RISK MANAGEMENT SCOPE

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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1. ISSUE

1.1 Draft Screening Assessment Report Conclusion

The Ministers of the Environment and of Health have conducted an ecological and human health screening assessment under section 68 and 74 of the Canadian Environmental Protection Act, 1999 (CEPA 1999) to determine whether the following substances meet the definition of “toxic” as set out in section 64 of CEPA 1999: perfluorooctanoic acid, Chemical Abstracts Service Registry Number (CAS RN)\(^1\) 335-67-1, its salts and its precursors. Precursors to perfluorooctanoic acid were considered on the basis of their contribution to the total presence of perfluorooctanoic acid and its salts (Canada 2010b).

Furthermore, the Minister of the Environment conducted an ecological screening assessment of Long-Chain (C9-C20) Perfluorocarboxylic Acids, their salts and their precursors under sections 68 and 74 of CEPA 1999 to determine whether these substances meet the definition of “toxic” as set out in section 64 of CEPA 1999 (Canada 2010a). The fact that some of the precursors to the long-chain (C9-C20) perfluorocarboxylic acids are structurally similar to four fluorotelomer-based substances prohibited by the Minister of the Environment under the authority of section 84 of CEPA 1999 contributed to the decision to undertake the ecological screening assessment of the long-chain (C9-C20) perfluorocarboxylic acids.

Perfluorooctanoic acid, its salts, and its precursors and perfluorocarboxylic acids containing 9 to 20 carbon atoms, their salts and their precursors will be referred to throughout this document as PFOA and long-chain PFCAs respectively.

Notices summarizing the scientific considerations of the draft screening assessment report for PFOA and the draft ecological screening assessment report for long-chain PFCAs were published by Environment Canada and Health Canada in the Canada Gazette, Part I, on October 30, 2010, under subsection 77(1) and under paragraphs 68b and 68c of CEPA 1999. The draft screening assessment reports propose that 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. However, it is proposed that PFOA and its salts are 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.

The draft screening assessment reports also propose that based on available data, PFOA and long-chain PFCAs meet the criteria for persistence, as defined by the Persistence and Bioaccumulation Regulations made under CEPA 1999 (Canada 2010a, Canada 2010b) and that three chain lengths (C11, C12 and C14) meet the criteria for bioaccumulation. Additionally, the presence of PFOA and long-chain PFCAs in the environment results primarily from human activity.

\(^1\)CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information 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 of Canada 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.
For further information on the proposed draft screening assessment report conclusions for either PFOA or long-chain PFCAs, refer to the reports (Canada 2010a, Canada 2010b). Please note that the conclusions described in this document and in the draft screening assessment reports are preliminary and are subject to change.

1.2 Current Uses and Releases of Concern to the Environment

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 paper and chemical manufacturing. Both PFOA and long-chain PFCAs are used in the production of fluoropolymers and fluorotelomers and as additives and components in consumer and industrial products.

Within Canada, C9 to C15 PFCAs were measured in the liver of seals, foxes, fish, polar bears, Greenland shark, narwhals, beluga whales and birds either in the Arctic or the Great Lakes region. In addition, C14 and C15 PFCAs have been found in fish, invertebrates and polar bears. Owing to their combined lipophilic and hydrophobic properties, PFOA and long-chain PFCAs primarily bind to proteins in biota and preferentially partitions to liver, blood and kidney rather than to lipid tissue.

PFOA was detected in effluent from Canadian wastewater treatment facilities and measured in Canadian fresh water and freshwater sediments at trace levels. PFOA has also been detected in a variety of Canadian biota in southern Ontario, Nunavut, and the Canadian Arctic such as in benthic invertebrate, burbot liver, polar bear liver, caribou liver, ringed seal liver and walrus liver.

The presence of both PFOA and long-chain PFCAs in the environment is thought to result 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. Potential precursors also include related
fluorochemicals (e.g. fluorotelomer alcohols [FTOHs], fluorotelomer iodides and fluorotelomer olefins), some of which are currently used and detectable in the atmosphere and can degrade or transform to PFOA or long-chain PFCAs through biotic or abiotic pathways.

Once in the environment, PFOA and long-chain PFCAs are 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).

2. OVERVIEW OF EXISTING RISK MANAGEMENT

2.1 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:

1. 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.

2. 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 agreement includes early 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. The agreement is consistent with the voluntary Stewardship Program of the United States Environmental Protection Agency (US EPA) (see section 2.2 of the present document).

