



## Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

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### Chemical Review Committee

#### Eighth meeting

Geneva, 19–23 March 2012

Item 5 (c) (iii) of the provisional agenda\*

**Technical work: consideration of draft decision guidance****documents: perfluorooctane sulfonic acid, its salts and its precursor perfluorooctane sulfonyl fluoride**

### Comments and further information related to the draft decision guidance document for perfluorooctane sulfonic acid, perfluorooctanesulfonates, perfluorooctanesulfonamides and perfluorooctanesulfonyls

#### Note by the Secretariat

1. In accordance with the process for the development of decision guidance documents set out in decision RC-2/2 of the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, an internal proposal for perfluorooctane sulfonic acid, its salts and its precursor perfluorooctane sulfonyl fluoride was circulated to the Chemical Review Committee and its observers for their information and comments. A tabular summary of the comments received thereon and how they were taken into account in preparing the draft decision guidance document for those substances was considered by the Chemical Review Committee at its eighth meeting. The Committee revised<sup>1</sup> and then agreed upon for consideration by the Conference of the Parties both the tabular summary and the draft decision guidance document.
2. The tabular summary of comments is set out in the annex to the present note. It has not been formally edited by the Secretariat.
3. The draft decision guidance document is set out in the annex to document UNEP/FAO/RC/CRC.8/6/Rev.1.

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\* UNEP/FAO/RC/CRC.8/1.

1 The title of the draft decision guidance document had previously referred to perfluorooctane sulfonic acid, its salts and its precursor perfluorooctane sulfonyl fluoride; the title of the document as agreed upon at the eighth meeting of the Committee refers to perfluorooctane sulfonic acid, perfluorooctanesulfonates, perfluorooctanesulfonamides and perfluorooctanesulfonyls. The title of the tabular summary of comments was not revised, however, and therefore does not reflect the change in the title of the draft decision guidance document.

## Annex

### Tabular summary of comments on perfluorooctane sulfonic acid, its salts and its precursor perfluorooctane sulfonyl fluoride

Country	Section	Comment/Suggestion	Response
Ecuador	Standard Core List of Abbreviations	Suggested deletion of all the abbreviations not in text	Specific abbreviations for this DGD have been added and some irrelevant ones deleted.
	Throughout document	Change l to L	Accepted
	Throughout document	] changed to ( )	Accepted
	Section 1 Formulation types and Annex 2	Slight changes in names and abbreviations	Accepted
	Annex 1 3.3 and 3.4	Slight changes in wording	Accepted
	Annex 1 Section 4.2.2	Unio complamatus: 96 hour NOEC = 50 mg/l (PFOS potassium salt) Unio complamatus: 96 hour EC50 = 59 mg/l (PFOS potassium salt)	Change is made
Peru	Standard Core List of Abbreviations	Suggested deletion of all the abbreviations not in text	Specific abbreviations for this DGD have been added and some irrelevant ones deleted.
	Section 3 3.4	Precursors	Not accepted it is just one precursor
	Section 4	Organizations	Accepted
	Annex 1 Section 4.2.2	Unio complamatus: 96 hour NOEC = 50 mg/l (PFOS potassium salt) Unio complamatus: 96 hour EC50 = 59 mg/l (PFOS potassium salt)	Change is made
Norway	Section 1 Uses in regulated categories	UNIDO is currently preparing a PFOS inventory that could be cited here when it is finished	This is not available within the timetable of the DGD preparation
		A section entitled "Others" was added on uses listed in Stockholm Convention on POPs.	Added
		To get updated information - check with the Stockholm Convention secretariat what use categories have been notified to the secretariat since PFOS was listed in the Stockholm Convention i.e. what uses are currently registered by parties to the SC.	Will be checked

