory action submitted by Norway and Canada meet the information requirements of Annex I and all the criteria set out in Annex II to the Convention.

63. The Committee also concludes that the final regulatory actions taken by Norway and Canada provide a sufficient basis for including perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex III to the Convention in the industrial category and that a decision guidance document should be drafted on the basis of the notifications.