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Revised Risk Management Scope

for

Per- and polyfluoroalkyl substances (PFAS)

Environment and Climate Change Canada

Health Canada

July 2024

Canada

Summary of Proposed Risk Management

The class of PFAS, excluding fluoropolymers as defined in the Updated Draft State of PFAS Report (ECCC, HC 2024), is proposed to meet the criteria under paragraph 64(*a*) and (*c*) of the *Canadian Environmental Protection Act, 1999* (CEPA), as these substances are entering or may enter the environment in a quantity or concentration or under conditions that have or may have immediate or long-term harmful effects on the environment or its biological diversity, and that constitute or may constitute a danger in Canada to human life or health.

In particular, the Government of Canada is considering:

- As a first step, a regulatory instrument under CEPA to restrict PFAS not currently regulated in firefighting foams (see section 4.2.1 for context); and
- Additional regulatory instrument(s) under CEPA to prohibit other uses or sectors in relation to PFAS. Prioritization for prohibition may be based on factors such as socio-economic considerations, the availability of feasible alternatives, and the potential for human and environmental exposure.

The risk management options outlined in this Revised Risk Management Scope document may evolve through consideration of assessments and risk management options or actions published for other Chemicals Management Plan (CMP) substances as required to ensure effective, coordinated, and consistent risk management decision-making, or other sources.

Note: PFAS meeting the definition of fluoropolymers, as defined in the Updated Draft State of PFAS Report, are not addressed within that report or this Revised Risk Management Scope and are planned for consideration in a separate assessment. Refer to section 3 of this document for more details.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of the Environment and the Minister of Health (the Ministers) to conduct assessments to determine if substances are toxic to the environment and/or harmful to human health as set out in section 64 of CEPA[1,2] , and if so, to manage the associated risks.

In April 2021, the Government of Canada published a Notice of Intent signaling an intent to move forward with activities to address the class of PFAS based on scientific evidence indicating that the PFAS used to replace prohibited PFAS, such as perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and long-chain perfluorocarboxylic acids (LC-PFCAs), may be associated with environmental or human health effects.

Addressing PFAS as a class will help to protect the environment and human health by, among other things, reducing the chance of regrettable substitution (replacing one PFAS with another less-well characterized equally problematic PFAS), supporting improved research and monitoring programs, and reducing future environmental and human exposure to PFAS. The class of PFAS is based on the Organisation for Economic Co-operation and Development (OECD) definition of PFAS, which is defined as "fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), that is, with a few noted exceptions, any chemical with at least a perfluorinated methyl group ($–CF_3$) or a perfluorinated methylene group ($–CF_2–$) is a PFAS" (OECD 2021).

The most commonly identified groups of polymeric PFAS include side-chain fluorinated polymers, perfluoropolyethers and fluoropolymers. Fluoropolymers are defined in the Updated Draft State of PFAS Report as polymers made by the polymerization or copolymerization of olefinic monomers (at least 1 of which contains fluorine bonded to 1 or both of the olefinic carbon atoms), which forms a carbon-only polymer backbone with fluorine atoms directly bonded to it. Given

[1] Section **64 of CEPA:** *For the purposes of* [Parts 5 and 6 of CEPA]*, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
b) constitute or may constitute a danger to the environment on which life depends; or
c) constitute or may constitute a danger in Canada to human life or health.

[2] A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazard Product Regulations*, which are a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

information suggesting their differences from the other PFAS in the class, additional work on fluoropolymers is warranted. PFAS meeting the definition of fluoropolymers are not addressed within this document and are planned for consideration in a separate assessment.

2. Issue

On July 13, 2024, Health Canada and Environment and Climate Change Canada prepared an Updated Draft State of PFAS Report under section 68 of CEPA. A notice indicating the measure the Ministers propose to take and summarizing the scientific considerations of the report was published under subsection 77(1) of the Act in the *Canada Gazette*, Part I, on July 13, 2024 (ECCC, HC 2024). For further information, refer to the Updated Draft State of PFAS Report.

2.1 Updated Draft State of PFAS Report conclusion

The Updated Draft State of PFAS Report proposes that the class of PFAS, excluding fluoropolymers as defined in that report, is toxic under paragraphs 64(*a*) and 64(*c*) of CEPA as these substances are entering or may enter 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; and constitute or may constitute a danger in Canada to human life or health (ECCC, HC 2024). However, the class of PFAS, excluding fluoropolymers as defined in the Updated Draft State of PFAS Report, is proposed not to meet the criteria under paragraph 64(*b*) of CEPA as these substances are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends.

