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Risk Management Scope

for

Per- and polyfluoroalkyl substances (PFAS)

Environment and Climate Change Canada

Health Canada

May 2023

Canada

Summary of proposed risk management

This document outlines the proposed risk management options under consideration for the class of per- and polyfluoroalkyl substances (PFAS), which have been proposed to be harmful to the environment and human health.

Per- and polyfluoroalkyl substances are a class of over 4,700 human-made substances. There are many potential sources of PFAS in Canada that can lead to human exposure and releases to the environment. In particular, humans can be exposed to PFAS from various sources such as food and food packaging, cosmetics, products available to consumers, ambient air, indoor air and dust, and drinking water. Furthermore, PFAS-impacted contaminated sites represent “hot spot” areas across Canada where Canadians and the environment may be exposed to elevated concentrations of PFAS. Such sites include those associated with use of aqueous film-forming foams (AFFF), typically released during activities associated with fighting fuel fires, including training activities and maintenance of firefighting equipment at airports and military facilities. As it is not possible to separate PFAS-containing waste from the general waste stream, PFAS-containing products can be found in municipal solid waste (MSW) landfills or destined for MSW incineration. Composting of PFAS-containing food packaging, releases into wastewater treatment systems and subsequent application of biosolids to land provide additional routes of entry for PFAS into the environment. It should be noted that PFAS contamination is present throughout Canada and is not limited to a few sources and areas.

While there are various potential sources of PFAS in Canada, exposure sources of concern include firefighting foams containing PFAS, and other sources and products that contain PFAS.

In particular, the Government of Canada is considering:

- Regulatory and/or non-regulatory controls to minimize environmental and human exposure to the class of PFAS from firefighting foams;
- Gathering information necessary to identify and prioritize options for reducing environmental and human exposure from the class of PFAS from other sources and products; and
- Aligning with actions in other jurisdictions, where appropriate.

To inform risk management decision-making, information on the following topics should be provided (ideally on or before July 19, 2023), to the contact details identified in section 8 of this document:

- availability of alternatives to PFAS, in products including but not limited to firefighting foams;
- socio-economic impacts of replacing PFAS, including costs and feasibility of replacement; and

- types, quantities, and concentrations of PFAS (including Chemical Abstract Service registry numbers, units of measurement, and applications) in products manufactured in, imported into, and sold in Canada.

The risk management options outlined in this 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.

Note: The above summary is an abridged list of options under consideration to manage this class of substances and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management options may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

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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 to move forward with activities to address the class of per- and polyfluoroalkyl substances (PFAS) (Canada 2021), including the publication of a draft State of PFAS Report, because scientific evidence was emerging to indicate that PFAS may be associated with environmental or human health effects.

Addressing PFAS as a class of chemicals would reduce the chance of regrettable substitution, support more holistic research and monitoring programs, and provide an opportunity for a decrease of future environmental and human exposure to PFAS. The class of per- and polyfluoroalkyl substances, referred to throughout this document as PFAS, is based on the Organisation for Economic Co-operation and Development (OECD) chemical definition, which is "fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e., 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).

2. Issue

On May 20, 2023, Health Canada and Environment and Climate Change Canada published a draft State of PFAS Report conducted under section 68 of CEPA. A notice summarizing the scientific considerations of the draft report was published in

[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*

1. *have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
2. *constitute or may constitute a danger to the environment on which life depends; or*
3. *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.

the *Canada Gazette*, Part I, on May 20, 2023 (Canada 2023). For further information, refer to the draft State of PFAS Report.

2.1 Draft State of PFAS Report conclusion

Owing to the extreme persistence of these substances, impacts on the environment are expected to increase if entry to the environment continues. On the basis of what is known about well-studied PFAS and the potential for other PFAS to behave similarly, it is proposed that the class of PFAS meets the criteria under paragraph 64(*a*) 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 immediate or long-term harmful effects on the environment or its biological diversity. However, it is proposed to conclude that the class of PFAS does not 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.

Owing to the widespread use of PFAS combined with their ubiquitous presence in the environment, humans are continuously exposed to multiple PFAS, which have the potential to cause adverse effects of concern. On the basis of what is known about well-studied PFAS and the potential for other PFAS to behave similarly, and on the expectation that combined exposures to multiple PFAS increase the likelihood of detrimental impacts, it is proposed that the class of PFAS meets the criteria under paragraph 64(*c*) of CEPA as these substances are entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is proposed to conclude that the class of PFAS meets one or more of the criteria set out in section 64 of CEPA.

The draft State of PFAS Report identifies exposure sources that may be of concern. These include firefighting foams and other sources and products (refer to section 5).

2.2 Proposed Recommendation under CEPA

On the basis of the findings of the draft State of PFAS Report conducted pursuant to CEPA, the Ministers propose to recommend that the class of PFAS be added to the List of Toxic Substances in Schedule 1 of the Act[3].

