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Implementation of the Strategic Approach to International Chemicals Management: emerging policy issues

Submission by the United States of America on managing perfluorinated chemicals and transitioning to alternatives

Note by the secretariat

The secretariat has the honour to circulate, in the annex to the present note, a submission by the United States of America on managing perfluorinated chemicals and the transition to alternatives for the information of the Conference. The submission sets out relevant background information on managing perfluorinated chemicals and the transition to alternatives together with proposed cooperative actions. It is being circulated, as received by the secretariat, without formal editing.

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Annex

Submission by the United States of America

Proposed actions on emerging policy issues – Managing Perfluorinated Chemicals (PFCs) and Transitioning to Alternatives

Cover Note

The United States submits for participants' information and consideration a background/INF document and proposed cooperative actions on Managing Perfluorinated Chemicals (PFCs) and Transitioning to Alternatives. This may be introduced and discussed under agenda item 4 (f) consistent with the Annotated Provisional Agenda¹ and the functions of the Conference.² See in particular the proposed cooperative actions section and accompanying Annexes to review language and options for how this issue might be considered by the Conference.

The submission is the result of consultations with Strategic Approach participants and other experts and stakeholders following an International Workshop on PFCs³ co-sponsored by UNEP and the U.S. on 12-13 February 2009 and held back-to-back with the Informal Workshop on Stakeholder Needs for Information on Chemicals in Products co-sponsored by Sweden and Japan. The submission's development mirrors what has also been prepared on the other four emerging policy issues slated for detailed consideration.

A side event is to be held 9 AM Monday, 11 May, to present a summary of the Workshop, review the attached paper and further discuss proposed cooperative actions and options before the Conference. The inclusion of the side event was recommended by the Friends of the Secretariat group recognizing that as a practical matter, there was insufficient time to include it on the Sunday technical briefing. The Friends group also further clarified and confirmed that the Conference was not limited by the four issues selected for detailed consideration and that any stakeholder could identify and request the Conference to consider additional emerging policy issues.⁴

¹ SAICM/ICCM.2/1/Add.1 paragraphs 27 and 28 iterate that: The Conference will also have before it a number of other pertinent documents submitted by stakeholders, including... ...submissions by the proponents of emerging policy issues recommended for consideration by the Conference. The Conference may wish to consider the above reports with a view to recommending possible cooperative action on priority emerging issues.

² Under Article 24(j) of SAICM's Overarching Policy Strategy, the functions of the Conference include: To focus attention and call for appropriate action on emerging policy issues as they arise and to forge consensus on priorities for cooperative action.

³ For the final Workshop report, background material and presentations, see http://www.chem.unep.ch/unepsaicm/cheminprod_dec08/PFCWorkshop/default.htm

⁴ See Friends of the Secretariat Summary of 8th and 9th Teleconferences available at http://www.saicm.org/index.php?menuid=11&pageid=105&submenuheader=

Managing Perfluorinated Chemicals (PFCs) and Transitioning to Alternatives

Background (INF) Document

Perfluorooctyl sulfonate (PFOS), perfluorooctanoic acid (PFOA), and some other perfluorinated chemicals (PFCs) are persistent, are widely present in humans and the environment, have long half-lives in humans, and can cause adverse effects in laboratory animals, including cancer, developmental, reproductive and systemic toxicity. Some PFC precursors, chemicals that can be transformed to produce PFCs, are also present worldwide in humans and environment and, in some cases, might be present at higher concentrations than PFOS and PFOA and may be more toxic. PFC higher homologues (HHs) are chemicals with carbon chain lengths longer than PFOA and PFOS, and available evidence suggests that toxicity and bioaccumulation appear to increase with increasing carbon chain length.

How people are exposed to PFCs is not yet fully understood; however, pathways likely involve environmental exposure to PFOS, PFOA, PFC precursors, and HHs, and to residual levels of these PFCs in industrial, commercial, and consumer products. There are several possible exposure sources, including industrial emissions, both from primary manufacturer(s) and downstream users for production applications, and the environmental degradation of precursor compounds from consumer products.

Developing substitute materials to replace these chemicals, or new processes to reduce and eliminate their presence as impurities in products, has been a significant technical challenge. Nevertheless, there has been considerable progress in the development and introduction of substitutes and alternatives. Many substitutes are shorter-chain compounds that still provide the needed functionality, but lack the toxicity and bioaccumulation potential of the longer-chain chemicals.

PFCs and PFC precursors present considerable scientific challenges, including development and assurance of accurate and reproducible results in chemical analyses. Leading companies in the industry have been working cooperatively with other parties to address these scientific challenges, and continue to be committed to establish scientifically credible analytical standards and laboratory methods for measuring these chemicals and to continue research to better understand the sources, pathways of exposure, and potential risks of these chemicals.