Well-studied PFAS meet the persistence criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA. Based on available information and structural similarities, it is expected that other substances within the class of PFAS are also highly persistent or transform to persistent PFAS. It is therefore proposed that the class of PFAS meets the persistence criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA. There is a high concern identified for the biomagnification and trophic magnification potential of well-studied PFAS in air-breathing organisms; however, the numeric criteria for bioaccumulation, outlined in the *Persistence and Bioaccumulation Regulations*, are based on bioaccumulation data for freshwater aquatic species which do not account for biomagnification potential. Therefore, application of the criteria would not reflect the concern for dietary-based biomagnification, the primary route of foodweb exposure identified for well-studied PFAS. It is therefore proposed that the bioaccumulation potential of PFAS cannot reasonably be determined according to the regulatory criteria set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

2.2 Proposed recommendation under CEPA

On the basis of the findings of the Updated Draft State of PFAS Report, the Ministers propose, from the measures set out in subsection 77(2) of the Act, to recommend that the class of PFAS, excluding fluoropolymers as defined in the Updated Draft State of PFAS Report, be added to Part 2 in Schedule 1 to CEPA.[3] Addition of a substance to Schedule 1 to CEPA enables the Government to propose certain risk management measures under CEPA to manage potential ecological and human health risks associated with the substance.

Under subsection 77(3), the Ministers are required to propose recommending the addition of a substance that meets the criteria set out in paragraph (a), (b) or (c) to Part 1[4] of Schedule 1 of the Act and, in developing a proposed regulation or instrument respecting preventive or control actions, to give priority to the total, partial or conditional prohibition of activities in relation to the substance or to the release of the substance into the environment. For other substances recommended for addition to Part 2 of Schedule 1 of the Act, the Ministers shall give priority to pollution prevention, and this could include regulatory or non-regulatory measures, such as prohibition if warranted.

Until regulations specifying criteria for the classification of substances that pose the highest risk or that are carcinogenic, mutagenic or toxic to reproduction are available, the class of PFAS, excluding fluoropolymers as defined in the Updated Draft State of PFAS Report, is proposed to be recommended for addition to Part 2 of Schedule 1. Following the availability of the aforementioned criteria, the substances may be moved to Part 1 of Schedule 1, if applicable.

The Ministers have taken into consideration comments made by stakeholders during the public comment period on the Draft State of PFAS Report and its

[3] After an assessment of a given substance under Part 5 of CEPA, other than section 83, the Ministers shall propose one of the following measures: take no further action with respect to the substance, add the substance to the List referred to in section 75.1 of the Act (unless the substance is already on that List), recommend the addition of the substance to Part 1 of the list of toxic substances in Schedule 1 to CEPA (for substances that pose the highest risk) or recommend the addition of the substance to Part 2 of the list of toxic substances in Schedule 1 to CEPA (for other CEPA-toxic substances).

[4] Under subsection 77(3), a substance must be recommended for addition to Part 1 of Schedule 1 to the Act when the substance is determined to be toxic and the Ministers are satisfied that:

(a) the substance may have a long-term harmful effect on the environment and
  (i) is inherently toxic to human beings or non-human organisms, as determined by laboratory or other studies,
  (ii) is persistent and bioaccumulative in accordance with the regulations,
  (iii) is present in the environment primarily as a result of human activity, and
  (iv) is not a naturally occurring radionuclide or a naturally occurring inorganic substance;
(b) the substance may constitute a danger in Canada to human life or health and is, in accordance with the regulations, carcinogenic, mutagenic or toxic for reproduction; or
(c) the substance is, in accordance with the regulations, a substance that poses the highest risk.

associated Risk Management Scope document that were published in May 2023. The Ministers will also take into consideration additional comments provided by stakeholders during the public comment period on the Updated Draft State of PFAS Report and its associated Revised Risk Management Scope.

If the Ministers finalize the recommendation to add the class of PFAS, excluding fluoropolymers as defined in the Updated Draft State of PFAS Report, to Part 2 of Schedule 1, risk management instruments must be proposed – unless an exception to section 91 applies - within 24 months from the date on which the Ministers recommended that the class of PFAS, excluding fluoropolymers as defined in the Updated Draft State of PFAS Report, be added to Schedule 1 of CEPA, and finalized within 18 months from the date on which the risk management instrument is proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 of this document for publication timelines applicable to this group of substances). Adding a substance to Schedule 1 does not, in itself, restrict its use, manufacture, or import. Rather, it enables the Government of Canada to take risk management actions under CEPA.