[3] When a substance is found to meet one or more of the criteria under section 64 of CEPA, the Ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

The Ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft State of PFAS Report and this risk management scope document.

If the Ministers finalize the recommendation to add the class of PFAS to Schedule 1, a risk management instrument will be proposed within 24 months from the date on which the Ministers recommended that the class of PFAS be added to Schedule 1 of CEPA, and finalized within 18 months from the date on which the risk management instrument is proposed (refer to section 8 for publication timelines applicable to the class of PFAS).

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 are, respectively, to:

- reduce releases of these substances to the Canadian environment so as not to cause adverse effects; and
- reduce exposure of the general population to these substances to levels that are protective of human health.

3.2 Proposed risk management objectives

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 is to, over time, achieve the lowest levels of environmental and human exposure that are technically and economically feasible, taking into consideration socio-economic factors.

These objectives will be refined, if needed, on the basis of stakeholder consultation and new information, the proposed risk management options, the outcome of the final State of PFAS Report, and socio-economic and technical considerations (refer to section 6). Final environmental, human health and risk management objectives will be presented in the risk management approach document that will be published concurrently with the final State of PFAS Report.

3.3 Proposed risk management options under consideration

To achieve the proposed risk management objectives and to work towards achieving the proposed environmental and human health objectives, the proposed risk management options under consideration for the class of PFAS are actions to minimize releases of PFAS to the environment and to reduce human exposure from certain sources of concern, as described in section 5. These include:

- Regulatory and/or non-regulatory controls to minimize environmental and human exposure to the class of PFAS from firefighting foams;
- Gathering information necessary to identify and prioritize options for minimizing environmental and human exposure from the class of PFAS from other sources and products; and
- Considering aligning with actions in other jurisdictions, where appropriate.

Note that these proposed risk management options are preliminary and subject to change. Following the publication of this document, additional information obtained from the public comment period and from other sources will also be considered in the instrument selection and development process[4]. 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.

In addition, work on PFAS will continue. This includes ongoing work on drinking water guidelines, support for the management of contaminated sites, and the existing risk management actions outlined in section 7.1.

3.4 Performance measurement evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[5]. ECCC and HC have developed a Performance Measurement Evaluation Strategy that sets out the

[4] The proposed risk management regulations, instrument(s) or tool(s) 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).

[5] 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).

approach to evaluating the effectiveness of actions taken on substances found to be toxic under CEPA. The aim is to determine whether human health and/or environmental objectives have been met and whether there is a need to revisit the risk management approach for those substances. In evaluating progress and revisiting risk management, as warranted, these activities together will aim to manage risks effectively over time. To achieve this, the Government of Canada plans to review, on a regular basis, the effectiveness of the risk management actions developed for the class of PFAS.

The Government of Canada plans to measure the effectiveness of the risk management actions by collecting and analyzing data to measure progress towards meeting the risk management objectives.

In addition, the Government of Canada plans to collect and analyze data, such as monitoring data obtained from the Monitoring and Surveillance Program under the CMP on the presence of PFAS in various environmental media.

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

3.5 Risk management information gaps

Interested stakeholders can provide further information to inform risk management decision-making regarding the class of PFAS, including information on:

- availability of alternatives to PFAS, including for use in firefighting foams;
- socio-economic impacts of replacing PFAS, including costs and feasibility of elimination or replacement; and
- types, quantities, and concentrations of PFAS (including Chemical Abstract Service registry numbers, units of measurement, and applications) in products manufactured in, imported into, and sold in Canada.

Stakeholders that have information to help address these gaps should provide it on or before July 19, 2023, to the address identified in section 8.

Data collection initiatives (including a CEPA section 71 Notice in the *Canada Gazette*) are planned to collect additional information on the class of PFAS to inform risk management decision making. If any information becomes available that reasonably supports the conclusion that the class of PFAS is toxic or capable of becoming toxic, the person who is in possession of the information, and is involved in activities with PFAS, is obligated, under section 70 of CEPA, to provide that information to the Minister without delay. PFAS are being considered for addition to the National Pollutant Release Inventory (NPRI) as of the 2025 reporting requirements.

4. Background

4.1 General information on PFAS

The class of PFAS encompass 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). The OECD Global Perfluorinated Chemicals Group has developed a non-exhaustive list of 4,730 PFAS as part of a Comprehensive Global Database, compiled from public sources (OECD 2018).

PFAS possess a unique set of practical traits that are useful 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.

The widespread use of these substances, their extreme persistence in the environment, propensity for accumulation and mobility has led to PFAS being commonly detected in the environment and humans.

4.2 Current uses and identified sectors

Due to their unique properties, PFAS have a wide range of uses in products available to consumers, industrial applications, and other specialized applications, including food packaging, non-stick cookware, drugs, cosmetics, textiles, vehicles, electronics and certain firefighting foams.

Glüge et al. (2020) identified more than 200 uses within 64 use categories for more than 1,400 PFAS and presents in detail the known PFAS uses, functions and related sectors. Fluoropolymers have uses in a variety of applications including medical devices, mechanical parts, and chemical processing equipment (Henry et al. 2018).

