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Persistent Organic Pollutants Review Committee
Third meeting**

Geneva, 19–23 November 2007

Item 6 (e) of the provisional agenda*

Consideration of draft risk management evaluations: perfluorooctane sulfonate

Draft risk management evaluation: perfluorooctane sulfonate

Note by the Secretariat

1. At its second meeting, the Persistent Organic Pollutants Review Committee adopted decision POPRC-2/5 on perfluorooctane sulfonate.¹ By paragraph 4 of the decision, the Committee decided to establish an ad hoc working group to prepare a risk management evaluation that included an analysis of possible control measures for perfluorooctane sulfonate in accordance with Annex F to the Convention.
2. The members of the ad hoc working group on perfluorooctane sulfonate and its observers are listed in annex V of document UNEP/POPS/POPRC.2/17.
3. A standard workplan for the preparation of a draft risk management evaluation was adopted by the Committee at its second meeting.²
4. In accordance with decision POPRC-2/5 and the standard workplan adopted by the Committee, the ad hoc working group on perfluorooctane sulfonate prepared the draft risk management evaluation set forth in the annex to the present note. The draft risk management evaluation has not been formally edited.

Possible action by the Committee

5. The Committee may wish:
 - (a) To adopt, with any amendments which it deems appropriate, the draft risk management evaluation set forth in the annex to the present note;

* UNEP/POPS/POPRC.3/1/Rev.1.

1 UNEP/POPS/POPRC.2/17, annex I.

2 Ibid., para. 39 and annex II B.

(b) To decide, in accordance with paragraph 9 of Article 8 of the Convention, based on the risk profile adopted at its second meeting (UNEP/POPS/POPRC.2/17/Add.5) and the risk management evaluation, whether the chemical should be recommended for consideration by the Conference of the Parties for listing in Annexes A, B, and/or C.

Annex

PERFLUOROOCTANE SULFONATE

DRAFT RISK MANAGEMENT EVALUATION

Draft prepared by the ad hoc working group on
Perfluorooctane sulfonate
under the Persistent Organic Pollutants Review Committee
of the Stockholm Convention

August 2007

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Executive summary

PFOS and 96 PFOS-related substances were proposed as a POPs candidate by Sweden in 2005. The 2nd meeting of the POPs Review Committee decided that PFOS is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects, such that global action is warranted.

PFOS is both an intentionally produced substance and an unintended degradation product of related anthropogenic chemicals. Under the Convention, the most adequate control measures include listing in Annex A or B and/or C. To allow for certain critical uses of PFOS and PFOS-related substances, which may ultimately degrade to PFOS, an acceptable purpose/specific [time-limited] exemption for use of PFOS and production of PFOS as an intermediate, only as required to produce other chemical substances designated for these critical uses, could be given together with a detailed description of the conditions for these uses in a new Part III to Annex A or B. [Listing in both Annex A and C or Annex B and C would address the manufacture, use, sale, import, and export of PFOS as well as the unintentional formation of PFOS from PFOS-related substances.] Stockpiles and waste containing PFOS or PFOS-related substances would be subject to the provisions in Article 6.

1. Introduction

1.1 Chemical identity of the proposed substance

On July 14, 2005, the government of Sweden made a proposal for listing perfluorooctane sulfonate (PFOS) and 96 PFOS-related substances in Annex A of the Stockholm Convention on Persistent Organic Pollutants (POPs).

1.1.1. PFOS

Chemical name: Perfluorooctane Sulfonate (PFOS)

Molecular formula: C₈F₁₇SO₃⁻

PFOS, as an anion, does not have a specific CAS number. The parent sulfonic acid has a recognised CAS number (CAS No. 1763-23-1). Some examples of its commercially important salts are listed below:

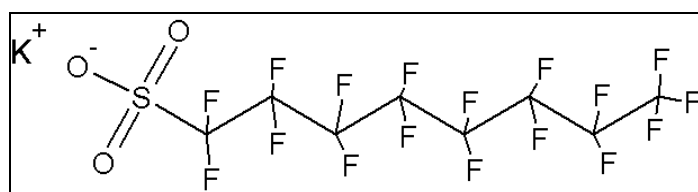
Potassium salt (CAS No. 2795-39-3)

Diethanolamine salt (CAS No. 70225-14-8)

Ammonium salt (CAS No. 29081-56-9)

Lithium salt (CAS No. 29457-72-5)

Structural formula: Structural formula of PFOS shown as its potassium salt



1.1.2. Issues regarding PFOS-related substances

PFOS is a fully fluorinated anion, which is commonly used as a salt or incorporated into larger polymers. PFOS and its closely related compounds, which may contain PFOS impurities or substances which can give rise to PFOS, are members of the large family of perfluoroalkyl sulfonate substances. In its regulatory measures on PFOS, the European Union (EU) has addressed all molecules having the following molecular formula: C₈F₁₇SO₂Y, where Y = OH, metal or other salt, halide, amide and other derivatives including polymers (European Union, 2006). In the context of this draft risk management evaluation, this definition of PFOS has been used.

PFOS can be formed (by environmental microbial degradation or by metabolism in larger organisms) from PFOS-related substances, i.e., molecules containing the PFOS-moiety. Although the ultimate net contribution of individual PFOS-related substances to the environmental loadings of PFOS cannot be predicted readily, there is a potential that any molecule containing the PFOS moiety could be a precursor to PFOS. This is further supported by modelling the fate of perfluorinated chemicals (PFCs) in the environment (Canada, 2007).

The majority of PFOS-related substances are polymers of high molecular weights in which PFOS is only a fraction of the polymer and final product (OECD, 2002). PFOS-related substances have been defined somewhat differently in different contexts and there are currently a number of lists of PFOS-related substances containing varying numbers of PFOS-related substances that are thought to have the potential to break down to PFOS.

The Organisation for Economic Co-operation and Development (OECD), within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) has published "Risk Management Series No.21: Preliminary lists of PFOS, PFAS, PFOA and related compounds, and chemicals that may degrade to PFCA (ENV/JM/MONO(2006)15)". Annexes I and II contain Lists of Perfluorooctane Sulfonate (PFOS) and Related Compounds and Perfluoroalkyl Sulfonate (PFAS) and Related Compounds. These lists are currently being updated and the updated lists are due to be published shortly.

DEFRA in the United Kingdom (RPA and BRE, 2004) has recently proposed a list of 96 PFOS-related substances. However, the properties of the 96 substances have not generally been determined. According to 3M (submission to the secretariat of Stockholm Convention (SC), 2006), they may have very different environmental characteristics such as solubility, stability and ability to be absorbed or metabolised. Nevertheless, the document by the United Kingdom infers that all of these substances would give rise to PFOS as their final degradation product (RPA and BRE, 2004).

Environment Canada's ecological risk assessment defines PFOS precursors as substances containing the perfluorooctylsulfonyl ($C_8F_{17}SO_2$, $C_8F_{17}SO_3$, or $C_8F_{17}SO_2N$) moiety that have the potential to transform or degrade to PFOS (Canada, 2007). The term "precursor" applies to, but is not limited to, some 51 substances identified in the ecological assessment. However, this list is not considered exhaustive, as there may be other perfluorinated alkyl compounds that are also PFOS precursors. This information was compiled based on a survey to Canadian industry, expert judgement and CATABOL modelling, in which 256 perfluorinated alkyl compounds were examined to determine whether non-fluorinated components of each substance were expected to degrade chemically and/or biochemically and whether the final perfluorinated degradation product was predicted to be PFOS. While the assessment did not consider the additive effects of PFOS and its precursors, it is recognized that the precursors to PFOS contribute to the ultimate environmental loading of PFOS. Precursors may also play a key role in the long-range transport and subsequent degradation to PFOS in remote areas, such as the Canadian Arctic.