2.3 Public comments received on the Draft State of PFAS Report and the Risk Management Scope

The Draft State of PFAS Report (ECCC, HC, 2023a) and its associated Risk Management Scope document (ECCC, HC, 2023b) summarizing the proposed risk management options under consideration at that time, were published on May 20, 2023. Industry and other interested stakeholders were invited to submit comments on both documents during a 60-day comment period.

Comments received on the Draft State of PFAS Report and the Risk Management Scope document were taken into consideration in the development of this document. A summary of responses to public comments received is available.

3. Proposed risk management

3.1 Proposed environmental and human health objectives

Proposed environmental and human health objectives are quantitative or qualitative goals to address environmental and human health concerns.

The proposed environmental and human health objectives for the class of PFAS, excluding fluoropolymers as defined in the Updated Draft State of PFAS Report, are, respectively, to:

- reduce releases of these substances to the Canadian environment so as to avoid adverse effects; and
- reduce exposure of the general population, including disproportionately impacted populations, to these substances to protect human health.

3.2 Proposed risk management objective

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instruments and/or tools for a given substance or substances.

In this case, the proposed risk management objective for the class of PFAS, excluding fluoropolymers as defined in the Updated Draft State of PFAS Report, is to, over time, achieve the lowest levels of environmental and human exposure that are technically feasible, taking into consideration socio-economic factors.

3.3 Proposed risk management options under consideration

To achieve the proposed risk management objective and to work towards achieving the proposed environmental and human health objectives, the proposed risk management options under consideration for the class of PFAS, excluding fluoropolymers as defined in the Updated Draft State of PFAS Report, through a phased approach, are the following:

- As a first step, due to their high potential for environmental and human exposure, a regulatory instrument under CEPA to restrict PFAS not currently regulated in firefighting foams (see section 4.2.1 for more information); and
- Additional regulatory instrument(s) under CEPA to prohibit other uses or sectors in relation to PFAS. Prioritization for prohibition may be based on factors such as socio-economic considerations, the availability of feasible alternatives, and the potential for human and environmental exposure.

Note that these proposed risk management options are preliminary and subject to change. Proposed risk management will take into consideration those groups of individuals within the Canadian population who, due to greater exposure, may be disproportionately impacted.

Following the publication of this document, additional information obtained from the public comment periods and from other sources will be considered in the instrument selection and development process[5]. The risk management options may also evolve through consideration of assessments and risk management options or actions published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

[5] The proposed risk management regulations, instruments or tools will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulation (TBS 2018), the Red Tape Reduction Action Plan (TBS 2012), and in the case of a regulation the *Red Tape Reduction Act* (Canada 2015).

Proposed risk management options under consideration are meant to be complementary in order to avoid duplication with existing Acts and regulations, such as the *Prohibition of Certain Toxic Substances Regulations, 2012* and the *Ozone-depleting Substances and Halocarbon Alternatives Regulations*, as well as with voluntary actions outlined in section 3.4.

In addition, other ongoing actions on PFAS will continue, such as development of drinking water guidelines and environmental quality guidelines, management of contaminated sites, and the continued administration of existing risk management actions outlined in section 7.1.

3.4 Additional complementary risk management actions

Voluntary risk management actions are also being considered to achieve early results to reduce releases of PFAS, as a complement to the proposed regulatory instruments. This work would be informed by stakeholder engagement and would reflect and align with the suite of broader risk management options under consideration, particularly those outlined in section 3.3. Voluntary initiatives under consideration include:

- exploring opportunities to increase disclosure of information (such as labelling) regarding chemicals of concern, that would enable consumers and importers to identify products containing PFAS;
- engaging with interested sectors on options for voluntarily phasing out of PFAS; and
- working with North American trading partners on alternatives assessment and informed substitution of PFAS.

3.5 Performance measurement and evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[6]. The aim is to determine whether environmental and/or human health objectives have been met and whether there is a need to revisit the risk management approach for the class of PFAS, to ensure that risks are managed effectively over time. To achieve this, the Government of Canada plans to review, on a regular basis, the effectiveness of any risk management actions for the class of PFAS.

The Government of Canada plans to measure the effectiveness of the risk management actions by collecting and analyzing data such as the presence of

[6] Performance measurement can be performed at two levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management or assessment is needed (*i.e.*, evaluate whether risk management objectives have been met); and
- Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the environment or human health (*i.e.*, evaluate whether human health and/or environmental objectives have been met).

