



**United Nations  
Environment  
Programme**

Distr.: General  
25 August 2006

English only

---

**Stockholm Convention on Persistent Organic Pollutants**  
**Persistent Organic Pollutants Review Committee**  
Geneva, 6–10 November 2006  
Item 5 (e) of the provisional agenda\*  
**Consideration of draft risk profiles: perfluorooctane sulfonate**

## **Comments and responses relating to the draft risk profile on perfluorooctane sulfonate**

### **Note by the Secretariat**

The draft risk profile on perfluorooctane sulfonate (PFOS), prepared during the intersessional period by the working group established by the Committee for this purpose, is set out in document UNEP/POPS/POPRC.2/11. The annex to the present note contains a table listing the comments received in accordance with the standard workplan for the preparation of a draft risk profile and responses to those comments by the working group. The annex was prepared by the working group and has not been formally edited.

---

\* UNEP/POPS/POPRC.2/1.

## Annex

### Comments and responses relating to the draft risk profile on PFOS and PFOS-related substances

The table below summarizes comments received and the responses to them for the 11<sup>th</sup> May Draft Risk Profile distributed by the Secretariat to Parties and observers for comments by 16 June 2006. The 11<sup>th</sup> May Draft Risk Profile incorporates information and comments received to that date.

Some extended comments that were of a more generic nature have been briefly summarized in the table and the reader is referred to the original submission posted on the website.

The table has been subdivided between comments from members of the POPRC and those from observers to the Committee. References to pages in the table refer to the 11th May Draft Risk Profile that was posted on the web.

The submissions from Australia and ICCA-WCC were received two weeks after the deadline. Time has not allowed a full scrutiny of all references and data in the Australian submission.

#### POPRC Members

Country	Comment	Response
Armenia	Full support for the draft risk profile	No action needed
Canada	<i>Section: 1.1 Chemical Identity of the proposed substance</i>	
	<i>Page 1.</i> Letter dated 14 July 2005	Date included
	<i>Page 1.</i> Recommend deleting Synonyms from the Risk Profile. The identity is already well defined, and these synonyms are seldom used and provide no further clarity	Done
	<i>Section: 2.1.1 Production, trade and stockpiles</i>	
	<i>Page 5.</i> It seems that the usual acronym used to denote this substance is POSF, not PFOSF. The Profile should use the POSF acronym, unless there is a specific good rationale for adopting the PFOSF acronym	The abbreviation PFOSF has a F included for fluoro in the same way as for PFOS
	<i>Page 5.</i> Spell out SC	Done
	<i>Section: 2.1.2 Uses</i>	
	<i>Page 7.</i> This comment can also apply elsewhere in the discussions of uses – While general information on uses is desirable in the risk profile, detailed discussions, including relating to efficacy, is best deferred to the Annex F review.	Changed

Country	Comment	Response
	<i>Page 9.</i> Defer deleted text to Annex F Review?	Yes
	<i>Page 9.</i> Delete the following text. Notably, the text on the need to maintain EU competitiveness is inappropriate in the context the Stockholm Convention.  <i>..which is critical to continuing...</i>	Deleted
	<b>Section: 2.2.2 Bioaccumulation</b>	
	<i>Page 12.</i> When key data such as this is presented, it may be preferable to cite the original study rather than a review document	Done
	<b>Section: 2.4.1 Toxicity</b>	
	<i>Page 20.</i> Some of the ecological concerns are associated with high accumulation in wild mammals. The data in Section 2.4.1 is relevant to consideration of effects on wildlife, not only on humans. Therefore suggest re-naming this section "Mammalian toxicity".	Accepted
	<i>Page 20.</i> Different jurisdictions have different classifications. I suggest that presentation of such classification may not be relevant here. If desired, such classification information should be included in Section 1.4 instead.	Text concerning classification has been deleted in the Risk Profile.
	<i>Page 20.</i> Suggest adding the two following studies. They were considered as key studies in the Canadian assessment, and results have been expressed in terms of corresponding concentrations in sera and liver, allowing comparisons with measured levels in wildlife.	Accepted
	<i>Page 20.</i> A study by Grasty <i>et al.</i> An indication should be given of the exposures associated with such effects.	Done