3. Pursuing further assessment of PFCAs and precursor substances already in Canadian commerce

   Proposed draft screening reports for PFOA and long-chain PFCAs were published in Canada Gazette, Part I, on October 30, 2010.

4. 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.

5. **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.

### 2.2 Existing International Risk Management

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 will 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.

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 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.

### 3. PROPOSED RISK MANAGEMENT

Following a screening assessment of a substance under section 68 or 74 of CEPA 1999, a substance may be found to meet the criteria under section 64 of CEPA 1999. 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 CEPA 1999. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Minister proposed to recommend the addition of PFOA, its salts and its precursors, as well as the addition of long-chain PFCAs, their salts, and their precursors to the List of Toxic Substances in Schedule 1 of CEPA 1999. As a result, the Ministers will develop risk management measures respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to these substances. The risk management being considered is the prohibition through regulations of the manufacture, use, sale, offer for sale,
import and export of PFOA, its salts and its precursors, and long-chain PFCAs, their salts, and their precursors, where substitutes are economically and technically feasible.

In addition, the final screening assessment reports will provide a conclusion as to whether or not PFOA and its salts and/or any long-chain PFCAs and their salts meet the virtual elimination criteria set out in subsection 77(4) of CEPA 1999. If the following criteria are met, virtual elimination will be implemented:

- The substance(s) meet the criterion set out in paragraph 64 of CEPA 1999;
- The substance(s) meet the criteria for “persistence” and “bioaccumulation” as defined in the Persistence and Bioaccumulation Regulations made under CEPA 1999;
- The presence of the substance(s) in the environment results primarily from human activity; and
- The substance(s) are not a naturally occurring radionuclide or a naturally occurring inorganic substance.

If the final screening assessment report concludes that PFOA and its salts and/or any long-chain PFCAs and their salts meet the criteria under sections 64 and 77(4) of CEPA 1999, options for risk management will focus on regulatory controls toward virtually eliminating releases of the substances to the environment.

If the final screening assessment report does not conclude that PFOA and its salts and/or any long-chain PFCAs and their salts meet the conditions set out in subsection 77(4) of CEPA 1999, the substance(s) will not be subject to the virtual elimination provisions under CEPA 1999.

This proposed action is part of a comprehensive approach to managing these substances and their releases as outlined in the Action Plan for the Assessment and Management of Perfluorinated Carboxylic Acids and their Precursors. It is intended to complement, build upon and take into consideration the actions that are being implemented through the Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (Four New Fluorotelomer-based Substances) and the Environmental Performance Agreement Respecting PFCAs and their Precursors in Perfluorochemical Products Sold in Canada (see section 2.1 of the present document).

The final screening assessment reports will provide a conclusion as to whether or not PFOA, its salts and its precursors and long-chain PFCAs, their salts, and their precursors meet one or more of the criteria set out in section 64 of CEPA 1999.

In accordance with the Government of Canada’s Cabinet Directive on Streamlining Regulation, the proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration the information available at this time.

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3 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.”
4. NEXT STEPS

Industry and other interested stakeholders are invited to submit comments on the content of this risk management scope or other information. Although all submitted information will be considered, specific information of the type described below would help to address uncertainties and inform decision-making:

**Use of PFOA, long-chain PFCAs and their precursors**
- Changes in import/manufacture/use quantities and use patterns since the 2004 reporting year, and expected future trends;
- Considerations on potential alternatives (substitutes or technologies);
- Description of costs associated with potential alternatives and control technologies.

**Use and disposal of products containing PFOA, long-chain PFCAs and their precursors**
- Identification of specific product lines or types, their typical operating conditions and environmental exposure, and the degradation of the substances over their lifecycle;
- Product lines that are not currently reported under the *Environmental Performance Agreement Respecting PFCAs and their Precursors in Perfluorochemical Products Sold in Canada*;
- Potential for releases during use and disposal of products containing these substances.

**Other pertinent information**

Please submit comments prior to December 29, 2010, since the Government of Canada will be moving forward with the development of the risk management approach after this date. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister of the Environment under CEPA 1999 may submit with the information a request that it be treated as confidential. The proposed risk management approach will be released with the publication of the final screening assessment reports. At that time, there will be opportunity for further consultation. Comments and information submissions on the risk management scope should be submitted to the address provided below:

Existing Substances Division  
Gatineau QC K1A 0H3  
Tel.: 1-888-228-0530 / 819-956-9313  
Fax: 1-800-410-4314 / 819-953-4936  
Email: substances@ec.gc.ca
5. REFERENCES