PFAS in various environmental compartments, monitoring data obtained from the Monitoring and Surveillance Program under the CMP, and biomonitoring data such as that collected under the Canadian Health Measures Survey (CHMS). These data sources may also be used to estimate the presence of PFAS in surface water and wastewater treatment plants' effluents, and in wildlife and ambient air. They may also be used as measures of human exposure and environmental presence prior to implementation of risk management actions, in order to establish a baseline and in the future to evaluate the performance of risk management actions.

The results of performance measurement and evaluation would be used to inform whether further risk management action is warranted, which will be made available to Canadians along with recommendations for further action, if applicable.

3.6 Risk management information gaps

Many commenters have submitted a significant amount of information in response to the Draft State of PFAS Report and Risk Management Scope, which helped to address certain data gaps and provide a better understanding of challenges they are facing. Interested stakeholders continue to be invited to provide new information to inform risk management decision-making regarding the class of PFAS, including:

- availability of alternatives to PFAS, or lack thereof, in products and applications in which they are currently used;
- socio-economic impacts of replacing PFAS, including costs and feasibility of elimination or replacement; and,
- types, quantities, and concentrations of PFAS (including Chemical Abstracts Service Registry Numbers, units of measurement, and applications) in products manufactured in, imported into, and sold in Canada.

Stakeholders that have new information that was not already submitted should provide it to help address these gaps on or before September 11, 2024, to the address identified in section 8. While some of the information requested above will be collected via a section 71 notice (noted below), any additional information that stakeholders have that could help address the gaps should be provided to the government.

3.6.1 Information gathering

Data collection initiatives, as well as certain reporting requirements, are planned to collect additional information on the class of PFAS, including the following:

- Gathering information under a mandatory survey notice under section 71 of CEPA.
- Future consultations on uses without alternatives and the potential need for regulatory exemptions.

- Considering the addition of reporting requirements to the National Pollutant Release Inventory (NPRI) in line with Environment and Climate Change Canada's process for proposing and considering changes to NPRI. A notice would be published on the Proposed Changes to the NPRI webpage to consult on these changes.
- Considering including the requirement to report on the use of fume suppressants in certain applications, some of which contain substances that are PFAS as defined in the Updated Draft State of PFAS Report as part of the proposed amendments to the *Chromium Electroplating, Chromium Anodizing and Reverse Etching Regulations* (ECCC 2022b).
- Continuing to monitor PFAS in food through the Total Diet Study (TDS). Health Canada's Food Directorate has analyzed food samples for PFAS for a number of years. However, the available data for PFAS in food are still limited for this class of substances (that is, because there are thousands of PFAS).
- Monitoring of existing notifications for PFAS in a range of products such as cosmetics, natural health products, and drugs.
- Monitoring and reviewing pesticide active ingredients and the list of pesticide formulants to identify any PFAS in pesticide products.
- Gathering information on the transition from PFAS-containing firefighting foams to alternatives in Canada as part of a socio-economic study. Canadian users and suppliers of aqueous film-forming foams (AFFF) and their alternatives may be contacted to collect relevant information. Nevertheless, these stakeholders are also invited to submit comments and information in response to this Revised Risk Management Scope.

4. Background

4.1 General information on PFAS

PFAS are a class of thousands of human-made substances that encompasses a broad range of structures, including those with varying degrees of fluorination and chain length (Buck et al. 2011; ITRC 2020; OECD 2021; Wang et al. 2017; OECD 2018).

PFAS possess a set of practical traits that serve a functional purpose in a broad spectrum of applications such as:

- oil and water repellency that results in stain resistance, soil repellency and non-stick properties;
- high resistance to chemical, physical, and temperature degradation; and
- low surface tension resulting in their use as surfactants and lubricants.

4.2 Current uses and identified sectors

The widespread use of these substances as well as their extreme persistence in the environment, propensity for accumulation and mobility has led to PFAS being commonly detected in the environment and certain PFAS being commonly detected in humans. Due to their properties, PFAS are used in many industrial sectors and are found in a wide range of products, including certain firefighting foams, food packaging, drugs, cosmetics, sunscreens, pesticides, textiles, vehicles, and electronics. A study published in 2020 (Glüge et al. 2020) identified more than 200 current uses within 64 use categories for more than 1400 PFAS and presents in detail their functions and the related sectors.

The understanding of current uses of certain PFAS in Canada has been informed by data gathered from notices for certain perfluoroalkyl and fluoroalkyl substances issued pursuant to section 71 of CEPA (most of which were conducted more than 10 years ago), New Substances Notifications received under the *New Substances Notification Regulations (Chemicals and Polymers)* of CEPA, Cosmetic Notifications received under the *Cosmetic Regulations* of the *Food and Drugs Act* and voluntary submissions received by Health Canada related to food packaging materials. The information collected may not fully represent all uses in Canada. Public comments submitted following the publication of the Draft State of PFAS Report and Risk Management Scope also provided information about uses of PFAS in Canada.