A preliminary substance flow analysis for Switzerland in 2005 based on the international literature estimated remaining PFOS-related substances in products after the retreat of 3M products to be approximately 230 kilogram /a. (Switzerland, 2007)

1.2 Conclusions of the Review Committee Annex E information

The POPs Review Committee has developed and adopted the risk profile for perfluorooctane sulfonate contained in document UNEP/POPS/POPRC/17/Add.5, in accordance with Annex E of the Convention. The Committee concluded, in accordance with paragraph 7 (a) of Article 8 of the Convention, that perfluorooctane sulfonate is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects such that global action is warranted (Decision POPRC-2/5). The Committee also concluded (item 3 of the Decision) that issues related to the inclusion of potential perfluorooctane sulfonate precursors should be dealt with in developing the draft risk management evaluation for perfluorooctane sulfonate.

1.3 Data sources

Data relating to Annex F were submitted by the following Parties: Algeria; Armenia; Australia; Brazil; Canada; Czech Republic; European Commission; Former Yugoslav Republic of Macedonia; Germany; Japan; Mauritius; Monaco; Switzerland, and the following observers: European Photo and Imaging Association; European Electronic Component Manufacturers Association; International Imaging Industry Association; European Semiconductor Industry Association (EECA-ESIA); International Indian Treaty Council (IITC)- Indigenous Environmental Network (IEN); International POPs Elimination Network (IPEN); Japan Electronics and Information Technology Industries Association –Japan Semiconductor Industry Association (JEITA-JSIA); Photo Sensitized Materials Manufacturers' Association; Semiconductor Industry Association (SIA); Semiconductor Equipment and Materials International (SEMI) and United States of America

1.4 Status of the chemical under international conventions

PFOS is undergoing risk management evaluation under the UNECE Convention on Long-Range Trans-Boundary Air Pollution (LRTAP) Protocol on POPs. The POPs Task Force met in Vienna in June 2007 to explore possible risk management options for PFOS. The evaluation produced by the Task Force will be submitted to the Working Group on Strategies and Review in September 2007 and the Executive Body in December 2007 for further consideration.

1.5 Any national or regional control actions taken

Australia has produced three Alerts concerning PFOS through its National Industrial Chemicals Notification and Assessment Scheme (NICNAS). PFOS-based chemicals are not currently manufactured in Australia; however products containing these chemicals have been made and are used in Australia.

The first Alert indicated the phasing-out of water, oil, soil and grease repellent products containing PFOS by September 2002. As well, the use of PFOS for leather products was to be phased out by March 2003. Stocks of PFOS fire fighting foams are being held at some sites in Australia. These will be replaced as they run past the expiry date or when stocks run out. NICNAS is looking at developing a strategy to phase out use of PFOS in Australia.

The second Alert makes recommendations regarding PFOS, perfluorosulfonates (PFAS) and perfluorooctanic acid (PFOA). These recommendations include:

- that PFOS (and PFAS-based chemicals) be used only for essential uses for which there is no suitable alternative, such as certain class B fire fighting foams, but not for use in fire training exercises; and
- that caution be used in selecting PFOA as an alternative for PFOS since PFOA may show the same environmental and health concerns as PFOS.

The third Alert published in February 2007 updates the uses of PFOS and related substances in Australia. The recommendations in this Alert include:

- PFOS (and PFAS-based chemicals) be used only for essential uses for which there is no suitable alternative.
- The existing PFOS-based fire fighting foam not be used for fire training purposes to limit environmental release.
- PFOS not be replaced by PFOA as an alternative, as PFOA may have the same environmental and health concerns as PFOS.

Canada has proposed regulations to prohibit the production and use of PFOS and its salts and substances that contain on of the following groups: C8F17SO₂, C8F17SO₃ or C8F17SO₂N (Canada 2007 [Canada Gazette, vol. 140, No 50, December 16, 2006]).

The proposed regulations for PFOS would:

- prohibit the manufacture, use, sale, offer for sale and import of PFOS or products containing these substances;
- exempt the use of PFOS-based aqueous film-forming foam, sometimes also referred to as aqueous fire fighting foam (AFFF), manufactured or imported before the coming into force of the proposed Regulations for a period of five years after the coming into force of the proposed Regulations (but this AFFF may not be used for training or testing purposes);
- exempt the use of PFOS-based fume suppressants, and sale, offer for sale and import for that use, for a period of five years after the coming into force of the Regulations for chromium electroplating, chromium anodizing, reverse etching, electrolysis nickel-polytetrafluoroethylene plating and etching of plastic substrates prior to their metallization;
- exempt the use, sale, offer for sale and import of the following manufactured items: semiconductor or similar components of electronic or other miniaturized devices and photographic films, papers and printing plates;
- exempt the use, sale and offer for sale of manufactured items, that were manufactured or imported before the coming into force of the proposed Regulations; and
- provide standard exemptions for laboratories, scientific research and laboratory analytical standards.

Importers of PFOS-based fume suppressants will be required to submit annual reports detailing types, quantities, sales and end uses for the substances that are imported.

The European Union has adopted Directive 2006/122/EC of the European Parliament and the Council Directive 76/769/EEC of the Council of 12 December 2006 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use and preparations of perfluorooctane sulfonates and related substances. The restrictions include the following:

- PFOS and related substances will be banned as substances or constituents of preparations in concentrations equal to or higher than 0.005%, in semi-finished products and articles at a level of 0.1% except for textiles or coated materials in which the restricted amount of PFOS will be 1 µg/m².

- Exemptions were provided for the following PFOS uses, as well as for the substances and preparations needed to produce them: photoresists or anti-reflective coatings for photolithography processes, industrial photographic coating, mist suppressants for chromium plating and other electroplating applications, as well as aviation hydraulic fluids; in addition, stocks of PFOS-based AFFF supplied on or before the date 12 months before the legislation comes into force may be used for a period of 54 months.

The United States Environmental Protection Agency (US EPA) has adopted federal Significant New Use Rules (SNURs) for 88 PFOS substances which apply to new manufacture and new uses of these substances. A proposed SNUR for 183 additional perfluoroalkyl sulfonate substances was posted in April 2006 for public consultations, and the publication of the final SNUR is expected in 2007. The SNURs require manufacturers and importers to notify the US EPA at least 90 days before manufacture or import of these substances for any use other than certain narrow, ongoing uses. This provides the US EPA with the necessary time to evaluate the intended new use and prohibit or limit the new activity, if necessary. While the SNURs did not require current manufacturers to stop manufacturing or selling the substances, the primary manufacturer in the United States voluntarily discontinued production between 2000 and 2002. Therefore, once the SNURs pertaining to the 88 substances became effective, they essentially restricted all manufacture and importation of PFOS other than manufacture and importation other than for certain specific uses, excluded from the SNURs. Those uses include:

- use in aviation hydraulic fluids;
- as a component of a photoresist substance, including a photo acid generator (PAG) or surfactant, or as a component of an anti-reflective coating used in a photomicro lithography process to produce semiconductors or similar components of electronic or other miniaturized devices;
- in coatings for surface tension, static discharge, and adhesion control for analogue or digital imaging films, papers and printing plates; and
- as an intermediate only to produce other chemical substances to be used solely for the uses listed above.

Public comments on the proposed SNUR for 183 additional substances indicated that at least one of these chemicals is currently being used for acid mist suppression in metal plating operations, and requested that such use also be excluded from the SNUR. These comments will be addressed in the final SNUR.

