



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

Distr.: General

23 March 2012

Original: English

Chemical Review Committee

Eighth meeting

Geneva, 19–23 March 2012

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

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

Draft decision guidance document for perfluorooctane sulfonic acid, perfluorooctanesulfonates, perfluorooctanesulfonamides and perfluorooctanesulfonyls

Note by the Secretariat

1. At its seventh meeting, the Chemical Review Committee reviewed notifications of final regulatory action for perfluorooctane sulfonic acid (PFOS), its salts and its precursor perfluorooctane sulfonyl fluoride (PFOSF) from Canada, the European Union and Japan, along with the supporting documentation referenced therein, and concluded that the requirements set out in Annex I and Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade had been met.
2. Accordingly, the Committee agreed to recommend to the Conference of the Parties that PFOS, its salts and its precursor PFOSF should be listed in Annex III to the Convention. In addition, the Committee adopted a rationale for that recommendation and agreed to establish an intersessional drafting group to produce a draft decision guidance document.¹ A detailed workplan for the development of the draft decision guidance document was prepared by the Committee in line with the process adopted by the Conference of the Parties in decision RC-2/2. The rationale, recommendation and workplan were annexed to the report of the Committee's seventh meeting (UNEP/FAO/RC/CRC.7/15, annex II). The workplan was subsequently modified and an updated version posted on the Convention website.
3. The material available to the intersessional drafting group included a summary of the outcome of the Committee's seventh meeting, a copy of a working paper on the preparation of internal proposals and decision guidance documents for banned or severely restricted chemicals and the notifications of final regulatory actions and associated supporting documentation available to the Committee at its seventh meeting.
4. In accordance with the agreed workplan, the co-chairs of the intersessional drafting group, in consultation with the Secretariat, prepared an internal proposal based on the notifications and the supporting documentation. That proposal was circulated to the members of the drafting group for comments on 17 May 2011. It was amended in the light of the comments received and was circulated, on 2 August 2011, to all Committee members and the observers who had attended the Committee's seventh meeting. Responses

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

¹ The members of the drafting group were: Ms. Anja Bartels (Austria), Ms. Hang Tang (Canada), Ms. Lucia Jacqueline Arroyo Daul (Ecuador), Ms. Mirijam Kristina Brigitta Seng (Germany), Mr. Masayuki Ikeda (Japan), Mr. Peter Simon Opiyo Ombajo (Kenya), Mr. Idris Goji (Nigeria), Ms. Magdalena Balicka (Poland), Ms. Hala Sultan Saif Al-Easa (Qatar), Mr. Jürgen Heinrich Helbig (Spain) and Mr. Azhari Omer Abdelbagi (Sudan).

were received from Committee members and observers and taken into consideration in the revision of the draft decision guidance document.

5. The intersessional drafting group's work, including a compilation of the comments and the draft decision guidance document, was circulated to the drafting group members on 11 October 2011 for further comment. Changes resulting from that round of comments were incorporated into the draft decision guidance document.

6. During the eighth meeting of the Committee the draft decision guidance document was further revised² and then agreed upon by the Committee and forwarded for consideration by the Conference of the Parties. The text of the draft decision guidance document is set out in the annex to the present note. It has not been formally edited by the Secretariat.

7. A tabular summary of all comments received and how they were dealt with is set out in the annex to document UNEP/FAO/RC/CRC.8/INF/7/Rev.1.

2 The title of the draft decision guidance document had previously referred to perfluorooctane sulfonic acid, its salts and its precursor perfluorooctane sulfonyl fluoride; the title of the draft decision document as agreed upon at the eighth meeting of the Committee refers to perfluorooctane sulfonic acid, perfluorooctanesulfonates, perfluorooctanesulfonamides and perfluorooctanesulfonyls.

Annex**Rotterdam Convention****Operation of the prior informed consent procedure for banned or severely restricted chemicals****Draft Decision Guidance Document****Perfluorooctane sulfonic acid, perfluorooctanesulfonates, perfluorooctanesulfonamides and perfluorooctanesulfonyls**

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



Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals¹ for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties² in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its [...] meeting, held in [...] on [...], the Conference of the Parties agreed to list [chemical name] in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on [...], in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

1 According to the Convention, the term “chemical” means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

2 According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
μg	Microgram
μm	micrometer
ArfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
atm	Atmosphere
BCF	bioconcentration factor
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CA	Chemicals Association
CAS	Chemical Abstract Service
cc	cubic centimetre
CCD	charge-coupled device
cm	Centimetre
DNA	Deoxyribose Nucleic Acid
dw	dry weight
E.C.	European Community
EC ₅₀	effect concentration, 50%
ED ₅₀	effect dose, 50%
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Substances
EtFOSE	1-octanesulfonamide, <i>N</i> -ethyl-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptafluoro- <i>N</i> -(2-hydroxyethyl)-(N-ethylperfluorooctane sulfonamidoethanol
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	Gram
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
h	Hour
ha	Hectare
i.m.	Intramuscular
i.p.	Intraperitoneal
IARC	International Agency for Research on Cancer
IC ₅₀	inhibition concentration, 50%;
ILO	International Labour Organisation
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
kg	Kilogram
Koc	organic carbon-water partition coefficient

STANDARD CORE SET OF ABBREVIATIONS	
L	Litre
LC ₅₀	lethal concentration, 50%
LD ₅₀	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LD _{LO}	lowest lethal dose
LOEL	lowest observed effect level
M	Metre
MeFOSE	1-octanesulfonamide, <i>N</i> -ethyl-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-hepta-decafluoro- <i>N</i> -(2-hydroxyethyl)- <i>N</i> -methyl-(<i>N</i> -methylperfluorooctane sulfonamidoethanol)
m.p.	melting point
mg	Milligram
ml	Millilitre
mPa	milliPascal
MTD	maximum tolerated dose
ng	Nanogram
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect-concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PBT	persistent, bioaccumulative, toxic
PFOA	perfluorooctanoic acid
PFOS	perfluorooctane sulfonic acid
PFOSF	perfluorooctane sulfonyl fluoride
PNEC	predicted no effect concentration
POP	persistent organic pollutant
Pow	octanol-water partition coefficient
ppb	parts per billion
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RfD	Reference dose for chronic oral exposure (comparable to ADI)
RTECS	Registry of toxic effects of chemical substances
SCHER	Scientific Committee on Health and Environmental Risks (EU)
SMR	standardized mortality ratio
STEL	short term exposure limit
TLV	threshold limit value
TWA	time-weighted average
UK	United Kingdom
USA	United States of America
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
VOC	volatile organic compound
WHO	World Health Organization
wt.	Weight
wwt.	wet weight

Decision guidance document for a banned or severely restricted chemical

Perfluorooctane sulfonic acid, perfluorooctanesulfonates,
perfluorooctanesulfonamides and perfluorooctanesulfonyls

Published:

1. Identification and uses (see Annex 1 for further details)

Common name

Perfluorooctane sulfonic acid (PFOS)

Note: PFOS in general may refer to any of anionic, acid or salt forms of perfluorooctane sulfonate

Examples for PFOS acids

1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-1-octanesulfonic acid
 Heptadecafluoro-1-octanesulfonic acid
 Perfluoro-*n*-octane sulfonic acid
 Perfluorooctane sulfonic acid
 Perfluorooctyl sulfonic acid

Chemical name and other names or synonyms

PFOS salts

Ammonium perfluorooctane sulfonate
 Diethanolamine perfluorooctane sulfonate
 Potassium perfluorooctane sulfonate
 Lithium perfluorooctane sulfonate

PFOS Precursor

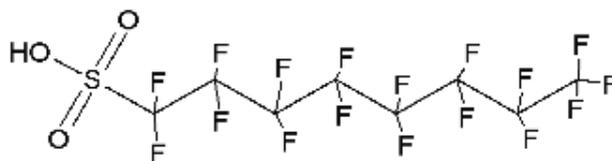
Perfluorooctane sulfonyl fluoride (PFOSF)

Molecular formula

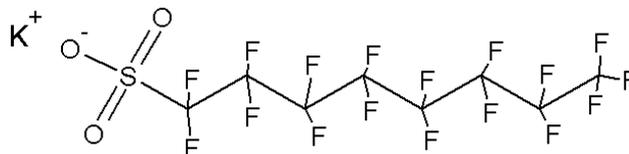
 $C_8F_{17}SO_2X$ (X = OH, Metal salt (O^-M^+), halide, amide, and other derivatives)

Chemical structure

(EA, 2004)



PFOS acid



Potassium salt

CAS-No.(s)

The perfluorooctane sulphonate anion (PFOS) did not have a specific CAS number when the notifications were submitted. CAS number 45298-90-6 has recently been listed on some chemical databases as that for the PFOS anion (1-octanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-, ion(1-)). The acid and salts have the following CAS numbers:

	1763-23-1 (acid) 29081-56-9 (ammonia salt) 70225-14-8 (diethanolamine (DEA) salt) 2795-39-3 (potassium salt) 29457-72-5 (lithium salt) The precursor perflourooctane sulfonyl fluoride has the following CAS number: 307-35-7
Harmonized System Customs Code	2904 90
Other numbers	RTECS KL2975000 EINECSW 203-860-0 Combined Nomenclature code of the European Union (CN code): 2904 90 20
Category	Industrial
Regulated category	Industrial
Use(s) in regulated category	<p>Canada</p> <p>The principal applications for PFOS and its salts were as water, oil, soil and grease repellents for use on surface and paper-based applications, such as rugs and carpets, fabric and upholstery, and food packaging. These applications have largely ceased following the main manufacturer's phase out of PFOS in 2002 and the coming into force of the PFOS Regulations in 2008. The use of PFOS and its salts in fire fighting foams and fume suppressants is still permitted until the end of May 2013. Certain other uses such as in aviation hydraulic fluid, and products for photography or photolithographic processes, continue to be allowed.</p> <p>European Union</p> <p>The major use of PFOS and PFOS related substances in consumer applications was to provide grease, oil and water resistance to materials such as carpets, leather/apparel, textiles/upholstery, paper and packaging, coatings, and in industrial and household cleaning products. These uses have largely been abandoned following the decision of the main global producer 3M to phase out manufacture and use of PFOS consumer applications.</p> <p>industrial/professional usage of PFOS in smaller volume is continuing and has been confirmed in the following sectors in the EU (demand in 2004):</p> <ul style="list-style-type: none"> - Metal (chromium) plating (8600-10 000 kg/year) - Fire fighting foams (estimated quantity held in stock: 122 tonnes) - Photographic industry (approximately 850 kg/year) - Semiconductor industry (436 kg/year) - Aviation industry (hydraulic fluids; approximately 730 kg/year) <p>Japan</p> <p>Metal plating, photo masks in semiconductor, etching agent, photo-resist and fire-fighting foams.</p> <p>Stockholm Convention on POPs</p> <p>Historical applications and uses of PFOS include; fire-fighting foams, carpets, leather/apparel, textiles/ upholstery, paper and packaging, coatings and coating additives, pesticides and insecticides, photographic industry, photolithographic processes and semiconductor industry, hydraulic fluids, metal plating (POPRC, 2006, POPRC, 2010, Besides these uses, China also used PFOS in the petroleum industry and for nano-material processing (POPRC, 2010).</p> <p>PFOS is listed in Annex B of the Stockholm Convention with exemptions. The current intentional use of PFOS is widespread and includes: electric and electronic parts, fire fighting foam, photo imaging, hydraulic fluids and textiles. PFOS is still produced in several countries.</p>

Trade names

PFOS

FC-95

This is an indicative list. It is not intended to be exhaustive.