The following subsections expand on the use of PFAS in firefighting foams because it is proposed as a first step for risk management actions, and on PFAS subgroups that have been singled out by many commenters as having critical applications in their sectors.

4.2.1 PFAS-containing firefighting foams and PFAS fire-suppressing agents

PFAS-containing firefighting foams are synthetic mixtures with the ability to rapidly extinguish hydrocarbon fuel fires, where the main function of the PFAS is to act as a surfactant. Aqueous film-forming foam (AFFF) is the most widely used and available of these foams and, for this reason, PFAS-containing firefighting foams are often simply referred to as AFFF, including in this document. There are, however, other types of PFAS-containing firefighting foams with slightly different compositions used in specialized applications, such as alcohol-resistant AFFF (AR-AFFF) for polar solvents, and film-forming fluoroprotein foam (FFFP) for an added burn back resistance for deeper pool fires.

AFFF is one of the main sources of contamination from PFAS in drinking water and in the environment as this use is dispersive and significant quantities have been released during firefighting testing, training and use in fire incidents. As a result, controls and bans of AFFF are increasing in jurisdictions globally (ECHA 2022a), in particular in some states in the United States (California 2020, Illinois 2021).

AFFF is mainly used in civil and military aviation, and in the chemical and petroleum industries. Municipal fire services may also use AFFF to extinguish fires, sometimes as part of mutual aid agreements with facilities in these sectors, which allow emergency responders to lend assistance across their jurisdictional boundaries. For example, municipalities or townships neighbouring an airport may agree to provide personnel and other resources during emergency aircraft rescue and firefighting operations. AFFF are frequently divided into three general categories depending on the type of compounds and/or composition profile in PFAS-containing surfactant they contain (ITRC 2022, ECHA 2022b):

- Legacy PFOS AFFF,
- Legacy fluorotelomer AFFF, or “C8 AFFF”, which contain a very significant proportion of long-chain PFAS compounds of carbon chain length of 8 or longer (i.e., PFOA and LC-PFCAs, their salts and precursors); and
- Modern fluorotelomer AFFF, or “C6 AFFF”, which mainly contain PFAS compounds of carbon chain length of 6 or shorter with no intentionally added or significant impurities of long-chain PFAS compounds.

In Canada, legacy PFOS and fluorotelomer AFFF (i.e., containing PFOS, PFOA and/or LC-PFCAs, their salts and precursors) are prohibited under the *Prohibition of Certain Toxic Substances Regulations, 2012* with limited exemptions (Canada 2012). The exemptions related to the use of C8 AFFF are proposed to be phased out by the end of 2025 under the proposed *Prohibition of Certain Toxic Substances Regulations, 2022* (Canada 2022). The proposed development of a regulatory instrument for PFAS-containing firefighting foams described in section 3.3 would prohibit all remaining PFAS from use in firefighting foams, including but not limited to their use as surfactants.

Table 1. Milestones for the phase out of the use of PFAS in firefighting foams in Canada

General category	**Phase out in Canada**	**Key driver**
PFOS AFFF	Completed in 2013	PFOS[1] found to be toxic[2] and added to Schedule 1 of CEPA
C8 AFFF	Proposed to be completed by the end of 2025	PFOA[1] and LC-PFCAs[1] found to be toxic[2] and added to Schedule 1 of CEPA
C6 AFFF	Under consideration, timelines to be determined[3]	Class of PFAS proposed to be toxic[2] and to be recommended to be added to Schedule 1 of CEPA

[1] including their salts and precursors.
[2] toxic under section 64 of CEPA.
[3] additional opportunities for public and stakeholder engagement will be provided during the subsequent development of risk management activities.

Moreover, a few fluorinated gases that are PFAS, such as hydrofluoroethers (HFEs) or hydrofluorocarbons (HFCs), are or were also used as fire-suppressing agents for extinguishing fires in high-risk situations and are commonly referred to as “clean agents” (NFPA 2022). Such agents are different from firefighting foams, which are aqueous mixtures.

4.2.2 Hydrofluoroolefins (HFOs) and hydrochlorofluoroolefins (HCFOs)

Several HFOs and HCFOs are gaseous or liquid PFAS that are used as refrigerants, foam-blowing agents, aerosol propellants, and solvents.

