Government of Canada / Gouvernement du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Perfluorooctanoic Acid (PFOA), its Salts, and its Precursors

and

Long-Chain (C9-C20) Perfluorocarboxylic Acids (PFCAs), their Salts, and their Precursors

Environment Canada
Health Canada

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Canada

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This proposed risk management approach document builds on the previously released risk management scope document for Perfluorooctanoic Acid (PFOA), its Salts, and its Precursors and Long-Chain (C9-C20) Perfluorocarboxylic Acids (PFCAs), their Salts, and their Precursors and outlines the proposed control actions for these substances. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

SUMMARY OF RISK MANAGEMENT

The Government of Canada plans to take the following actions with respect to PFOA and long-chain PFCAs:

1. Implementing regulations to prohibit the manufacture, use, sale, offer for sale, import and export of PFOA and long-chain PFCAs and products containing them.

Note: This summary is an abridged list of the instruments and tools proposed to risk manage these substances. Please see section 9.1 of this document for a complete explanation of risk management.

1. ISSUE

1.1 Categorization

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations,* and "inherently toxic" (iT) to humans or other organisms, or b) present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets any of the criteria set out in section 64 of CEPA 1999.

The substance, perfluorooctanoic acid (PFOA), Chemical Abstracts Service Registry Number[1] 335-67-1, its salts and its precursors, is referred to throughout this document as "PFOA". The

[1] Chemical Abstracts Service Registry Number; The Chemical Abstracts Service Registry Number (CAS RN) is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the government when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society

Ministers of the Environment and of the Health (the Ministers) have conducted an assessment under sections 68 and 74 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) to assess whether the substance meets one or more of the criteria as set out in section 64 of CEPA 1999. The ammonium salt of PFOA (CAS RN 3825-26-1) and some precursors to PFOA(CAS RN 53515-73-4, CAS RN 678-39-7, CAS RN 65530-61-2, and CAS RN 70969-47-0), present on the DSL, were categorized as requiring assessment under section 73 of CEPA 1999. While PFOA itself is not on the DSL, PFOA can be formed in the environment through degradation from a variety of other perfluorinated chemicals. PFOA was identified for assessment based on its persistent nature, widespread occurrence in biota, presence in the Canadian Arctic due to long range transport, and emerging international interest in PFOA indicating a potential concern for the environment and human health from PFOA and its salts. In addition, precursors to PFOA were considered in this assessment on the basis of their contribution to the total presence of PFOA and its salts in the environment.

In addition, under CEPA, 1999 (Canada 1999), the Minister of the Environment has also conducted an ecological screening assessment of the long-chain (C9-C20) perfluorocarboxylic acids, their salts and precursors, referred to throughout this document as "long-chain PFCAs". Although the long-chain PFCAs, themselves, are not on Canada's Domestic Substances List (DSL), some precursors to long-chain PFCAs (CAS RNs 65530-63-4, 65530-71-4, 65530-72-5, 65530-74-7, 68391-08-2, 68412-68-0, 115592-83-1, 65530-61-2, 70969-47-0, 65530-66-7, 65605-58-5, 65605-70-1, 65636-35-3, 68239-43-0 and 110053-43-5), which are present on the DSL, were categorized under section 73 of CEPA 1999. These were identified as substances of concern as a result of Environment Canada's New Substances notification process and through the *Action Plan for the Assessment and Management of Perfluorinated Carboxylic Acids and their Precursors* (Canada, 2006a).

1.2 Final Screening Assessment Reports Conclusion for PFOA and long-chain PFCAs

Notices summarizing the scientific considerations of the final screening assessment reports were published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for PFOA and long-chain PFCAs on August 25, 2012, under subsection 77(6) of CEPA 1999. The final screening assessment reports concluded that both PFOA and long-chain PFCAs

- are entering or may be entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

The final screening assessment reports also concluded that both PFOA and long-chain PFCAs meet the criteria for persistence as set out in the *Persistence and Bioaccumulation Regulations.* Both PFOA and long-chain PFCAs do not meet the regulatory criteria for bioaccumulation. Nevertheless, the weight of evidence is sufficient to conclude that both PFOA and long-chain PFCAs and their salts accumulate and biomagnify in terrestrial and marine mammals. The presence of PFOA and long-chain PFCAs in the environment result primarily from human activity.

The final screening assessment report for PFOA also concludes that PFOA is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Long-chain PFCAs have not been assessed for risk to human health, however, it was considered important to publish the ecological Screening Assessment Report (SAR) in order to initiate the implementation of risk management measures as well as fulfill the Government's commitment to assess PFCAs under the *Perfluorinated Carboxylic Acids (PFCAs) and Precursors: An Action Plan for Assessment and Management (*Canada, 2006a).

For further information on the final screening assessment report conclusion for PFOA and long-chain PFCAs, refer to the final screening assessment report, available at:
http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=CA29B043-1 (PFCAs)
http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=370AB133-1 (PFOA)

1.3 Proposed Measure

When, as a result of a screening assessment of a substance under 74 of CEPA 1999, a substance is found to meet any of the criteria set out in section 64 of the Act, the Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act. In certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances and to recommend the implementation of virtual elimination. In this case, the Ministers proposed to recommend the addition of both PFOA and long-chain PFCAs to the List of Toxic Substances in Schedule 1 of CEPA 1999. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the environment from the potential effects of exposure to these substances.