PFAS are commonly used in AFFF. AFFF is a synthetic mixture that may contain hydrocarbon-based surfactants and fluorinated surfactants with the ability to rapidly extinguish hydrocarbon fuel fires.

The understanding of uses of PFAS in Canada has been informed by surveys for certain perfluoroalkyl and fluoroalkyl substances issued pursuant to section 71 of CEPA, 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. It may not fully represent all uses in Canada.

5. Exposure sources targeted for risk management

Releases of PFAS to the Canadian environment are expected to occur during the manufacture, processing, use and disposal of products. Exposure of the general population to PFAS is generally from environmental media and/or the use of products. PFAS enters 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 Firefighting foams

PFAS-impacted contaminated sites where AFFF has been or is being used (e.g., fire fighting training areas) represent “hot spot” areas where the environment may be exposed to PFAS. 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 (i.e., on-site), but also off-site due to the potential for significant migration in surface water and groundwater or by wind-erosion or

over-spray of the AFFF product during use. PFAS have demonstrated the ability to travel long distances (greater than 2 km) 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 present in a wide variety of consumer and industrial products. The manufacture, use and disposal of products and materials that contain PFAS are sources of releases of and exposure to PFAS. The disposal of products and materials that contain PFAS, including PFAS contaminated soils and biosolids, into landfills can become an indirect pathway of release to the environment.

As it is not possible to separate PFAS-containing waste from the general waste stream, PFAS-containing products can be found in MSW landfills, or are destined for MSW incineration.

PFAS may leach out of these products and materials and 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 composting facilities, scrapyards and recycling facilities, may also be a source of release to the environment.

6. Risk management considerations

6.1 Alternatives and alternate technologies

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

A number of alternatives to the use of firefighting foams containing PFAS have been developed and are now widely available. These include fluorine-free firefighting foams and other developing firefighting foam technologies that avoid the use of fluorine (ECHA 2022).

Potential alternatives for PFAS applications in surface protection exist. For example, wax-coated, Kaolin clay-coated and uncoated papers, 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 (OECD 2022).

6.2 Socio-economic and technical considerations

Socio-economic factors will be considered in the selection process for a regulation or instrument respecting preventive or control actions, and in the development of the risk management objective(s) 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 regulations, instrument(s) or tool(s), to address risk management objective(s), as identified in the Cabinet Directive on Regulation (TBS 2018) and Red Tape Reduction Action Plan (TBS 2012) and the *Red Tape Reduction Act* (Canada 2015a).

7. Overview of existing risk management

7.1 Related Canadian risk management context

7.1.1 Risk assessment and management under CEPA

In Canada, three well-defined subgroups of PFAS have been assessed under CEPA, have been found to be of concern for the environment and therefore have been added to Schedule 1 of CEPA:

- Perfluorooctane sulfonate and its salts and precursors (PFOS) (EC 2006, HC 2006);
- Perfluorooctanoic acid and its salts and precursors (PFOA) (EC, HC 2012); and
- Long-chain perfluorocarboxylic acids and their salts and precursors (LC-PFCAs) (EC 2012).

These Schedule 1 substances capture entire subgroups based on moieties of concern.

A 2006 Risk Management Strategy for PFOS stated that the ultimate environmental objective was to reduce concentrations of PFOS in the Canadian environment to the lowest level possible (Government of Canada 2006). In 2008, the *Perfluorooctane Sulfonate and Its Salts and Certain Other Compounds Regulations* were published to prohibit manufacture, import, sale and use of PFOS, with a limited number of exemptions to allow for the transition to alternatives (Government of Canada 2008). In 2009, PFOS and its salts were added to the Virtual Elimination List under CEPA.

In 2010, the Government of Canada initiated an *Environmental Performance Agreement respecting PFCAs and their Precursors in Perfluorochemical Products Sold in Canada*. Over the term of this voluntary five-year agreement, the four participating companies met their commitment to eliminate residual PFOA, residual LC-PFCAs, and residual precursors from their perfluorochemical products sold in Canada.

The manufacture, use, sale, offer for sale and import of PFOA, LC-PFCAs, their salts and precursors and products that contain them have been prohibited since 2016, under the *Prohibition of Certain Toxic Substances Regulations, 2012* (PCTSR), with a limited number of exemptions (Canada 2012b). For example, PFOA and LC-PFCAs in certain AFFF for limited uses and manufactured items are exempt. PFOS was also added to the regulations in 2016, which maintained the regulatory requirements of the *Perfluorooctane Sulfonate and Its Salts and Certain Other Compounds Regulations* and removed certain exemptions. As a result, the *Perfluorooctane Sulfonate and Its Salts and Certain Other Compounds Regulations* were repealed. The PCTSR currently address 94 PFAS identified as being present in Canadian commerce through the Domestic Substances List (DSL), as well as other PFAS for which presence in Canada is unknown.