Country	Comment	Response
	<b>Section: 3 SYNTHESIS OF THE INFORMATION</b>	
	<i>Page 21.</i> For consistency between documents and between different substances, discussion of criteria should be presented in same order as in Annex D of the Convention, i.e., persistence, bioaccumulation, long range transport, and adverse effects. I have re-ordered the following paragraphs in that way (identity and uses, persistence, bioaccumulation, long range transport, and adverse effects, followed by statements on certain risk elements), although the change in order does not show up in Revision Mode. Any actual additions or deletions are indicated in Revision Mode.	Change accepted
	<i>Page 22.</i> The Risk Profile should present, to the extent possible, a discussion of levels of risk that could be associated with the substance. From that perspective, certain elements from the domestic Canadian Ecological Assessment have been added for consideration but should be re-worked in the context of this Risk Profile.	Included
Australia		N.B. Comments not strictly concerning PFOS or potential PFOS precursors, see definition below, have been excluded from this compilation.  Definition: C <sub>8</sub> F <sub>17</sub> SO <sub>2</sub> Y, where Y = OH, metal salt, halide, amide and other derivatives including polymers.
	<b>General Comment</b>	
	When discussing PFOS, it is important to note whether PFOS specifically is meant, or the broader family of related substances. While PF have been phased out, PFOA and other perfluorochemicals may still be in production and use.	The definition on page 3 in the Risk Profile clearly defines what the abbreviation PFOS stands for.
	<b>Section: 1.4 Summary of available risk information</b>	
	The paragraph mentioning the Canadian Environmental Screening Assessment Report on PFOS, Its Salts and Precursors does not mention that PFOS and its salts was proposed as a candidate for virtual elimination under the <i>Canadian Environmental Protection Act 1999</i> (CEPA).	Canada has not provided this information. No change in text.

Country	Comment	Response
	<i>Section: 2.1.2 Uses</i>	
	The report assumes that other historical uses such as carpets, leather/apparel, textiles/upholstery and packaging, coatings and coating additives, industrial and household cleaning products and pesticides and insecticides have ceased within the UK. This supposition cannot necessarily be made for other markets including the US and Australian markets.	Agreed but data concerning other markets is missing.
	<b>Section: 2.2.3 Releases to the environment</b>	
	<p>There has been a lot of research recently conducted in this area including a large European (1,104,500 Euro) joint project called PERFORCE (<b>PER</b>Fluorinated <b>OR</b>ganic Chemicals in the European environment) researching how PFC's get into the environment, how they move within and between different environmental compartments, their key environmental properties. This research is led by the University of Amsterdam and has Norwegian, Swedish and Belgian partners as well as representatives from DuPont. It has EU funding of 790,000 Euro under the 6<sup>th</sup> Framework Programme.</p> <p>Informative recently published articles include:</p> <p><b>Significant Residual Fluorinated Alcohols Present in Various Fluorinated Materials</b> Dinglasan-Panlilio, M.J.A. and Mabury, S.A. <i>Environ. Sci. Technol.</i>, 40, 5, 1447 - 1453, 2006, 10.1021/es051619+</p> <p><b>Mass Loading and Fate of Perfluoroalkyl Surfactants in Wastewater Treatment Plants</b> Sinclair, E. and Kannan, K. <i>Environ. Sci. Technol.</i>, 40, 5, 1408 - 1414, 2006, 10.1021/es051798v</p>	Response to be provided later.
	<p>Page 22. Reference to U.S Releases Estimation 1997 doesn't seem to be fully referenced in the References section of the risk profile and needs to be provided.</p>	Done

Country	Comment	Response
	<b>Section: 2.3 Exposure – Measured Environmental Levels</b>	
	<p>The section detailing US environmental exposure to perfluorochemicals should also include the following:</p> <p>3M faces lawsuits due to alleged perfluorochemical contamination in Minnesota from their Cottage Grove facility as well as from its Decatur, Alabama facility. Minnesota Pollution Control Agency scientists have collected blood samples from fish in the Mississippi River showing very high levels of PFOS. The results were apparently “10 times higher than had been reported anywhere for fish or wildlife”.</p> <p>See Reference: Investigation Of Perfluorochemical (PFC) Contamination In Minnesota Phase One – Report to Senate Environment Committee</p>	<p>This report has been referred to in the Risk Profile.</p>
	<b>Section 2.3.1 Bioavailability</b>	
	<p><i>Page 19.</i> Australia questions whether PFOS is in fact mainly released to the environment through water from sewage treatment plants given recent research mentioned above concerning long-range transport of fluorinated alcohols.</p>	<p>Text has been changed</p> <p>The suggested articles concern other fluorinated substances.</p>