Formulation types

The main production process of PFOS and PFOS-related substances is electrochemical fluorination (ECF) (POPRC, 2006). The ECF method results in a mixture of isomers and homologues with about 35-40% 8-carbon straight chain Perfluorooctane sulfonyl fluoride (PFOSF)³. PFOSF is the primary intermediate for the synthesis of PFOS and related substances (OECD, 2002). It may be further reacted with methyl- or ethylamine to form *N*-methylperfluorooctane sulfonamide or *N*-ethylperfluorooctane sulfonamide and subsequently with ethylene carbonate to form *N*-ethyl- and -methylperfluorooctane sulfamidoethanol (*N*-EtFOSE and *N*-MeFOSE). *N*-EtFOSE and *N*-MeFOSE were the principal building blocks of 3M products. PFOS is formed after the chemical or enzymatic hydrolysis of PFOSF (POPRC, 2006).

Uses in other categories

Insecticides for control of red imported fire ants and termites. Insect baits for control of leaf-cutting ants from *Atta* spp. and *Acromyrmex* spp. (POPRC, 2010)

Basic manufacturers

Based on various chemical buyer's guides (Directory of World Chemical Producers, 2000; ChemSources USA, 2000; OPD Chemical Buyers Directory, 2000) the following companies have been identified as offering PFOS-related chemicals for sale (OECD, 2002)⁴:

3M (Belgium, USA)

MiteniS.p.A. (Italy)

EniChem Synthesis S.p.A. (Italy)

Dianippon Ink & Chemicals, Inc. (Japan)

Midori Kaguka Co., Ltd. (Japan)

Tohkem Products Corporation (Japan)

Tokyo Kasei Kogyo Company, Ltd. (Japan)

Fluka Chemical Co, Ltd. (Switzerland)

BNFL Fluorochemicals Ltd. (United Kingdom)

Fluorochem Ltd. (United Kingdom)

Milenia Agro Ciencias S.A. (Brazil)

Changjiang Chemical Plant (China)

Indofine Chemical Company, Inc. (India)

Scientific Industrial Association P & M Ltd. (Russian Federation)

3M was previously the major global producer of PFOS, but in May 2000 3M announced a voluntary phase out from 2001 onwards (POPRC, 2006) and by the beginning of 2003 the production ceased completely.

It should be noted that the four Japanese companies listed above stopped the production of PFOS in 2010.

This is an indicative list of current and former manufacturers. It is not intended to be exhaustive

³ Commercial PFOSF products on the other hand were a mixture of approximately 70 % linear and 30 % branched PFOSF derivate impurities (POPRC, 2006).

⁴ This information has not been corroborated independently, except for MiteniS.p.A. of Italy. The list was updated on the basis of information received from Parties concerned.

2. Reasons for inclusion in the PIC procedure

Perfluorooctane sulfonic acid, perfluorooctanesulfonates, perfluorooctanesulfonamides and perfluorooctanesulfonyls are included in the PIC procedure as industrial chemicals. They have been listed based on final regulatory actions that severely restrict their use as notified by Canada, the European Union and Japan.

2.1 Final regulatory action (see Annex 2 for further details)

Canada

Perfluorooctane sulfonate and its salts and certain other compounds are regulated under subsection 93(1) of the Environmental Protection Act, 1999 (CEPA, 1999). PFOS and its salts are listed in the List of Toxic Substances in Schedule 1 of CEPA 1999.

The Regulations prohibit the manufacture, use, sale, offer for sale or import of PFOS, its salts and its precursors or a product containing any such substance unless the substance is incidentally present. A limited number of exemptions are listed below.

The Regulations do not apply to PFOS, its salts and its precursors that are:

- (a) contained in a hazardous waste, hazardous recyclable material or non-hazardous waste to which Division 8 of Part 7 of CEPA 1999 applies;
 - (b) contained in a pest control product within the meaning of subsection 2(1) of the Pest Control Products Act;
 - (c) present as a contaminant in a chemical feedstock used in a process from which there are no releases of the substance and provided that, in that process, the substance is destroyed or completely converted to a substance other than the one referred to in section 1 of the Regulations;
- or
- (d) used in a laboratory for analysis, in scientific research or as a laboratory analytical standard.

The manufacture, use, sale, offer for sale, or import of the following products containing PFOS, its salts or its precursors is permitted:

- (a) photoresists or anti-reflective coatings for photolithography processes;
- and
- (b) photographic films, papers and printing plates.

The use, sale, offer for sale or import of aviation hydraulic fluid containing PFOS, its salts or its precursors is also permitted.

The use of PFOS, its salts, or its precursor or a product containing any such substance, as a fume suppressant in the following processes, as well as their sale, offer for sale or import for that use, is permitted until May 29, 2013:

- (a) chromium electroplating, chromium anodizing and reverse etching;
- (b) electroless nickel-polytetrafluoroethylene plating; and
- (c) etching of plastic substrates prior to their metallization.

The use, sale or offer for sale of a manufactured item containing PFOS, its salts or its precursors is permitted if manufactured or imported before May 29, 2008.

The use of aqueous film forming foam (AFFF) containing PFOS, its salts or its precursors is permitted:

- (a) at any time, if the concentration of the substance is less than or equal to 0.5 ppm; or
- (b) until May 29, 2013, other than for testing or training purposes, if the concentration of the substance is greater than 0.5 ppm and the foam was manufactured or imported before May 29, 2008.

AFFF containing PFOS, its salts or its precursors perfluorooctane sulfonyl fluoride may be:

- (a) used in a military vessel deployed, before May 29, 2008 or within five years after that day, for a military operation; or
- (b) used or imported in a military vessel or military fire fighting vehicle contaminated during a foreign military operation occurring after May 29, 2008.

Reason: Environment

European Union

Pursuant to Regulation (EC) 1907/2006 concerning the registration, evaluation, authorization and restriction of chemicals (REACH) as amended by Commission Regulation (EC) No 552/2009 amending Regulation (EC) No 1907/2006:

- (a) PFOS may not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0.005% by weight⁵.
- (b) PFOS may not be placed on the market in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or higher than 0.1% by weight calculated with reference to the mass of structurally or microstructurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is equal to or higher than 1 µg/m² of the coated material.

These restrictions do not apply to products that were in use in the European Union before 27 June 2008.

According to the same regulation, the use and the first placing on the market of the following items, as well as the use of the substances and preparations needed to produce them remain allowed:

- (a) Photoresists or anti-reflective coatings for photolithography processes,
- (b) Photographic coatings applied to films, papers, or printing plates,
- (c) Mist suppressants for non-decorative hard chromium (VI) plating and wetting agents for use in controlled electroplating systems where the amount of PFOS released into the environment is minimised, by fully applying relevant best available techniques developed within the framework of Directive 2008/1/EC of 15 January 2008 concerning integrated pollution prevention and control (OJ L 24, 29.01.2008, p. 8),
- (d) Hydraulic fluids for aviation.

Until 27 June 2011 the fire-fighting foams that have been placed on the market before 27 December 2006 were also allowed, in order to limit emissions to that of the existing stocks of fire-fighting foams.

In the regulation, the European Commission is requested to review each of the derogations in paragraph 3 as soon as new information on details of uses and safer alternative substances or technologies for the uses become available.

The Commission is also requested to keep under review the ongoing risk assessment activities and the availability of safer alternative substances or technologies related to the uses of perfluorooctanoic acid and related substances and propose all necessary measures to reduce identified risks, including restrictions on marketing and use, in particular when safer alternative substances or technologies, that are technically and economically feasible, are available..

Reason: Human Health and the Environment⁴

Japan

In Japan the use of PFOS is severely restricted under the Chemical Substances Control Law (CSCL) and its enforcement order and the chemical is designated as a Class I Specified Chemical Substance. It is prohibited to manufacture, import or use this chemical substance. However, certain essential uses under strict control are permitted as an exception; these are listed below:

- (a) Etching agents for voltage filters or high-frequency compound semiconductors.
- (b) Photo resists for semiconductor production.
- (c) Photo films for industrial purposes
- (d) Fire-fighting foams

It is obligated to meet technical standards and labelling obligations

Reason: Human Health

⁵ Following the listing of PFOS in the Stockholm Convention, the EU adopted in 2010 additional restrictions and reduced this figure to 0.001% by weight. There were further changes to the already existing restrictions including a time limit until 26 August 2015 for wetting agents for use in controlled electroplating systems (Commission Regulation (EU) 757/2010).

2.2 Risk evaluation (see Annex 1 for further details)
--

Canada**Environment**

An ecological screening assessment was undertaken on perfluorooctane sulfonate (PFOS), its salts and its precursors that contain the $C_8F_{17}SO_2$, $C_8F_{17}SO_3$ or $C_8F_{17}SO_2N$ moiety (Environment Canada, 2006). PFOS is resistant to hydrolysis, photolysis, microbial degradation, and metabolism by vertebrates. PFOS has been detected in fish, and in wildlife worldwide and in the northern hemisphere. This includes Canadian wildlife located far from known sources or manufacturing facilities, indicating that PFOS and/or its precursors may undergo long-range transport. Maximum concentrations in liver of biota in remote areas of the Canadian Arctic include:

- (a) Mink ($20 \mu\text{g.kg}^{-1}$)
- (b) Common loon ($26 \mu\text{g.kg}^{-1}$)
- (c) Ringed seal ($37 \mu\text{g.kg}^{-1}$)
- (d) Brook trout ($50 \mu\text{g.kg}^{-1}$)
- (e) Arctic fox ($1400 \mu\text{g.kg}^{-1}$)
- (f) Polar bear ($>4000 \mu\text{g.kg}^{-1}$)

Unlike many other persistent organic pollutants, certain perfluorinated substances, such as PFOS, are present as ions in environmental media and partition preferentially to proteins in liver and blood rather than to lipids. Therefore, the bioaccumulation potential of PFOS may not be related to the typical mechanisms associated with bioaccumulation in lipid-rich tissues. The numeric criteria for bioaccumulation, outlined in the *Persistence and Bioaccumulation Regulations* (CEPA, 1999) are based on bioaccumulation data for aquatic species (fish) only and for substances that preferentially partition to lipids. As a result, the numeric criteria may not completely reflect the bioaccumulation potential of PFOS that is preferentially partitioning in the proteins of liver, blood and kidney in terrestrial and marine mammals.

European Union**Human Health**

Based on a UK environmental risk evaluation report (EA, 2004) and a risk reduction strategy document prepared for UK authorities by RPA (RPA, 2004), and considering the oral assimilation of PFOS in fish and mammals and the low elimination rate, the Scientific Committee on Health and Environmental Risks (SCHER) of the EU has concluded that PFOS poses environmental concerns similar to other substances that are very bioaccumulative (SCHER, 2005). In their opinion, SCHER confirmed the toxicity associated with oral exposure to PFOS and the high persistency of the substance, and concluded that a scientifically based assessment of persistence, bioaccumulation and toxicity indicated that PFOS fulfils the criteria for very persistent, very bioaccumulative and toxic substances. Furthermore, established that there is a potential concern for secondary poisoning even at regional level when taking into account the concentrations in some aquatic and terrestrial organisms that have been reported in several areas, and that there is a need for risk reduction strategies. It also highlights that serum levels of workers (up to $13 \mu\text{g/ml}$) are already in the range of those levels at which toxicity has been observed in animal studies and call for a full human health risk assessment to be conducted. An OECD Hazard Assessment also concluded that PFOS is persistent, bioaccumulative and toxic in mammals, and provided documentation showing that PFOS was present in serum of both occupationally exposed workers and individuals of the general population (OECD, 2002). The assessment also established that there was a statistically significant association between PFOS exposure and bladder cancer and that there appeared to be an increased risk of episodes of neoplasm of the male reproductive system, the overall category of cancers and benign growths, and neoplasms of the gastrointestinal tract.