In 2018, a consultation document was published on proposed amendments to the PCTSR (Government of Canada 2018). The proposed regulatory approach would be to continue to phase out the use of the toxic substances currently controlled by the regulations. Some exemptions were initially available for PFOS, PFOA, and LC-PFCAs to allow specific market sectors to transition to using alternatives. The next phase of risk management for these substances will be to remove or provide a time limit for the remaining exemptions. Comments and information received in response to the consultation document were considered in the development of proposed Regulations, which were published on May 14, 2022 in *Canada Gazette*, Part I (Canada 2022).

In addition, Health Canada and Environment and Climate Change Canada are responsible for administering the *New Substances Notification Regulations (Chemicals and Polymers)* and the *New Substances Notification Regulations (Organisms)* (NSNR). This set of regulations ensure that new substances (chemicals, polymers and living organisms not listed on the DSL) are assessed for potential risks to human health and the environment and that, if required, 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). Since 1994, about one third of approximately 270 new PFAS were subject to risk management measures under the new substances regime to mitigate the risks to human health and/or the environment These included Ministerial prohibitions (Canada 2004) and Ministerial Conditions (Canada 1996). 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 being toxic under the CEPA. Substances subject to Ministerial Conditions are not eligible for addition to the DSL, and must be notified under the new substances notification regime whenever a new notifier wishes to import or manufacture the substance

7.1.2 Guidelines for protection of human health and the environment

A number of guidelines for the protection of human health and the environment have been developed by the Government of Canada (i.e., Federal Environmental Quality Guidelines) or through the Canadian Council of Ministers of the Environment (CCME) (i.e., Canadian Environmental Quality Guidelines).

Federal Environmental Quality Guidelines are available for PFOS in surface water for the protection of aquatic life, fish tissue, wildlife diet for mammalian and avian consumers of aquatic biota, and in bird eggs (ECCC 2018). Canadian Soil and Groundwater Quality Guidelines (SQGs and GWQGs) are also available for PFOS for the protection of human health and the environment(CCME 2021b). These guidelines include a number of exposure pathways, including ecological pathways, drinking water, off-site migration, and the protection of groundwater. These SSVs for PFAS are used to assess soil at federal contaminated sites. In addition, given the uncertainties associated with the assessment of PFAS contamination, a precautionary approach is warranted. Further work is on going to investigate the feasibility of assessing PFAS at contaminated sites as a class or group. Canadian Drinking Water Quality Guidelines are available for PFOS and PFOA (HC 2018a, 2018b). In the absence of Canadian Drinking Water Quality Guidelines for PFAS other than PFOS and PFOA, HC has developed drinking water screening values (DWSVs) for nine select PFAS[6]. These drinking water quality guidelines and screening values for PFAS are used to assess potable groundwater or surface water at federal contaminated sites and are used by provinces and territories to manage drinking water in their regions (HC 2022). In close collaboration with the Federal-Provincial-Territorial Committee on Drinking Water the Government of Canada is reviewing the PFAS drinking water guidelines and screening values using a group approach. In February 2023, a consultation document was published on a proposed interim objective that will recommend a single treatment-based value for a group of PFAS in drinking water (HC 2023).

In the absence of Canadian SQGs for other PFAS at this time, Health Canada has developed soil screening values (SSVs) based on human direct contact with soil for ten select PFAS (HC 2022). These SSVs are based on readily available scientific studies. They are not subject to the extensive internal review completed for the approved CCME SQGs, which undergo internal peer review and public consultation prior to CCME approval. These SSVs for PFAS are used to assess soil at federal contaminated sites. In addition, given the uncertainties associated with the

[6] Water talk: Summary of drinking water values for PFOS, PFOA and other PFAS

assessment of PFAS contamination, a precautionary approach is warranted. Further work is on going to investigate the feasibility of assessing PFAS at contaminated sites as a class or group.

Development of Environmental quality guidelines for PFOA for surface water, soil and groundwater are currently under consideration.

Provinces and territories develop guidelines that respond to needs within their jurisdictions to address sites on provincial/territorial lands and those sites on private properties, including industrial facilities. Through the *Contaminated Site Regulation*, British Columbia has developed guidelines for PFOA for the protection of human health, and for PFOS and PFBS for the protection of the environment and human health (Government of British Columbia 1996). In addition, Ontario has published Toxicity Reference Values for PFOS and PFOA in their May 2021 publication of *Human Health Toxicity Reference Values (TRVs) Selected for use at Contaminated sites in Ontario* (OMECP 2021). These by contrast are lower than the TRVs developed by Health Canada (2018a, 2018b) for PFOS and PFOA respectively. For the assessment and remediation of potentially contaminated sites in the four Atlantic Provinces, they have adopted Health Canada and British Columbia's screening levels and guidelines for drinking water and soil in the publication of the *Atlantic RBCA Environmental Quality Standards and Pathway Specific Standards* (APIRI 2021).