The US EPA also negotiated a phase-out of PFOS-related pesticide products containing sulfluramid, a substance that is manufactured using a PFOS derivative and will degrade to PFOS, or the lithium salt of PFOS (LPOS), concurrently with the 2002 publication of the final SNUR on 88 PFOS substances. Sulfluramid and LPOS were formulated in bait stations for use in the control of ants, cockroaches, termites, wasps, and hornets, and in one granular broadcast bait for use in the control of leaf cutter ants in pine reforestation areas. The registrants associated with those products agreed to voluntarily cancel some of their products and to phase out the remaining products under an agreed-upon timeline. The continuing products being phased out were produced using stocks of sulfluramid produced before the completion of the PFOS production phase-out in the US in 2002.

2. Summary information relevant to the risk management evaluation

2.1 Identification of possible control measures

The objective of the Stockholm Convention (Article 1) is to protect human health and the environment from persistent organic pollutants. When assessing control measures under the Convention, consideration should be given to the potential for all PFOS-related substances to degrade to PFOS and thus contribute to the total environmental load. When assessing whether specific exemptions would be appropriate, among other considerations identified in Annex F to the Convention, factors such as exposure; production volume; and societal costs and the ubiquitous contamination of humans, the environment and possible impact on future generations should be considered.

Under the convention this may be achieved in different ways.

- PFOS and/or PFOS-related substances may be listed in Annex A, with or without specific exemptions, or accompanied with a new Part III that details actions for each or groups of PFOS-related substances or uses of such substances; or
- PFOS and/or PFOS-related substances may be listed in Annex B, with acceptable purposes/specific exemptions or a Part III of Annex B that details actions for each or groups of PFOS-related substances or uses of such substances; or
- PFOS may be listed in Annex C as an unintentional POP to capture all PFOS-related substances that may give rise to PFOS when released into the environment; or

- PFOS may be listed in Annex A or B, as described above, and at the same time also be listed in Annex C.

In the Annex F process, some certain uses have been identified by Parties and observers. They may be grouped into two subgroups.

A. Based on the information submitted to the Secretariat, technically feasible alternatives may not be available for certain uses. These uses are: photo imaging, photo mask ; semi-conductor; aviation hydraulic fluids; radio-opaque catheters, such as catheters for angiography and indwelling needle catheters; and manufacture of ant baits for leaf-cutting ants.

B. Based on the information submitted to the Secretariat, the uses for which alternative substances or technologies are or may be available but would need to be phased in. These uses are: metal plating; electric and electronic parts; and fire fighting foam.

These uses and the potential substitutes will be further described in section 2.3 below.

2.2 Efficacy and efficiency of possible control measures in meeting risk reduction goals

The phase-out and regulation in the US successfully reduced the volume of these chemicals produced and/or used in the U.S. from approximately 2,900 tonnes in 2000 to less than 8 tonnes in 2006.

Canada has provided a cost-benefit analysis for the proposed Canadian regulation of PFOS and PFOS-related substances. The key assumptions used in the cost-benefit analysis included:

- Time frame: The proposed control measures could come into force in 2009, with the exemption for AFFF and the metal plating sector expiring 5 years later in 2014;
- Time span for analysis: A time frame of 25 years is selected to account for the life span of PFOS containing AFFF as well as the service life of metal plating equipment. Thus, the analysis time frame is 2008 to 2032;
- Cost and benefit perspective: costs and benefits which directly or indirectly affect human health and the environment are included in the analysis to the extent possible;
- Discount rate: A discount rate of 5.5%, and all monetized costs and benefits are expressed in 2006 €or US\$.

For Canada the net benefits of the proposed regulations were estimated at US\$337 000. It should be noted that this does not include benefits to the ecosystem as these could not be quantified due to data limitations and uncertainties (Canada, 2007).

2.3 Information on alternatives (products and processes), where relevant³

The POPRC has agreed that PFOS is likely a POP due to its long-range environmental transport and significant adverse human health and environmental effects such that global action is warranted. The target or aim of any risk reduction strategy for PFOS should be to reduce or eliminate emissions and releases taking into consideration the indicative list in Annex F including technical feasibility of possible control measures and alternatives, the risk and benefits of the substances and their continued production and use. In considering any strategy for a reduction in such risks, it is important to consider the availability of substitutes in the sectors of concern. In this regard, the replacement of a PFOS-related substance by another chemical or an alternative system needs to take account factors such as:

- technical feasibility
- costs, including environmental and health costs
- efficacy
- risk
- availability and accessibility

A discussion of the availability and suitability of substitutes for the 'continuing uses' of PFOS-related substances is provided below. The discussion focuses on continuing uses; in the absence of information to the contrary, substitution is considered to already have taken place in the other sectors.

A significant proportion of previous users of PFOS-related substances have moved to other fluorochemical products (telomers and related products). These telomers are not related to PFOS but under certain circumstances may degrade to perfluorooctanoic acid (PFOA) or related perfluorinated carboxylic acids. It is important to note that, while there is little information currently available to assess the environmental and health impacts of telomers, extensive work is currently on-going in the U.S. and other countries where there is some concern over the fate and behaviour of these

³ Not relevant for unintentionally produced POPs

substances. Until these studies are concluded, it will not be possible to draw any firm conclusions concerning the environmental/human health advantages of telomers and related products over the PFOS-related substances for which they have been substituted.

The manufacture of PFOS has been phased out in several countries, including the U.S., as indicated in Section 1.5 above. There is no manufacture of PFOS in Canada or Australia. Manufacture of PFOS and PFOS-related substances occurs in certain countries as noted in the survey conducted by the Organization for Economic Cooperation and Development in 2006 (OECD, 2006).

A. Uses for which at present, according to responses received, no technically feasible alternatives are available

In addition to those listed below, it has recently been reported that another use for which there may be no alternatives would be use as a component of an etchant (including a surfactant or fume suppressant), used in the plating process to produce electronic devices. Further information on this use is not available.

2.3.1 Photo imaging

According to the photographic industry, chemicals or classes of chemicals that may be considered alternatives to PFOS or PFOS-related substances on an industry-wide basis (or even a company-wide basis) are reported as not currently being available. Successful alternatives to PFOS materials have included non-perfluorinated chemicals such as hydrocarbon surfactants, chemicals with short perfluorinated chains (C3 - C4), silicones, telomers. In very few cases, it has been possible to reformulate coatings so that they are inherently less sensitive to static build-up.

According to the industry, the imaging products/applications where there are currently no identified alternatives to PFOS-related substances and which represent critical uses are as follows:

- surfactants for mixtures used in coatings applied to films, papers, and printing plates; PFOS chemicals are critical for creating coatings of high complexity in a highly consistent manner, thus avoiding the creation of large amounts of waste due to irregularities in coating thickness;
- electrostatic charge control agents for mixtures used in coatings applied to films, papers, and printing plates. The antistatic properties of PFOS materials also provide important safety features by controlling the build-up and discharge of static electricity, thus preventing injuries to employees and users, damage to operating equipment and products, and fire and explosion hazards;
- friction control and dirt repellent agents for mixtures used in coatings applied to films, papers, and printing plates; and
- adhesion control agents for mixtures used in coatings. Adhesion control is a property imparted to film coatings as a result of the use of PFOS materials as coating aids.

Estimates of releases from the photo imaging industry, as developed by UK Defra, are 1.02 kilogram into waste water and 0.051 kilogram into air from manufacturing uses in the EU. The industry estimates a total of less than 2 kilogram worldwide, by extrapolation.

Personal and area monitoring in the workplace show that airborne concentrations are below the level of detection (< 0.013 mg/m³). A study on worker exposure to PFOS during manufacturing indicates a dose-responsive association of fluoride exposure with spontaneous abortions in female workers (RR = 1.79 95% CI = 1.22-2.54) and photoresist chemicals (RR = 1.35 – 2.18 95% CI = 0.89 – 2.01; 1.30 – 3.40, respectively), although correlation was not with PFOS specifically.⁴

Most consumer and professional imaging papers do not contain PFOS-related substances. For papers that do contain the substances, the coatings contain concentrations in the range of 0.1-0.8 µg/cm². Most of this material will not be on the surface of the coating as the PFOS-related substance is contained within a matrix and is bound to coating matrices.