Country	Section	Comment/Suggestion	Response
	Formulation types	<p>For your information, more updated information may be found in a recently published book: Perfluorinated alkylated substances Series: Reviews of Environmental Contamination and Toxicology, Vol. 208 De Voogt, Pim (Ed.) 1st Edition., 2010, XV, 132 p. 17 illus. Springer Verlag,</p> <p>Insert reference from POPRC 2006. “3M The science of organic fluorochemistry. 1999”</p> <p>A current UNIDO project on creating a PFOS inventory has identified the following producers based on the OECD 2002 Hazard assessment of PFOS. UNITAR has moreover assembled a more updated list (not included here) that is intended as a guidance to customs authorities.</p> <p>New text addition- 3M was previously the major global producer of PFOS, but in May 2000 3M announced a voluntary phase out from 2001 onwards (POPs, 2006). In the beginning of 2003 3M’s production ceased completely. Based on various chemical buyer’s guides (Directory of World Chemical Producers, 2000; ChemSources USA, 2000; OPD Chemical Buyers Directory, 2000) the following companies have been identified as offering PFOS-related chemicals for sale (OECD, 2002)<sup>1</sup>:  3M (Belgium, USA)  MiteniS.p.A. (Italy)  EniChem Synthesis S.p.A. (Italy)  Dianippon Ink &amp; Chemicals, Inc. (Japan)  Midori Kaguka Co., Ltd. (Japan)  Tohkem Products Corporation (Japan)  Tokyo Kasei Kogyo Company, Ltd. (Japan)  Fluka Chemical Co, Ltd. (Switzerland)  BNFL Fluorochemicals Ltd. (United Kingdom)  Fluorochem Ltd. (United Kingdom)  Milenia Agro Ciencias S.A. (Brazil)  Changjiang Chemical Plant (China)  Indofine Chemical Company, Inc. (India)  Scientific Industrial Association P &amp; M Ltd. (Russian Federation)  <sup>1</sup>This information has not been corroborated independently, except for MiteniS.p.A. of Italy and Dianippon Ink &amp; Chemicals, Inc. of Japan</p>	<p>No change as the book is not an authoritative source freely available</p> <p>The POPRC reference is internationally recognised while the 3M reference is not, so no change has been made</p> <p>List from OECD, 2002 added as suggested</p>
	Section 2	<p>It would be useful to highlight that (some of) the notifications were made subsequent to/ as a result of the listing of PFOS in the Stockholm Convention. This seems to be the case for Japan at least). A possible suggestion for text to insert is:</p> <p>“The notifications of PFOS submitted by these three parties/ Japan to the Rotterdam Convention were made subsequent to the listing of PFOS in Annex B of the Stockholm Convention in 2009 whereby</p>	<p>Not accepted.</p> <p>The timing of events is not considered relevant. The Japanese notification refers to the risk profile but not to the decision taken under Stockholm. The proposed wording would be misleading.</p>

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		production and use of PFOS, its salts and PFOS-F were restricted to a limited number of acceptable purposes and specific exemptions ( <a href="http://chm.pops.int/Convention/ThePOPs/tabid/673/Default.aspx">http://chm.pops.int/Convention/ThePOPs/tabid/673/Default.aspx</a> ).“	
	Section 2.1	<p>Please note that this text is based solely on the original EU notification i.e. regulation No 1907/2006 and 552/2009. Since 2010 the EU also regulates PFOS via Commission Regulation (EU) No 757/2010). Hence, changes in the text may be necessary. Please check with the EU.</p> <p>This information from the original EU notification could be useful - Pursuant to Regulation (EC) 1907/2006 concerning the registration, evaluation, authorization and restriction of chemicals (REACH) as amended by Commission Regulation (EC) No 552/2009 amending Regulation (EC) No 1907/2006 and regulation Commission Regulation (EU) No 757/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III Information from the original EU notification that was not included here. It should perhaps be added?</p> <p>In the regulation, the European Commission is requested to review each of the derogations in paragraph 3 as soon as new information on details of uses and safer alternative substances or technologies for the uses become available.</p> <p>The Commission is also requested to keep under review the on-going risk assessment activities and the availability of safer alternative substances or technologies related to the uses of perfluorooctanoic acid and related substances and propose all necessary measures to reduce identified risks, including restrictions on marketing and use, in particular when safer alternative substances or technologies, that are technically and economically feasible, are available.</p> <p>Do we need this? It may cause confusion regarding ban vs severe restriction... It should be noted that the restriction also apply without prejudice to Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 08.04.2004, p. 1).</p>	<p>Reference to legal acts reported in the notification added but not to later acts. Mention to later acts has been added in a footnote.</p> <p>Partly added (se reasoning above)</p> <p>Added</p> <p>Added</p> <p>Sentence deleted</p>
	Section 2.2	<p>Insert reference to the Canadian environmental assessment here</p> <p>Merge human and environmental data under one section “Human Health and Environment” to save space. A lot of the text in the “Environment” section below is a repetition of the text in the “Human Health” section</p>	<p>Added</p> <p>It is considered important to outline the assessments for human health and environment separately.</p>