7.1.3 Contaminated sites

7.1.3.1 Federal contaminated sites

Federal contaminated sites are located on land owned or leased by the federal government, or on land where the federal government has accepted responsibility for the contamination. The Federal Contaminated Sites Inventory shows more than 23,000 suspected, active, and closed federal contaminated sites, of which there are over 100 sites with confirmed or suspected PFAS contamination (see Figure 3 in section 2.3 of the draft State of PFAS Report (ECCC, HC 2023)). The most common sources of PFAS at federal contaminated sites are associated with the use of AFFF, and include activities such as firefighter training and maintenance of firefighting equipment. The Government of Canada continues to take action through the Federal Contaminated Sites Action Plan (FCSAP) to reduce environmental and human health risks from known federal contaminated sites.

Environment and Climate Change Canada, Fisheries and Oceans Canada, and Health Canada are science-based expert support departments in the FCSAP program, providing guidance, training, and advice for the assessment of ecological and human health risks at federal contaminated sites relevant to their mandates. For example, Fisheries and Oceans Canada has supported the development of reports that provide relevant information on PFOS including the *Federal Contaminated Sites Action Plan (FCSAP): Ecological Risk Assessment Guidance* (DFO 2022) and the *Guidance for Assessing and Managing Aquatic Contaminated Sites in Working Harbours, Version 1.1* (ECCC 2021). Health Canada has prepared a *Human Health*

Risk Assessment (HHRA) Framework for Federal Sites Impacted with Per- and Polyfluoroalkylated Substances (HC 2019) to provide direction in conducting human health risk assessments at federal sites which have been impacted by PFAS associated with past and/or current use of AFFF. This framework is considered to be "evergreen" and will be updated based on the evolving science in this area to remain current.

Available guidelines and screening values (see section 8.1.3 of the State of PFAS Report (ECCC, HC 2023)) can be used for contaminated sites to evaluate risks to human health and the environment, and to establish remediation objectives (CCME 2021b; HC 2022). Guidelines and screening values are only available for a small number of PFAS, and for specific pathways, and thus are not protective of all human exposure or ecological pathways for all PFAS that may be detected at a site. This presents challenges for risk assessment and risk management at contaminated sites. As an example, existing environmental and drinking water guidelines were not developed to be protective of the fish consumption by human pathway; thus, additional media-specific investigation (i.e., analysis of fish tissue) may be needed to assess the risks associated with fish consumption.

There are numerous technical challenges associated with the assessment, remediation (refer to section 3.2.6 of the draft State of PFAS Report (ECCC, HC 2023)) and risk management activities at contaminated sites. The disposal of PFAS-impacted waste from PFAS-contaminated sites requires special consideration given the long-term ("forever") presence of this class of contaminants. The current analytical suite for environmental samples at commercial laboratories includes a small percentage of the known PFAS overall and those found specifically in AFFF. Therefore, the current analytical capacity is only capturing a small number of PFAS found at sites impacted with AFFF. The current approach of considering a small number of the known PFAS individually at contaminated sites has limitations and results in uncertainty with respect to the assessment, remediation and management of PFAS contaminated sites. Given these challenges of managing sites contaminated with PFAS (from AFFF and other sources), considering PFAS as a class would reduce uncertainty and allow for a more comprehensive and precautionary approach for the assessment, remediation and management of PFAS contaminated sites.

Where potential ecological or human health risks are identified at PFAS contaminated sites, action may be necessary to eliminate or reduce exposure to PFAS. Such actions may include: provision of alternative drinking water sources (i.e., bottled water), installation of water treatment systems, implementation of food consumption advisories, and remediation of specific areas of the site to remove PFAS hot spots/source area. Long-term monitoring and management of PFAS-impacted sites is essential as environmental conditions affecting migration or degradation of PFAS precursors may change, the analytical suite of PFAS may expand, and environmental guidelines may be revised. Moreover, there is need to verify that mitigation measures are indeed reducing exposure as planned.

7.1.3.2 Non-federal contaminated sites

Non-federal PFAS contaminated sites also exist in Canada. For example, AFFF used in the oil and gas industry and by municipal firefighting departments may have resulted in the release of PFAS to the environment. Contamination on non-federal lands is dealt with by the province/territory and/or the local health authority.

7.1.4 Waste management

In Canada, waste management operations are most often dealt with at the provincial and territorial level; therefore, these jurisdictions regulate the approval, licensing, and monitoring of waste treatment and disposal facilities, including municipal solid waste and hazardous waste. The collection, recycling, composting, and disposal of waste is managed by municipal authorities. The Government of Canada is responsible for the control of waste management activities on federal lands and the international and interprovincial movement of hazardous waste and hazardous recyclable materials. The Government of Canada can also apply its authorities under CEPA and other applicable laws to waste management when there is a potential for release of toxic substances (based on inclusion on Schedule 1 of CEPA) to the air, land or water (CCME 2014).