Background

The Business and Industry Advisory Committee to the OECD (BIAC) Fluoro Chemicals Team proposed *PFOA Emission and Release Reduction* as an emerging policy issue for consideration by ICCM2. The U.S. Government proposed *Managing Perfluorinated Chemicals and Transitioning to Safer Alternatives* as an emerging policy issue. Both submissions called for the establishment of a voluntary stewardship programs at the international and national level with the aim to reduce the emissions and releases of PFOA and other PFCs. In addition, the U.S. proposal included support for the development and introduction of alternatives.

Both proposals, from BIAC and U.S., are based on experiences to date by Organisation for Economic Co-operation and Development (OECD) countries and the recommendations from the <u>OECD</u> <u>Workshop on Perfluorocarboxylic Acids (PFCAs) and Precursors</u> ("2006 OECD Workshop on PFCs") held in Sweden in November 2006. In addition, a recent international Workshop on PFCs, <u>Managing Perfluorinated Chemicals and Transitioning to Safer Alternatives</u> ("2009 PFCs Workshop"), hosted by United Nations Environment Programme (UNEP) and the U.S. Environmental Protection Agency (EPA) in Geneva, Switzerland, on 12-13 February, 2009, had similar recommendations to those

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expressed at the 2006 OECD Workshop on PFCAs, especially a recommendation to establish voluntary stewardship program(s) at the international and national level with the aim to reduce and work toward elimination of emissions and product content of PFCs internationally.

Magnitude of the problem

The worldwide presence, combined with the persistence, toxicity, and bioaccumulative potential of certain perfluorinated compounds has created international concern.,

Bullets below, from the 2006 OECD Workshop on PFCs, summarize the problem and identify data needs:

- The widespread occurrence of certain perfluorinated compounds in the environment, in certain animal species, as well as in humans, has attracted great attention. Some perfluorinated compounds are known to be persistent. Some of these compounds are bioaccumulating, in particular those with long carbon chains greater than eight carbons, and some have been reported to cause toxic effects in laboratory animals;
- PFCAs in the environment come from different sources. Examples of point sources are production plants, e.g. production of fluorotelomers, fluoropolymers, or APFO. Another possible source of the wide occurrence of PFCs in the environment has been reported to be releases of PFCA-precursors, such as fluorotelomer alcohols, from products. PFCA-precursors are present in the products either as residuals or can possibly be formed through degradation of fluorotelomer-based substances. Another source that has been identified is release of PFCs from the manufacture of fluoropolymers, such as polytetrafluoroethylene (PTFE).
- Further studies, such as biomonitoring studies and multi-media studies, are needed to clarify direct and indirect sources of PFCs and to inform on human and environmental exposure assessment;
- Toxicity studies are needed especially on PFCs with chain lengths other than those of PFOS and PFOA, and on precursors to PFCs;
- Further studies are needed regarding toxicokinetics, growth, development, hepatic effects tumorogenicity;
- Further studies are needed to address bioaccumulation and biomagnification potential in wildlife other than fish.

Additional issues and data needs were raised at the 2009 PFCs Workshop in Geneva:

- Various end groups of fluorinated chemicals are reactive, primarily through oxidation, to yield PFCs. These chemicals have been demonstrated to yield PFCs via multiple pathways;
- A large number of PFC precursors likely contributes to the environmental dissemination and burden of PFCs, and it's clear that humans are exposed through multiple pathways;
- Fluorinated polymers remain a large potential source of PFC production;
- Reactive intermediates in the transformation process from PFC precursors to PFCs should be examined for potential toxicity;
- Other per- and poly-fluorinated chemicals, not just PFOA and PFOS, need to be further examined.

In 2002, OECD released the Hazard Assessment and Recommendations on PFOS and its Salts.

In 2008, OECD released the Screening Information Data Set (SIDS) Initial Assessment Profile on PFOA.

Relevance of the issue

At the 2006 OECD Workshop on PFCs, participants identified the following recommendations for actions to address the risks presented by these chemicals:

- Encourage member countries to launch outreach efforts to promote risk reduction programmes (in particular the present US/Canada Stewardship Programmes) and play a coordinating role in collating information on available programmes;
- Encourage BRIC-countries and other non-OECD countries to be involved in programmes similar to the US Stewardship Programme aimed at reducing exposure levels. Governments and Industry should report to the OECD ongoing scientific risk assessments and risk reduction programmes in place that are aimed at reducing potential exposures;
- Encourage Industry to share information on technologies effective in reducing environmental releases;
- Encourage Governments to support companies to provide information on the chemical content of articles in the form of labeling or web-based product content disclosures;
- Encourage Governments to support Industry to apply the basic principles of Green Chemistry to new product development.