Country	Section	Comment/Suggestion	Response
		Multiple changes in the text suggested	Some suggested changes to the text have been made
	Section 3.2	Japan submitted the Stockholm Convention risk profile on PFOS as supporting documentation. The summary of the risk profile should therefore be provided here. See <b>UNEP/POPS/POPRC.2/17/Add.5</b> and text proposal below	Noted but different text added which reflects the process in Japan. Results from POPRC (2006) hazard assessment, which was also based on the OECD (2002) and RPA (2004) documents, are reflected in the annex.
	Section 3.1	Insert for Japan the following text: "Prohibition of manufacture, import or use of PFOS is forbidden, while certain essential uses under strict control are permitted as an exception. See section 2.1 for further details"	Added
	Section 3.3	Rewording on introduction to Table - Stockholm Convention on POPs  To assist parties in identifying alternatives to PFOS the Persistent Organic Pollutants Review Committee (POPRC) of the Stockholm Convention developed a guidance on alternatives to PFOS (POPRC, 2010). In their guidance POPRC identified the following use areas and PFOS alternatives:	Suggested text added
	Section 4.2	Please insert references	Added
	Section 4.5	Don't know how relevant this information is. I just wanted to let you know that this report exist. The reference here is: BIPRO, 2011. Study on waste related issues of newly listed POPs and candidate POPs, pp 841  Following the inclusion of the nine new POPs, including PFOS, in the Stockholm Convention in 2009 the EU commissioned a comprehensive study on POPs and waste that provide information on sources, concentrations, past uses, waste and recycling issues (BIPRO, 2011). The report will be used by the EU and its member states to identify, manage and regulate POPs containing waste e.g. to set limit values for POPs in waste and to classify whether a waste is a POP waste or not.	Suggested text and reference to the study added, which is "ESWI, 2011".
	Annex 1 Introduction	Please clarify the wording	Suggested text added
	Annex 1 Section 2 (General comment)	Please make sure to include relevant information from the POPRC risk profile that was submitted by Japan as supporting information and the environmental and health assessments made by Canada .	The POPRC and Canadian documents used the same sources of toxicological information (OECD, 2002; RPA, 2004) quoted in these sections but reference to these documents have been added. Text for Japan and Canada has also been added in Section 4.