Because PFOS and PFOS related substances pose potential risk to human health and the environment, the SCHER agreed with the RPA assessment (RPA, 2004) that risk reduction measures might be necessary. SCHER considered that the on-going critical uses in aviation, semiconductor photographic industries do not pose a relevant risk provided that releases into the environment and workplace exposure are minimised, while for fire-fighting foams, the risks of substitutes should be assessed before reaching a final decision. It also proposed to minimize the use of PFOS in plating industry by applying the Best Available Techniques (BAT).

Environment

Considering the oral assimilation in fish and mammals and the low elimination rate, SCHER concluded that PFOS poses similar environmental concerns for bioaccumulation to substances that are very bioaccumulative. The toxicity associated with oral route exposure is confirmed as well as its high persistency. Therefore, a scientifically based assessment of persistence, bioaccumulation and toxicity indicates that PFOS fulfils the criteria for very persistent, very bioaccumulative and toxic substances.

To be considered as a Persistent Organic Pollutant under the Stockholm Convention, a substance has to be persistent, bioaccumulative, have a potential for long range environmental transport and have the potential to give adverse effects. PFOS fulfils the criteria for all these properties given in Annex D of the Stockholm Convention and was included in Annex B at its fourth meeting in May 2009 of the Conference of the Parties.

The OECD Hazard Assessment (OECD, 2002), reported that PFOS has been detected in tissues of a number of species of wildlife (wild birds and fish including marine mammals), in surface water and sediment, wastewater treatment plant effluent, sewage sludge and landfill leachate. The data indicated that PFOS is persistent in the environment and bioaccumulates. There was also evidence that it bioconcentrated in fish and was acutely toxic to honey bees, but appeared to be of low to moderate toxic to aquatic organisms. The assessment provided no information on effects on soil- and sediment-dwelling organisms.

Japan

Human Health

In Japan an initial ecological risk assessment of PFOS and its salts was conducted on the basis of environmental monitoring data collected from FY2002 through FY2007 by the Ministry of the Environment in order to verify the effectiveness of certain restrictions. It was shown that the estimated maximum exposure amount based on environmental concentrations was below the acceptable amounts (*i.e.*, the no observed adverse effect level for humans/estimated no-observed-effect concentration for flora and fauna in the human living environment based on toxicity data with respect to PFOS and its salts).

Meanwhile, the risk evaluation focusing on the Tokyo Bay was conducted by the NITE (Incorporated Administrative Agency, National Institute of Technology and Evaluation). The results showed that environmental concentrations of PFOS and its salts decreased rapidly in association with the reduction of their releases. The risk evaluation taking into account biological concentration caused by the said three usages and the use of fire-fighting foam at the time of an accident also showed that the estimated maximum exposure amount was below the acceptable amount/acceptable concentration for humans, flora and fauna in the human living environment, and predator animals at higher trophic level.

Based on that risk evaluation it was concluded that if the use of PFOS and its salts remained restricted to the three usages in years to come that have low substitutability and based on currently available information, it could be judged that they pose little risk of causing damage to humans, and flora and fauna in the human living environment, considering that their amount used would decrease, followed by their reduced releases to the environment.

In addition evaluations on biodegradability, bioaccumulation potential and long-term toxicity of PFOS and its salts were conducted on the basis of available information including the risk profiles prepared for the Stockholm Convention. As a result, they were designated as the Class I Specified Chemical Substances.

The result of that regulatory process is that the use of PFOS is severely restricted and the chemical is designated as a Class I Specified Chemical Substance. It is prohibited to manufacture, import or use this chemical substance. However, certain essential uses under strict control are permitted as an exception.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

- Canada** The prohibition of manufacture, use, sale, offer for sale, or import of PFOS, its salts and its precursors will work towards the objective of virtual elimination of the substance. Therefore, this regulatory action will also result in a reduction of risk for Canada's environment.
- European Union** The severe restriction is intended to cover the major part of the exposure risks, while the other minor uses exempted do not seem to pose a risk. Although PFOS is persistent, it is considered that, as long as re-occurrence of former major uses is not allowed, the concentrations of PFOS in the environment may eventually diminish.
- Japan** Prohibition of manufacture, import and use of PFOS, while certain essential uses under strict control are permitted as an exception. See section 2.1 for further details. The expected effect of the final regulatory action is the reduction of human exposure to this substance as its use is phased out.

3.2 Other measures to reduce exposure

Canada
No Available information

European Union
A number of suggestions were made in the reports of Risk & Policy Analysts Ltd. (RPA, 2004) and Scientific Committee on Health and Environmental Risks (SCHER, 2005) to reduce exposure in industries where the use of PFOS would continue for defined periods.

Fire fighting foams

It was suggested that the ongoing use of remaining stocks should be subjected to a number of conditions, such as that they are not used at incidents where firewater containment is not possible.

Photographic and semiconductor industries

Conditions for permitted use should include that PFOS related substances are only used in closed systems, and high temperature incineration of all PFOS containing waste. An industry voluntary agreement at ensuring emissions control and high temperature incineration of waste containing PFOS related substances was also suggested.

Aviation industry

PFOS related substances should be subject to conditions of permitted use, involving provision for the collection and disposal of aviation hydraulic fluids via high temperature incineration with efforts to secure an industry voluntary agreement.

Japan
No Available information

General
No available information

3.3 Alternatives

It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Canada
Alternative for PFOS aqueous film forming foam (AFFF): PFOS-free AFFF.
Alternatives for fume suppressants in metal plating industries: non-PFOS-based fume suppressants; other control technologies such as composite mesh pads or closed covers.

European Union

A number of alternatives have been suggested by RPA (2004).

Metal plating

For decorative chromium plating, substitution of Cr (VI) by Cr (III) was considered possible with the subsequent decreased use of PFOS for mist suppression.

Fire fighting foams

A number of alternatives are available or under development, including:

- (a) Non-PFOS based fluorosurfactants;
- (b) Silicone based surfactants;
- (c) Hydrocarbon based surfactants;
- (d) Fluorine-free fire fighting foams; and
- (e) Other developing fire fighting foam technologies which avoid the use of fluorine.

Photographic industry

Successful alternatives to PFOS have included non-perfluorinated chemicals such as hydrocarbon surfactants, chemicals with short perfluorinated chains (C₃-C₄), silicones, telomers, and in some cases it has been possible to reformulate coatings that are inherently less sensitive to static build-up.

Replacement efforts have resulted in the elimination of certain uses of PFOS in imaging products: defoamer, photo acid generators and surfactants.

Alternatives are less easily developed for the semi-conductor and aviation hydraulic fluid industries (RPA, 2004).

Japan

No information available

Others**Stockholm Convention on POPs**

To assist parties in identifying alternatives to PFOS the Persistent Organic Pollutants Review Committee (POPRC) of the Stockholm Convention developed guidance on alternatives to PFOS (POPRC, 2010). In their guidance POPRC identified the following use areas and PFOS alternatives:

Table. 1. Use areas of PFOS and alternatives

Use area	Use of PFOS-related substances	Alternatives used
Impregnation of textiles, leather and carpets	PFOS-related substances have been phased out in most OECD countries.	Other fluorinated compounds, like C ₆ -fluorotelomers and perfluorobutane sulfonate (PFBS), silicone-based products, stearamidomethyl pyridine chloride
Impregnation of paper and cardboard	PFOS-related substances have been phased out in most OECD countries.	Fluorotelomer-based substances and phosphates, mechanical processes
Cleaning agents, waxes/ polishes for cars and floors	PFOS-related substances have been phased out in most OECD countries.	Fluorotelomer-based substances, fluorinated polyethers, C ₄ -perfluorinated compounds
Surface coatings, paint and varnish	PFOS-related substances have been phased out in most OECD countries.	Telomer-based compounds, fluorinated polyethers, PFBS, propylated aromatics, silicone surfactants, sulfosuccinates, polypropylene glycol ethers
Oil production and mining	PFOS derivatives may occasionally be used as surfactants in the oil and mining industries.	PFBS, telomer-based fluorosurfactants, perfluoroalkyl-substituted amines, acids, amino acids and thioether acids
Photographic industry	A shift to digital techniques has reduced the use drastically.	Telomer-based surfactants products, hydrocarbon surfactants, silicone products, C ₃ -C ₄ -fluorinated chemicals
Electrical and electronic parts	PFOS-based chemicals are or have been used in the manufacturing of digital cameras, mobile phones, printers, scanners, satellite communication and radar systems, etc.	For most of these uses, alternatives are available or are under development.

Semiconductor industry	PFOS is still used but in lower concentrations.	No substitutes with comparable effectiveness have been identified, and doing so may take up to 5 years, according to the industry. It should be possible to use PFBS, fluorinated polyethers or telomers.
Aviation hydraulic oils	PFOS-related compounds may still be used.	Other fluorinated substances and phosphate compounds could be used.
Pesticides	Sulfluramid is used in some countries as an active substance and surfactant in pesticide products for termites, cockroaches and other insects. Other fluorosurfactants may be used as “inert” surfactants in other pesticide products.	Synthetic piperonyl compounds such as S-Methoprene, Pyriproxyfen, Fipronil and Chlorpyrifos are alternative active substances, sometimes used in combination. Alternative surfactants may exist.
Medical devices	Old video endoscopes at hospitals contain a CCD colour filter that contains a small amount of PFOS. PFOS is also used as an effective dispersant for contrast agents in radio-opaque catheters.	Repairing such video endoscopes requires a CCD colour filter containing PFOS. New CCD filters are PFOS-free. For radio-opaque ethylene tetrafluoroethylene, PFBS can replace PFOS.
Metal plating	PFOS-compounds are still used in hard chrome plating. Cr-III has replaced Cr-VI in decorative chrome plating.	Some non-fluorinated alternatives are marketed but they are not considered equally effective in hard chrome plating. A C ₆ -fluorotelomer is used as a substitute and may be effective. PFBS derivatives may also be used. Physical barriers may also apply.
Fire-fighting foams	The use of PFOS-related substances in new products has been phased out in most OECD countries. Stocks are still being used up.	C ₆ - fluorotelomers are used as substitutes in new products; fluorine-free alternatives are used for training exercises and possibly in other settings than offshore.

3.4 Socio-economic effects

Canada

The costs associated with prohibiting aqueous film forming foams (AFFFs) relate to the safe disposal of existing stocks, as well as the incremental costs of replacing the stock with alternatives. The costs associated with metal plating relate to the replacement of the stock with alternatives or the conversion to other control technologies. Costs incurred by the federal government relate to enforcement and compliance promotion activities. The benefits of prohibiting PFOS, its salts and its precursor include protection from PFOS exposure of wildlife and ecosystems, including those in remote areas such as the Canadian Arctic, as a result of the reduction in the use of PFOS and protection of water supply sources through the avoidance of contamination as a result of handling, release and use of PFOS. Costs associated with tapping alternate water sources are thus avoided.