HFOs and HCFOs are used by industry as alternatives to other organofluorine compounds that have been identified as being potent greenhouse gases contributing to climate change (hydrochlorofluorocarbons (HCFCs) and HFCs) and as ozone depleting substances (ODS) that destroy the protective ozone layer (chlorofluorocarbons (CFCs) and HCFCs).

The import, export, manufacture, and use of CFCs, HCFCs and HFCs, as well as certain products that contain or are designed to contain these substances are already controlled in Canada under the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* (ODSHAR). These regulations implement Canada's international obligations under the *Montreal Protocol on Substances that Deplete the Ozone Layer*, including the phasedown on the production and consumption of HFCs established under the Kigali Amendment.

As such, the Government of Canada acknowledges the important role that HFOs and HCFOs serve as alternatives to ODS and high-global warming potential HFCs in a diverse range of applications, and also the concerns related to the significant challenges associated with developing, testing and adopting new alternatives once again.

One such example of this use is medical propellants used in metered dose inhalers (MDIs) to treat respiratory diseases, such as asthma and chronic obstructive pulmonary disorder. MDIs currently rely on HFC-134a and HFC-227ea, both of which are PFAS. There are efforts to move away from these two HFCs for MDIs due to their high global warming potential. However, one of the two alternatives that currently has been developed (HFO-1234ze(E)) is also considered to be a PFAS. In developing future risk management for PFAS, consideration will be given to the socio-economic impacts, including the burden and impacts of the respiratory illnesses MDIs treat.

Additionally, any risk management actions for PFAS would be developed within the context of Canada's climate and clean-energy objectives and obligations. The availability of alternatives and critical nature of some use patterns will be considered. Should risk management actions on HFOs and/or HCFOs be required, they would be developed in alignment with, and complementary to, existing regulations with controls on PFAS, such as the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* and the *Prohibition of Certain Toxic Substances Regulations, 2012*.

5. Exposure Sources

Releases of PFAS to the Canadian environment are expected to occur during the manufacture, processing, use, recycling, and disposal of PFAS or products containing PFAS. Exposure of the general population to PFAS is often attributed to environmental media and/or the use of products. PFAS enter the environment from human activity, as there are no known natural sources of these substances. The following subsections address the exposure sources being considered for proposed risk management.

5.1 PFAS-containing firefighting foams

PFAS-impacted contaminated sites where AFFF has been or is being used (for example, firefighting training areas) represent "hot spot" areas where PFAS is

being released to the environment. In addition, Canadians can also be exposed to PFAS through various environmental media as a result of AFFF use.

PFAS contamination may pose risks to human health and the environment not only at the contaminated site (that is, on-site), but also off-site due to the potential for significant migration in surface water and groundwater or by wind-erosion. PFAS have demonstrated the ability to travel long distances, several kilometers in the sub-surface (groundwater) and surface water, which can lead to a large area of impact from a single point source of PFAS (Bhavsar et al. 2016; CCME 2021a).

5.2 Other sources and products

PFAS are used in many industrial processes and are present in a wide variety of consumer and industrial products. Their manufacture, use in manufacturing and industrial processes and use of products containing PFAS can result in the release of and exposure to PFAS. The disposal of materials, such as PFAS-contaminated soils and biosolids, can also become an indirect pathway of release to the environment.

As it is not possible to separate PFAS-containing waste from the general waste stream, it is expected that PFAS-containing waste will be sent for disposal at a municipal solid waste landfill, incinerated, or recycled. PFAS may leach out of these products and materials, accumulate in landfill leachate, and eventually be released to the environment, even if that leachate is sent to a wastewater treatment system. Other solid waste facilities, such as organic processing facilities, scrapyards, and recycling facilities, may also have releases to the environment. Biosolids that contain PFAS may also be sold as commercial fertilizers for application on agricultural lands and result in releases to the environment. Consult section 7 for more information.

The Government of Canada considers, where available, information relevant to those groups of individuals within the Canadian population who, due to greater susceptibility or greater exposure, may be disproportionately impacted.

As part of the Chemicals Management Plan, the Government asked industry and interested stakeholders to submit any information on the substances that may be used to inform risk assessment, risk management and product stewardship.

6. Risk management considerations

6.1 Alternatives and alternate technologies

Due to the large number of substances included in the definition of PFAS as defined in the Updated Draft State of PFAS Report, and the wide range of products with which PFAS are implicated, the availability of alternatives cannot be described in detail here for all possible applications. Potential alternatives described below have not been evaluated by the government to determine whether they are less harmful and functionally equivalent to the PFAS they would replace.

Fluorine-free alternatives are currently available for many uses. However, in some cases substitution is not happening (ECHA 2023).