The final screening assessment reports did not conclude that either PFOA or long-chain PFCAs meet the conditions set out in subsection 77(4) of CEPA 1999. As a result, PFOA, and long-chain PFCAs will not be subject to the statutory implementation of virtual elimination.

2. BACKGROUND

2.1 Substance Information

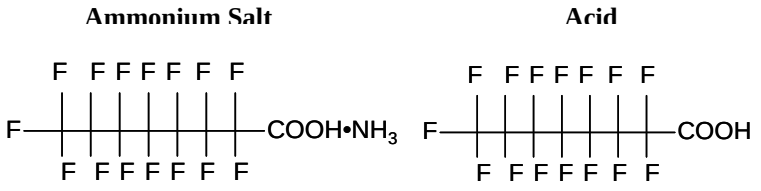
PFOA is an anthropogenic substance belonging to a class of chemicals known as perfluorocarboxylic acids (PFCAs). PFCAs, in turn, belong to the broader class of chemicals known as perfluoroalkyls (PFAs). PFOA and long-chain PFCAs are fluorocarbon-based chemicals (consisting of fluorine bound to carbon atoms), containing a carboxyl group (COOH). It is the strength of the carbon-flourine bonds that contributes to the extreme stability and unique properties of these substances.

The PFOA molecule contains 8 carbon atoms and the long-chain PFCAs contain between 9 and 20 carbon atoms. PFOA may refer to the acid, its conjugate base or its principal salt forms; precursors to PFOA are substances where the perfluorinated alkyl moiety has the formula

C_nF_{2n+1} (where n= 7 or 8) and is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom. Long-chain perfluorocarboxylic acids and their salts are a homologous series of substances with the molecular formula of $C_nF_{2n+1}CO_2H$ (where $8 \leq n \leq 20$); precursors to long-chain PFCAs are any substance where the perfluorinated alkyl moiety has the formula C_nF_{2n+1} (where $8 \leq n \leq 20$) and is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom

Table 1 and Table 2 present other names, trade names, chemical groupings, the chemical formula, and the chemical structure for PFOA and long-chain PFCAs, respectively.

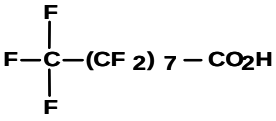
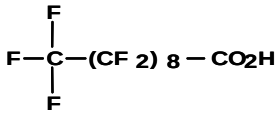
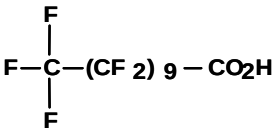
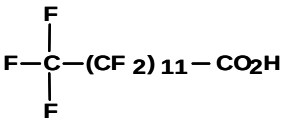
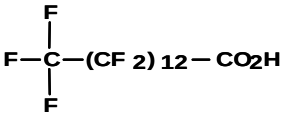
Table 1. Substance identity of PFOA

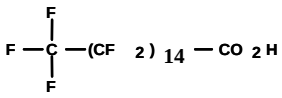
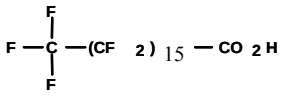
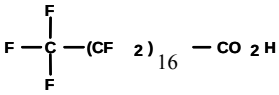
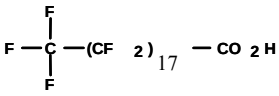
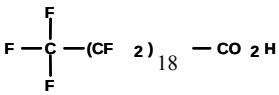
Chemical Abstracts Service Registry Number (CAS RN)	**335-67-1**
Chemical name	Perfluorooctanoic acid
National Chemical Inventories (NCI) names[1]	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (TSCA) Octanoic acid, pentadecafluoro- (AICS, ASIA-PAC, NDSL, NZloC, PICCS, SWISS) Pentadecafluorooctanoic acid (ECL, EINECS, PICCS, REACH) Perfluorooctanoic acid (ENCS)
Other names	EF 201; Eftop EF-201; NSC 95114; Pentadecafluoro-1-octanoic acid; Pentadecafluoro-*n*-octanoic acid; Perfluorocaprylic acid; Perfluoro-1-heptanecarboxylic acid; Perfluoroheptanecarboxylic acid; *n*-Perfluorooctanoic acid
Chemical group	Discrete organics
Major chemical class or use	Perfluoroalkyls
Major chemical subclass	Perfluorocarboxylic acids
Chemical formula	$C_8HF_{15}O_2$
Chemical structure (salt and acid form)	
SMILES[2]	FC(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(=O)O

[1]NCI 2009 : AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); NDSL (Non-Domestic Substances List (Canada)); NZIoC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals (European Commission); SWISS (Swiss Giftliste 1 and Inventory of Notified New Substances); TSCA (*Toxic Substances Control Act* Chemical Substance Inventory).