More information on the costs and benefits are outlined in the Regulatory Impact Analysis Statement published with the Regulations.

European Union

No information available

Japan

No Information available

4. Hazards and Risks to human health and the environment	
4.1 Hazard Classification	
WHO / IPCS	1b
IARC	Not evaluated
European Union	<p>Hazard classification pursuant to Directive 67/548/EEC: Carcinogen Category 3 R40 - Limited evidence of a carcinogenic effect. Toxic for Reproduction Category 2; R61 - May cause harm to the unborn child. T; R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed. Xn; R20/22 - Harmful by inhalation and if swallowed. R64 - May cause harm to breastfed babies. N; R51-53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>Hazard classification pursuant to Regulation (EC) 1272/2008 implementing the UN GHS: Carc. 2 - H351 - Suspected of causing cancer Repr. 1B - H360D - May damage the unborn child STOT RE 1 - H372 - Causes damage to organs through prolonged or repeated exposure Acute Tox. 4* - H332 - Harmful if inhaled Acute Tox. 4* - H302 - Harmful if swallowed Lact. - H362 - May cause harm to breast-fed children Aquatic Chronic 2 - H411 - Toxic to aquatic life with long lasting effects * = This classification shall be considered as a minimum classification.</p>
US EPA	-

4.2 Exposure limits

Drinking Water

In the light of pollution incidents, a number of national bodies have issued guidelines for PFOS, based on human health effects.

Germany - in 2006, guidance for maximum values of combined PFOS and perfluorooctanoic acid (PFOA) were issued. These values ranged from 0.1 to 5 µg/L (Wilhelm *et al.* 2008 J Toxicol. Environ. Health, Part A, 71, 725-733)

UK - in 2007, guidance was produced by the Drinking Water Inspectorate of England and Wales based on a three-tiered system with values ranging from 0.3 to 9 µg/L with requirement for increased monitoring through to action to decrease concentrations.

USA - in 2009, a provisional health advisory of 0.2 µg/L was set by the US Environmental Protection Agency.

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing Group:	-
International Maritime Dangerous Goods (IMDG) Code	None
Transport Emergency Card	None

4.4 First aid

NOTE: *The following advice is based on information available from the World Health Organisation and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.*

Specific first aid for PFOS is not available from the World Health Organization or the notifying countries. There is no International Chemical Safety Card on PFOS prepared by IPCS. In the absence of this information, the following is taken from a Chemical Hazards document prepared by the UK Health Protection Agency (HPA, 2008)

Decontamination and First Aid

Important Notes

- Ambulance staff, paramedics and emergency department staff treating chemically contaminated casualties should be equipped with gas-tight (Respirex) decontamination suits based on EN466:1995, EN12941:1998 and prEN943-1:2001, where appropriate.
- Decontamination should be performed using local protocols in designated areas such as a decontamination cubicle with adequate ventilation.

Dermal Exposure

- Remove patient from exposure.
- The patient should remove all clothing and personal effects.
- Double-bag soiled clothing and place in a sealed container clearly labelled as a biohazard.
- Brush away any adherent solid particles and gently blot away any adherent liquid from the patient.
- Wash hair and all contaminated skin with copious amounts of water (preferably warm) and soap for at least 10-15 minutes. Decontaminate open wounds first and avoid contamination of unexposed skin.
- Pay special attention to skin folds, axillae, ears, fingernails, genital areas and feet.

Ocular Exposure

- Remove patient from exposure.
- Remove contact lenses if necessary and immediately irrigate the affected eye thoroughly with water or 0.9% saline for at least 10-15 minutes.
- Patients with corneal damage or those whose symptoms do not resolve rapidly should be referred for urgent ophthalmological assessment.

Inhalation

- Remove patient from exposure.
- Ensure a clear airway and adequate ventilation.
- Give oxygen to symptomatic patients.
- Apply other supportive measures as indicated by the patient's clinical condition.

Ingestion

- Give oxygen to symptomatic patients.
- Apply other supportive measures as indicated by the patient's clinical condition.

4.5 Waste management

Basel Convention

In all cases, waste should be disposed in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines there under (Basel Convention, 1994), and any other relevant regional agreements.

The relevant measures identified are as follows:

- (a) classification as hazardous waste; and
- (b) specified disposal, methods and/or conditions, for example, incineration (temperature and time).

The emphasis of these measures is on the disposal of final products of manufacture after industrial and professional use.

In the near future, the Basel Convention technical guidelines on the environmentally sound management of persistent organic pollutants will be updated to encompass PFOS along with the other new POPs that were listed in the Stockholm Convention in 2009. The work is proposed undertaken in collaboration with the Stockholm Convention (POPRC-6/3).

European Union

Following the inclusion of the nine new POPs, including PFOS, in the Stockholm Convention in 2009, the EU commissioned a comprehensive study on POPs and waste that provide information on sources, concentrations, past uses, waste and recycling issues (ESWI, 2011). The report will be used by the EU and its member states to identify, manage and regulate POPs containing waste e.g. to set limit values for POPs in waste and to classify whether a waste is a POP waste or not.

Annexes

- | | |
|---------|---|
| Annex 1 | Further information on the substance |
| Annex 2 | Details on Final regulatory action |
| Annex 3 | Address of designated national authorities |
| Annex 4 | References |

Annex 1**Further information on the substance****Introduction**

The information presented in the present Annex reflects the conclusions of the three notifying Parties, namely Canada, the European Union and Japan. Where possible, information provided by these three parties has been presented together, while the risk assessments, which are specific to the conditions prevailing in the Parties, are presented separately. This information is taken from the documents referenced in the notifications in support of the final regulatory actions severely restricting perfluorooctane sulfonic acid, perfluorooctanesulfonates, perfluorooctanesulfonamides and perfluorooctanesulfonyls. This DGD is the result of four notifications: perfluorooctane sulfonate, its salts and precursors (Canada); perfluorooctane sulphonates (European Union); perfluorooctane sulfonate (PFOS) and its salts (Japan), and perfluorooctane sulfonyl fluoride (PFOSF) (Japan). All four notifications were considered at CRC7 and CRC8, and consequently the CRC recommended the listing of perfluorooctane sulfonic acid, perfluorooctanesulfonates, perfluorooctanesulfonamides and perfluorooctanesulfonyls .

There have been a number of reviews on PFOS, its salts and its precursors, mainly from the US (OECD, 2002), UK (RPA, 2004; EA, 2004) and Canada (Health Canada, 2004; Environment Canada, 2006). The Persistent Organic Pollutants Review Committee of the Stockholm Convention has also prepared a risk profile on PFOS (POPRC, 2006). These reports have been taken into consideration in the final regulatory action of Canada, the European Union and Japan and are referenced in the present document. There have been a wide range of continuing studies on PFOS since the publication of these reports but, they have not been reviewed by an authoritative body and so, although mentioned, these are not considered in detail in this DGD.

Annex 1 – Further information on PFOS, its salts and the precursor perfluorooctane sulfonyl fluoride

1. Physico-Chemical properties		
1.1 Identity	PFOS	
1.2 Formula	$C_8F_{17}SO_2X$ (X=OH, metal salt (O^-M^+), halide, amide, and other derivatives)	
1.3 Appearance	White powder	
1.4 Melting point	$\geq 400^\circ C$	
1.6 Boiling point	Not calculable	
1.7 Vapour pressure	3.31×10^{-4} Pa at $20^\circ C$ (3.27×10^{-9} atm)	
1.8 Henry's Law Constant	3.5×10^{-9} atm.m ³ /mole (pure water)	
	4.7×10^{-9} atm.m ³ /mole (freshwater)	
	1.4×10^{-7} atm.m ³ /mole (unfiltered seawater)	
	2.4×10^{-8} atm.m ³ /mole (filtered seawater)	
	4.43×10^{-7} atm.m ³ /mole at $20^\circ C$ (pure water)	
1.9 Solubility in water	570 mg/L (pure water) 370 mg/L (freshwater) 12.4 mg/L (unfiltered seawater) 25 mg/L (filtered seawater) (OECD, 2002)	
2 Toxicological properties		
2.1 General	The data for toxicity given below are mainly for PFOS and its salts. The information for the precursor perfluorooctane sulfonyl fluoride, although more limited and variable, indicates that their toxicological effects are similar to those of PFOS itself. Based on the data identified, health-related effects associated with exposure to these substances would appear to be somewhat less severe and/or observed at higher exposures (doses) than those associated with exposure to PFOS itself (Health Canada, 2004).	
2.1.1 Mode of Action	PFOS appears to be toxic to liver and thyroid and leads to tumours in these two organs in experimental animals. Evidence suggests that it is non-genotoxic. The mechanism of action underlying these toxicities is not clear at present (OECD, 2002; Health Canada, 2004).	
2.1.2 Symptoms of poisoning	There have been no reported cases of acute poisoning in humans.	
2.1.3 Absorption, distribution, excretion and metabolism in mammals	<p><i>European Union</i></p> <p>PFOS is reported to be well absorbed following oral administration. Approximately 95% of the total radioactivity was absorbed after 24 hours, following oral administration of radiolabelled PFOS to rats. Approximately 86% of the radioactivity was found in the carcass after 24-48 hours. There is no evidence of selective retention in red blood cells. Urinary excretion is reported to be the primary route of excretion in rats; 89 days after administration of a single intravenous dose of radiolabelled PFOS, $30.2 \pm 1.5\%$ of the total radiolabel was recovered in urine. Mean cumulative faecal excretion was $12.6 \pm 1.2\%$. The half-life of elimination of PFOS from the plasma of male rats is reported to be 7.5 days. There is evidence of enterohepatic recirculation of PFOS. In two separate occupational exposure studies in humans, serum PFOS half-lives of approximately 4 years and 8.67 years have been calculated.</p>	
2.2 Toxicology studies	Results given are for PFOS unless stated otherwise.	
2.2.1 Acute toxicity	<p>Acute Toxicity:</p> <p>PFOS</p> <p>LD₅₀ (rat, oral, male); 233 mg/kg bw (95% C.I. of 160-339 mg/kg bw)</p> <p>LD₅₀ (rat, oral, female); 271 mg/kg bw (95% C.I. of 200-369 mg/kg bw)</p> <p>LD₅₀ (rat, oral); 251 mg/kg bw (95% C.I. of 199-318 mg/kg bw)</p>	

LD₅₀ (rat, oral); >50-<1500 mg/kg bw
 LC₅₀ (rat, inhalation); 5.2 mg/L (95% C.I. of 4.4 and 6.4 mg/L)

Irritation and Sensitisation:

PFOS is reported to be non-irritating to the skin of rabbits. In an eye irritation study, rabbits were observed 1, 24, 48 and 72 hours after treatment with PFOS. Maximum irritation was reported after 1 and 24 hours, however, the severity of irritation was not reported, although the Health Canada review listed this as severe irritation.