Country	Comment	Response
	<p>Australia suggests mentioning specifically that PFOS has recently been detected in the blood serum of the general population. International and Australian references include:  OECD Hazard Assessment of PFOS 2002 p17 <a href="http://www.oecd.org/dataoecd/23/18/2382880.pdf">http://www.oecd.org/dataoecd/23/18/2382880.pdf</a></p> <p>Perfluorochemicals in Pooled Serum Samples from United States Residents in 2001 and 2002. Calafat, A.M., Kuklenyik, Z., Caudill, S.P., Reidy, J.A., and Needham, L.L. <i>Environ. Sci. Technol.</i>, 40, 7, 2128 - 2134, 2006,</p>	<p>Some of the articles has been evaluated and also included in the Risk Profile.</p>
	<p>Levels of 12 Perfluorinated Chemicals in Pooled Australian Serum, Collected 2002-2003, in Relation to Age, Gender, and Region Karrman, A., Mueller, J.F., vanBavel, B., Harden, F., Toms, L.-M.L., and Lindstrom, G. <i>Environ. Sci. Technol.</i>, 40, 12, 3742 - 3748, 2006,</p> <p>Biological Monitoring of Polyfluoroalkyl Substances: A Review Houde, M., Martin, J.W., Letcher, R.J., Solomon, K.R., and Muir, D.C.G. <i>Environ. Sci. Technol.</i>, 40, 11, 3463 - 3473, 2006, 10.1021/es052580b</p> <p>Advocacy groups have recently found PFOS and PFOA in household dust in composite samples from seven US states. Reference:</p> <p>Sick of Dust - Chemicals In Common Products — A Needless Health Risk In Our Homes. Clean Production Action March 2005 <a href="http://www.safer-products.org/downloads/Dust%20Report.pdf">http://www.safer-products.org/downloads/Dust%20Report.pdf</a></p>	
	<b>Section: 2.4.1 Toxicity</b>	
	<p>Include most recent US EPA Science Advisory Board findings if agreed to by US EPA</p>	<p>Data not available</p>

Country	Comment	Response
	<b>Section: 4 Concluding Statement</b>	
	<p>There is currently some uncertainty as to whether the voluntary phase out of PFOS production by 3M “has led to a significant reduction in the current use of PFOS-related substances”. This could be clarified by requesting current production data from the companies still producing perfluorinated chemicals mentioned above. This information has probably already been made available to the US EPA through the recently launched US EPA Global Stewardship Program. Continued use of perfluorochemicals has been demonstrated through the following recent publication: <i>OECD (2005) Results Of Survey On Production And Use Of PFOS, PFAS And PFOA, Related Substances And Products/ Mixtures Containing These Substances, January 2005</i>. This survey is currently being repeated with 2006 data.</p>	<p>The OECD Survey from 2005 has been evaluated, but we find data concerning PFOS difficult to separate from data on other perfluoroalkyl sulfonates</p>

#### Observers

Country	Comment	Response
United States of America	<b>Section: 2.1.2 Uses</b>	
	<p>Page 6. This says all uses occurred in the US, but only the final two in the EU. This is incorrect as there has already been reference to EU uses of fire fighting foams (the first listed use).</p>	Text has been revised
	<p>Page 7. PFAS is only used once as an abbreviation, so it would be better to simply spell it out (define on p 4 and used on p 7)</p>	Done
	<b>Section: 2.2.2 Bioaccumulation</b>	
	<p>Page 14. This reference would seem better replaced with a different Jones et al: Jones PD, Hu W, De Coen W, Newsted JL, Giesy JP. Binding of perfluorinated fatty acids to serum proteins. Environ Toxicol Chem. 2003 Nov;22(11):2639-49.</p>	Done



Country	Comment	Response
	<p>Additional and more current information should be provided on the bioconcentration and effects of PFOS in wildlife. See the following:</p> <p>Ankley, G.T., D.W. Kuehl, M.D. Kahl, K.M. Jensen, B.C. Butterworth and J.W. Nichols. 2004. Partial life-cycle toxicity and bioconcentration modeling of perfluorooctanesulfonate in the Northern leopard frog (<i>Rana pipiens</i>). Environ. Toxicol. Chem. 23, 2745-2755.</p> <p>Ankley, G.T., D.W. Kuehl, M.D. Kahl, K.M. Jensen, A. Linnam, R.L. Leino, and D.L. Villeneuve. 2005. Reproductive and developmental toxicity and bio-concentration of perfluorooctane-sulfonate (PFOS) in a partial-life cycle test with the fathead minnow (<i>Pimephales promelas</i>). Environ. Toxicol. Chem. 24, 2316-2324.</p> <p>In addition, there was a recent review paper on the topic that the authors of the document could consult to further update this section of the report.</p> <p>Beach S.A., J.L. Newsted, K. Coady and J.P. Giesy. 2006. Ecotoxicological evaluation of perfluorooctanesulfonate (PFOS). Rev. Environ. Contam. Toxicol. 186, 133-174]</p>	<p>Suggested references have been evaluated and Ankley et al., (2005) is included in the Risk Profile.</p>
	<p><b>Section: 2.4.1 Toxicity</b></p>	
	<p>Page 20. Table: Rat Maternal PFOS Doses and Tissue Levels</p>	<p>Lack of supporting data and full references made the table difficult to evaluate and it was not included.</p>

