POPRC-11/4: Pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds

The Persistent Organic Pollutants Review Committee,

Having examined the proposal by the European Union to list pentadecafluorooctanoic acid (CAS No.: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annexes A, B and/or C to the Convention and having applied the screening criteria specified in Annex D to the Convention,

- 1. *Decides*, in accordance with paragraph 4 (a) of Article 8 of the Convention, that it is satisfied that the screening criteria have been fulfilled for pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), as set out in the evaluation contained in the annex to the present decision;
- 2. Also decides, in accordance with paragraph 6 of Article 8 of the Convention and paragraph 29 of decision SC-1/7, to establish an ad hoc working group to review the proposal further and to prepare a draft risk profile in accordance with Annex E to the Convention;
- 3. *Decides* further that issues related to the inclusion of PFOA-related compounds that potentially degrade to PFOA and the inclusion of PFOA salts should be dealt with in developing the draft risk profile;
- 4. *Invites*, in accordance with paragraph 4 (a) of Article 8 of the Convention, parties and observers to submit to the Secretariat the information specified in Annex E, by 11 December 2015, for the following substances:
 - (a) Pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid);
- (b) Any substance that has a perfluoroalkyl group with the formula C_8F_{17} or C_7F_{15} -C as one of its structural elements and that potentially degrades to PFOA, excluding perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride, which are listed in Annex B to the Convention:
- 5. Requests the Secretariat, for the purpose of facilitating information collection, to make available to parties and observers a non-exhaustive list of CAS numbers for PFOA, its salts and PFOA-related compounds when the Secretariat invites them to submit information specified in Annex E.

Annex to decision POPRC-11/4

Evaluation of pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds against the criteria of Annex D

A. Background

- 1. The primary source of information for the preparation of the present evaluation was the proposal submitted by the European Union (UNEP/POPS/POPRC.11/5).
- 2. Additional sources of scientific information included critical reviews prepared by recognized authorities.

B. Evaluation

3. The proposal was evaluated in the light of the requirements of Annex D regarding the identification of the chemical (paragraph 1 (a)) and the screening criteria (paragraphs 1 (b)–(e)):

(a) Chemical identity:

- (i) Adequate information was provided in the proposal, which relates to PFOA, its salts and PFOA-related compounds;
- (ii) The chemical structures were provided;

The chemical identity of PFOA, its salts and PFOA-related compounds is adequately established. The proposal includes PFOA-related compounds that may degrade to PFOA.

- (b) Persistence:
- (i) Due to its high persistence, no environmental half-lives for PFOA are available;
- (ii) The results of various degradation tests and field monitoring data support the conclusion that no biodegradation of PFOA occurs. PFOA is very persistent and does not undergo any abiotic or biotic degradation under relevant environmental conditions (Meesters and Schroeder, 2004; Schröder 2003; Hanson et al., 2005; Liou et al., 2010; Siegemund et al., 2000);
- (iii) PFOA and a number of PFOA-related substances are found in humans and the environment although there are no natural sources (Moody et al., 1999 and 2003), including in remote areas like the Arctic, which indicates their potential for long-range transport (NILU, 2013).

There is sufficient evidence that PFOA meets the criterion on persistence.

- (c) Bioaccumulation:
- (i) Due to the formation of an emulsified layer between the octanol-water surface interface, the determination of log Kow is impossible (U.S. EPA, 2014). PFOA is a surface active substance and, as a result, log Kow values are not relevant (Ahrens, 2009; ECHA, 2013a);
- (ii) Due to high water solubility, the bioconcentration factor (3M Co., 1995; Martin et al., 2003) and bioaccumulation factor for PFOA and its salts are below 5000 (e.g. Martine et al., 2003). Bioconcentration factor values are not good predictors of bioaccumulation for this substance, as its bioaccumulation is not related to lipophilicity and accumulation does not primarily occur in lipid tissues (UNEP/POPS/POPRC.3/20, annex VI);
- (iii) There is evidence that PFOA biomagnifies in air-breathing animals, as field biomagnification factors for PFOA including various locations and several food webs are higher than 1 (Houde et al., 2006; Butt et al., 2008, Müller et al., 2011); Trophic magnification factors were found to be higher than 1 for selected food chains (Houde et al., 2006 and Kelly et al., 2009, Müller et al., 2011), indicating that PFOA can biomagnify in food chains and webs;
- (iv) Levels of PFOA analysed in polar bear tissue and blood indicate uptake and accumulation from the surrounding environment and food (Butt et al., 2008). These data clearly show the presence of PFOA in various species in remote regions. PFOA is found in human blood in the general population (e.g., Fromme et al., 2007, 2009) and at elevated concentrations in more exposed populations. Mothers excrete PFOA via breast milk and transfer PFOA to infants. After birth and at the end of breast feeding PFOA re-accumulates in maternal blood (ECHA, 2013a); human plasma half-lives of PFOA were reported as 2.3 to 3.5 years (geometric mean, range: 1.0 14.7 years). PFOA levels increase with age due to the chemical's long half-life (Haug et al., 2010, 2011). Taken together, the long plasma half-life and the persistence of PFOA provide enough evidence to conclude that PFOA bioaccumulates in humans.

There is sufficient evidence that PFOA meets the criterion on bioaccumulation.

- (d) Potential for long-range environmental transport:
- (i) PFOA measured at sites remote from known point sources indicates that it has the potential for long-range environmental transport, e.g., via ocean currents and/or via atmospheric transport of volatile precursors of PFOA (NILU, 2013); (Environment Canada and Health Canada, 2012);
- (ii) The atmospheric lifetime of PFOA has been predicted to be 130 days (Hurley et al., 2004). In silico methods predict that PFOA is globally distributed. This screening tool gave the following result for PFOA: Pov = 1,038 days; critical travel distance (CTD) 1,745 km (Gomis et al., 2015);

(iii) PFOA has been detected in concentrations from the low- to mid-picograms per litre (pg/L) in remote regions of the Arctic cap (US. EPA, 2014). In the Norwegian Arctic, PFOA was detected in sediment, water and pooled soil samples and various biota samples (NILU, 2013; US. EPA, 2014; Müller et al., 2011).

There is sufficient evidence that PFOA meets the criterion for long-range environmental transport.

- (e) Adverse effects:
- (i) There is epidemiological evidence for kidney and testicular cancer, disruption of thyroid function and endocrine disruption in women (Steenland et al., 2012; Knox et al., 2011a, b; Melzer et al., 2010; ECHA 2014);
- (ii) There exists experimental evidence from animal studies (Sibinski et al., 1987 and Biegel et al, 2001, cited in ECHA, 2011) that PFOA induces tumours (e.g., in the liver). Developmental effects have been observed in mice (e.g. Lau et al., 2006). Postnatal administration of ammonium salts of PFOA (APFO) in mice indicated adverse effects on mammary gland development (delayed/stunted) in offspring. Repeated oral exposure of several species to PFOA showed adverse effects such as mortality, reduced body weight gain, cyanosis and liver cell degeneration and necrosis (ECHA, 2011). Mothers excrete PFOA via breast milk, which causes concern for the health of breastfed infants (ECHA, 2011).

There is sufficient evidence that PFOA meets the criterion on adverse effects.

C. Conclusion

4. The Committee concludes that PFOA meets the screening criteria specified in Annex D.

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