2.2.2 Short term toxicity

Subchronic Toxicity:

Rat (diet, 90 days)

LOAEL = 30 mg/kg diet (approximately 1.5 mg/kg bw/day) (decreased bodyweight and food consumption, increased absolute and relative liver weight (females))

Monkey

(gavage, 90 days): LOAEL = 10 mg/kg bw/day (death of all animals)

(gavage, 90 days): LOAEL = 0.5 mg/kg bw/day (occasional gastrointestinal tract toxicity, occasional decreased activity)

(oral capsule, 6 months): NOAEL = 0.03 mg/kg bw/day (alterations in lipoprotein cholesterol levels (both sexes) and triiodothyronine levels (females))

2.2.3 Genotoxicity (including mutagenicity)

Negative results have been reported in *in vitro* reverse mutation assays in *Salmonella typhimurium* and *Escherichia coli*, with and without metabolic activation. Negative results were reported in an unscheduled DNA synthesis assay conducted in rat hepatocytes, and in a chromosomal aberration assay conducted in human lymphocytes, with and without metabolic activation. Negative results have been reported *in vivo* in mice bone marrow micronucleus assays.

Negative results have also been reported for T-2247 CoC (50% by weight solution of diethanolammonium salt of PFOS) in *in vitro* assays with *Salmonella typhimurium* and *Saccharomyces cerevisiae*.

2.2.4 Long term toxicity and carcinogenicity

Chronic Toxicity:

Rat

(diet, 2 years, male): NOAEL = 0.5 mg/kg diet (approximately 0.025 mg/kg bw/day) (hepatotoxicity)

(diet, 2 years, female): NOAEL = 2 mg/kg diet (approximately 0.1 mg/kg bw/day) (hepatotoxicity)

Carcinogenicity:

Rat

Incidences of hepatocellular adenomas, thyroid follicular cell adenomas, and combined thyroid follicular cell adenomas and carcinomas were increased in both sexes. Incidences of combined hepatocellular adenomas and carcinomas, mammary fibroadenoma/adenomas, and combined mammary fibroadenoma/adenomas and carcinomas were increased in females.

2.2.5 Effects on reproduction

Rat

(developmental study): Maternal NOAEL = 1 mg/kg bw/day (reduced bodyweight, haunched posture, anorexia, bloody vaginal discharge, uterine stains, alopecia, rough coat)

Developmental NOAEL = 1 mg/kg bw/day (decreased foetal weight)

(developmental study): Maternal NOAEL = 1 mg/kg bw/day (reduced bodyweight)

Developmental NOAEL = 1 mg/kg bw/day (pup mortality)

(2 generation study): F0 males NOAEL = 0.1 mg/kg bw/day (reduced bodyweight gain and food consumption)

F0 females NOAEL = 0.1 mg/kg bw/day (reduced bodyweight gain and food consumption)

F1 parental males LOAEL = 0.1 mg/kg bw/day (reduced food consumption)

F1 parental females NOAEL = 0.1 mg/kg bw/day (reduced bodyweight gain and food consumption)

F1 offspring NOAEL = 0.4 mg/kg bw/day (reduction in number of implantation sites, litter size, pup viability, pup bodyweight and pup survival)

F2 offspring NOAEL = 0.1 mg/kg bw/day (reduced bodyweight gain)

Mouse

(developmental study): Maternal NOAEL = 1 mg/kg bw/day (increased liver weight)
Developmental NOAEL = 5 mg/kg bw/day (foetal mortality)

Rabbit

(developmental study): Maternal NOAEL = 0.1 mg/kg bw/day (reduced bodyweight gain)
Developmental NOAEL = 1 mg/kg bw/day (decreased foetal weight and reduction in ossification of the sternum)
(OECD, 2002; Health Canada, 2004)

- 2.2.6 Neurotoxicity/ delayed neurotoxicity, Special studies where available** None available
- 2.2.7 Summary of mammalian toxicity and overall evaluation** Sufficient information exists to address all toxicological endpoints. These studies indicate that PFOS is persistent, bioaccumulative and toxic to mammalian species. There are distinct differences in the elimination half-life of PFOS: 100 days in rats, 200 days in monkeys, and years in humans. The toxicity profile for rats and monkeys is similar with repeat dose exposure resulting in hepatotoxicity and mortality. The dose-response curve is very steep for mortality. This response occurs in animals of all ages, although neonates may be more sensitive. PFOS and its salts are not genotoxic, however, a two-year bioassay in rats has shown that exposure to PFOS results in hepatocellular adenomas and thyroid follicular adenomas. The hepatoadenomas do not appear to be related to the non-genotoxic mechanism, peroxisome proliferation. Further studies to elucidate species difference in toxicokinetics and the mode of action of PFOS will increase our ability to predict the risk to humans. Epidemiological studies have shown an association between PFOS exposure and the incidence of bladder cancer; further work is needed to understand this association. (OECD, 2002)

3 Human exposure/Risk evaluation

- 3.1 Food** There are no data on the presence of PFOS in food in the authoritative reviews upon which the regulatory actions of the notifying parties are based. However, there have been a number of more recent studies showing that PFOS is present in foodstuff at low concentrations in various countries worldwide including Europe and Canada. It has been most often described in fish, crustaceans, shellfish and offal (for an example study and references for further studies world-wide, see FSA, 2008).
- 3.2 Air** Manufacturing processes constitute a major source of PFOS to the local environment. During these processes, volatile PFOS-related substances may be released to the environment. Overall, the conclusion is that PFOS itself is a substance with a very low and possibly negligible volatility. (OECD, 2002)
- 3.3 Water** PFOS and PFOS-related substances could also be released via sewage effluents. High concentrations of PFOS had been detected in the liver and blood of fish collected in the Mississippi River at the immediate vicinity of a 3M fluorochemical plant at Cottage Grove in Minnesota. Fire training areas have also been shown to be a source of PFOS emissions due to the presence of PFOS in fire fighting foams. High levels of PFOS have been detected in neighbouring wetlands of such an area in Sweden.
- PFOS was also detected in surface water as a result of a spill of fire-fighting foam from Canada's Toronto International airport into nearby Etobicoke Creek. Concentrations of PFOS ranging from <0.017 to 2210 µg/L were detected for a period of 153 days. Levels of 31 ng/L and 54 ng/L were detected in Lake Erie and Lake Ontario, respectively. These are similar results to those found for environmental waters worldwide.
- Many recent studies published since the authoritative reports have detected the presence of PFOS in both environmental and drinking water after contamination incidents in UK, Germany and USA. PFOS has also been detected in surface water,

- groundwater and drinking water worldwide.
- 3.4 Occupational exposure** There have been a number of studies completed and underway on workers exposed to PFOS compounds in manufacturing sites mainly in the USA but also in sites in Europe. The earlier studies were reviewed in the OECD review of 2002. There have been a number of further studies reported since then but these have not been reviewed by authoritative bodies and so are not included here.
- In human blood samples, PFOS has been detected in the serum of occupational and general populations. The highest level of 12.83 ppm being detected in a manufacturing employee at the 3M plant in Decatur, Alabama in 1995. Mean levels have been decreasing at this plant and another in Antwerp Belgium since then with mean levels in 2000 of 1.32 and 0.80 ppm, respectively.
- 3.5 Medical data contributing to regulatory decision** Several occupational studies have been carried out on volunteers at the 3M plants in Decatur and Antwerp. In the years 1995 and 1997, cross-sectional studies based on a medical surveillance program did not show any consistent effects on haematological, hormonal and clinical chemistry parameters in workers with PFOS levels less than 6 ppm. In a larger study in 2000 including male employees from both plants, certain chemical parameters (triglycerides, alkaline phosphatase, total bilirubin and alanine aminotransferase) were raised in workers with the highest PFOS levels (1.69-10.06 ppm). Thyroid markers, serum triiodothyronine was significantly higher and thyroid hormone binding ratio lower in workers with the highest PFOS levels. A longitudinal analysis did not reveal any statistically significant associations over time between PFOS exposure and cholesterol, triglycerides and other lipid and hepatic parameters. Hormones were not included in this study. There are a number of limitations to both of these types of studies including small numbers of subjects, voluntary medical surveillance and differences in exposure, etc. between the two works.
- In a mortality study which followed workers for 37 years, mortality risks for most cancers and non-cancer causes were not elevated. However, there was a significantly increased risk of death from bladder cancer reported with three male workers dying (0.12 expected). All had been employed in the plant for more than 20 years with high exposure jobs for at least 5 years. To examine morbidity, health claims were analysed for employees working at the plant between 1993 and 1998, examining many cancers and non-malignant conditions. An increased risk of episodes was reported for male reproductive cancers, the overall category of cancers and benign growths and cancer of the gastrointestinal tract. These risk ratios were highest in employees with the highest and longest exposure to fluorochemicals.
- 3.6 Public exposure** PFOS compounds have been detected in blood serum samples taken from the general population both from areas around manufacturing sites but also worldwide. In the general population, serum collected from blood banks and commercial sources have indicated mean PFOS levels of 30-53 ppb. In individual serum samples taken from adults and children in various regions of the USA, mean PFOS levels were approximately 43 ppb. Similar results have been seen in the Netherlands, Belgium and Germany. As with occupational exposure, studies on background levels in the blood of the general population have continued since the OECD review but the results have not been assessed by an authoritative body. However, they have been published in peer-reviewed journals and show a downward trend in PFOS compounds present in the serum of the general population.
- 3.7 Summary-overall risk evaluation** When the authoritative review was published by OECD there were only limited data on the emissions and pathways of PFOS to the environment. The occurrence of PFOS in the environment is a result of anthropogenic manufacturing and use, since PFOS is not a naturally occurring substance. Releases of PFOS and its related substances are likely to occur during their whole life cycle. They can be released at their production, at their assembly into a commercial product, during the distribution and industrial or consumer use as well as from landfills after the use of the products.
- Further recent studies have shown the presence of PFOS in food, air and environmental and drinking water. Epidemiological studies on health effects of PFOS in occupationally exposed populations and the surrounding general population have continued. However, they have not as yet been reviewed by an authoritative body and

there is no consensus of opinion, therefore, they are not detailed in this DGD.

The data on PFOS clearly show that it is persistent, bioaccumulative and toxic to mammalian species. PFOS has been detected in the serum of occupational and general populations. There is a statistically significant association between PFOS exposure and bladder cancer and there appears to be an increased risk of episodes of neoplasm of the male reproductive system, the overall category of cancers and benign growths, and neoplasms of the gastrointestinal tract.

4 Environmental fate and effects

4.1 Fate

Japan

PFOS fulfils the POPs criteria of the Stockholm Convention and 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 (POPRC, 2006).

PFOS is an atypical POP as it does not follow the “classical” pattern of partitioning into fatty tissues followed by accumulation, which is typical of many persistent organic pollutants. This is because PFOS is both hydrophobic and lipophobic. Instead, PFOS binds preferentially to proteins in the plasma, such as albumin and β -lipoproteins, and in the liver, such as liver fatty acid binding protein (L-FABP). Due to the properties of PFOS, which binds preferentially to proteins in non-lipid tissues, application of numeric criteria for BCF or BAF, which are derived based on consideration of lipid-partitioning substances, may be inappropriate for PFOS (POPRC, 2006).

4.1.1 Soil

A number of aerobic and anaerobic studies have concluded that PFOS is not biodegradable.

Degradation of EtFOSE and MeFOSE results in the formation of PFOS anion and PFOA.

A degradation study in a soil and sediment culture indicated no PFOS degradation in 20 weeks.

Sorption studies of PFOS to three types of soil, a sediment and sludge from a domestic wastewater treatment plant was measured using a method based on OECD 106. Adsorption occurred rapidly in all cases and the concentration remained fairly constant after 16 hours.