Most provinces and territories have regulations in place to control waste management operations and/or facilities. Some jurisdictions choose to have all of their requirements outlined in a regulation, while others prefer to refer to a standard or guidance document in the regulations. However, the level of detail or the depth of the requirements included vary significantly across Canada. In addition, no specific requirements for the acceptance and/or disposal of waste containing PFAS are identified in any of the regulations and/or standards in place in the provinces and territories, and PFAS compounds in MSW landfills do not appear to be monitored at the provincial/territorial level in Canada.

7.1.5 Great Lakes Water Quality Agreement

Under the Great Lakes Water Quality Agreement (GLWQA), Canada and the US have agreed to protect human health and the environment through cooperative and coordinated measures to reduce the anthropogenic release of chemicals of mutual concern (CMCs) into the waters of the Great Lakes. Under the GLWQA, the Parties have agreed to adopt, as appropriate, the principles of virtual elimination and zero discharge for releases and control of CMCs. The Government of Canada published Canada's Great Lakes Strategy for PFOS, PFOA, and LC-PFCAs in 2022 (ECCC 2022). The document outlines risk mitigation and management actions to further protect the Great Lakes from these substances.

Through the Great Lakes Protection Initiative, the Government of Canada takes action to address the most significant environmental challenges affecting Great Lakes water quality and ecosystem health by delivering on Canada's commitments

under the GLWQA. To support the goal of reducing releases of harmful chemicals, the Government provides funding to projects seeking to increase participation in the application of measures that go beyond regulatory compliance to reduce releases of CMCs (including PFOS, PFOA, and LC-PFCAs) by developing, implementing, assessing and promoting the use of innovative approaches.

7.1.6 Ozone-depleting substances and halocarbon alternatives regulations

The *Ozone-depleting Substances and Halocarbon Alternatives Regulations* (ODSHAR) under CEPA set out rules on the import, export and manufacture of certain ozone-depleting substances (ODS) and products containing, or designed to contain, ozone-depleting substances, as well as concerning halocarbon alternatives. Hydrofluorocarbons (HFCs), hydrochlorofluorocarbons (HCFCs) and chlorofluorocarbons (CFCs) are substances covered by the ODSHAR that are, in most cases, also considered PFAS under the OECD definition.

HFCs are replacements to ODS that are potent greenhouse gases, some with global warming potentials hundreds to thousands of times greater than that of carbon dioxide. The ODSHAR mandates a reduction of domestic HFC consumption by 85% from baseline by 2036.

HFCs are imported into Canada in bulk for use in the manufacture, servicing and maintenance of refrigeration and air-conditioning equipment, as blowing agents in the manufacture of foam products and as a propellant in aerosol products. As an alternative to HFCs, the industry has been transitioning to hydrofluoroolefins (HFOs) for some applications, as they have a much lower global warming potential. HFOs are not regulated under the ODSHAR, but are considered as PFAS under the definition of the OECD.

Tables 3 and 4 of the ODSHAR include some PFAS (HCFCs and HFCs) which were regulated under the NSNR, but for which risk management was rescinded, when they became subject to the ODSHAR.

7.2 Pertinent International risk management context

The Government of Canada works with other governments through a number of initiatives including the Stockholm Convention on Persistent Organic Pollutants, the OECD, and tri-laterally with the U.S. Environmental Protection Agency (US EPA) and the European Chemicals Agency (ECHA) on the Accelerating the Pace of Chemical Risk Assessment initiative to collaborate and discuss scientific and regulatory needs. Information about certain key international actions are provided below for context.

7.2.1 Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention on Persistent Organic Pollutants (POPs) aims to protect human health and the environment from substances that are of global concern. POPs listed to the Convention are persistent, bioaccumulative, undergo long-range transport and lead to significant adverse human health and/or environmental effects. The Convention requires Parties to eliminate or severely restrict the production, use, import and export of intentionally produced POPs, and to implement measures to reduce unintentionally produced POPs. In addition, stockpiles and wastes containing POPs must be managed and disposed of in a safe, efficient, and environmentally sound manner. The Stockholm Convention has assessed and listed PFOS, its salts and perfluorooctane sulfonyl fluoride (PFOSF) in 2009; PFOA, its salts and PFOA-related compounds in 2019, and PFHxS, its salts and PFHxS-related compounds in 2022.

In 2021, the Government of Canada nominated long-chain PFCAs to the Stockholm Convention. At the 18th meeting of the POPs Review Committee (Sept. 26-30, 2022), it was decided to adopt the Risk Profile, and advance to the Risk Management Evaluation stage of the listing process (POPRC 2022).