[2] Simplified Molecular Input Line Entry Specification

Table 2. Substance identity of long-chain PFCAs

Chemical Abstracts Index name	Acronym	Molecular formula	Structural formula	Chemical Abstracts Service Registry Number	Synonyms
Nonanoic acid, heptadecafluoro- (C9 PFCA)	PFNA	$C_9 H F_{17} O_2$		375-95-1 (NDSL)	C 1800; Heptadecafluorononanoic acid; Perfluorononanoic acid; Perfluoropelargonic acid
Decanoic acid, nonadecafluoro- (C10 PFCA)	PFDA	$C_{10} H F_{19} O_2$		335-76-2 (NDSL)	Nonadecafluoro-n-decanoic acid; Nonadecafluorodecanoic acid; Perfluoro-n-decanoic acid; Perfluorocapric acid; Perfluorodecanoic acid
Undecanoic acid, heneicosafluoro- (C11 PFCA)	PFUnDA	$C_{11} H F_{21} O_2$		2058-94-8 (not listed on NDSL or DSL)	Heneicosafluoroundecanoic acid; Perfluoroundecanoic acid; Perfluoroundecylic acid
Dodecanoic acid, tricosafluoro- (C12 PFCA)	PFDoDA	$C_{12} H F_{23} O_2$		307-55-1 (NDSL[1])	Perfluorododecanoic acid; Perfluorolauric acid
Tridecanoic acid, pentacosafluoro- (C13 PFCA)	PFTrDA	$C_{13} H F_{25} O_2$		72629-94-8 (not listed on NDSL or DSL)	Perfluorotridecanoic acid
Tetradecanoic acid, heptacosafluoro- (C14 PFCA)	PFTDA	$C_{14} H F_{27} O_2$		376-06-7 (NDSL)	Perfluoromyristic acid; Perfluorotetradecanoic acid
Pentadecanoic acid, nonacosafluoro- (C15 PFCA)	PFPeDA	$C_{15}H F_{29}O_2$		141074-63-7 (not listed on NDSL or DSL)	Perfluoropentadecanoic acid

Chemical Abstracts Index name	Acronym	Molecular formula	Structural formula	Chemical Abstracts Service Registry Number	Synonyms
Hexadecanoic acid, hentriacontafluoro- (C16 PFCA)	PFHxDA	$C_{16}HF_{31}O_2$		67905-19-5 (NDSL)	Perfluoropalmitic acid, perfluorohexadecanoic acid Hexadecanoic acid
Perfluoroheptadecanoic acid (C17 PFCA)	PFHpDA	$C_{17}HF_{33}O_2$		57475-95-3 (not listed on the NDSL or DSL)	–
Octadecanoic acid, pentatriacontafluoro- (C18 PFCA)	PFODA	$C_{18}HF_{35}O_2$		16517-11-6 (NDSL)	Perfluorostearic acid Perfluorooctadecanoic acid Octadecanoic acid
Perfluorononadecanoic acid (C19 PFCA)	PFNDA	$C_{19}HF_{37}O_2$		133921-38-7 (not listed on NDSL or DSL)	–
Perfluoroeicosanoic acid (C20 PFCA)		$C_{20}HF_{39}O_2$		68310-12-3 (NDSL)	Eicosanoic acid, nonatriacontafluoro- (9CI); Nonatriacontafluoroeicosanoic acid

NDSL = Non-domestic Substances List: substances not appearing on the DSL are considered to be new to Canada and are subject to notification. Substances listed on the NDSL are subject to notification but with reduced information requirements.

3. WHY WE NEED ACTION

3.1 Characterization of Risk

The presence of both PFOA and long-chain PFCAs, their salts and their precursors result from anthropogenic activity. Both PFOA and long-chain PFCAs may be found in the environment due to releases from fluoropolymer manufacturing or processing facilities, effluent releases from wastewater treatment plants, landfill leachates and due to degradation/transformation of PFOA precursors and precursors to long-chain PFCAs. PFOA, itself, is not manufactured in Canada. However, quantities of the ammonium salt are imported. Long-chain PFCAs are not manufactured in Canada; however, several precursors to the long-chain (C9-C20) perfluorocarboxylic acids were reported to be imported into Canada.

Once in the environment, PFOA is extremely persistent and not known to undergo significant abiotic or biotic degradation under relevant environmental conditions. The presence of PFOA in the Canadian Arctic is likely attributable to the long-range transport of PFOA (e.g., via ocean currents) and/or volatile precursors to PFOA (e.g., via atmospheric transport). Based on a weight of evidence approach regarding persistence, bioaccumulation, temporal trends in some species (i.e. the polar bear), long-range transport and the widespread occurrence and concentrations of PFOA in the environment and in biota (including remote areas of Canada), it is concluded that PFOA, its salts and its precursors are entering or may be entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

Based on a weight of evidence approach regarding persistence, bioaccumulation, the widespread occurrence, temporal trends in some species (i.e. Canadian Arctic birds, terrestrial and marine mammals), long-range transport and concentrations of long-chain PFCAs in the environment and in biota (including remote areas of Canada) it is concluded that long-chain PFCAs, their salts and their precursors are entering or may be entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

4. CURRENT USES AND INDUSTRIAL SECTORS

The Government of Canada first collected data on the manufacture, import and export of certain perfluoroalkyl and fluoroalkyl (PFA/FA) substances, their derivatives and polymers, including PFOA and long-chain PFCAs, through a survey published in 2000 (Canada 2000) under the authority of section 71 of CEPA 1999. No manufacturing or import of PFOA or long-chain PFCAs in Canada were reported above the 100 kg reporting threshold. However, the import of several long-chain PFCA precursors into Canada was reported in quantities greater than 100 kg.

In 2005, a second industry survey regarding PFA/FA substances was conducted by Environment Canada under the authority of section 71 of CEPA 1999 (Canada 2005). Long-chain PFCAs were not reported to be manufactured in Canada for the 2004 calendar year. However, some PFOA salts and long-chain PFCAs precursors were imported into Canada in quantities greater than the reporting threshold of 100 kg.

