Government of Canada / Gouvernement du Canada

CONSULTATION DOCUMENT

Proposed Risk Management Measure for

Perfluorooctanoic Acid (PFOA) Its Salts, and Its Precursors and Long-Chain (C_9-C_{20}) Perfluorocarboxylic Acids (PFCAs), their Salts, and their Precursors

Environment Canada

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Canada

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1. OBJECTIVE OF CONSULTATION

The objective of this Consultation Document and the corresponding 30 day electronic public comment period is to solicit feedback from stakeholders and the public regarding the proposed risk management measure for Perfluorooctanoic Acid (PFOA), its salts, and its precursors and Long-Chain (C_9-C_{20}) Perfluorocarboxylic Acids (LC-PFCAs), their salts, and their precursors. Comments received will help to inform the development of the proposed risk management measure for publication in *Canada Gazette,* Part I.

2. BACKGROUND

2.1 Substance and Release Information

PFOA and LC-PFCAs are fluorocarbon-based chemicals (consisting of fluorine bound to carbon atoms). The PFOA molecule contains 8 carbon atoms and LC-PFCAs contain between 9 and 20 carbon atoms. Both substances may also be found in salt form (e.g. PFOA ammonium salt). These substances may be formed from the degradation or transformation of their precursors, which include parent compounds and chemical products containing PFOA or LC-PFCAs.

PFOA is a synthetic substance belonging to the PFCA class of chemicals. In general, PFOA and its salts are used as polymerization aids in the production of fluoropolymers. Fluoropolymers are used in the manufacture of coatings that are water and stain resistant for a variety of applications. PFOA, its salts and its precursors (compounds that degrade to become PFOA) have also been used in the past in many industrial processes as well as in commercial and consumer products.

Only one LC-PFCA substance, containing a 9-carbon chain, is known to be used for surfactant applications and in the production of fluoropolymers. Other LC-PFCAs, containing carbon chains of 10–20 atoms, are rarely used intentionally in products. However, some substances, such as fluorotelomers, are PFCA precursors and can degrade to form LC-PFCAs. These substances are commonly used and found in commercial products to provide oil-, grease-, water- and stain-repellent properties to products.

PFOA, itself, is not manufactured in Canada. However, quantities of the ammonium salt are imported. LC-PFCAs are not manufactured in Canada; however, several precursors to the long-chain (C9-C20) perfluorocarboxylic acids were reported to be imported into Canada.

PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors were historically used, and may continue to be used, in the following industry sectors and are potentially contained in the associated products (OECD 2013).

- Films, paints and coatings: paint, photographic film, water-based inks
- Fire-Fighting: aqueous fire-fighting foams
- Electrical and Electronics: cables, wiring, semiconductors
- Product components and finished products: hoses, gaskets, non-stick cookware, personal care products

- Paper and packaging: oil and grease repellent
- Polymerization: polymerization processing aids (surfactants)
- Textiles: protective clothing, oil and water repellent and stain release fabrics, carpet

Other industry sectors would be implicated if they use product components or finished products identified in the list above.

Both PFOA and LC-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 LC-PFCAs.

2.2 Final Screening Assessment Report Conclusion for PFOA and Long-Chain PFCAs

The final screening assessment reports concluded that PFOA, its salts and precursors and LC-PFCAs, their salts and precursors 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 (Canada 2012a, 2012b) also concluded that PFOA and its salts and LC-PFCAs and their salts meet the criteria for persistence as set out in the *Persistence and Bioaccumulation Regulations;* however, PFOA and its salts and LC-PFCAs and their salts do not meet the regulatory criteria for bioaccumulation. Nevertheless, the weight of evidence is sufficient to conclude that PFOA and its salts and LC-PFCAs and their salts accumulate and biomagnify in terrestrial and marine mammals.

The final screening assessment report (Canada 2012a) also concludes 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.

LC-PFCAs and its salts 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, 2006). The Action Plan is available at: *http://publications.gc.ca/gazette/archives/p1/2006/2006-06-17/pdf/g1-14024.pdf*.

For further information on the final screening assessment report conclusions for PFOA, its salts and its precursors and LC-PFCAs, theirs salts and their precursors, refer to the final screening assessment reports, available at: http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=en&n=F68CBFF1-1.

2.3 Alternatives

Substances which are new to Canada, including new substitutes for PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors, are subject to the New Substances provisions of the *Canadian Environmental Protection Act*, 1999 (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, its salts and its precursors and LC-PFCAs, their salts and their precursors have been notified to the New Substances Program.

The United States Environmental Protection Agency (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 new chemical notices on alternative substances of various types have been received and reviewed by EPA. Under the 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.

While fluoro-alternatives exist for most, although not all current uses, there will likely be several alternatives rather than one single replacement. Non-fluorinated alternatives are available for some applications but may not provide equivalent performance as the fluorinated substances they are replacing.

2.4 Domestic 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 2006). This Action Plan addresses the assessment and management of the broad class of PFCAs and PFCA precursors including:

- **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)* (EC 2010) 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 LC-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 2010). The Performance Agreement was identified as early risk management action as Environment Canada and Health Canada pursued further assessment to guide future risk management actions. The agreement includes action

to reduce PFOA, LC-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 data received from companies indicates that significant progress is being made in reaching the targets set out in the Environmental Performance Agreement Respecting Perfluorinated Carboxylic Acids (PFCAs) and their Precursors in Perfluorinated Products Sold in Canada. The Environment Performance Agreement is available at: http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=AE06B51E-1 .

In August 2012, Environment Canada and Health Canada published a Risk Management Approach for PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors with the objective of minimizing releases of PFOA and LC-PFCAs to the environment to the greatest extent practicable that is technically and economically feasible (http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=451C95ED-1).