7.2.2 OECD Global Perfluorinated Chemicals Group

The OECD Global Perfluorinated Chemicals Group considers the development, facilitation, and promotion of international stewardship programs and regulatory approaches to reduce emissions of PFAS that are present in products.
The OECD developed a Portal on PFAS to facilitate information exchange and to support the global transition towards safer alternatives. Governments and industries can share information on activities related to regulatory and stewardship efforts, updates on scientific developments, new technologies, available alternatives, and PFAS-related events. In 2017, the OECD developed a non-exhaustive list of 4,730 PFAS, including Chemical Abstract Service registry numbers, as part of a new Global Database on PFAS. The compilation of the list utilised publicly accessible information sources, including lists from national or international regulatory bodies, public national/regional inventories of chemicals and chemicals in specific uses, national/regional inventories of chemicals subject to specific regulations, and scientific databases. Canada, the US, and the European Union were major contributing sources of PFAS data to the database (OECD 2018). As indicated in section 1.1 of the draft State of PFAS Report (ECCC, HC 2023), this organization also authored the reference and guidance document *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance* (OECD 2021).

7.2.3 United States of America

In October 2021, a government-wide approach[7] to address current and future PFAS contamination was announced, which included the *US EPA PFAS Strategic Roadmap* (US EPA 2021a) that will guide the agency's activities on PFAS through to 2024. Under the roadmap, the US EPA has proposed to take a number of actions including measures under their new chemicals program, adding certain PFAS to their Toxics Release Inventory, and proposing a data gathering rule. The US EPA also recently published a *National PFAS Testing Strategy* that uses a stepwise testing approach to identify and select candidate PFAS for further testing by developing categories of PFAS based on similarities in structure, physicochemical properties, existing toxicity data, and current manufacturing implications (US EPA 2021b). The information from these candidates may be extrapolated to characterize the hazard potential of their broader corresponding group.

The US approach also includes actions by the Department of Defense to address their PFAS-contaminated sites, by the Food and Drug Administration to expand testing of the food supply, by the Department of Agriculture to support research, by the Department of Homeland Security to inventory their PFAS uses and releases and to consider actions related to emergency responders. Research by a number of other US agencies was announced. They have also established the Interagency Policy Committee on PFAS that will work to coordinate and help develop new policy strategies to support research, remediation and removal of PFAS in communities across the country.

The US also has a number of actions addressing PFAS in drinking water, such as the *Fifth Unregulated Contaminant Monitoring Rule* to collect new data on 29 PFAS in drinking water (US EPA 2021c), and is moving forward with developing national primary drinking water standards under the Safe Drinking Water Act for PFOA and PFOS. An advanced copy of the proposed PFAS National Primary Drinking Water Regulation Rulemaking was published in March 2023, and will become official once published in the Federal Register (US EPA 2023).

In 2016, the US FDA revoked a number of authorizations for LC-PFAS in food packaging. A voluntary phase out of 6:2 FTOH was announced by the FDA in 2020. Beginning 2021, the three remaining manufacturers agreed to a 3-year phase-out of sales of compounds that contain 6:2 FTOH as a food contact substance. A fourth manufacturer discontinued US sales of FCM that contain 6:2 FTOH in 2019. In an effort to help federal purchasers identify and procure environmentally preferable products and services, the US EPA (2022) recommends the Biodegradable Products Institute's (BPI) certification standard of 100 ppm total fluorine for food service ware (containers, cutlery, dishware) and trash bags. The BPI certification scheme states that organic fluorinated chemicals, such as PFAS, cannot be present in formulas for

[7] FACT SHEET: Biden-Harris Administration Launches Plan to Combat PFAS Pollution

BPI Certified items.[8] The 100 ppm limit acknowledges that PFAS may be incorporated into some products unintentionally.

At the state level, contamination of drinking water has led many states to prohibit the use of firefighting foams (AFFF) containing any type of PFAS including Arkansas, California, Colorado, Illinois, Indiana, Kentucky, Maine, Maryland, Louisiana, Michigan, Minnesota, Nevada, New Hampshire, Vermont, Washington, West Virginia and Wisconsin (Safer States 2021). Many states have also taken action to prohibit the use of PFAS in food packaging including Maine, New York, Minnesota, Vermont and Washington.

Some states have taken broader measures on PFAS, for example:

- California
    - Prohibition of the use of all PFAS in products for juveniles (under 12 years old) by 2023 (State of California 2021a);
    - Prohibition of the use of all PFAS in certain food packaging and imposing disclosure for cookware by 2023 (State of California 2021b);
    - Prohibition of all PFAS from cosmetics by 2025 (State of California 2022b);
- Maine
    - Reporting and removal of most PFAS in products will start in 2023 with a complete ban of all non-essential uses by 2030 (State of Maine 2021).
- Vermont
    - Prohibition of PFAS from consumer products (carpets, rugs, aftermarket treatments and ski waxes) and food packaging by 2024 (State of Vermont 2021).
- Maryland
    - Prohibition of 13 PFAS from cosmetics by 2025 (State of Maryland 2021)

7.2.4 European Union

Like Canada, the EU and its member States, except for Italy, are Parties to the Stockholm Convention on POPs.

Restrictions are currently in place in the EU for PFOS and PFOA, while restrictions on LC-PFCAs (European Commission 2021) will be coming into force in phases from 2023 through 2025. In addition, the EU is currently evaluating restrictions on PFHxA[9] and PFHxS[10].