Manufacturing was the main industrial sector using these substances according to the reported North American Industry Classification System (NAICS) codes. The manufacturing sub-sectors identified include:

- Textile Mills
- Paper Manufacturing
- Chemical Manufacturing
- Plastic and Rubber Products Manufacturing

Historical uses of PFOA include applications in industrial processes and in commercial and consumer products. PFOA and its salts are used as polymerization aids in the production of fluoropolymers and fluoroelastomers. APFO (PFOA ammonium salt), the most common commercially used salt form of PFOA, is the ammonium salt, is used primarily as a commercial polymerization aid in the manufacture of fluoropolymers such as polytetrafluoroethylene and polyvinylidene fluoride (US Government 2003; OECD 2006; Prevedouros et al. 2006), which are used in various sectors, including the automotive, electronics, construction and aerospace industries. Fluoropolymers are used in the manufacture of stain- and water-resistant coatings on textiles and carpet; hoses, cable and gaskets; non-stick coatings on cookware; and personal care products (US Government 2003). APFO is also used as a constituent in aqueous fluoropolymer dispersions, which are formulated into paints, photographic film additives and in the textile finishing industry (OECD 2006). Aqueous fire-fighting foams may also contain APFO as a component (OECD 2006; Prevedouros et al. 2006). Fluorochemicals that are potential PFOA precursors are used in the treatment of food packaging materials to enhance their properties as a barrier to moisture and grease (Begley et al. 2005). Thus, although APFO is typically not intended to remain in manufactured articles, trace amounts may be present as a contaminant or degradation product.

C9 PFCA is used for surfactant applications and in the production of fluoropolymers, primarily polyvinylidene fluoride (Prevedouros et al. 2006). Based on available information, long-chain PFCAs are rarely used intentionally in products. However commonly used precursors which are present in commercial products, such as fluorotelomers, e.g., substances derived from fluorotelomer alcohols (FTOHs), or other fluorotelomer-based substances, can degrade to long-chain PFCAs. FTOHs may be released from polymeric materials or chemicals that incorporate FTOHs, or residual amounts of FTOHs that failed to be covalently linked to polymers or chemicals during production. FTOHs are used in fire-fighting foams, personal care and cleaning products, and oil, stain, grease and water repellent coatings on carpet, textiles, leather and paper (US EPA 2006a). FTOHs are also used in the manufacture of a wide range of products, such as paints, adhesives, waxes, polishes, metals, electronics and caulks.

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

As noted above, PFOA itself is not manufactured in Canada; however, quantities of the ammonium salt are imported. Long-chain PFCAs are not manufactured in Canada; however, several precursors to the long-chain PFCAs were reported to be imported into Canada.

The presence of both PFOA and long-chain PFCAs in the environment results from human activity as there are no known natural sources of these substances. Releases of PFOA and long-chain PFCAs may occur during the manufacture and processing operations as well as during the use of industrial and consumer products containing these substances. PFOA and long-chain PFCAs may be found in the environment due to releases from fluoropolymer manufacturing or processing facilities, effluent releases from wastewater treatment plants, landfill leachates and degradation/transformation of precursors. Such precursors may include parent compounds, chemical products containing PFOA or long-chain PFCAs (either as part of formulations or as unintended residuals) and substances transforming to intermediates that ultimately degrade to PFOA or long-chain PFCAs.

Once in the environment, PFOA and long-chain PFCAs are extremely persistent and not known to undergo any further abiotic or biotic degradation under relevant environmental conditions. PFOA and long-chain PFCAs are highly water soluble and typically present as an anion (conjugate base) in solution. They have low vapour pressure; therefore, the aquatic environment is expected to be their primary sink, with some additional partitioning to sediment. The presence of PFOA and long-chain PFCAs in the Canadian Arctic indicates the long-range transport of these substances (e.g. via ocean currents) or volatile precursors (e.g. via atmospheric transport).

5.2 Exposure Sources

Manufacture and Processing

PFOA and long-chain PFCAs have been manufactured as salts by four distinct synthesis routes, namely: electrochemical fluorination (ECF), fluorotelomer iodide oxidation, fluorotelomer olefin oxidation, and fluorotelomer iodide carboxylation. Up until 2002, the ECF process was used worldwide to manufacture the majority (80−90% in 2000) of ammonium perfluorooctanoate (APFO). The largest production sites were in the United States and Belgium, with smaller scale producers in Italy and Japan. The remaining 10−20% of APFO was manufactured by direct oxidation of perfluorooctyl iodide in Germany and Japan (Environmental Science and Technology, 2006). In May 2000, 3M (a primary manufacturer) announced the phase-out of the production of PFOA, PFOS, and PFOS-related products (3M, 2012), leaving only a number of relatively small producers in Europe and in Asia.

In 2002, there were 33 fluoropolymer manufacturing sites worldwide located in North America (eight), Japan (seven), China (seven), Europe (seven), Russia (two), and India (one) with a total fluoropolymer manufacturing capacity of 144 000 t (Environmental Science and Technology, 2006).

Based on the information collected in the industry survey regarding PFA/FA substances conducted by Environment Canada, PFA/FA substances were imported from the U.S.A, France, Germany and Japan in 2000 (Canada 2000).