2.5 International Risk Management

Risk management actions have been proposed in the United States, Norway, Germany and the European Union. On September 30, 2013, the EPA issued a Significant New Use Rule, which requires companies to report their intent to manufacture or import products containing LC-PFCAs intended for use as part of carpets or to treat carpets, as well as their intent to import carpets already containing these chemicals (http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/pfcs.html#final) (US EPA 2013). Norway has banned the use of PFOA in consumer products (including textiles) through regulations which restrict the production, import, export or sale of consumer products that contain PFOA (OECD 2013). The regulations will take effect in June 2014.

Canada is a member of the Global Perfluorinated Chemicals (PFC) Group, consisting of governments, international organizations, and other stakeholders. The objectives of the Group is to consider the development, facilitation and promotion in an open, transparent and inclusive manner of national and international stewardship programs 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. The Global PFC Group has published a synthesis paper that provides an overview of key issues, scientific evidence, alternatives and regulatory approaches. The synthesis paper includes a comprehensive summary of existing international risk management (http://www.oecd.org/chemicalsafety/risk-management/synthesis-paper-on-per-and-polyfluorinated-chemicals.htm)(OECD 2013).

3. PROPOSED RISK MANAGEMENT

3.1 Proposed Measure

To achieve the risk management objective, and as outlined in the 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, that was published in August 2012 (Canada. 2012c), the Government of Canada is proposing to implement regulations to prohibit the manufacture, use, sale, offer for sale, and import of PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors and products containing these chemicals.

This will be achieved through the addition of PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors to the *Prohibition of Certain Toxic Substances Regulations, 2012* (EC, 2012), herein referred to as the "Prohibition Regulations".

Future consideration will be given to the addition of PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors to the *Export Control List* (Schedule 3 of CEPA 1999) to restrict exports. Separate consultations will be undertaken for export controls when deemed timely and appropriate.

3.2 Elements of the Proposed Prohibition

3.2.1. Intent

The intent of the proposed risk management measure is to prohibit the manufacture, import, use, sale, and offer for sale of PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors and products containing these substances, effective from the coming into force of the regulations.

3.2.2. Application

The proposed risk management measure would apply to all Canadians, including chemical manufacturers and importers, material processors, importers of product components and finished products, product assemblers, and the general public.

It is proposed to add PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors to either Schedule 1 (Prohibited Toxic Substances) or Schedule 2, Part 2 (Temporary Permitted Uses) of the Prohibition Regulations to prohibit the manufacture, use, sale, and offer for sale or import of the substances and products containing the substances in Canada.

3.2.3. Coming Into Force

It is anticipated that the coming into force date for the final regulations will be three months following the February 2016 publication date in *Canada Gazette*, Part II. Currently, the coming into force date of May 2016 is being considered.

It is anticipated that the final regulations will include a coming into force date whereby the regulations would only apply to the manufacture, import, use, sale, offer for sale of PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors and products containing

these substances, manufactured or imported after the coming into force date. Products containing PFOA, its salts and/or its precursors and LC-PFCAs, their salts and/or their precursors manufactured or imported before the coming into force date would not be affected by the regulations.

Comments on the proposed coming into force date are welcomed and necessary to assist with a coordinated and timely transition away from PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors to suitable chemical alternatives and alternative non-chemical techniques.

4. REQUEST FOR INFORMATION

To achieve the risk management objective as outlined in the Risk Management Approach, and taking into consideration comments received on the Approach, the Government of Canada is working with industry to identify uses where there may be a need for accommodations, such as time-limited exemptions, permitted uses, use concentration limits, etc. to allow for the development of alternatives or alternative non-chemical techniques and the subsequent phase out of PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors.

Through previous consultations, the following uses were identified where chemical alternatives or alternative non-chemical techniques are not commercially available or where phase out and transition to alternatives may be required:

- Manufacture of semi-conductors,
- Fire protection products,
- Surfactants in water-based inks, and
- Processing aids in coatings for photo media products.

Stakeholders are being asked to provide information, related to their operations or industry operations as a whole, to identify uses and evaluate the need for accommodations, such as time-limited exemptions, permitted uses, use concentration limits, etc. Submissions should include the following information, to the extent that is possible:

- Description of the specific use.
- Description of the alternative development process for the specific use.
- Details of the expected timelines for alternative development.
- Description of the necessary performance attributes of the alternative and testing timelines to confirm viability of the alternative.
- Description of the transition process and timing.
- Description of any other phase out considerations.

All input received will help to inform the development of the proposed regulations prior to their publication in *Canada Gazette*, Part I. Responses, comments and other materials should be sent to the contact listed below.

5. SOCIO-ECONOMIC CONSIDERATIONS

Socio-economic factors have been considered in the selection process for a regulation and/or 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 regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (TBS 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

6. NEXT STEPS AND TIMELINES

Actions	Date
End of 30-day electronic public consultation period on this Consultation Document	November 2013
Publication of the proposed regulations in *Canada Gazette*, Part I	No later than August 2014
End of Formal public comment period on the proposed regulations	No later than October 2014
Publication of the final regulations in *Canada Gazette*, Part II	No later than 18 months following the publication of the proposed instrument, February 2016
Coming into force of the regulations	May 2016

Industry and other interested stakeholders are invited to submit comments on the content of this consultation document or provide other information that would help to inform decision making. Please submit comments prior to November 30, 2013, since the development of the proposed regulations for PFOA, its salts and its precursors and LC-PFCAs, their salts and their precursors will be moving forward after this date. Comments and information submissions 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

7. REFERENCES

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