Several alternatives to the use of firefighting foams containing PFAS have been developed and are now widely available. These include fluorine-free firefighting foams (F3) and non-foam fire suppression systems, such as ignitable liquid spill drainage floor (ECHA 2022a, US DoD 2022). There is a large variety of hydrocarbon-based and detergent-based F3 available on the market. However, there are concerns that the available F3 may not be as effective as the PFAS-containing AFFF. Research and development on F3 with improved performance continues (SERDP 2019). F3 used in aviation applications must be tested and meet the performance criteria as described in the following standards: CAN/ULC 563:2022 (ULC 2022) and MIL-PRF-32725 (US DoD 2023).

Potential alternatives for PFAS applications in other products are also available. For example, in surface protection, wax-coated, Kaolin clay-coated and uncoated papers as well as silicone-based and cellulose-based products were identified as potential alternatives in food packaging applications (State of Washington 2021, OECD 2020). Silicones/siloxanes, polyurethanes and derivatives of fatty acids are some of the potential alternatives identified in treatments for converted textiles (State of California 2022a). In addition, non-PFAS alternatives are commercially available for coatings, paint additives and varnishes and also for cosmetics (OECD 2022, 2024).

However, for some important applications, alternatives appear to be either not yet available or not suitable, such as for certain fluorinated gases used as refrigerants or blowing agents, or fire suppressants in critical aviation and military applications (ECHA 2023).

6.2 Socio-economic and technical considerations

Comments received from stakeholders indicate that many alternatives are available for some sectors, such as most textiles and food packaging, but are lacking for some other uses, such as certain applications using fluorinated gases that are PFAS. It has been noted that some industrial sectors in Canada and globally are in the process of voluntarily phasing out PFAS from their processes, supply chain and products (3M 2023). Where information is available, socio-economic factors will be considered in the selection process for an instrument respecting preventive or control actions, and in the development of the risk management objective as per the guidance provided in the Treasury Board document Assessing, Selecting, and Implementing Instruments for Government Action (TBS 2007).

In addition, socio-economic factors will be considered in the development of the regulations, instrument(s) or tool(s), to address risk management objective(s), as identified in the Cabinet Directive on Regulation (TBS 2018), Red Tape Reduction Action Plan (TBS 2012) and the *Red Tape Reduction Act* (Canada 2015).

7. Overview of existing risk management

A brief summary of the key risk management actions for PFAS in Canada and internationally is provided below. More detail is provided in section 8 of the Updated Draft State of PFAS Report.

7.1 Related Canadian risk management context

- The *Prohibition of Certain Toxic Substances Regulations, 2012* prohibit the manufacture, use, sale, and import of PFOS, PFOA, and LC-PFCAs, along with their salts and precursors, with a limited number of exemptions. On May 14, 2022, the Government of Canada published draft Regulations (proposed *Prohibition of Certain Toxic Substances Regulations, 2022*) to remove or phase-out most of those exemptions. The publication of the final Regulations is expected to take place in fall 2024 and would come into force six months later.
- The *Ozone-depleting Substances and Halocarbon Alternatives Regulations* set out rules on the import, export, and manufacture of certain ozone-depleting substances and halocarbon alternatives, many of which meet the PFAS definition.
- The *New Substances Notification Regulations (Chemicals and Polymers)* require that new substances (that are not listed on the Domestic Substances List) that meet regulatory thresholds be notified to the government so that they can be assessed for potential risks to human health and the environment and that, if appropriate, control measures are put in place before they are imported into or manufactured in Canada. PFAS are not grouped when they are assessed under the NSNR; each new substance is notified to the government at a different point in time and is individually evaluated for potential risks to the environment and the general public originating from industrial and other relevant uses (for example, consumer uses, cosmetics, pharmaceuticals). Approximately 100 of the over 280 PFAS notified to the New Substances program have been subject to actions under CEPA intended to mitigate the risks to human health and/or the environment. These include 5 Ministerial Conditions (Canada 1996) and, beginning in 2004, 4 Ministerial prohibitions (Canada 2004). A Ministerial Condition is a control measure imposed on a new substance to minimize a suspected risk to human health or the environment, in response to a suspicion that the substance may meet the criteria for “toxic” under CEPA. Substances subject to Ministerial Conditions are not eligible for addition on the Domestic Substances List and must be notified to the New Substances program whenever a new notifier wishes to import or manufacture the substance.
- Drinking Water Quality Guidelines are available for PFOS and PFOA, and drinking water screening values are available for nine other PFAS (HC 2019). These can be used to assess potable groundwater or surface water at federal contaminated sites and by provinces and territories, to manage drinking water in their regions. In February 2023, a consultation document

was published on a proposed Drinking Water Objective that will recommend a single treatment-based value for a group of PFAS in drinking water (HC 2023). Publication of the final objective is anticipated by late Summer 2024.