Country	Section	Comment/Suggestion	Response
	Annex 1 Section 2.1.3	Grammar changes	Not accepted language was correct
	Annex 1 Section 3	Please make sure to include relevant information from the POPRC risk profile that was submitted by Japan as supporting information and the “Screening Assessment Report-Health” that was submitted by Canada .	The POPRC and Canadian documents used the same sources of toxicological information (OECD, 2002; RPA, 2004) quoted in these sections but reference to these documents have been added. Text for Japan and Canada has also been added in Section 4.
	Annex 1 Section 4.1	<p>Added text: Japan:</p> <p>PFOS fulfils the POPs criteria of the Stockholm Convention and is extremely persistent (POPRC, 2006). It has not shown any degradation in tests of hydrolysis, photolysis or biodegradation in any environmental condition tested. The only known condition whereby PFOS is degraded is through high temperature incineration (3M, 2003a).</p> <p>PFOS is an atypical POP as it does not follow the “classical” pattern of partitioning into fatty tissues followed by accumulation, which is typical of many persistent organic pollutants. This is because PFOS is both hydrophobic and lipophobic. Instead, PFOS binds preferentially to proteins in the plasma, such as albumin and <math>\beta</math>-lipoproteins (Kerstner-Wood et al., 2003), and in the liver, such as liver fatty acid binding protein (L-FABP; Luebker et al., 2002). Due to the properties of PFOS, which binds preferentially to proteins in non-lipid tissues, application of numeric criteria for BCF or BAF, which are derived based on consideration of lipid-partitioning substances, may be inappropriate for PFOS.</p>	Text added for Japan, although reference for POPRC, 2006 used as internationally accepted reference.
	Annex 1 Section 4.1.5	<p>Information from the notification by Japan (i.e. POPRC, 2006 doc) and Canada is missing?</p> <p>Bioconcentration and bioaccumulation is by definition not the same thing. Information on these two processes treated in two separate sections or alternatively in a joint section “Bioconcentration and bioaccumulation”</p> <p>Add information from the notifications by theJapan</p> <p>HBCD bioaccumulates and highly elevated concentrations that have been found in top predators such as the polar bear, seal, bald eagle and mink (for reported levels see POPRC, 2006). Based on the concentrations found in their prey, high BMFs have been estimated for these predators. However, PFOS which is both hydrophobic and lipophobic.is an atypical POP and does not follow the “classical” pattern of partitioning into fatty tissues followed by accumulation, which is typical of many persistent organic pollutants. Instead, PFOS binds</p>	<p>New section on Bioaccumulation added for Japan and Canada.</p> <p>Text added for new section on Bioaccumulation</p>

Country	Section	Comment/Suggestion	Response
		<p>preferentially to proteins in the plasma, such as albumin and <math>\beta</math>-lipoproteins (Kerstner-Wood et al., 2003), and in the liver, such as liver fatty acid binding protein (L-FABP; Luebker et al., 2002). Due to the properties of PFOS, which binds preferentially to proteins in non-lipid tissues, application of numeric criteria for BCF or BAF, which are derived based on consideration of lipid-partitioning substances, may be inappropriate.</p> <p>Canada</p> <p>Unlike many other persistent organic pollutants, certain perfluorinated substances, such as PFOS, are present as ions in environmental media and partition preferentially to proteins in liver and blood rather than to lipids. Therefore, the bioaccumulation potential of PFOS may not be related to the typical mechanisms associated with bioaccumulation in lipid-rich tissues. See also section EU and Canada also.</p>	Text added for Canada.
	Annex 1 Section 4.1.6	<p>Add text:</p> <p>Canada</p> <p>PFOS is resistant to hydrolysis, photolysis, microbial degradation, and metabolism by vertebrates. PFOS has been detected in fish, in wildlife worldwide and in the northern hemisphere. This includes Canadian wildlife located far from known sources or manufacturing facilities indicating that PFOS and/or its precursors may undergo long-range transport. PFOS has been detected in the liver of biota in remote areas of the Canadian Arctic.</p>	Text added for Canada.
	Annex 1 Section 5	Where relevant, please make sure to include information from the notification by Japan (i.e. POPRC, 2006 doc) and Canada also. In the text I can only see references from the EU notification, and the OECD, 2002 assessment.	Text has been added for Japan and Canada as shown, but the same source of information was used in the POPRC document (OECD, 2002 and RPA, 2004) as in the Canadian and EU assessments
	Annex 1 Section 5.4 Summary – overall risk evaluation	<p>This section should be rewritten. It is important to include information from both the Japanese and the Canadian submission here in addition to the information provided by the EU. See text proposal</p> <p>It is important to clarify that this classification is only valid in the EU – rephrase sentence to make this point clear to the reader. Ask the EU to provide a reference (CLP regulation ?).</p> <p>Note that PFOS is also listed in the POP protocol of LRTAP. See <a href="http://live.unece.org/env/lrtap/pops_h1.html">http://live.unece.org/env/lrtap/pops_h1.html</a></p>	<p>Rewritten as suggested</p> <p>This has been added to Section 2.2</p>