PFOA and its salts are not manufactured in Canada (Environment Canada 2001). There are no published data on direct releases to air, water or land from Canadian industrial facilities (Ellis et al. 2004b). Similarly, there are no available data on the direct release through industrial use/manufacturing of long-chain PFCAs to the Canadian environment. Indirect sources in the

environment are those where PFOA and long-chain PFCAs are present as chemical reaction residuals/impurities, or where substances may degrade from fluorotelomer-based substances.

Releases of PFOA to the environment may occur during manufacturing and processing operations and throughout the service life and subsequent disposal of articles containing PFOA. Potential point sources thus include direct releases from manufacturing or processing facilities; however, as PFOA and its salts are not manufactured in Canada (Environment Canada 2011), there are no published data on direct releases to air, water or land from Canadian industrial facilities (Ellis et al. 2004b). Indirect releases may result, for example, from the degradation or transformation of precursors in wastewater treatment plants (WWTPs) and landfills. Such precursors may include parent compounds or chemical products containing PFOA. Potential precursors include related fluorochemicals that are detectable in the atmosphere (e.g., 8:2 fluorotelomer alcohols [FTOH], which have eight fluorinated carbons and a two-carbon ethyl alcohol group) and can degrade or transform to PFOA through biotic or abiotic pathways.

Potential sources for the formation of PFOA, such as the degradation or transformation of precursors, could lead to indirect environmental releases and contribute to the total amount of PFOA found in the environment.

Product Use

PFOA is primarily used as a reactive intermediate, while its salts are used as processing aids in the production of fluoropolymers, fluorotelomers and surfactants (US EPA, 2003, 2006). Certain long-chain PFCAs are used as processing aids in the production of fluoropolymers. While very low concentrations of PFOA and long-chain PFCAs may be present in the finished products, they are generally not intentionally incorporated into the polymer structure.

PFCAs are rarely used intentionally in products. However commonly used precursors which are present in commercial products, such as fluorotelomers, e.g. substances derived from fluorotelomer alcohols (FTOHs), or other fluorotelomer-based substances, can degrade to long-chain PFCAs. Long-chain PFCAs may be detected in typical North American homes with carpeted floors, pre-treated carpet, and commercial carpet-care liquids, while floor waxes and stone/tile/wood sealants that contain fluorotelomer products are also potential sources in homes and commercial buildings containing these materials. Other potential sources include treated home textile, upholstery and apparel and household carpet/fabric care liquids and foams. FTOHs have also been found in all-weather clothing and as emissions from non-stick frying pans. PFCAs themselves (and in some cases, fluorotelomer carboxylic acids (FTCAs) and fluorotelomer unsaturated carboxylates (FTUCAs) may also be released in small amounts from products, including all-weather clothing, cookware, commercial fabric protector and food contact materials.

Disposal

The Government of Canada is undertaking research, evaluating findings from new studies, collecting information and investigating potential releases of toxic substances from waste management (e.g. landfills) and recycling facilities in Canada. PFOA and long-chain PFCAs would continue to be included in any monitoring from the waste sector, if needed. Based on the findings, the Government of Canada will implement further risk management activities if warranted.

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

In June 2006, the Government of Canada published its *Action Plan for the Assessment and Management of Perfluorinated Carboxylic Acids and their Precursors* (Canada 2006a). This Action Plan addresses the assessment and management of the broad class of PFCAs and PFCA precursors. The following actions were included:

Preventing the introduction into Canada of new substances which would contribute to the observed load of long-chain PFCAs in the environment
On October 13, 2010, the *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (Four New Fluorotelomer-based Substances)* (Canada 2010d) were published in *Canada Gazette*, Part II. These Regulations prohibit the manufacture, use, sale, offer for sale and import of four fluorotelomer-based substances, found to be precursors to long-chain PFCAs, unless present in certain manufactured items.

Seeking action from industry to address confirmed sources of PFCAs from substances already in Canadian commerce
A voluntary *Environmental Performance Agreement Respecting PFCAs and their Precursors in Perfluorochemical Products Sold in Canada* was signed on March 30, 2010 (Canada 2010c). The Performance Agreement was identified as early risk management action as Environment Canada and Health Canada pursued further assessment to guide further risk management actions. The agreement includes action to reduce PFOA, long-chain PFCAs and their precursors, which are present in the form of residuals or impurities in perfluorinated products currently in commerce in Canada, by 95% by December 31, 2010, and to eliminate them by December 31, 2015.

Shortly following the release of the PFCAs Action Plan in 2006, Environment Canada and Health Canada began working with industry to establish an Environmental Performance Agreement. Potential signatories were identified through the industry survey's published in 2000 and 2005, or their involvement in the US EPA Voluntary Stewardship Program, and included E. I. Dupont, Ciba Specialty Chemicals (which has since been purchased by BASF), Clariant Canada Inc, 3M Canada, Asahi Glass Company Ltd., Arkema Canada Inc. and Daikin Industries). To date the following four companies from the perfluorinated products industry are signatories to the Performance Agreement: Arkema Canada Inc., Asahi Glass Company Ltd., Clariant Canada Inc., and E.I. du Pont Canada Company. Environment Canada and Health Canada continues to engage industry to become a signatory to the Performance Agreement (of note, 3M has phased out of the production and use of PFOA-related products (3M, 2012).