Country	Comment	Response
	<b>Section: 3 SYNTHESIS OF THE INFORMATION</b>	
	The following discussion needs to provide the specific, relevant information on whether PFOS is likely, as a result of long range environmental transport, to cause significant adverse effects on human health or the environment, such as that global action is warranted. This should be an argument that compares the information we have to the ultimate decision of “does this constitute a risk” – i.e., PFOS meets Annex D screening criteria, in the absence of production controls the levels go up linearly as demonstrated by monitoring data in remote locations, the substance is building up in human tissues and the environment in these remote locations, and there are some troubling toxicological studies that demonstrate effects at tissue doses whose relevance to humans at the various body burden levels found remains under close and ongoing review.	See revised text.
	<b>Section: 4 Concluding Statement</b>	
	The conclusions should state clearly which criteria were met and how these criteria as well as other necessary and relevant information may contribute to making the determination that PFOS is likely, as result of long-range environmental transport, to cause significant adverse effects on human health or the environment such that global action is warranted. If the dossier does not provide the relevant or adequate information to support this statement, then a clear conclusion to that effect should be stated.	See revised text.
Semiconductor Industry Association (SIA)	Suggestions to use some other reference sources, e.g. the 2004 report by the Scientific Committee on Health and Environmental Risks (SCHER), titled “Opinion on ‘RPA’s report ‘Perfluorooctane Sulphonates: Risk reduction strategy and analysis of advantages and drawbacks ’”.	No additional information provided.
	The text should reflect that the refractive index of the ARC must be aligned to the refractive index of the resist during photolithography. Any change to the chemical application in a resist cannot be achieved in isolation; it must be carefully considered in conjunction with viable alternative chemicals in ARCs that could precisely align with the substitute chemical in the resist. This is a complicated, symbiotic relationship, further highlighting the criticality of PFOS during photolithography across different applications.	The text on uses has been shortened to a minimum. Proposal not included.

Country	Comment	Response
	Concerns about including the PFOS-related chemicals as precursors and lack of data about the specific precursors. The issue of how to treat precursors raises general policy questions that the POPRC must address. Concerns relate to the difficulty in understanding (a) precisely which chemicals are subject to the ongoing review, and (b) how those chemicals fit within the Convention's criteria and procedures for reviewing candidate chemicals for inclusion.	PFOS-related substances are defined on page 3 in the draft report. Available data and modelling indicate that precursors may degrade to PFOS. Substances that are degraded to POPs fall within the scope of the Convention.  No change in text.
	Concerns about the last sentence of the draft risk profile, which concludes that "[d]ue to the harmful POP properties and risks related to its possible continuing production and use, global action is warranted to eliminate the pollution caused by PFOS." Suggests that the statement be removed before the risk profile is finalized and formally transmitted to the POPRC.	The review under E (i.e. the risk profile) should 'evaluate whether the chemical is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action is warranted'. Conclusion is kept.
3M	General comments regarding risk characterization, the omission of the SCHER Opinion and an internal 3M assessment of the UK assessment.	No additional information provided.
	Concerns about the inclusion of precursors.	See response to SIA
	Concerns about the mixing of fire fighting foams containing PFOS without other foams.	This issue belongs to the development of risk management options, which is the next phase in the process under Article 8. Not addressed in the risk profile.
ICCA-WCC	Generic comments on how the risk profiles should be written and how the chemical industry would like to see the issues addressed. Comments were received two weeks after deadline.	The generic comments from ICCA-WCC did not contain any additional factual information or challenge of conclusions. No action taken.
	PFOS; Treatment of Precursors. General views on the inclusion of precursors.	No additional information provided. See also response to SIA.
	PFOS; Sources, Sections 2.1.1 – 2.1.3. General views on how sections could be drafted.	No additional information provided.
	PFOS; Synthesis of Information, Section 3 General views on how section could be drafted.	No additional information provided.
	PFOS; Concluding Statement, Section 4. Concerns about the inclusion of the concluding statement.	No additional information provided. See also response to SIA.