The 2009 PFCs Workshop had similar outcomes and included several consistent themes that emphasized:

- The need for more information while recognizing that information is already sufficient to warrant necessary cooperative action;
- The need to continue to raise and broaden awareness;
- The need to enhance the application of technologies to reduce exposure and monitoring activities;
- The need to raise interest in tapping supply and demand to facilitate transitioning to alternatives; and
- The need for international engagement with stakeholders and a range of cooperative actions.

Extent to which the issue is a cross-cutting nature

International interest to reduce and work toward elimination of emissions and product content of relevant PFCs of concern needs the involvement of government, business, and civil sectors interested in working together. A multi-country multi-stakeholder effort is needed first identify those relevant PFCs of concern, then to work toward reduction of emissions and product content, while encouraging the development and introduction of substitutes. Additionally, effort is needed to provide information regarding monitoring, emissions, exposure, environmental fate and transport, bioaccumulation, as well as potential effects on human health and the environment.

The 2006 OECD Workshop on PFCs summarized the then current knowledge on the chemistry of PFOS, PFOA, their precursors and higher homologues, environmental monitoring, long-range transport, health implications, environmental implications, uses, sources, and on-going risk reduction activities, and identified the data gaps and research needs. The 2009 PFCs Workshop, hosted by UNEP and the EPA, reviewed the latest updates on the efforts to manage PFCs and explored potential cooperative actions on managing PFCs.

Extent to which the issue is being addressed by other bodies

The Stockholm Convention Secretariat reviewed the nomination status of PFOS and perfluorooctanesulfonyl fluoride (PFOSF), the primary intermediate for synthesis of PFOS and PFOS-related substances, for listing under either Annex A or B of the Convention, which will be considered at the next Conference of the Parties in May, 2009. Several issues associated with the listing were noted, including PFOS' uses in processes versus products, confidential business information (CBI), exemptions, acceptable uses, and alternatives. Information sharing and capacity building with policy formulation, implementation, and technology conversion were highlighted as needs for developing countries while the listing would also enable access to financial assistance. Despite this progress, some perfluorinated chemicals may not satisfy the scientific criteria necessary to be listed under the Convention and other actions can be taken in tandem with the pursuit of such listings or other national actions.

A 2009 PFC survey by OECD will endeavor to collect more reliable data on the production and use of relevant PFCs, including information from producers on environmental releases of targeted substances from manufacturing and the content of targeted substances in products. The OECD is also following-up on additional recommendations from 2006, particularly to engage non-participating countries in this work, and to also consider how its work might inform or be coordinated with the Stockholm Convention Secretariat.

Additional updates by countries on their efforts to manage PFCs are available at the <u>2009 PFCs Workshop</u> website.

Proposed actions and potential cooperative actions

The overarching proposed cooperative actions are to:

- 1. support development of and participation in voluntary national and international PFC stewardship programs to reduce and work toward elimination of emissions and product content of relevant PFCs of concern, and
- 2. promote information exchange on more acceptable, economically viable alternatives, and their use, as called for by SAICM OPS Article 15(g). This includes PFCs with shorter carbon chain lengths.

Information exchange should also include progress on and examples of regulatory actions, voluntary programs, monitoring, emissions, exposure, environmental fate and transport, as well as potential effects on human health and the environment, as called for by SAICM OPS Article 15(b).

Participants may also wish to recognize and support the continued progress of existing programs and activities, such as those emanating from the 2006 OECD Workshop on PFCs, in addition to supporting, and where relevant or possible, contributing information to the recently developed <u>OECD Survey of Product Content and</u> Environmental Release Information on PFOS, PFOA, their Related Substances and Product/Mixtures Containing these Substances.

Parties to the Stockholm Convention on Persistent Organic Pollutants (POPs) may wish to also consider nominating relevant PFCs that meet the scientific criteria for listing under the Convention.

For more details on potential and proposed cooperative actions, see the attached paper on PFCs Cooperative Actions and accompanying Annexes below.

Feasibility of the actions proposed

The proposed actions complement previous recommendations, ongoing work and outcomes of the recent 2009 PFCs Workshop. The actions are also consistent with key components of the Strategic Approach's Dubai Declaration (Articles 14, 17, 19), numerous objectives and sub-objectives of the Overarching Policy Strategy (as contained in Articles 14, 15, 16 & 17) and various aspects of the Global Plan of Action (Executive Summary Articles 7 & 8, several work areas and activities).