Companies participating in this agreement have submitted baseline and annual reporting data. The data received from companies indicates that significant progress is being made in reaching the targets set out in the Performance Agreement, and companies are reducing residual PFCAs in perfluorochemical products sold in Canada (http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=AE06B51E-1).

The agreement is consistent with the voluntary Stewardship Program of the United States Environmental Protection Agency (US EPA) to reduce product content of PFOA and related chemicals by 95 percent by 2010, and to work toward eliminating product content by 2015.

Pursuing further assessment of PFCAs and precursor substances already in Canadian commerce
The final screening reports for PFOA and long-chain PFCAs were published in *Canada Gazette*, Part I, on August 25, 2012.

Advancing scientific understanding of issues through further research
Research and monitoring efforts were initiated in 2006 and are ongoing. Results generated by these initiatives will contribute to the understanding of the substances regarding their environmental fate, distribution, ecotoxicology and related human exposure to the substances. Furthermore, the research and monitoring activities will help identify the need for further risk assessment and risk management efforts.

Engaging other regulatory jurisdictions in global action to reduce risk from longer chain PFCAs
The Government of Canada has participated in several international conferences on PFCAs, including the *Workshop on PFCAs and their Precursors* organized by the Organisation for Economic Co-operation and Development (OECD) in 2006 and the *Workshop on Managing Perfluorinated Chemicals and Transitioning to Safer Alternatives*, sponsored by the US EPA and the United Nations Environment Programme (UNEP), that took place in February 2009.

6.2 Existing International Risk Management

OECD
In November 2006, the OECD sponsored a workshop on PFCAs and precursors to make recommendations on assessment and research needs, risk reduction approaches, and alternative chemistries. The workshop brought together 56 representatives of regulatory bodies, the research community, industry and environmental non-governmental organizations.

In May 2009, the second session of the International Conference on Chemicals Management (ICCM2) adopted Resolution II/5 for the management of PFCs and transition to safer alternatives. The resolution invites governments, international organisations, and other stakeholders to consider the development, facilitation and promotion in an open, transparent and inclusive manner of national and international stewardship programmes and regulatory approaches to reduce emissions and the content of relevant perfluorinated chemicals of concern in products and to work toward global elimination, where appropriate and technically feasible.

As one of the OECD's contributions to implement the ICCM2 Resolution II/5 a web portal was designed to facilitate information exchange on perfluorinated chemicals (PFCs). Stakeholders can share information on government activities related to their regulatory and stewardship efforts, updates on scientific developments, new technologies, available alternatives, and PFC-related events (OECD PFC Portal, 2012).

In addition, to the web portal, the PFC Steering group has held a number of webinars and side-events to better disseminate information about PFCs. The OECD has conducted three surveys on production and releases of PFCs. Canada has participated in a Steering Group on PFCs working

to develop the 2006 survey directed at PFC producers on the their production, import and use of PFOS, PFAS, PFOA, and PFCAs to identify gaps in knowledge and assessment needs for both long and short-chain PFCAs and precursors. The next survey questionnaire is scheduled for 2013 OECD PFC Portal, 2012).

U.S. EPA

In January 2006, the US EPA introduced a voluntary Stewardship Program to reduce and eliminate facility emissions and product content for PFOA, and their precursors. Participating companies have agreed to undertake to decrease emissions from the production and product contents of PFOA and PFOA-related compounds by 95% before the year 2010, and to eliminate them completely by the year 2015. The 2010 progress report shows significant progress has been made in reaching the targets (US EPA, 2011).

In February 2009, the US EPA and UNEP sponsored the *Workshop on Managing Perfluorinated Chemicals and Transitioning to Safer Alternatives*. This workshop provided participants with the opportunity to review developments regarding perfluorinated chemicals (PFC) since the 2006 OECD workshop, especially as they relate to risk reduction programs.

Of note, as outlined in the US EPA's Long-Chain Perfluorinated Chemicals (PFCs) Action Plan, 2009, the US EPA intends to consider initiating rulemaking under the Toxic Substances Control Act (TSCA) section 6 to manage long-chain PFCs. If the US EPA can make certain findings with respect to these chemicals (further analysis of the information will be performed as part of TSCA section 6 rulemaking), TSCA section 6 provides authority for EPA to ban or restrict the manufacture (including import), processing, and use of these chemicals.

Norway

In May 2007, the Norwegian Pollution Control Authority (SFT) established a proposal to introduce regulations banning the content levels of 10 substances, including PFOA, in consumer products that can be harmful to health and environment. The ban will include production, imports, exports and trade of consumer products that contain one or more of the ten substances when the substance content in the product exceeds or is equal to established limit values. This initiative was on hold pending the results of a separate process under the European Union proposing to control a number of substances in the proposed Norwegian regulations -not including PFOA.

On December 20, 2011, Norway released proposed regulations to restrict the production, import, export or sale of consumer products that contain PFOA in consumer products if they exceed certain limit values. According to Norway's notification, the proposed regulation does not apply to food products, food packaging, fertilizer, tobacco, medicine, means of transport, permanently mounted equipment for means of transport and tires and similar accessories for means of transport. PFOA is considered a high-priority hazardous substance which is persistent, bio-accumulative and/or toxic, e.g. toxic to human reproduction. These restrictions are due to come into force on July 1, 2012 (Norwegian Ministry of the Environment, 2012).