The cost, so far, for replacement of PFOS materials is estimated to be in the range of €20-40 M for the full range of imaging products. These costs are based on the estimated cost of achieving the current reduction of 83% in the use of PFOS-related substances. The cost to be incurred from further work on replacements (for the remaining 17%) is expected to be significantly higher than the above figure as the replacement work is increasingly more difficult.

⁴ Schenker MB, Gold EB, Beaumont JJ, Eskenazi B, Hammond SK, Lasley BL, McCurdy SA, Samuels SJ, Saiki CL, Swan SH. (1995) Association of spontaneous abortion and other reproductive effects with work in the semiconductor industry. *American Journal of Industrial Medicine* 28:639 – 659.

Based on the previous cost estimates of US\$20-40 M for reduction that took place between 2000 and 2004, i.e., a reduction of roughly 15 tonnes, the average cost is US\$2 M per tonne. Further reductions are estimated to cost more than twice as much, up to US\$5 M per tonne. The cost of substituting the remaining 10 tonnes would be US\$50 M. Since only 2 kilogram is estimated to be released into the environment the cost of reducing the release to zero, using these estimates would be US\$25 M per kilogram. This calculation indicates the level of magnitude of the costs of reducing the release.

2.3.2. Photoresist and Semi-conductor

According to the semi-conductor industry, the operation of PFOS based photo acid generators (PAGs) is critical to the semiconductor industry in the photolithography process. ESIA, JSIA, SIA and SEMI indicate that there are currently no substitutes known that give the same level of critical functionality to cause effective, efficient transformation in leading edge photoresists and which can be used in volume manufacturing.

For anti-reflective coatings used in combination with photoresists, ESIA indicates that there is also no alternative available that fulfils the specific technical requirements necessary (ESIA, 2003). The industry is also evaluating one additional specialized application for which PFOS use may have no current substitute -- use in liquid etchant in the photo mask rendering process.

The semiconductor industry indicates that the industry and its suppliers continue to search for alternatives for these critical uses. The nature of semiconductor production is such that if alternatives to PFOS are eventually identified at the fundamental research stage, critical adjustment to the chemistry of inputs such as PFOS use in the photolithography process will trigger far-reaching adjustments throughout the manufacturing process and supply chain to ensure that the chemical processes throughout the production process remain aligned. Thus, the semiconductor industry believes it could take an additional ten years to design, operationalize and integrate the new technology, once it has been identified, into the semiconductor manufacturing process. According to the industry, the delay is a necessary function of the semiconductor technology development cycle: technological innovations generally require 10 years of further development before they can be reflected in high volume manufacturing (ESIA, JSIA, SIA, SEMI 2007).

It should also be noted that during the chemical formulation of photolithography products, worker exposure potential is very low because the process occurs under highly automated, largely closed system conditions. The same process for electronics fabrication is similarly automated, with a low volume of PFOS used, and use of protective equipment. Chemical isolation is also an intrinsic part of quality control procedures.

Environmental release potentials are deemed to be low. Due to the low vapour pressure of PFOS, and the nature of the process, no emissions to air are expected. However, waste products, including 93% of the resist formulation (PAGs and surfactants) are incinerated. Releases to water are also considered to be negligible. Furthermore, there is no residual PFOS compound present in manufactured microprocessors and therefore no consumer exposure or concern about releases from electronic waste disposal or recycling.

PFOS releases from photolithography uses are small compared with PFOS use in other industry sectors. In 2002 for the whole of Europe, an estimated 43 kilogram of PFOS were released in the effluent from photolithography uses, on the order of only 0.45 percent of all PFOS releases at that time in Europe. Mass balance data for Europe in 2004 indicates an estimated 54 kilogram of these releases. It has been estimated that a similarly small proportion of releases in the United States and Japan is attributable to the photolithography uses, based on recent past use patterns.

It is difficult to quantify the costs that will ultimately be involved in replacing PFOS use in the photolithography industry with alternative substances, given that such alternatives are not currently available. The requirements for innovation and the limits of technical feasibility are the main factors that currently limit access to alternatives. If those hurdles can eventually be overcome, however, there will be substantial costs associated with the transition to the use of alternative substances in the photolithography process. For example, there are likely to be extensive introduction costs associated with bringing a new system into high volume production, including re-qualification costs and possible loss of revenues associated with much lower yield as new systems are brought on line. Many resists are specifically tailored to one individual company's process, which means that a valid replacement for one cannot necessarily be applied industry-wide. Given those uncertainties, the estimate below, derived for this evaluation, is only an indication of the order of magnitude of the costs involved.

Replacing existing resists systems would require extensive R&D followed by a time-consuming manufacturing process re-qualification. The development cost of one completely new photoresists system for the industry has been estimated at US\$192M for 193nm resist, US\$287M for 157nm, and US\$218M for EUV resist. The cost for 157nm resist development is the highest, because it has more novel requirements than either 193nm or EUV resists.

Development costs of a new photoresist system would be US\$700M. Assuming that variable costs are the same as in the present system, it takes 5 years to develop the new system and the time span for the analysis is 25 years. This would imply that the reduction in release of PFOS related substances is equal to 20 years of releases (50 kilogram per

year), i.e. a total of 1000 kilogram. Costs would be US\$0.7M per kilogram PFOS. This calculation indicates the level of magnitude of the costs of reducing the release. By comparison, the semiconductor industry had global sales of \$248 billion in 2006.⁵

The semiconductor industry recently signed an agreement to curtail the use of PFOS-based chemicals at the global level. Under the agreement, members of the World Semiconductor Council, which comprises the trade associations representing the microchip industries of most of the world's leading semiconductor-producing countries (including SIA, ESIA and trade associations in Asia), and SEMI have committed to the following actions: (i) ending non-critical uses for PFOS by specific dates; (ii) working to identify substitutes for PFOS in critical uses for which no other materials are presently available; (iii) destroying solvent wastes from critical uses; and (iv) taking other steps to mitigate the potential environmental impacts of PFOS use in these critical applications.

2.3.3 Photo masks in the Semiconductor and Liquid Crystal Display (LCD) Industries

Photo masks are an essential part of the photolithography process of semiconductor and LCD production. Photo mask production is mainly outsourced from semiconductor or LCD producers to other companies.

Three major photo mask producers in Japan report that a wet process is used in the production of most photo masks. PFOS and PFOS-related substances are contained in etchants for semiconductor and Thin Film Transistor (TFT) panels, because these products require very fine patterning. In the case of photo masks for semiconductors, a dry process is also used for some specific cases. All TFT photo masks are produced using a wet process because of their large size.

The total amount of PFOS (including PFOS moiety in PFOS-related substance) use for this purpose in Japan is estimated at approximately 70 kilogram per year. It is estimated that Japanese companies play a major role in photo mask production, and have more than a 70% share of the worldwide market. Thus it is estimated that total use of PFOS and PFOS-related substances for this use in the world is approximately 100 kilogram.

Because of strong acid of etchants, non-fluoro surfactant is not stable in etchants, thus it is not applicable for this process. Furthermore, other fluoro-surfactants such as shorter chain PFAS are not suitable because their ability to lower surface tension is not sufficient.

A dry etching process is applied to high-end ultra-fine patterns of semiconductor photo masks. However, the yield and productivity of the dry etching process is much (15 to 20 times) lower than the wet process. Furthermore, the dry process is not useable for LCD panels because of their large size (more than 1m by 1m).