Country	Section	Comment/Suggestion	Response
Japan	Section 1	Use(s) in regulated category of PFOS, section on Japan (p.7), please delete the "etc" , since Japan does not have any extra uses.	Deleted
	Section 1	Please insert the following statement on Japanese companies listed in the list of basic manufacturers since they stopped producing PFOS in 2010:  In addition, Japanese four companies which are listed below ceased to produce PFOS in 2010.	Slightly modified text added.
European Union		The title of the Draft document as well as the descriptions in chapter '1. Identification and uses' show that the entry is considered to be a collective entry. For this reason, all data relating to the identity are of exemplary nature.  This should be noted in the report. It was mentioned that there is no CAS-No for the perfluorooctansulphonat anion. (Meanwhile) there is a CAS-No for the anion which reads 45298-90-6. It is unknown to which substance the PC-data refer.	The Physico-Chemical properties data come from the notifications with the chemical identified as PFOS  Corrected. This CAS No. appears to be only listed on some of the databases, and was not located in the original drafting or in any of the notifications.
	2.1 Final regulatory action	European Union - The threshold was lowered to 0.001 % (see Regulation (EU) No 757/2010 to amend POP-regulation 850/2004/EC). See also commission regulation (EU) No 207/2011  Please update due to amendments in regulation 850/2004/EC by regulations (EU) No 757/2010 and 756/2010; e.g.: additional use: "until 26 August 2015, wetting agents for use in controlled electroplating systems"	The DGD is based on the regulatory action identified in the notifications. More recent regulation is mentioned.
	2.2 Risk Evaluation	European Union Human Health paragraph 3 please include the information that PFOS was also considered a POP under the "Protocol on Persistent Organic Pollutants (POPs)" under the Convention on Long-range Transboundary Air Pollution and was included there in Annex I and II  ...and was included in Annex B by the fourth conference of the parties (COP4) in May 2009 Environment paragraph 2  ...and was included in Annex B by the fourth conference of the parties (COP4) in May 2009 Formatting of the table should be corrected as the rightmost column is incomplete No entry for Hazard Class and Packing Group?	This section is updated as suggested  No entry located
	3.3 Alternatives	Source of information?	Added
	4.3 Packaging and labelling	Information on reference to regulatory document should be updated	The DGD is based on the regulatory action identified in the notifications. More recent regulation is mentioned.

Country	Section	Comment/Suggestion	Response
	Annex 1 Section 2.1.1 Mode of action	Style sheets should be used consistently throughout the document (some parts occur grey when printed). – several places	Formatting problems will be solved in final version
	Annex 2 European Union	Update EU regulatory document.	DGD is based on regulatory action described in notifications. Newer regulations are mentioned
	Annex 4 References	Two references should be separate (POPs and Basel Convention)	Corrected
<b>Switzerland</b>	Section 1 Identification and uses	Add to the uses in other categories section Insect baits for control of leaf-cutting ants from <i>Atta spp.</i> and <i>Acromyrmex spp.</i> [POPs, 2010]	Accepted
<b>Canada</b>	2.1 Final regulatory action Japan	Formatting: This isn't the same format as the other two boxes above.	Formatting problems will be solved in final version
	3.3 Alternatives	Formatting of Table  Definition of PFBS in Table	Formatting problems will be solved in final version  Added
	Annex 1 Section 1 Physico-chemical Properties	Solubility in water 12.4 mg/l (filtered seawater) - I believe this should be "unfiltered seawater" as per the cited report.	Corrected
	Annex 1 Section 3.3	PFOS was also detected in surface water as a result of a spill of fire-fighting from Canada's Toronto International airport into nearby Etobicoke Creek. Should be Spill of fire-fighting foam?	Corrected
	Annex 3	Altered address and email address for Canada	Corrected