Germany

In July 2009, the German Federal Environment Agency (UBA) and the Drinking Water Commission proposed that legally binding quality standards and reduction targets applicable to

bodies of water, wastewater, and soils be introduced with respect to PFCs. A background document was developed by the UBA further outlining the impacts of PFCs and their releases into the environment (German Federal Environment Agency, 2009).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

In Canada, manufacturing is the main industrial sector using PFOA and long-chain PFCAs, specifically, paper and chemical manufacturing (note PFOA and long-chain PFCAs are not manufactured or imported; however their salts and precursors have been reported to be imported). Both PFOA and long-chain PFCAs are used in the production of fluoropolymers and fluoroteomers and as additives and components in consumer and industrial products.

In January 2006, the US EPA introduced a voluntary Stewardship Program to reduce facility emissions and product content of PFOA and related chemicals on a global basis and to work toward eliminating emissions and product content of these chemicals by 2015. This Stewardship Program has been a major driver for companies to reduce residuals in products and to switch from PFOA products to safer alternatives.

The US EPA is also reviewing substitutes for PFOA, PFOS, and other long-chain perfluorinated substances as part of its review process for new chemicals under EPA's New Chemicals Program. Over 150 alternatives of various types have been received and reviewed by EPA. Under the US EPA's New Chemical Review of Alternatives for PFOA and Related Chemicals (US EPA, 2012), shorter chain-length perfluorinated telomeric substances have been notified as alternatives for a variety of uses including, for example, textile, carpet and paper additive uses and tile surface treatments. The major industry users in the global community are moving quickly to replace uses of C-8 and higher homologues (OECD PFC Portal, 2012). Based on work done to date by industry, C-6 (Fluorotelomer) and C-4 (Sulfonate) chemistries meet the criteria for replacement of most current C-8 and higher homologue uses, and are preferred as drop-in replacements. Alternatives with a shorter fluorinated alkyl chain are persistent in the environment but have rapid bioelimination. "Non-fluorinated alternatives, such as different hydrocarbon surfactants and silicone products, have been identified…. however,… in most cases or at least in larger application areas, other fluorinated compounds are used instead…. non-fluorinated alternatives do not work as well, especially in situations, where extreme low surface tension is needed" (Danish EPA, 2006).

While fluoro-alternatives exist for most, although not all current uses, there will likely not be one single replacement but rather several alternatives. Non-fluorinated alternatives are available for some applications but may not work as well.

Substances which are new to Canada, including new substitutes for PFOA and Long Chain PFCAs, are subject to the New Substances provisions of CEPA 1999 and the New Substances Notification Regulations. Any company intending to import or manufacture such a substance must submit a notification, with the substance undergoing an assessment by Environment Canada and Health Canada to determine whether it meets the definition of "toxic" set out in

section 64 of CEPA 1999. Many substitutes to PFOA and long-chain PFCAs have been notified to Environment Canada's New Substances Program

7.2 Alternative Technologies and/or Techniques

No information is available on alternative technologies and/or techniques.

7.3 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for an instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

7.4 Children's Exposure

The Government of Canada considered risk assessment information relevant to children's exposure, including children living in Northern Canada, in the PFOA screening assessment. Based on this assessment, it is proposed that no risk management actions to specifically protect children are required at this time.

8. PROPOSED OBJECTIVES

8.1 Environmental Objective

An environmental objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.

The proposed environmental objective for PFOA and long-chain PFCAs is to minimize release of the substances to the Canadian environment.

8.2 Risk Management Objective

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management tool(s) and/or instrument(s). The proposed risk management objective for PFOA and long-chain PFCAs is to minimize releases of PFOA and long-chain PFCAs to the environment to the greatest extent practicable that is technically and economically feasible.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Instrument