2.3.4 Aviation hydraulic fluids

According to information received from one of the major producers of hydraulic fluids, there are no alternatives to the PFOS substances currently being used in aircraft systems and there is no known alternative chemistry that will provide adequate protection to aircraft.

The process of qualifying a new fluid for use in commercial aircraft has historically taken about 10 years from concept to actual commercial manufacture. There are no current alternatives to PFOS substances currently being used in aircraft systems and there is no information on costs or environmental/human health attributes of alternatives.

2.3.5 Use of PFOS derivative in production of ant baits for control of leaf-cutting ants

Sulfluramid (1-octanesulphonamide-N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro; CAS: 4151-50-2), is manufactured using a PFOS derivative (perfluorooctyl sulfonyl fluoride, CAS No 307-35-7). Sulfluramid is the active ingredient in the manufacture of ant baits in ready-to-use formulations and is known to degrade to PFOS. It is estimated that the production of sulfluramid in Brazil is about 30 metric tonnes per annum. Sulfluramid is used at a 0.3% concentration, resulting in a production of around 10,000 metric tonnes of ant baits/year. In 2006, around 400 metric tonnes of ant baits (sulfluramid 0.3%) were exported to 13 countries in South and Central America. Sulfluramid cannot be manufactured without the use of PFOS derivatives. Its use represents a direct release of PFOS to the environment.

Several mechanical, cultural, biological and chemical methods, including different formulations, have been studied for controlling leaf-cutting ants. Granulated baits represent the most widely used method for leaf-cutting ant control, consisting of a mixture of an attractant (usually orange pulp and vegetable oil) and an active ingredient (insecticide), presented in the form of pellets. This method features some significant advantages over other methods. It is a low-cost method, delivering high efficiency with reduced health hazards to humans and the environment during application and being specific to the pest target. Its formulation is developed with low concentrations of active ingredients, and its localized application does not require application equipment. The utilization of ready-to-use formulations should reduce

⁵ http://www.sia-online.org/pre_facts.cfm

or impede releases to humans but the release of 30 tonnes of sulfluramid annually to the environment will eventually result in all of it being degraded to PFOS.

Currently, the active ingredients used in ant baits are: sulfluramid, fipronil and chlorpyrifos. Fipronil and chlorpyrifos are more acutely toxic to mammals, water organisms, fish and bees than sulfluramid. Comparative studies demonstrate low efficiency of ant baits with chlorpyrifos and fipronil. According to the Brazilian Annex F information, sulfluramid cannot be efficiently replaced in Brazil by other registered products commercialized for the same purpose. In the EU, PFOS-related substances are not used in the manufacture of pesticides (RPA 2004).

There has been no information provided either on associated worker exposure to PFOS from the manufacture of sulfluramid baits nor on potential exposure to the community and environment from the use of sulfluramid baits.

2.3.6 Medical devices

The medical device industry has been using many raw materials containing PFOS for a very long time. For example, PFOS is used as an effective dispersant when contrast agents are incorporated into an ethylene tetrafluoroethylene copolymer (ETFE) layer. PFOS plays an essential role in radio-opaque ETFE production, allowing the achievement of the levels of accuracy and precision required in medical devices (e.g., radioopaque catheters, such as catheters for angiography and indwelling needle catheters).

Since about 2000, when the effects of PFOS on the environment were identified as a problem, radio-opaque ETFE manufacturers have been working with chemical material suppliers to find alternatives.

The 2006 OECD survey identified use of perfluorobutane sulfonate (PFBS) as surfactant in coating products. In some cases, this substance can be used as a dispersant for inorganic contrast agent when it is mixed into ETFE. For many other medical devices, alternatives that allow the achievement of the same standard, however, remain to be found. It is expected that, due to its unique properties, PFOS will continue to be used for a variety of medical devices.

B. Uses for which alternative substances or technologies may be available but would need to be phased in.

2.3.7. Metal plating

PFOS-related substances are used in the following main applications:

- decorative chromium plating; and
- hard chromium plating.

Other important uses are: pre-treatment agent for plastic plating, PTFE powder plating treatment agent, pre-treatment agent for printed circuit board plating; chromic acid anodizing; nickel cadmium, or lead plating; alkaline zinc plating; stainless steel electric grinding agent; and chemical abrasive agent for copper alloy.

The 2006 OECD survey identified use of perfluorobutane sulfonate (C4 PFAS) as mist suppressants. Other information indicates that there are currently no known effective alternative chemical mist suppressants to PFOS-related substance for these applications (Japan, 2007; US, 2007)).

However, information received from a number of industry and regulatory authorities indicates that the substitution of Cr (VI) or hexavalent chromium with the less hazardous Cr (III) in decorative plating applications would eliminate the need for the use of PFOS-related substances in this application. Such substitution has potentially significant cost savings and health and safety and environmental benefits for the metal plating sector.

The higher costs of using Cr (III) are more than offset by the savings from reduced waste treatment costs, reduced air monitoring costs, record keeping, and the reduced reject rate. The major benefit, however, relates to the significantly reduced risk of employee ill health induced by working with hexavalent chromium. The progress of substitution is different due to the quality requirements of the different markets e.g. in Japan only 40-50 of about 1000 companies have changed their process. In such cases, PFOS mist control agents are still needed to protect workers' health

For hard chromium plating, information received indicates that the direct substitution of Cr (VI) with Cr (III) is not currently a viable option. While industry has indicated that substitute processes for Cr (VI) hard chrome plating have been developed for certain small applications, currently there are no technologies that are available on a large, commercial scale to replace the majority of Cr (VI) plating applications. In Japan alternatives for uses other than hard chromium plating are not yet identified partially because of the requirements for high reliability e.g. for automobile pumping parts.

The cost of improved ventilation with extraction, which is the recommended substitute for PFOS-based mist suppressants, has been calculated to be €3400 per year in each production unit where the investment period is 15 years (RPA 2004). Assuming a few hundred units in the EU the total cost would be one or two million euros. In Japan it has been estimated that the cost would be US\$40 000 for each 1000 litre bath (Japan, 2007).

The anticipated costs of the proposed Canadian regulations (See Section 1.5) by firm size are US\$0.65 M for 34 small firms, US\$2.6 M for 52 medium firms and US\$0.68 M for 14 large firms. The total estimated compliance costs for Canadian facilities using PFOS fume suppressants to comply with the proposed regulations is approximately US\$3.9 M (discounted at 5.5% over 25 years). This would result in a reduction in PFOS releases of approximately 86 tonnes over the 2013 to 2032 period (Canada, 2007)). Based on these Canadian calculations, the cost of reduction is US\$46 per kilogram of PFOS reduced.

2.3.8. Fire fighting foam

A number of alternatives to the use of PFOS-based fluorosurfactants in fire fighting foams are now available/under development. These alternatives include: non-PFOS-based fluoro-surfactants; silicone based surfactants; hydrocarbon based surfactants; fluorine-free fire fighting foams; and other developing fire fighting foam technologies that avoid the use of fluorine. The efficacy of alternatives would need to be considered.

Fluorine-free foams are approximately 5-10% more expensive than the fluorosurfactant-based foams (including those PFOS-based foams marketed previously). The manufacturers, however, indicate that prices for fluorine-free foams would reduce if the market size increased. It is, therefore, assumed that prices are broadly comparable.

As the transition from PFOS-based products has already taken place for most uses in many countries, there are only limited developmental or operational costs associated with the substitution of PFOS-based foams by foam manufacturers or users. The main costs for phasing out PFOS-based foams are related to managing stockpiles and waste containing such foams.

With regard to the toxicological and ecotoxicological suitability of non-PFOS based fluorosurfactants, data are limited. Whether telomers represent a significant concern for human health and the environment is under review elsewhere and conclusions are awaited.