Notably, the recent 2009 PFCs Workshop helped focus attention and call for appropriate action on relevant PFCs of concern in line with OPS Article 24 (j), which pertains to functions of the Conference, SAICM's governing body, and with regard to emerging policy issues. This helped to prepare and present for consideration by the Conference on PFCs as a priority for cooperative action.

Perhaps the strongest support in terms of feasibility can be found in the following observations and outcomes stemming from the implementation of the U.S. PFOA Stewardship Program. First, the effort has involved agreed commitments and timeframes on behalf of senior political and organizational leadership, flexibility in pursuit of meeting the commitments and periodic reporting and transparency to report progress. Second, initial results from the Stewardship Program along with other regulatory actions have resulted in emission and use reductions of PFCs including reductions in blood levels in the U.S. population. In November 2007, the <u>U.S.</u> <u>Centers for Disease Control and Prevention (CDC) reported results from their analysis of U.S. human blood levels of PFOA and PFOS collected in 2003-2004</u> and found a 25 percent reduction of PFOA and 32 percent reduction of PFOS from levels found in samples collected in 1999-2000. CDC attributed this decline largely to efforts by USEPA and industry on PFCs. Further progress by companies to reduce PFOA emissions and product content should contribute to additional reductions in PFOA levels in humans. CDC is continuing this sampling and analysis, and additional reports will be available in the future.

Attachments

Managing Perfluorinated Chemicals (PFCs) and Transitioning to Alternatives

Cooperative Actions

Introduction

The proposed cooperative actions stem from themes discussed at the <u>International Workshop on Managing</u> <u>Perfluorinated Chemicals and Transitioning to Safer Alternatives</u>, held in Geneva, 12-13 February 2009. They also build upon and complement recommendations from a 2006 <u>OECD Workshop on Perfluorocarboxylic Acids</u> (<u>PFCAs</u>) and <u>Precursors</u> held in Sweden in November 2006. While many of these OECD recommendations continue to be implemented, there is a need to supplement them with international action on behalf of ICCM2 participants (see INF document and other background from the Workshops for additional information).

Proposed Cooperative Actions

- 1. Develop and implement voluntary national and international PFC stewardship programs to reduce and work toward elimination of emissions and product content of relevant PFCs of concern.
- 2. Information exchange on:
 - More acceptable, economically viable alternatives, and their use;
 - technology transfer; and
 - progress on and examples of regulatory actions, voluntary programs, monitoring, emissions, exposure, environmental fate and transport, as well as potential effects on human health and the environment.
- 3. Possible contributions to the ongoing implementation of current relevant work and information gathering, e.g., the recently developed <u>OECD Survey of Product Content and Environmental Release Information on PFOS, PFOA, their Related Substances and Product/Mixtures Containing these Substances, including other pertinent actions and activities (see attached Annex).</u>
- 4. Parties to the Stockholm Convention on Persistent Organic Pollutants (POPs) may wish to also consider nominating relevant PFCs that meet the scientific criteria for listing under the Convention.

Participants at ICCM2 will have several options available to them to signal their support for and pursue cooperative actions on PFCs:

- a) At a minimum, PFCs Workshop attendees, those joining the PFCs side event and ICCM2 participants can voice their support during the plenary agenda item on emerging policy issues and could also independently follow-up on and collaborate on such actions.
- b) Proponents could also propose that the Conference recognize its support for these actions by including reference to them amongst those listed in the report of the meeting and its requisite discussion on emerging policy issues.
- c) A stronger option is for the Conference to also consider endorsing the following proposed resolution on PFCs, see Annex 1.
- d) Finally, the Conference may also wish to consider including such cooperative actions amongst the activities listed in the Global Plan of Action, see Annex 2., since they are supported by language contained in its Executive Summary (Article 8) and, while some emerging policy issues may already include commensurate activities listed in the GPA, it would be appropriate to also include others not already listed. It should be noted that the supporting background document on PFCs arguably satisfies other proposals for how activities might otherwise be considered in the future for addition to the GPA and, that this option, to add an emerging policy issue to the GPA, is without prejudice to the broader issue or question of a procedure to with respect to other activities.

Managing Perfluorinated Chemicals (PFCs) and Transitioning to Alternatives

PFCs Cooperative Actions Annex 1.