- Guidelines and screening values are also available for up to 10 PFAS in various environmental media to assess contaminated sites (CCME 2021b, ECCC 2018 and HC 2022).
- While the regulation of the treatment, land application, and disposal of biosolids (solids from municipal sewage treatment plants) is primarily the responsibility of the provinces and territories in Canada, the Canadian Food Inspection Agency (CFIA) regulates the sale and import of biosolid fertilizer products. In May 2023, the CFIA proposed to adopt an interim standard for municipal biosolids that will require that biosolids intended for use as commercial fertilizers contain less than 50 ng/g of PFOS before they can be imported or sold in Canada. The proposed interim standard will effectively prevent the small proportion of municipal biosolids products that are heavily impacted by industrial inputs (both domestic and imported) from being imported or sold as fertilizers in Canada and spread on crops or grazing land. This interim approach is intended to provide a risk control measure for biosolids that is protective of the environment and the safety of food and feed crops grown in Canada.

7.2 Pertinent international risk management context

The US Environmental Protection Agency (US EPA) has developed a PFAS Strategic Roadmap for subgroups of PFAS with three primary goals: research, restriction, and remediation (US EPA 2021a). A growing number of US states have proposed and/or implemented control measures including bans of the class of PFAS for certain uses such as firefighting foams, textiles, food packaging or products intended for children (State of California 2021a, 2021b; State of Vermont 2021). Some US states (State of Maine 2022) also banned land application of municipal biosolids and others either have restrictions in place (State of Michigan 2022) or are considering various instruments to mitigate risks to food and feed arising from the use of PFAS-contaminated biosolids on agricultural land as fertilizers. On February 28, 2024, the US Food and Drug Administration announced that food-contact substances containing PFAS, intended for use as grease-proofing agents, are no longer being sold in the US (US FDA 2024).

The European Union (EU) has proposed a regulation restricting firefighting foams containing PFAS. If approved, the regulation would ban the placing on the market, use and export of PFASs in firefighting foams after use/sector-specific transitional periods (ECHA 2022a). The EU has also published a broad PFAS restriction proposal that aims to reduce PFAS emissions into the environment (ECHA 2023). If approved, this regulation would prohibit the manufacture, use and placing on the market of PFAS substances on their own, in mixtures or in articles for the vast majority of uses. This proposal does include use-specific time-limited derogations (18 months transition period plus either a five- or 12-year derogation period). The proposal underwent a 6-month consultation period that ended on September 25, 2023.

Due to the significant volume of comments received, a revised proposal is being discussed at the Risk Assessment Committee and Committee for Socio-Economic Analysis meetings on a sector-by-sector basis.

7.3 Risk management alignment

Actions taken in jurisdictions including the EU and the US are being taken into consideration in the development of risk management for PFAS in Canada, with the possibility of aligning, where appropriate.

8. Next steps

8.1 Public comment period

Industry and other interested stakeholders are invited to submit comments on the content of this Revised Risk Management Scope, provide other information that would help to inform decision-making (such as outlined in section 3.3), or offer ideas for other voluntary risk management actions that could be considered. Please submit additional information and comments prior to September 11, 2024.

If the final State of PFAS Report confirms that the class of PFAS is toxic, a Risk Management Approach document outlining and seeking input on the proposed risk management instruments would be published concurrently with the final State of PFAS Report. At that time and at subsequent stages, there would be further opportunity for consultation.

Comments and information submissions on the Revised Risk Management Scope should be submitted to the address provided below:

Environment and Climate Change Canada
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-5212
Email: substances@ec.gc.ca

Stakeholders who have a business interest in the class of PFAS are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding the class of PFAS and may be contacted for further information.

8.2 Timing of actions

Electronic consultation on the Revised Risk Management Scope: July 13, 2024 to September 11, 2024.

Publication of the section 71 information gathering notice: Summer 2024.

Publication of responses to public comments on the Updated Draft State of PFAS Report and Revised Risk Management Scope: concurrent with the publication of the final State of PFAS Report and, if required, the Risk Management Approach.

Consultation on a proposed instrument, if required: minimum 60-day public comment period starting upon publication of a proposed instrument.

Publication of a final instrument, if required: At the latest, 18 months from the publication of a proposed instrument.

These are planned timelines and are subject to change. Please consult the schedule of risk management activities and consultations for updated information on timelines.

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