With regard to fluorine-free foams, current information indicates that compared to PFOS based foams, they do not persist or bio-accumulate in the environment (due to the absence of fluorine). With regard to acute toxicity, fluorine-free foams appear to have a slightly lower acute toxicity, although the information provided to date is not conclusive.

For Canada, it is estimated that the proposed regulations would reduce the release of PFOS based AFFF into the environment in the order of 2.83 tonnes over the 2008 to 2032 period. The present value of the disposal and replacement costs experienced by airports, military facilities and refineries would be in the order of approximately US\$0.64 M (in 2006 \$) discounted at 5.5% over the 25-year time period (Canada, 2007). Based on these Canadian calculations the cost of reduction is US\$226 per kilogram of PFOS reduced.

For the EU, costs of replacement and destruction of foam have been estimated at €6000 per tonne. The stocks in the EU are 122 tonnes (RPA 2004). Based on the RPA's calculations, the cost of reduction is €6 per kilogram of PFOS reduced. Once the foam has been renewed, the cost of destruction may be as low as €1 per kilogram.

In Japan, it has been estimated that 86 tonnes of PFOS equivalent exist in AFFF products on the market. Based on this information, the estimated total amount of PFOS in the market is less than 200 tonnes in fire fighting foam concentrate. The market has stockpiled some 21,000 tons of PFOS fire fighting foam concentrate, and some 11,400 tons of fire fighting foam contains PFOS itself, the rest 9,600 tones contains PFOS derivatives. The majority of market stock is fire fighting foam for water-immiscible liquids such as oil, naphtha and hydrocarbon-fuels, and non-PFOS alternatives are already marketed for this use. It is estimated that replacement will take about 15 years based on present production capacity. On the other hand, some 2,000 tones of market stock, fire fighting foam for water miscible liquid such as alcohols glycols and acetone is more indispensable before long for biological fuels (bio-ethanol etc.). The foam for water miscible liquid is required to fulfil government standards and a non-PFOS alternative is not yet developed due to technical difficulties and technical feasibility. It is estimated that the alternative development will take several years and that replacement will take also about 15 years. Furthermore, fire fighting foam containing PFOS is also stored at airports (Japan, 2007).

The SNUR regulations in the U.S. restrict only new manufacture or importation of PFOS chemicals and PFOS-containing products. The U.S. regulations do not impose any restriction on the use of existing stocks of PFOS-based AFFF manufactured or imported into the U.S. prior to the effective date of the regulations, and no mandatory phase out of those existing stocks is either in place or contemplated.

2.3.9 Electric and electronic parts

PFOS is widely used in the production of electric and electronic parts. Major uses are as sealing agents and adhesives. For these uses, alternatives are available or are under development, and PFOS will be replaced relatively quickly. However, several uses have been identified for which alternatives will not soon be available. One such use is in the intermediate transfer belt of colour copiers/multi-function printers.

The intermediate transfer belt is an essential part of colour printers and colour copying machines. According to information provided to the Japanese government, the largest manufacturer (which supplies more than 60% of polyimide intermediate transfer belts) uses PFOS to ensure the required properties. Intermediate transfer belts of this manufacturer contain up to 100 ppm of PFOS. The part is used by 12 colour copier/multi-function printer manufacturers that dominate the global market; it is also supplied worldwide as a spare part. The properties of the intermediate transfer belt determine the design of the copier/multi-function printer. Due to the long life of copiers/multi-function printers, if supplies of this part are stopped, millions of copiers/multi-function printers might be discarded before the end of their product life, leading to unnecessary potential environmental damage.

Similar to intermediate transfer belts, PFA rollers and belts in fixing units contain PFOS for the same reason. The largest manufacturer of these units has reported that PFOS in the amount of 8×10^{-4} ppm is contained in an additive used in producing the units, and that additive is used in the amount of $3 \mu\text{g}/\text{cm}^2$. The production volume is 300,000 units per month, and annual consumption of PFOS is less than 3 g.

Furthermore, PFOS is used in various kinds of additives, such as grease additives for mechanical slides and micrometers, as well as a wider range of other uses in electric and electronic industries. However, due to the very low concentrations involved, as mentioned above, and the complex supply chain, use in this area was only recognized very recently, and thus further study is needed.

It is not clear what the impact of using alternatives to PFOS would be with regards to product performance.

2.4 Summary of information on impacts on society of implementing possible control measures

2.4.1 Health, including public, environmental and occupational health

A positive impact on human health and on the environment can be expected from reduction or elimination control measures on PFOS on a global scale. The establishment of further control measures for those uses of PFOS for which no substitution is yet possible, will presumably contribute positively to human health and the environment, especially concerning reprotoxicity and blood values.

A major, positive impact may be for vulnerable groups such as pregnant women, embryos and infants due to the reproductive toxicity of PFOS. Positive impacts would also be particularly beneficial to Arctic indigenous peoples who depend on traditional native foods and therefore are at much greater risk of PFOS exposure than other communities, given the widespread PFOS contamination of the Arctic food chain. The particular risks posed by POPs to Arctic ecosystems and indigenous communities is acknowledged in the preamble to the Convention.

If PFOS production and use is not managed, and were to continue or increase, then levels in the environment including in humans and animals will likely rise, even in locations distant from production and use. Industry has noted that no negative impact is anticipated to result from the ongoing small number of critical uses e.g. the imaging industry and the semi-conductor industry.

2.4.2 Agriculture, including aquaculture and forestry

The elimination of PFOS could adversely affect Brazilian agriculture through its impact on the production of sulfluramid ant baits claimed to be indispensable for the control of leaf-cutting ants in agricultural or forest undertakings. Specific exemptions or listing of acceptable purposes could permit the continued use of PFOS in the production of sulfluramid ant baits, which would protect commercial agricultural interests.

2.4.3 Biota (biodiversity)

As the persistent, bioaccumulative and toxic properties of PFOS were shown under the LRTAP-POPs-Protocol and under the Stockholm Convention, a positive impact on biota from a ban/restriction of the substance can be expected.

The scientific literature has identified that at current exposure levels, PFOS could harm certain wildlife organisms (e.g. polar bear, fish-eating birds), including those found in remote locations such as in the Canadian Arctic. The effects include growth inhibition of birds and aquatic invertebrates; liver and thyroid effects in mammals; lethality to fish (US EPA OPPT AR226-0097, OECD 2002) and saltwater invertebrates (US EPA OPPT AR226-0101); and changes in biodiversity (Boudreau *et al.* 2003a, Sanderson *et al.* 2002) (Canada, 2007).

Although polar bear and ringed seal sample data from 2005 have shown the first decline in levels since the reduction in worldwide production that began in 2000, more sample data must be collected in future years before it can be confirmed if the reductions are indeed the start of a long term downward trend in PFOS levels (Canada, 2007).

2.4.4 Economic aspects, including costs and benefits for producers and consumers and the distribution of costs and benefits

The potential benefit from avoided alternate water supply expenditure attributable to the proposed Canadian regulations (prohibiting production, marketing and use of PFOS and PFOS-related substances) is estimated to result in an average annual net benefit of US\$0.49 M per year. It is recognized that this benefit is uncertain; however, the value can be used to approximate the benefits to be derived as a result of the proposed regulations. Total benefits to Canadians are estimated to be approximately \$5.57 M. (Canada, 2007) It is recognized that this benefit is uncertain and that only a fraction of the benefits have been monetarized.

Photo-imaging

According to industry, restrictions on the remaining uses of PFOS-related substances would have a severe impact on the photo imaging industry's ability to manufacture a number of imaging products using current processes, including diagnostic medical products, industrial X-ray (non destructive testing), graphic printing (printing mask) and would impose a significant cost, not only on the manufacturers of photo imaging products, by requiring substantial investment in research and development, but also on users, by compelling them to replace their current systems with new systems, such as alternative digital systems.