Draft Resolution

The Conference,

Recognizing that certain perfluorinated chemicals (PFCs) are persistent, are widely present in humans and the environment, have a long half-life in humans, can cause adverse effects in laboratory animals, and that is not well understood how people are exposed to PFCs;

Mindful that developing substitute materials to replace these chemicals, or new processes to reduce and eliminate their presence as impurities in products, has been a significant technical challenge and that additional challenges exist across various levels of development;

Desiring to build from recommendations from the 2006 OECD Workshop on Perfluorocarboxylic Acids (PFCAs) and Precursors in Sweden and themes from the 2009 International Workshop on Managing Perfluorinated Chemicals and Transitioning to Safer Alternatives in Geneva;

Acknowledging that there has been considerable progress with regulatory and voluntary stewardship activities thus far and in the development and introduction of substitutes and alternatives, including shorter chain PFCs, but that more work remains to be done to achieve reductions and promote safer chemistries;

Pursuing implementation of the *Strategic Approach* objectives on risk reduction and knowledge and information with an emphasis on minimizing risks to human health throughout the life cycle of chemicals, ensuring that new and emerging issues are sufficiently addressed through appropriate mechanisms, promoting and supporting the development of safer alternatives and informed substitution, making information available and accelerating the pace of research;

- 1. **Agrees** that reducing exposure to certain perfluorinated chemicals (PFCs) contributes to strengthening chemicals management and activities to implement SAICM consistent with strategic priority (b) of the SAICM Quick Start Programme;
- 2. **Invites** the IOMC as part of their mandates and work programmes in support of strengthened SAICM implementation and risk management to facilitate an open, multi-stakeholder steering committee to develop a program, help secure commitments, track progress, collect and share information more broadly on actions, technologies, and alternatives related to the management of relevant PFCs, reductions toward elimination of relevant PFC releases and product content, and transitioning to more acceptable chemistries;
- 3. Urges participants in the *Strategic Approach* Governments, regional economic organizations, industry, non-governmental organizations and intergovernmental organizations, to participate in this activity and commit to national or an international stewardship program to reduce and work toward elimination of emissions and product content of relevant PFCs of concern;

- 4. **Encourages** the SAICM Secretariat to also participate in and help service the work of the steering committee and the IOMC to help share information on its progress at regional meetings and through its Clearinghouse function, including on: technologies to reduce potential exposures to relevant PFCs, the results of research, effects and monitoring information and to also help promote safer alternatives;
- 5. **Recognizes** that facilitating this activity and achieving its commitments may require sufficient human, financial and in-kind resources and that different participants at different levels of development may have additional assistance needs, thereby encourages participants in the *Strategic Approach* to provide such resources on a voluntary basis.
- 6. **Invites** the IOMC, stewardship programme and Steering Committee participants, SAICM Secretariat and other interested stakeholders to meet intersessionally and on the margins of relevant meetings, e.g., the 2010 and 2011 Commission on Sustainable Development and other Regional meetings, to make further progress on commitments, provide updates and share information and to report on its work to future sessions of the Conference.

Managing Perfluorinated Chemicals (PFCs) and Transitioning to Alternatives

PFCs Cooperative Actions Annex 2.

Work area	Activities	Actors	Targets/	Indicators of	Implementation aspects
			Timeframe	progress	
Managing PFCs and Transitioning to Alternatives	1. Develop and implement national and international PFC stewardship programs to reduce and work toward elimination of emissions and product content of relevant PFCs of concern.	National Governments Industry IOMC NGO	2009 - 2015	Emission and product content reductions.	Consider consistent reporting template/format for participants agreeing to commitments.
	2. Develop and exchange information on: safer economically viable alternatives, and their use; technology transfer; and progress on and examples of regulatory actions, voluntary programs, monitoring, emissions, exposure, environmental fate and transport, as well as potential effects on human health and the environment.	Industry National Governments IOMC Academia NGO	2009 - 2020	Number of available and viable alternatives; growing collection of materials and information available on various actions, monitoring and effects information.	Could utilize SAICM Secretariat Clearinghouse function among other outreach mechanisms of the IOMC, etc.
	3. Contribute to the ongoing implementation of current relevant work and information gathering, e.g., the recently developed <u>OECD Survey</u> of Product Content and <u>Environmental Release Information</u> on PFOS, PFOA, their Related <u>Substances and Product/Mixtures</u> <u>Containing these Substances</u> , including other pertinent actions and activities.	IOMC National Governments Industry NGO	2009 - 2020	Survey response rates and enhanced availability of information.	This could also be facilitated via the SAICM Secretariat Clearinghouse function and in coordination with the IOMC.
	4. Parties to the Stockholm Convention may wish to also consider nominating relevant PFCs that meet the scientific criteria for listing under the Convention.	National Governments	2009-2015	New/additional PFCs proposed for and listed under the Convention.	This can normally take several years and could be conducted in tandem with other activities.