4.1.2 Water

The concentrations of PFOS detected in environmental waters are outlined in Section 3.3 above.

Hydrolysis of the potassium salt of PFOS studied over a range of pH values from 1.5 to 11 showed no loss of PFOS.

PFOS does not appear to photolyse.

The biodegradation of PFOS was measured in a MITI-I test and no significant degradation was observed in 28 days, as net oxygen demand from degradation of parent compound, loss of total organic carbon or loss of parent compound identity.

4.1.3 Air

Overall, the conclusion is that PFOS itself is a substance with a very low and possibly negligible volatility. The estimated half-life is 114 days. Combined with the low volatility, this indicates that degradation in the atmosphere is not likely to be significant.

4.1.4 Bioconcentration

European Union

In a flow-through study on bluegill sunfish (*Lepomis macrochirus*), the bioconcentration factor (BCF) for edible tissue, non-edible tissue and whole fish were calculated from the rates of uptake and depuration because steady state had not been reached after 56 days of exposure. The BCF values obtained were 1124 (edible), 4103 (non-edible) and 2796 (whole fish). The exposure concentration was 0.086 mg/L.

A flow-through study on carp (*Cyprinus carpio*), resulted in lower BCF values of 720 at 20 $\mu\text{g/L}$ exposure and 200-1500 at 2 $\mu\text{g/L}$. Higher BCF values of 6300-125000 have been reported for *in situ* measurements at the scene of a spill of firefighting foam, but these were considered to be due to the uptake of derivatives which were

then metabolised to PFOS, hence the values were overestimated.

In summary, BCF values up to 2800 have been measured in laboratory studies, and this meets the B = bioaccumulative criterion from the GHS.

The occurrence of PFOS in a range of biota supports this conclusion. PFOS has been found in a range of higher organisms in Europe, including seals, dolphins, whales, cormorants, eagles, swordfish, tuna and salmon. The Global Biophase Monitoring Programme found PFOS in liver, blood and other tissues of animals, especially in fish-eating animals.

4.1.5 Bioaccumulation *Japan*

PFOS bioaccumulates and highly elevated concentrations have been found in top predators such as the polar bear, seal, bald eagle and mink (for reported levels see POPRC, 2006). Based on the concentrations found in their prey, high BMFs have been estimated for these predators. However, PFOS which is both hydrophobic and lipophobic, is an atypical POP and does not follow the “classical” pattern of partitioning into fatty tissues followed by accumulation, which is typical of many persistent organic pollutants. Instead, PFOS binds preferentially to proteins in the plasma, such as albumin and β -lipoproteins, and in the liver, such as liver fatty acid binding protein (L-FABP). Due to the properties of PFOS, which binds preferentially to proteins in non-lipid tissues, application of numeric criteria for BCF or BAF, which are derived based on consideration of lipid-partitioning substances, may be inappropriate (POPRC, 2006).

Canada

Unlike many other persistent organic pollutants, certain perfluorinated substances, such as PFOS, are present as ions in environmental media and partition preferentially to proteins in liver and blood rather than to lipids. Therefore, the bioaccumulation potential of PFOS may not be related to the typical mechanisms associated with bioaccumulation in lipid-rich tissues (Environment Canada, 2006).

4.1.6 Persistence

European Union

PFOS is persistent in the environment. It does not hydrolyse, photolyse or volatilise from the aquatic environment. PFOS does not undergo biodegradation; no significant biodegradation of PFOS was observed over 28 days, either as net oxygen loss, loss of total organic carbon or loss of primary compound identity. In the following tests, no evidence of biodegradation was observed:

- (a) Activated sludge
- (b) Acclimated activated sludge (including added soil and sediment materials) in both aerobic and closed vial exposures
- (c) Aerobic soil and sediment cultures
- (d) Anaerobic sludge from sludge digester
- (e) Pure microbial cultures

The conclusion drawn is that PFOS meets the P, persistent and vP, very persistent criteria of GHS.

Canada

PFOS is resistant to hydrolysis, photolysis, microbial degradation, and metabolism by vertebrates. PFOS has been detected in fish, in wildlife worldwide and in the northern hemisphere. This includes Canadian wildlife located far from known sources or manufacturing facilities indicating that PFOS and/or its precursors may undergo long-range transport. PFOS has been detected in the liver of biota in remote areas of the Canadian Arctic (Environment Canada, 2006).

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

Birds (OECD, 2002)

Mallard duck

Anas platyrhynchos: NOEC (bodyweight) = 73 mg/kg food (PFOS potassium salt, 5 days exposure followed by 3-17 days observation)

Anas platyrhynchos: NOEC (mortality) = 146 mg/kg food (PFOS potassium salt, 5 days exposure followed by 3-17 days observation)

Anas platyrhynchos: LC₅₀ = 628 mg/kg food (PFOS potassium salt, 5 days exposure followed by 3-17 days observation)

Northern bobwhite quail

Colinus virginianus: NOEC (bodyweight) = 73 mg/kg food (PFOS potassium salt, 5 days exposure followed by 3-17 days observation)

Colinus virginianus: NOEC (mortality) = 73 mg/kg food (PFOS potassium salt, 5 days exposure followed by 3-17 days observation)

Colinus virginianus: LC₅₀ = 220 mg/kg food (PFOS potassium salt, 5 days exposure followed by 3-17 days observation)

4.2.2 Aquatic species

Freshwater species

(OECD, 2002)

Algae: Acute, static

Green algae

Selenastrum capricornutum: 96 hour EC₅₀ (cell density) = 71 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 96 hour EbC₅₀ (area under the curve) = 71 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 96 hour ErC₅₀ (growth rate) = 126 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 96 hour NOEC (cell density, growth rate and area under the curve) = 44 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 72 hour EC₅₀ (cell density) = 70 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 72 hour EbC₅₀ (area under the curve) = 74 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 72 hour ErC₅₀ (growth rate) = 120 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 72 hour NOEC (cell density, growth rate and area under the curve) = 70 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 96 hour EC₅₀ (cell density) = 71, 82 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 96 hour EC₁₀ (cell density) = 10 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 96 hour NOEC (cell density) = 35 mg/L (PFOS potassium salt) (OECD, 2002)

Algae: Acute

Blue-green algae

Anabaena flosaquae: 96 hour NOEC (growth rate) = 94 mg/L (PFOS potassium salt)

Anabaena flosaquae: 96 hour EC₅₀ (growth rate) = 176 mg/L (PFOS potassium salt)

Diatom

Navicula pelliculosa: 96 hour NOEC (growth rate) = 206 mg/L (PFOS potassium salt)

Navicula pelliculosa: 96 hour EC₅₀ (growth rate) = 305 mg/L (PFOS potassium salt) (OECD, 2002)

Algae: Chronic, static

Green algae

Selenastrum capricornutum: 14 day NOEC (cell density) = <26 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 14 day EC₁₀ (cell density) = 16 mg/L (PFOS potassium salt)

Selenastrum capricornutum: 14 day EC₅₀ (cell density) = 95 mg/L (PFOS potassium salt)

Plant: Chronic**Duckweed**

(*Lemna gibba*): 7 day IC₅₀ = 108 mg/L (PFOS potassium salt)

Invertebrates: Acute, static**Water flea**

Daphnia magna: 48 hour NOEC = 33 mg/L (PFOS potassium salt)

Daphnia magna: 48 hour EC₅₀ = 14-61 mg/L (PFOS potassium salt)

Daphnia magna: 48 hour EC₅₀ = 27 mg/L (PFOS potassium salt)

Daphnia magna: 24 hour EC₅₀ = >42 mg/L (PFOS potassium salt)

Daphnia magna: 48 hour NOEC = 100 mg/L (PFOS lithium salt)

Daphnia magna: 48 hour EC₅₀ = 210 mg/L (PFOS lithium salt)

Daphnia magna: 48 hour NOEL = 2.2 mg/L (35% PFOS didecyldimethyl-ammonium salt)

(*Daphnia magna*): 48 hour EL₅₀ = 4.0 mg/L (35% PFOS didecyldimethylammonium salt)

Invertebrates: Acute, semi-static**Mussel**

Unio complamatus: 96 hour NOEC = 50 mg/L (PFOS potassium salt)

Unio complamatus: 96 hour EC₅₀ = 59 mg/L (PFOS potassium salt)

Invertebrates: Chronic, semi-static**Waterflea**

Daphnia magna: 21 day NOEC (reproduction) = 12 mg/L (PFOS potassium salt)

Daphnia magna: 21 day NOEC (survival) = 12 mg/L (PFOS potassium salt)

Daphnia magna: 21 day NOEC (growth) = 12 mg/L (PFOS potassium salt)

Daphnia magna: 21 day EC₅₀ (reproduction) = 12 mg/L (PFOS potassium salt)

Daphnia magna: 28 day NOEC (reproduction) = 7 mg/L (PFOS potassium salt)

Daphnia magna: 28 day EC₅₀ (reproduction) = 11 mg/L (PFOS potassium salt)

Fish: Acute, static**Fathead minnow**

Pimephales promelas: 96 hour NOEC = 3.3 mg/L (PFOS potassium salt)

Pimephales promelas: 96 hour LC₅₀ = 9.5-51 mg/L (PFOS potassium salt)

Pimephales promelas: 96 hour LC₅₀ = 4.7 mg/L (24.5% PFOS lithium salt)

Pimephales promelas: 96 hour LC₅₀ = 21 mg/L (PFOS ammonia salt)

Pimephales promelas: 96 hour NOEL = <170 mg/L (35% PFOS didecyldimethyl-ammonium salt, 5% residual perfluorochemicals)

Bluegill sunfish

Lepomis macrochirus: 96 hour NOEC = 4.5 mg/L (25% PFOS DEA salt)

Lepomis macrochirus: 96 hour LC₅₀ = 7.8 mg/L (25% PFOS DEA salt)

Lepomis macrochirus: 96 hour LC₅₀ = 68 mg/L (25% PFOS potassium salt)

Rainbow trout

Oncorhynchus mykiss: 96 hour LC₅₀ = 7.8 mg/L (PFOS potassium salt)

Oncorhynchus mykiss: 96 hour LC₅₀ = 22 mg/L (86.7% PFOS potassium salt)

Fish: Chronic, flow-through**Fathead minnow**

Pimephales promelas: 42 day NOEC (survival) = 0.3 mg/L (PFOS potassium salt)

Pimephales promelas: 42 day NOEC (growth) = 0.3 mg/L (PFOS potassium salt)

Pimephales promelas: 5 day NOEC (hatch) = >4.6 mg/L (PFOS potassium salt)

Pimephales promelas: 30 day NOEC (early life stages) = 1 mg/L (PFOS potassium salt)

Bluegill sunfish

Lepomis macrochirus: 62 day NOEC (survival) = >0.086 to <0.87 mg/L (PFOS potassium salt)

Amphibians: Acute**African clawed frog***Xenopus laevis*: 96 hour EC₅₀ (malformation) = 12.1 mg/L (PFOS potassium salt)*Xenopus laevis*: 96 hour LC₅₀ = 13.8 mg/L (PFOS potassium salt)*Xenopus laevis*: MIC (growth) = 7.97 mg/L (PFOS potassium salt)**Marine species**

(OECD, 2002)