Photoresists and semi-conductors

2005 global sales were US\$228 billion, with initial estimates for 2006 well above US\$260 billion. The semiconductor industry employed 226,000 people in the United States and 87,000 in Europe. Global employment in the industry was approximately 500,000 in 2003, but this figure has certainly increased.

However, the semi-conductor industry considers that implementation of control measures that effectively precluded the use of PFOS in critical applications for semiconductor manufacturing would likely shut down high volume production semiconductor manufacturing for a considerable time. The industry believes that this action could have a drastic effect on the global economy.

Metal plating

The cost of improved ventilation with extraction, which is the recommended substitute for PFOS-based mist suppressants, has been calculated to be €3400 per year in each production unit where the investment period is 15 years in the EU (RPA 2004). Assuming a few hundred units in the EU the total cost would be one or two million euros. In Japan it has been estimated that the cost would be US\$40 000 for each 1000 litre bath which would affect more than 1,000 plating companies, which are mainly SMEs (Japan, 2007). Based on the Canadian calculations the cost of reduction is US\$46 per kilogram of PFOS reduced.

Fire fighting foam

For the EU, costs of replacement and destruction of foam have been estimated at €6000 per tonne. The stocks in the EU are 122 tonnes (RPA 2004). Based on the RPA's calculations, the cost of reduction is €6 per kilogram of PFOS reduced. Once the foam has been renewed, the cost of destruction may be as low as €1 per kilogram. Based on the Canadian calculations, the cost of reduction is US\$226 per kilogram of PFOS reduced. In Japan, the cost of PFOS FFF incineration is estimated at approximately US\$1,000/t and incineration capacity is limited. Thus, it is difficult to estimate the time necessary for destruction (Japan, 2007).

Medical devices

According to the Japanese submission, at least 7500 catheters for angiography and 48 million in-dwelling needle catheters are produced annually in Japan, for which PFOS is required as part of the production process. Currently, alternatives for these medical devices have not been found yet in Japan. In order to identify appropriate alternatives, medical device manufacturers need to conduct numerous studies over several years covering such areas as feasibility, leachability, and safety and need approval by regulatory authorities. Therefore, at this stage it is very difficult to predict when alternatives will be available for use.

Cost comparisons

Rough calculations based on limited existing data and estimations indicate that the differences in costs for reduction of PFOS-related substances are very large. The cost per kilogram has been estimated at US\$25 M (€18.6 M) for photo imaging, US\$0.7 M (€0.52 M) for semi-conductors, US\$184 (€137) for destruction of fire fighting foam and US\$46

(€40) for metal plating. Lack of data has made it impossible to do similar estimates for photo masks, aviation hydraulic fluids, medical devices, electric and electronic parts and ant baits. These uses can be judged to have costs between the two uses that are expensive to reduce and the two that are relatively cheap to reduce.

2.4.5 Movement towards sustainable development

As the persistent, bioaccumulative and toxic properties of PFOS as well as its potential for a long-range transboundary transport were shown under the LRTAP Convention POPs-Protocol and in the risk profile agreed by the POPRC of the Stockholm Convention, a positive impact on a globally sustainable development from an elimination/restriction of the substance is expected.

2.4.6 Other impacts

Although PFOS is no longer used for the manufacturing of fire fighting foams, there are still stocks of about 122 tonnes in the EU (Germany, 2007).

Existing stocks of PFOS-based AFFF continue to be used in the U.S., although no new PFOS-based AFFF is being manufactured or imported into the U.S. The Fire-Fighting Foam Coalition, an industry group, estimated in 2004 that the total inventory of fluorine-containing AFFF products in the U.S. consisted of approximately 9.9 million gallons of concentrate, with approximately 4.6 gallons being 3% and 6% PFOS-based AFFF concentrates, and the remaining 5.3 million gallons being telomer-based materials.

The large use of PFOS in consumer products has implications for municipal waste and disposal along with attention to production stockpiles. A listing of PFOS in Annex A or B would subject wastes, products or articles containing the substance to Article 6 of the Stockholm Convention and require that they be disposed, "...in a safe, efficient and environmentally sound manner".

2.5 Other considerations

2.5.1 Access to information and public education

For more information on industry innovations regarding PFOS alternatives, please see the following websites:

SIA: <http://www.sia-online.org/home.cfm>

EECA-ESIA: <http://www.eeca.org/esia.htm>

SEMI: <http://www.semi.org/>

(Semiconductor)

Access to information on the U.S. regulation of these chemicals and the industry response is available through the online dockets for the U.S. EPA rulemaking proceedings. Information on those proceedings and dockets is available on the EPA website at <http://www.epa.gov/opptintr/pfoa/pubs/related.htm>.

Additional material on PFOS and related perfluorinated compounds is publicly available in a non-regulatory data repository maintained by the EPA Docket Office as Administrative Record AR-226. AR-226 is not available online, but an index to the documents can be requested by email from oppt.ncic@epa.gov, and documents in AR-226 are available on CD-ROM (USA, 2007).

Specific information on future needs relating to access to information and public education is not available at this time

2.5.2 Status of control and monitoring capacity

The worldwide semi-conductor industry associations will collect and make available aggregated industry information every 2 years to provide a transparent communication of member company progress, including:

- a) the results of PFOS wastewater treatment evaluations including any wastewater measurement data;
- b) a description of the current relevant research and development activities and any conclusions including the results of collaboration with equipment and chemical suppliers;
- c) industry phase-out schedules that are known for critical and non-critical uses in semiconductor manufacturing and processing; and
- d) the results of the PFOS mass balance model (SIA, 2007).

3. Synthesis of information

3.1 Summary of risk profile information

Perfluorooctane sulfonate (PFOS) is a fully fluorinated anion, which is commonly used as a salt in some applications or incorporated into larger polymers. Due to its surface-active properties, it has historically been used in a wide variety of applications, typically including fire fighting foams and surface resistance/repellency to oil, water, grease or soil. PFOS can be formed by degradation from a large group of related substances, referred to as PFOS-related substances (see definition in section 1.1.2).

PFOS and PFOS-related substances can be released to the environment during their manufacture, use in industrial and consumer applications, and from disposal of the chemicals or of products or articles containing them after their use.

The rate and the extent of the formation of PFOS from its related chemicals are largely unknown and may differ between individual substances. Lack of data makes it very difficult to estimate the net contribution of the transformation of each of the PFOS-related substances to the environmental loadings of PFOS. However, based on its extreme stability, it is expected that PFOS is likely to be the final degradation product of all PFOS-related substances.

PFOS is extremely persistent. 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 under controlled conditions.

With regard to bioaccumulation potential, PFOS meets the Annex D criteria given the highly elevated concentrations that have been found in top predators such as the polar bear, seal, bald eagle and mink. Most notable are the high concentrations of PFOS that have been found in Arctic animals, far from anthropogenic sources. PFOS has been detected in higher trophic level biota and predators such as fish, piscivorous birds, mink, and Arctic biota. Also, predator species, such as eagles, have been shown to accumulate higher PFOS concentrations than birds from lower trophic levels. Even with reductions in manufacturing of PFOS by some manufacturers, wildlife, such as birds, can continue to be exposed to persistent and bioaccumulative substances such as PFOS simply by virtue of its persistence and long-term accumulation.

According to available data, PFOS meets the criteria for the potential for long-range transport. This is evident through monitoring data showing highly elevated levels of PFOS in various parts of the northern hemisphere. It is especially evident in the Arctic biota, far from anthropogenic sources. PFOS also fulfils the specific criteria for atmospheric half-life.

PFOS fulfils the criteria for adverse effects. It has demonstrated toxicity towards mammals in sub-chronic repeated dose studies at low concentrations, as well as rat reproductive toxicity with mortality of pups occurring shortly after birth. PFOS is toxic to aquatic organisms with mysid shrimp and *Chironomus tentans* being the most sensitive organisms.