[8] BPI - Fluorinated Chemicals

[9] ECHA - Registry of restriction intentions until outcome: undecafluorohexanoic acid (PFHxA), its salts and related substances

[10] ECHA - Registry of restriction intentions until outcome: perfluorohexane-1-sulphonic acid, its salts and related substances

Certain PFAS are listed on the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) list of Substances of Very High Concern (SVHCs), including PFBS[11] and HFPO-DA (the ammonium salt of HFPO-DA is commonly known as GenX)[12].

In October 2020, the European Commission published a plan entitled *Chemical Strategy for Sustainability Towards a Toxic-Free Environment* (European Commission 2020) outlining their intent to ban all PFAS as a group in firefighting foams as well as in other uses, allowing their use only where they are essential for society. This objective is based upon the large number of cases of contamination of soil and water, including drinking water, the unacceptable risks to both the environment and human health, and the related societal and economic costs. Other measures that the EU has committed to include working on PFAS through international fora, and to work on PFAS under other legislation on water, sustainable products, food, industrial emissions and waste, supporting research and innovation for remediating PFAS contamination, and developing safe substitutes to PFAS.
In January 2022, ECHA submitted a proposal for an EU-wide restriction on all PFAS in firefighting foams, for consideration by the scientific Committees for Risk Assessment and Socio-Economic Analysis and for comment[13]. The EU also published a PFAS restriction proposal [14] that aims to reduce PFAS releases into the environment; this proposal started a 6-month consultation on March 22, 2023[15].

7.2.5 Australia and New Zealand

Like Canada, Australia and New Zealand are Parties to the Stockholm Convention on POPs.

Australia does not generally ban or restrict industrial chemicals at the federal level, rather these risk management actions fall under the jurisdiction of the state or territory. South Australia banned fluorinated firefighting foams as of 2018 with a transition period, which ended January 2020. The Australian government has developed drinking water quality and recreational water guidance values for PFOS, PFOA and PFHxS. The PFAS National Environmental Management Plan (Heads of EPA Australia and New Zealand 2020) provides the federal, state, and territory governments with a risk-based framework for the regulation of PFAS-contaminated sites and materials and an intergovernmental agreement provides further specific guidance on actions as PFAS contaminated sites (Council of Australian Governments 2020). The Australian government is also supporting research into PFAS exposure, health effects and new remediation treatments.

[11] ECHA - Registry of SVHC intentions until outcome: perfluorobutane sulfonic acid (PFBS) and its salts
[12] ECHA - All news: MSC unanimously agrees that HFPO-DA is a substance of very high concern
[13] ECHA - Registry of restriction intentions until outcome: per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams
[14] ECHA - All news: Proposal to ban 'forever chemicals' in firefighting foams throughout the EU
[15] ECHA - Registry of restriction intentions until outcome: per- and polyfluoroalkyl substances (PFAS)

In New Zealand, both PFOS and PFOA were banned in 2006 with an exemption for use in firefighting foams. However, since 2020, the import, manufacture, and use of PFOS and PFOA has been banned without any exemptions.

7.3 Risk management alignment

There is mixed risk management alignment between actions proposed to be undertaken in Canada, and those undertaken in other jurisdictions.

As described above, many jurisdictions have taken specific actions to prohibit the use of firefighting foams containing PFAS and some jurisdictions have taken actions or intend to take actions on other products containing PFAS. If the Government of Canada moves forward with the development of risk management measures on the class of PFAS in Canada, they would take into consideration aligning with these jurisdictions.

8. Next steps

8.1 Public comment period

Industry and other interested stakeholders are invited to submit comments on the content of this document or other information that would help to inform decision-making (such as outlined in section 3.5). Please submit additional information and comments prior to July 19, 2023.

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 risk management scope should be submitted to the address provided below:

Substances Management Information Line
Chemicals Management Plan
Environment and Climate Change Canada
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-3231
Email: substances@ec.gc.ca

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

Following the public comment period on the risk management approach, the Government of Canada will initiate the development of a risk management instrument, where necessary. Comments received on the risk management approach will be taken into consideration in the selection or development of the instrument. Consultation will also take place as any instruments are developed.

8.2 Timing of actions

Electronic consultation on the draft State of PFAS Report and risk management scope: May 20, 2023 to July 19, 2023. This should include the submission of public comments, additional studies and information on the class of PFAS.

Publication of the section 71 notice or other data collection initiative: fall 2023.

Publication of responses to public comments on the draft State of PFAS Report and risk management scope: concurrent with the publication of the final State of PFAS Report and, if required, the risk management approach.

Publication of responses to public comments on the risk management approach, if applicable and if required, a proposed instrument: At the latest, 24 months from the date on which the Ministers publish a recommendation that the class of PFAS be added to Schedule 1 of CEPA.

Consultation on a proposed instrument, if required: 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.

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