Algae: Acute**Diatom***Skeletonema costatum*: 96 hour NOEC (growth rate) = >3.2 mg/L (PFOS potassium salt)*Skeletonema costatum*: 96 hour EC₅₀ (growth rate) = >3.2 mg/L (PFOS potassium salt)**Invertebrates: Acute, static****Mysid shrimp***Mysidopsis bahia*: 96 hour NOEC = 1.1 mg/L (PFOS potassium salt)*Mysidopsis bahia*: 96 hour EC₅₀ = 3.6 mg/L (PFOS potassium salt)**Eastern oyster***Crassostrea virginica*: 96 hour NOEC = 1.9 mg/L (PFOS potassium salt)*Crassostrea virginica*: 96 hour EC₅₀ = >3.0 mg/L (PFOS potassium salt)**Brine shrimp***Artemia* sp. 48 hour LC₅₀ = 8.9 mg/L (PFOS potassium salt)**Invertebrates: Chronic, flow-through****Mysid shrimp***Mysidopsis bahia*: 35 day NOEC (reproduction) = 0.25 mg/L (PFOS potassium salt)*Mysidopsis bahia*: 35 day NOEC (survival) = 0.55 mg/L (PFOS potassium salt)*Mysidopsis bahia*: 35 day NOEC (growth) = 0.25 mg/L (PFOS potassium salt)**Fish: Acute, semi-static****Sheep head minnow***Cyprinodon variegatus* LC₅₀ = >15 mg/L (86.7% PFOS potassium salt)**Fish: Acute****Rainbow trout***Oncorhynchus mykiss* LC₅₀ = 13.7 mg/L (PFOS potassium salt)**4.2.3 Honeybees and other arthropods***Apis mellifera*: 72 hour NOEL = 0.21 µg/bee (PFOS potassium salt)*Apis mellifera*: 72 hour LD₅₀ = 0.40 µg/bee (PFOS potassium salt)*Apis mellifera*: 96 hour NOEL = 1.93 µg/bee (PFOS potassium salt)*Apis mellifera*: 96 hour LD₅₀ = 4.78 µg/bee (PFOS potassium salt)

(OECD, 2002)

4.2.4 Earthwormsspecies not stated: 14 day LC₅₀ = 373 mg/kg dw soil (artificial soil substrate) (OECD, 2002)**4.2.5 Soil microorganisms****Bacteria** (OECD, 2002)**Photobacterium phosphoreum:**15 minute EC₅₀ = >250 mg/L (PFOS lithium salt)30 minute EC₅₀ = >250 mg/L (PFOS lithium salt)**Activated sludge**3 hour IC₅₀ = >905 mg/L (PFOS potassium salt)3 hour IC₅₀ = >245 mg/L (24.5% PFOS potassium salt)7 minute IC₅₀ = >250 mg/L (25% PFOS DEA salt)

4.2.6	Terrestrial plants	The lowest no effect level for each endpoint is as follows: Emergence: 62.5 mg/kg onion, ryegrass Survival: 15.6 mg/kg onion, tomato Shoot height: < 3.91 mg/kg lettuce (23% reduced compared to control) < 3.91 mg/kg lettuce (35% reduced compared to control) (OECD, 2002)
5 Environmental Exposure/Risk Evaluation		
5.1	Terrestrial compartment	Toxicity data for earthworms and plants were assessed to derive a PNEC for this compartment. The lowest value for plants of <39 µg/kg wet weight was used in the evaluation. For a number of different scenarios of releases from different uses and with different degradation rates for PFOS-substances, all the risk characterisation ratios are below 1 except for the use area of formulation fire fighting foams. (EA, 2004)
5.2	Aquatic compartment (including sediment)	The lowest NOEC for the whole dataset was 0.25 mg/L for the mysid shrimp. This result was used with an assessment factor of 10 to give a PNEC for freshwater of 25 µg/L. The same result was used for the marine environment but with a safety factor of 100 to give a PNEC of 2.5 µg/L. For some intermittent release scenarios, the lowest acute value of 3.6 mg/L for mysid shrimp was used with a factor of 100 to give a PNEC of 36 µg/L. A sediment PNEC was derived using equilibrium partitioning in the absence of toxicity data for sediment organisms. Freshwater sediment PNEC of 67 µg/kg wwt and a marine sediment PNEC of 6.7 µg/kg were derived. The IC ₅₀ for activated sludge respiration was determined as >905 mg/L, and with an assessment factor of 100 this gave a PNEC of >9.05 mg/L. For a number of different scenarios of releases from different uses and with different degradation rates for PFOS-substances, all the risk characterisation ratios are below 1 except for the use area of formulation fire fighting foams and paper treatment (assuming complete conversion of PFOS-related substances to PFOS before release). (EA, 2004)
5.3	Specific effects relating to the food chain (secondary poisoning)	The lowest no effect level of 0.5 ppm was taken from mammalian toxicity studies and was for liver effects in male rats. This was from a chronic study so an assessment factor of 30 was appropriate giving a PNEC of 0.0167 mg/kg in food. This value was also protective to birds. For the freshwater food chain, all the uses and relevant scenarios indicate a secondary poisoning risk, while for the terrestrial food chain most uses and scenarios indicate a risk. (EA, 2004)
5.4	Summary – overall risk evaluation	PFOS is extremely persistent in the environment. It has been detected in sediment downstream of a production site and in effluent and sludge from sewage treatment plants. (OECD, 2004; EA, 2004). However, due to its ability to undergo long range transport PFOS is also detected in remote regions, far from anthropogenic sources (POPRC, 2006; Environment Canada, 2006). Its persistence and presence in the environment gives cause for concern as the substance also bioaccumulates and is toxic. PFOS is found in a number of species of wildlife, including marine mammals and has been shown to bioconcentrate in fish (POPRC, 2006). Elevated levels are found in top predators. While PFOS appears to be moderately toxic to aquatic organisms, there is evidence of high acute toxicity to honey bees. At present there are no available data to suggest effects on soil- and sediment-dwelling organisms. The toxicity of PFOS appears to reside with the PFOS anion as there are no obvious differences in the toxicity of different PFOS salts. PFOS meets the criteria for being a persistent organic pollutant and is listed in Annex B of the Stockholm Convention on POPs.

In the EU, PFOS meets the criteria for being classified as a very persistent, very bioaccumulating and toxic substance (SCHER, 2005). The inherent properties of PFOS as a PBT and POP were already a sufficient reason for taking regulatory action. In addition, a risk evaluation using risk characterisation ratios (PEC:PNEC comparison) has been carried out by the Environment Agency of England and Wales to assist in the setting of priorities for risk reduction (EA, 2004). This study concluded that there is a risk for secondary poisoning in freshwater and marine food chains for a number of different use and release scenarios. This conclusion was later supported by Scientific Committee on Health and Environmental Risks (SCHER) of the EU (SCHER, 2005). The risk evaluation conducted by the UK also indicated possible effects from the release of fire fighting foams to water and concluded that for freshwater, regional emissions would need to be reduced to less than one-twelfth of the estimated values in order to remove the risk.

Due to its ubiquitous environmental presence and inherent properties PFOS is considered a hazardous substance that may pose a threat to human health and the environment and its use has been restricted in many countries (Japan, Canada, European Union) and at global level (Stockholm Convention on POPs and Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution).

Annex 2 – Details on final regulatory actions reported

Country Name: CANADA

- | | | |
|-----|---|---|
| 1 | Effective date(s) of entry into force of actions | 29 May 2008 |
| | Reference to the regulatory document | The Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations are under subsection 93(1) and section 319 of the Canadian Environmental Protection Act, 1999 (CEPA 1999). PFOS and its salts and its precursors are listed in the List of Toxic Substances in Schedule 1 of CEPA 1999. |
| 2 | Succinct details of the final regulatory action(s) | Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations are under subsection 93(1) Environmental Protection Act, 1999 (CEPA 1999). PFOS and its salts and its precursors are listed in the List of Toxic Substances in Schedule 1 of CEPA 1999. The Regulations prohibit the manufacture, use, sale, offer for sale or import of PFOS and its salts and its precursors, or a product containing any such substance unless the substance is incidentally present. A limited number of exemptions are listed in Section 2.1 |
| 3 | Reasons for action | <p>An ecological screening assessment was undertaken on perfluorooctane sulfonate (PFOS) and its salts and its precursors containing the perfluorooctylsulfonyl (C₈F₁₇SO₂, C₈F₁₇SO₃, or C₈F₁₇SO₂N) moiety. PFOS is resistant to hydrolysis, photolysis, microbial degradation, and metabolism by vertebrates. PFOS has been detected in fish, in wildlife worldwide and in the northern hemisphere. This includes Canadian wildlife located far from known sources or manufacturing facilities indicating that PFOS and/or its precursors may undergo long-range transport. PFOS has been detected in the liver of biota in remote areas of the Canadian Arctic. Unlike many other persistent organic pollutants, certain perfluorinated substances, such as PFOS, are present as ions in environmental media and partition preferentially to proteins in liver and blood rather than to lipids. Therefore, the bioaccumulation potential of PFOS may not be related to the typical mechanisms associated with bioaccumulation in lipid-rich tissues.</p> <p>As a result of this assessment these substances were added to the List of Toxic Substances in Schedule 1 of the Canadian Environmental Protection Act, 1999 (CEPA, 1999).</p> |
| 4 | Basis for inclusion into Annex III | Final regulatory action that severely restricts the use of PFOS and its salts and its precursors, based on a risk evaluation. |
| 4.1 | Risk evaluation | The screening assessment indicated that these substances posed a risk to the environment based on persistence, bioaccumulation and/or inherent toxicity. As a result these substances were added to the List of Toxic Substances in Schedule 1 of the Canadian Environmental Protection Act, 1999 (CEPA, 1999). |
| 4.2 | Criteria used | Risk to the environment |
| | Relevance to other States and Region | PFOS production has been identified in the United States, Australia, Norway, Italy, Japan, Belgium, Germany and Asia. A number of countries and organizations (including United States, Australia, European Union, Norway, Stockholm Convention on Persistent Organic Pollutants and Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution) have either put in place or are proposing management measures to control the manufacture, import, use and releases of PFOS and manufactured products containing PFOS. Therefore, the countries aforementioned and many others would not be affected by these regulations. PFOS has been identified as a Persistent Organic Pollutant (POP) under the Stockholm Convention. As a result of past releases to the environment due especially to human activities, POPs are now widely distributed over large regions (including those where POPs have never been used) and, in some cases, they are found around the globe. POPs can be found in people and animals living in regions such as the Arctic, thousands of kilometres from any major POPs source. |

-
- | | | |
|----------|-------------------------|--|
| 5 | Alternatives | Alternative for PFOS aqueous film forming foam (AFFF): PFOS-free AFFF.
Alternatives for fume suppressants in metal plating industries: non-PFOS-based fume suppressants; other control technologies such as composite mesh pads or closed covers. |
| 6 | Waste management | No available information |
| 7 | Other | |