The voluntary phase out of PFOS production by the major producer in the USA, along with government regulatory actions, has led to a reduction in the current production and use of PFOS-related substances. However, PFOS or PFOS-related substances are still produced in some countries and it continues to be used in many countries. Given the inherent properties of PFOS, together with demonstrated or potential environmental concentrations that may approach or exceed the effect levels for certain higher trophic level biota such as piscivorous birds and mammals; and given the widespread occurrence of PFOS in biota, including in remote areas; and given that PFOS precursors may contribute to the overall presence of PFOS in the environment, POPRC2 concluded that PFOS is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects, such that global action is warranted.

3.2 Suggested risk management measures

Consistent with Article 1 of the Convention, PFOS should be managed with the objective of protecting human health and the environment from POPs. Consideration should also be given to the potential for all PFOS-related substances to degrade to PFOS and thus contribute to the total environmental load.

Listing of PFOS under the Convention is able to address various aspects of substance life-cycles, including manufacture, use, import and export as well as prescribing emissions measures e.g. BAT/BEP or others to reduce releases with the aim of eliminating them. Listing of PFOS under the Convention would also make it subject to the provisions on stockpiles and waste in Article 6.

Listing of PFOS in Annex A of the Convention would prohibit the manufacture, use, import and export of PFOS (except as allowed under the treaty for environmentally sound disposal) and could be linked with specific exemptions that specify deadlines for the eventual elimination of remaining PFOS manufacturing and use. Such listing could also be coupled with a Part III of Annex A that would describe in more detail the critical uses of PFOS and/or PFOS-related substances and appropriate conditions for their manufacturing and use, including time limits.

Listing of PFOS in Annex B of the Convention would prohibit the manufacture, use, import and export of PFOS except for specified acceptable purposes/specific exemptions such as those mentioned above for which at present no alternatives are available. The listing could be accompanied by a Part III to Annex B, which would describe in more detail the critical uses of PFOS and/or PFOS-related substances and appropriate conditions for their use, including timelines for review and revision, as appropriate.

Listing of PFOS in Annex C of the Convention to address the unintentional production of PFOS as a transformation or degradation product of PFOS-related chemicals would eventually eliminate all releases of PFOS and could potentially reduce or eliminate the manufacture and use of all PFOS-related substances that are degraded to PFOS to any degree.

The suggested options for control measures for PFOS are as follows:

1. PFOS may be listed in Annex A, with or without specific [time-limited] exemptions, and accompanied with a new Part III of Annex A that details actions for each or groups of PFOS-related substances or uses of such substances; or
2. PFOS may be listed in Annex B, with specified acceptable purposes [or specific time-limited exemptions], and accompanied with a new Part III of Annex B that details actions for each or groups of PFOS-related substances or uses of such substances
3. PFOS may be listed in Annex C as an unintentional POP to capture all present and future uses of all, also presently unknown, PFOS-related substances that may give rise to PFOS when released into the environment; or
4. PFOS may be listed in Annex A or B, as described above, and at the same time also be listed in Annex C.

These options are further described below.

Option 1. Listing of PFOS in Annex A.

Listing of PFOS in Annex A would be consistent with the POPs properties of this intentionally produced substance. Such a listing would send a clear signal that production and use of PFOS must be phased out. Such a listing may also have implications for countries joining the Convention for this substance, in light of ongoing uses for which no alternatives have been developed.

To allow for [time limited] use of PFOS and PFOS-related substances in critical applications, an exemption for production and use could be given, e.g., "as required to produce other chemicals substances to be used solely in accordance with Part III of this Annex". Specific exemptions for certain critical uses, where there are no available alternatives, could be difficult to develop or apply, however, given the general time limit of five years, with a possible extension applicable to specific exemptions, among other reasons.

This option could be exercised by all Parties, in which case they would not need to register the exemption. This would also imply that any restrictions with regard to time would appear in the new Part III of Annex A. The information that has been supplied indicates that for some uses, such deadlines could be difficult to determine at present.

Option 2. Listing of PFOS in Annex B.

Listing of PFOS in Annex B would be consistent with the POPs properties of this intentionally produced substance. This would allow for some specified acceptable purposes/specific [time-limited] exemptions due to the present uncertainty surrounding the availability of alternatives for several critical uses over the next five to ten years,

To allow for the [time-limited] use of PFOS-related substances in critical applications, an acceptable purpose for production of PFOS could be given, e.g., "as required to produce other chemical substances to be used solely in accordance with Part III of this Annex";

Option 3. Listing of PFOS in Annex C.

This option also regards PFOS as an unintentionally produced POP that results from the degradation of PFOS-related substances. The argument behind this would be that PFOS is no longer produced except as an intermediate for the production of PFOS-related substances to be used in critical uses. Releases of PFOS to the environment would then only occur as a result of degradation of the PFOS-related substances. The weakness of the argument is that a listing in Annex C would not capture production of PFOS itself. Listing on Annex C only would not eliminate or restrict PFOS, but it would depend on voluntary commitments not to produce PFOS except as an intermediate. All uses of any PFOS-related substance that degraded to PFOS would be affected by the listing, in that all measures should be taken to reduce with the aim to eliminate the releases of PFOS as a result of that use. The responsibility to identify whether a specific use of a PFOS-related substance was degraded to PFOS would rest with the user.

It can be argued that Article 5 of the Treaty could apply to POPs that are formed and released unintentionally from anthropogenic sources. PFOS-related substances are only found in nature due to human activity and the degradation to PFOS only occurs because they are unnaturally present in the environment due to human activity. Therefore, listing PFOS in Annex C could be appropriate for reducing and eliminating degradation of PFOS-related substances to PFOS. However, it can also be argued that Article 5 of the Treaty does not envision “unintentional production” to include substances that are the result of non-anthropogenic transformation processes. Accordingly, listing PFOS in Annex C on the basis of it resulting from the degradation of other intentionally produced chemical would not be appropriate.

Listing PFOS in Annex C alone would not be appropriate because PFOS is and will continue to be produced intentionally for some years at least, and will not occur solely as the unintended result of transformation or degradation from other chemicals

Option 4. Listing of PFOS in Annex A or B and Annex C.

This option could combine the listing of PFOS in Annex A or B, with the acceptable purposes/specific [time-limited] exemptions as noted above, with its listing as an unintentional POP in Annex C to capture existing and future uses of all substances that could potentially degrade to PFOS. This option would address the manufacture and use of PFOS as well as the unintentional formation of PFOS from PFOS-related substances.

Conclusions

In comparing options 1 and 2 with option 3 and 4, it seems most logical to regulate PFOS under the Convention as an intentionally produced POP, which should eventually be phased out. Given the toxicity and extreme persistence of PFOS, the goal should be elimination or restriction of production, use, and emissions of PFOS. It is, therefore, proposed to list PFOS in Annex [A or B] of the Convention.

Based on the information supplied to the Committee, the availability of alternatives is uncertain. Therefore, there is a need for certain critical uses over the foreseeable future. To allow for this, one could, based on the feasibility of substitution for such use and the time frame of substitution introduce specific/acceptable purposes and [time-limited] exemptions for production as required only to produce other chemical substances designated for these critical uses and to describe the conditions for the use of PFOS-related substances further in a new Part III to Annex A or B. A suggested outline of Part III can be found in the INF document. The new Part III should be reviewed by the COP periodically to ensure progress toward minimization of use.

4. Concluding statement

In accordance with paragraph 9 of Article 8 of the Convention, the Committee recommends the Conference of the Parties to the Stockholm Convention to consider listing and specifying the related control measures of PFOS in Annex [A or B and/or Annex C] as described above.

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