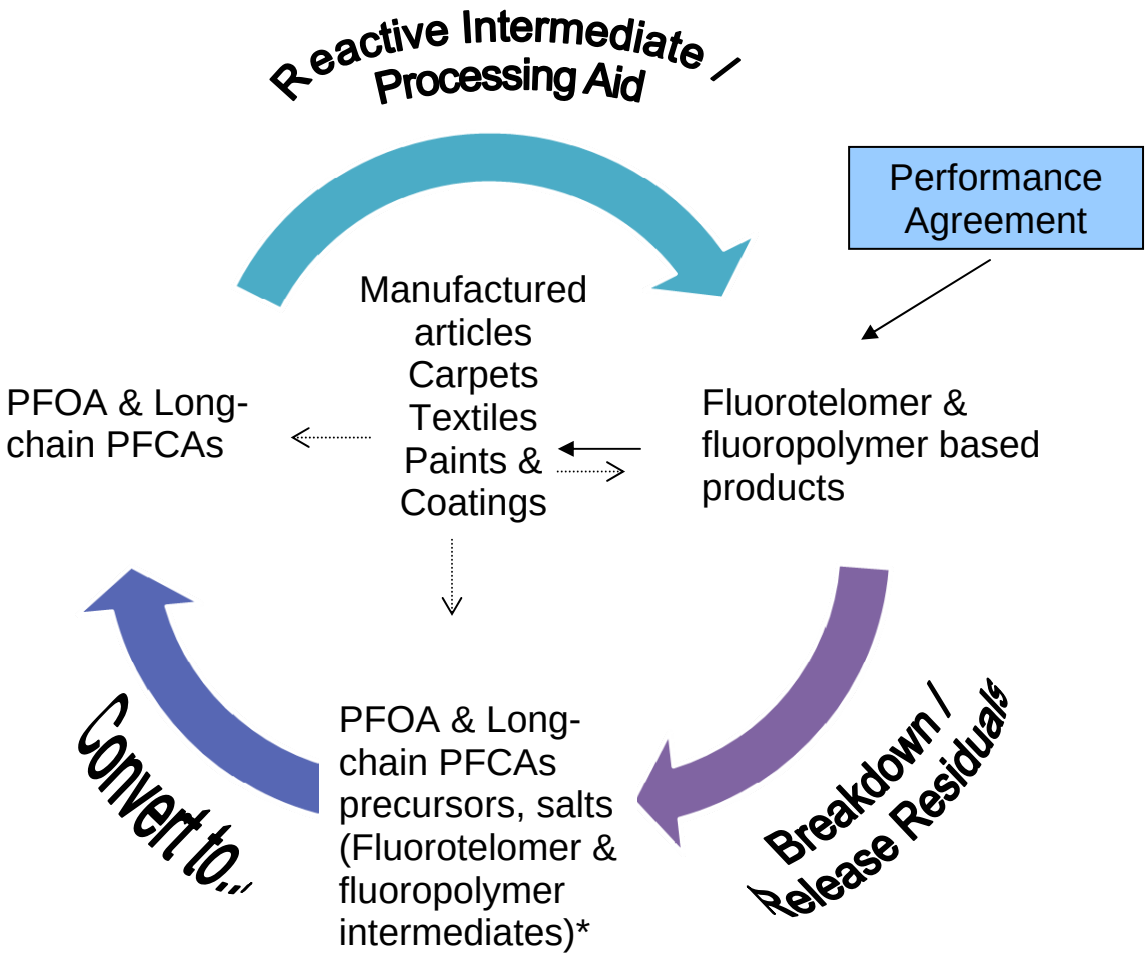
As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation,*[2] and criteria set out in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management instruments were selected using a consistent approach, and took into consideration information available at the time.

In order to achieve the risk management objective and to work towards achieving the environmental objective, the risk management being considered for PFOA and long-chain PFCAs is prohibition through regulation. A prohibition regulation would prohibit the manufacture, use, sale, offer for sale, import and export of PFOA and long-chain PFCAs and products containing PFOA and long-chain PFCAs. In accordance with the Government of Canada's Toxic Substances Management Policy, socio-economic factors will be taken into account when determining interim targets, appropriate management approaches and timelines for implementation.

The PFOA, and long-chain PFCAs life-cycle is complex; the complexity of the life-cycle is a consideration of risk management.

[2] Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

Figure 1: Life-cycle considerations for risk management



s Where PFOA & long-chain PFCAs precursors and salts can also be used directly in the manufacture of fluorotelomer and fluoropolymer based products.*

The Government of Canada is undertaking research, evaluating findings from new studies, collecting information and investigating potential releases of toxic substances from waste management (e.g. landfills) and recycling facilities in Canada. These substances would continue to be included in any monitoring from the waste sector, if needed. Based on the findings, the Government of Canada will implement further risk management activities if warranted.

9.2 Implementation Plan

The proposed instrument would be published in the *Canada Gazette*, Part I, no later than (2 years after final SAR publication), as per the timelines set out in CEPA 1999.

Continued monitoring of PFOA and long-chain PFCAs in the environment will be considered under the comprehensive monitoring and surveillance strategy for substances under the Chemicals Management Plan. Monitoring has been identified as a key pillar in the Chemicals Management Plan, and will serve the following functions: to collect and generate environmental data to inform decision-making, to provide an adaptive management framework to support

intervention and to measure the efficacy of preventive and mitigation actions. Also, continuing the testing of leachate for PFOA and long-chain PFCAs will be considered. These analyses and monitoring would be used to determine whether further action needs to be taken with respect to PFOA and long-chain PFCAs.

10. CONSULTATION APPROACH

The risk management scope for PFOA and long-chain PFCAs, which summarized the proposed risk management under consideration at that time, was published on October 30th, 2010, and is available at http://www.ec.gc.ca/Publications/default.asp?lang=En&xml=9A501352-BE72-4F7C-8BB8-FC9172EAED96.

Industry and other interested stakeholders were invited to submit comments on the risk management scope during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

The primary stakeholders include:

- Chemical Industry
- Industrial, Commercial and Consumer Products
- Environmental non-governmental organizations

There will be additional opportunities for public consultation during the development of the risk management instrument.

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed Risk Management Approach	August 25, 2012 to October 24, 2012
Response to comments on proposed Risk Management Approach	No later than at time of publication of proposed instrument
Consultation on the draft instrument	Late 2012/early 2013
Publication of the proposed instrument	No later than August 2014
Formal public comment period on the proposed instrument	No later than Fall 2014
Publication of the final instrument	No later than January 2016

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information prior to October 24, 2012,

since the Government of Canada will be moving forward with the risk management of PFOA and long-chain PFCAs after this date. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister under CEPA 1999 may submit with the information a request that it be treated as confidential. During the development of the risk management instrument(s) and/or tool(s), there will be opportunity for consultation on the proposed instrument(s). Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division
Gatineau, Quebec K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155
Email: GR-RM@ec.gc.ca

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