Country Name: EUROPEAN UNION

- | | | |
|---|---|---|
| 1 | Effective date(s) of entry into force of actions | 27 June 2009 |
| Reference to the regulatory document | | Regulation (EC) 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) of 18 December 2006 (OJ L 396, 31.12.2006, p. 1) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF as amended by Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (OJ L 164, 26.06.2009, p. 7) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:en:PDF |
| 2 | Succinct details of the final regulatory action(s) | <p>The placing on the market and the use of PFOS as a substance or in mixtures in concentrations equal to or greater than 50 mg/kg (0.005 % by weight) is prohibited pursuant to Regulation (EC) 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) as amended by Commission Regulation (EC) No 552/2009 amending Regulation (EC) No 1907/2006.</p> <p>In addition PFOS shall not be placed on the market in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or greater than 0.1 % by weight calculated with reference to the mass of structurally or microstructurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is equal to or greater than 1 µg/ m² of the coated material.</p> <p>However, certain uses remain allowed, as mentioned in paragraph 3 to 5 of point 53 of the Annex to Commission Regulation (EC) No 552/2009.</p> <p>The European Commission is requested to review each of the derogations in paragraph 3 as soon as new information on details of uses and safer alternative substances or technologies for the uses become available.</p> <p>The European Commission shall keep under review the ongoing risk assessment activities and the availability of safer alternative substances or technologies related to the uses of perfluorooctanoic acid and related substances and propose all necessary measures to reduce identified risks, including restrictions on marketing and use, in particular when safer alternative substances or technologies, that are technically and economically feasible, are available.</p> |
| 3 | Reasons for action | <p>The risk evaluation conducted by OECD and SCHER concluded that PFOS fulfilled all the criteria for very Persistent, very Bioaccumulative and Toxic substances under the Stockholm Convention.</p> <p>The Hazard Assessment concluded that PFOS is persistent, bioaccumulative and toxic in mammals. PFOS has been detected in the serum of occupational and general populations. There is a statistically significant association between PFOS exposure and bladder cancer and there appears to be an increased risk of episodes of neoplasm of the male reproductive system, the overall category of cancers and benign growths, and neoplasms of the gastrointestinal tract.</p> <p>The OECD Hazard Assessment indicates that PFOS is persistent and bioaccumulative. It is highly acutely toxic to honey bees and bioconcentrates in fish and it has been detected in tissues of wild birds and fish, in surface water and sediment, in wastewater treatment plant effluent, sewage sludge and in landfill leachate.</p> |
| 4 | Basis for inclusion into Annex III | Final regulatory action that severely restricts the use of PFOS and its salts and its precursor, based on a risk evaluation. |
| 4.1 | Risk evaluation | The risk evaluation conducted indicated that PFOS is very persistent, very bioaccumulative and toxic. PFOS presented a risk to human health as it has been detected in the serum of human population and is associated with increased risk of certain cancers. PFOS has also been found widely in the water, soil and wildlife and has been shown to be toxic. There it presents a risk to the environment. |

4.2	Criteria used	Risk to human health and the environment
	Relevance to other States and Region	PFOS concentrations have been detected in water sources, animals and humans in many parts of the world. Therefore, similar health and environment problems are likely to be encountered in other countries where the substance is used.
5	Alternatives	<p>A number of alternatives have been suggested by RPA (2004).</p> <p><u>Metal plating</u></p> <p>For decorative chromium plating, substitution of Cr (VI) by Cr (III) was considered possible with the subsequent decreased use of PFOS for mist suppression.</p> <p><u>Fire fighting foams</u></p> <p>A number of alternatives are available or under development, including:</p> <ul style="list-style-type: none"> (a) Non-PFOS based fluorosurfactants; (b) Silicone based surfactants; (c) Hydrocarbon based surfactants; (d) Fluorine-free fire fighting foams; and (e) Other developing fire fighting foam technologies which avoid the use of fluorine. <p><u>Photographic industry</u></p> <p>Successful alternatives to PFOS have included non-perfluorinated chemicals such as hydrocarbon surfactants, chemicals with short perfluorinated chains (C₃-C₄), silicones, telomers, and in some cases it has been possible to reformulate coatings that are inherently less sensitive to static build-up.</p> <p>Replacement efforts have resulted in the elimination of certain uses of PFOS in imaging products: defoamer, photoacid generators and surfactants.</p> <p>Alternatives are less easily developed for the semi-conductor and aviation hydraulic fluid industries (RPA, 2004).</p>
6	Waste management	No information available
7	Other	

Country Name: JAPAN

- | | | |
|-----|---|---|
| 1 | Effective date(s) of entry into force of actions | 1 April 2010 |
| 2 | Reference to the regulatory document | The Chemical Substances Control Law (CSCL) and its Enforcement Order |
| 3 | Succinct details of the final regulatory action(s) | This chemical is designated as Class I Specified Chemical Substance. It is prohibited to manufacture, import or use this chemical substance |
| 3 | Reasons for action | <p>An ecological risk assessment of PFOS and its salts was conducted on the basis of environmental monitoring data collected from 2002 to 2007 in order to verify the effectiveness of certain restrictions. It was shown that the estimated maximum exposure amount based on environmental concentrations was below the acceptable amounts. In addition a risk evaluation focusing on the Tokyo Bay was conducted and the results showed that environmental concentrations of PFOS and its salts decreased rapidly in association with the reduction of their releases. The risk evaluation taking into account biological concentration caused by the uses still allowed and the use of fire-fighting foam at the time of an accident also showed that the estimated maximum exposure amount was below the acceptable amount/acceptable concentration for humans, flora and fauna in the human living environment, and predator animals at higher trophic level.</p> <p>Based on that risk evaluation it was concluded that if the use of PFOS and its salts remained restricted to the three uses that were still allowed, it could be expected that they pose little risk of causing damage to humans, and flora and fauna in the human living environment, considering that their amount used would decrease, followed by their reduced releases to the environment.</p> <p>In addition evaluations on biodegradability, bioaccumulation potential and long-term toxicity of PFOS and its salts were conducted on the basis of available information including the risk profiles prepared for the Stockholm Convention. As a result, they were designated as the Class I Specified Chemical Substances. Based on that it was decided to prohibit the manufacture, import or use of this chemical. However, certain essential uses under strict control are permitted as an exception</p> |
| 4 | Basis for inclusion into Annex III | Final regulatory action that severely restricts the use of PFOS, its salts and its precursor, based on a risk evaluation. |
| 4.1 | Risk evaluation | This chemical is persistent, highly bioaccumulative and has long-term toxicity to humans. It has demonstrated toxicity towards mammals in subchronic repeated dose studies at low concentrations, as well as rat reproductive toxicity with mortality of pups occurring shortly after birth. |
| 4.2 | Criteria used | Risk to human health |
| | Relevance to other States and Region | No information available |
| 5 | Alternatives | No information available |
| 6 | Waste management | No information available |
| 7 | Other | |

Previous notifications

Annex 3 – Addresses of designated national authorities**CANADA**

Environment Canada
 Environmental Stewardship Branch
 Chemical Sectors Directorate
 Chemical Production Division

200 Sacré-Coeur Blvd., 3rd Floor

Gatineau, Quebec, K1A 0H3
 Canada
Bernard Madé
Director, Chemical Production Division

Phone: + 819 994 4404

Fax: + 819 994 5030

Email: ecs@exc.gc.ca

EUROPEAN UNION

European Commission
 B-1049 Brussels
 Belgium
Juergen Helbig
Policy Officer

Phone: +322 298 8521

Fax: +322 296 7617

Email : juergen.helbig@ec.europa.eu

JAPAN

Global Environment Division
 International Cooperation Bureau
 Ministry of Foreign Affairs of Japan
 2-2-1 Kasumigaseki, Chiyoda-ku
 Tokyo
 100-8919 Japan
Toshikatsu Aoyama
Senior Coordinator

Phone: +81 3 5501 8245

Fax: +81 3 5501 8244

Email: toshikatsu.aoyama@mofa.go.jp
Mayuka.ishida@mofa.go.jp

C Industrial chemicals
CP Pesticides and industrial chemicals
P Pesticides

Annex 4 – References**Regulatory actions**

Regulation (EC) 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) of 18 December 2006 (OJ L 396, 31.12.2006, p. 1).

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF>

as amended by Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (OJ L 164, 26.06.2009, p. 7).

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:en:PDF>

CEPA (1999) Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations (SOR/2008-178) under subsection 93(1) and section 319 of the Canadian Environmental Protection Act (CEPA), 1999.

Chemical Substances Control Law (CSCL) and its Enforcement Order, Chemical Safety Office, Chemical Management Policy Division, Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry, Japan.

Other Documents

Basel Convention (1994) Framework Document on Preparation of Technical Guidelines for the Environmentally Sound Management of Wastes Subject to the Basel Convention. Document no. 94/005. Secretariat of the Basel Convention, Geneva.

Commission Regulation (EU) No 757/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III (OJ L 223, 25.8.2010, p. 29).

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:223:0029:0036:en:PDF>

EA (2004) Environmental Risk Evaluation Report: Perfluorooctane sulphonate (PFOS). Environment Agency for England and Wales.

<http://publications.environment-agency.gov.uk/pdf/SCHO1009BRBL-e-e.pdf>

Environment Canada (2006) Ecological Screening Assessment Report on Perfluorooctane Sulfonate, its Salts and its Precursors that Contain the C₈F₁₇SO₂ or C₈F₁₇SO₃ or C₈F₁₇SO₂N Moiety.

ESWI (2011): Study on waste related issues of newly listed POPs and candidate POPs. http://ec.europa.eu/environment/waste/studies/pdf/POP_Waste_2010.pdf

FSA (2008) Survey of PFOS and related fluorochemicals in food, Report Number FD 08/04, Author: D B Clarke, Food Standards Agency, United Kingdom.

Health Canada (2004) Screening Assessment Report - Health. Perfluorooctane Sulfonate, Its Salts and Its Precursors that Contain the C₆F₁₇SO₂ or C₈F₁₇SO₃ Moiety. Health Canada. March 5, 2004.

HPA Compendium of Chemical Hazards, PFOS + PFOA (2008), Chemical Hazards and Poisons Division, Health Protection Agency, United Kingdom.

OECD (2002) Co-operation on Existing Chemicals, Hazard Assessment of Perfluorooctane Sulfonate and its Salts. JT00135607. Environment Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, Organisation for Economic Co-operation and Development. ENV/JM/RD (2002)17/FINAL.

<http://www.oecd.org/dataoecd/23/18/2382880.pdf>

POPRC (2006) Report of the Persistent Organic Pollutants Review Committee on the work of its second meeting Addendum Risk profile on perfluorooctane sulfonate at its second meeting, the Persistent Organic Pollutants Review Committee adopted the risk profile on perfluorooctane sulfonate, on the basis of the draft contained in document, UNEP/POPS/POPRC.2/11 (2006).

POPRC (2010) Guidance on alternatives to perfluorooctane sulfonate and its derivatives, Stockholm Convention on Persistent Organic Pollutants, UNEP/POPS/POPRC.6/13/Add.3 (2010).

RPA (2004) Perfluorooctane Sulphonate - Risk Reduction Strategy and Analysis of Advantages and Drawbacks. Report prepared for the Department for Environment, Food and Rural Affairs and the Environment Agency for England and Wales by Risk and Policy Analysts Limited.

<http://www.defra.gov.uk/environment/quality/chemicals/documents/pfos-riskstrategy.pdf>

SCHER (2005) Opinion on RPA's report "Perfluorooctane Sulphonates Risk reduction strategy and analysis of advantages and drawbacks" (Final Report – August 2004). European Commission Scientific Committee on Health and Environmental Risks, SCHER.

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_014.pdf

Relevant guidelines and reference documents

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996) available at www.basel.int
