Summary of public comments received on the Updated Draft State of Per- and Polyfluoroalkyl substances (PFAS) Report and the Revised Risk Management Scope for PFAS

Comments on the Updated Draft State of Per- and polyfluoroalkyl substances (PFAS) Report and a Revised Risk Management Scope for PFAS, assessed under the Chemicals Management Plan (CMP), were submitted by American Chemistry Council's Center for the Polyurethanes Industry, American Chemistry Council's Performance Fluoropolymer Partnership, Association of Home Appliance Manufacturers, AstraZeneca Canada, ATMOsphere, Breast Cancer Action Quebec, Canadian Academics (Professors from University of Toronto, Memorial University of Newfoundland, University of British Columbia, and Université de Montréal), Canadian Animal Health Institute, Canadian Apparel Federation, Canadian Association of Physicians for the Environment (CAPE), Canadian Beverage Association, Canadian Consumer Specialty Products Association, Canadian Environmental Law Association, Canadian Fuels Association, Canadian Institute of Plumbing and Heating, Canadian Oilseed Processors Association, Canadian Paint and Coatings Association, Canadian Partnership for Children's Health and Environment, Canadian Vehicle Manufacturers' Association, Centre for Health Science and Law, Chemistry Industry Association of Canada, The Chemours Company, Citizens' Network on Waste Management, Claigan Environmental Inc., Clean Production Action, Complex Products Manufacturers Coalition, Conseil Patronal de l'Environnement du Québec, CropLife Canada, David Suzuki Foundation, DuPont, Ecojustice, Electro-Federation Canada, Environmental Defence, Extruded Polystyrene Foam Association, Fenestration Canada, Fenestration and Glazing Industry Alliance, Fertilizer Canada, Forest Products Association of Canada, Genyk Polyurethane Inc., Global Automakers of Canada, Great Lakes and St. Lawrence Cities Initiative, Health and Environment Justice Support, Hearth, Patio & Barbecue Association of Canada, Heating, Refrigeration and Air Conditioning Institute of Canada, Hitachi Energy, Honeywell International Inc., Household & Commercial Products Association, Huntsman Corporation, International Association of Fire Fighters, Makivvik (Nunavik Research Centre), MedTech Canada, Mining Association of Canada, Moto Canada, National Council for Air and Stream Improvement Inc., National Institute of Standards and Technology, National Marine Manufacturers Association Canada, Northwatch, Ontario Biosolids Council, Ontario Environment Industry Association, Ottawa Riverkeeper, Peel Region, Port Coquitlam Fire & Emergency Services, Public Services and Procurement Canada, Retail Council of Canada, Responsible Distribution Canada, Restaurants Canada, Reverse Logistics Group Systems Canada Inc., Skeena Watershed Conservation Coalition, Soprema Canada Inc., Suzuki Canada Inc., Syensqo, Triangle Fluid Controls Ltd., United States Chamber of Commerce, Ville de Montréal, Vitalis, Whirlpool Canada LP, Willson Consulting and individuals of the general public.

Summarized public comments and responses are provided below, organized by topic:

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General comments

Comment summary 1: Commenters submitted comments or information that was already considered during the development of the Updated Draft State of PFAS Report and Revised Risk Management Scope.

Response 1: A number of comments on the Updated Draft State of PFAS Report and Revised Risk Management Scope (published July 13, 2024) were received that were considered to be the same or very similar to those submitted during the previous comment period (that is, on the Draft State of PFAS Report and Risk Management Scope, published on May 20, 2023). Comments and responses considered consistent to those included in the previous comment period and found in the Summary of public comments, published on July 13, 2024, have been updated and are provided in the annex to this document. Minor revisions have been made to them to reflect changes between the two public comment periods.

Comment summary 2: A commenter requested more information on the recent *Canadian Environmental Protection Act, 1999* (CEPA, the Act) amendments and how they might impact regulated entities. More specifically, the commenter asked for clarity regarding what a listing on Schedule 1 and adding substances to the Watch List entails in a practical sense.

Response 2: Bill S-5, *Strengthening Environmental Protection for a Healthier Canada Act* received Royal Assent on June 13, 2023. This Bill modernizes the CEPA by recognizing the right to a healthy environment as provided under the Act, strengthening Canada's chemicals management regime and increasing transparency in the way it is administered. A summary of the amendments can be found at: <u>Bill S-5, Strengthening Environmental Protection for a Healthier Canada Act - Summary of Amendments.</u>

Schedule 1 of CEPA is split into two parts to better implement the two-track approach for managing toxic substances under CEPA. For those substances on Part 1, priority is to be given to prohibition. Priority to pollution prevention, which may include prohibition, is to be given to substances on Part 2. The CEPA amendments also require the Minister of the Environment to maintain a list of substances capable of becoming toxic, colloquially known as the Watch List will include a list of substances that the Ministers have reason to suspect are capable of becoming toxic under section 64 of CEPA or that been determined to be capable of becoming toxic. The Watch List is expected to help importers, manufacturers, and Canadian consumers to select safer alternatives and avoid regrettable substitutions.

Comment summary 3: Commenters suggested revisions to sections of the State of PFAS Report related to environmental occurrence, guidelines for the protection of human health and the environment, and contaminated sites. Suggested revisions included reference changes, figure revisions, language, and additional information to improve clarity and comprehensiveness.

Response 3: The relevant sections of the final report have been revised, as appropriate.

Comment summary 4: A commenter suggested that a quicker and easier Non-domestic Substances List (NDSL) addition of potential PFAS-alternatives be established.

Response 4: The NDSL is a list of substances not used commercially in Canada above the trigger quantities specified in the *New Substance Notification Regulations (Chemicals and Polymers)* (the Regulations) and which are known to be in international commerce. Substances on the NDSL are subject to the notification requirements set out in the Regulations; however, they are subject to fewer information requirements in comparison to new substances that are not on the NDSL. Since the notification thresholds and information requirements depend on the NDSL listing status, criteria for addition to the NDSL were carefully established to ensure the regulations can achieve their objectives.

The NDSL is amended on a regular basis, including annual updates based on the United States Environmental Protection Agency's (US EPA) *Toxic Substances Control Act* (TSCA) Chemical Substances Inventory. There are no statutory timelines for NDSL amendments to add

substances, including for annual updates or following nomination of a substance to the NDSL. Given the constraints and procedures necessary to publish amendments to the NDSL in the *Canada Gazette*, and that it is contingent on TSCA listing, the New Substances Program will continue to strive to add substances to the NDSL annually.

Certain substances on the TSCA inventory are not added to the NDSL because ecological or human health concerns have been identified. This is the case for substances subject to risk management controls in Canada or the United States, or subject to the Stockholm Convention on Persistent Organic Pollutants or the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

The NDSL can also be amended following nomination of a substance through submission of a Nomination Form. To nominate a substance, an NDSL Nomination Form and applicable documentation demonstrating that the substance has been on the US EPA's TSCA Inventory for at least one year must be provided to the New Substances program.

Comment summary 5: A commenter noted that regulatory decisions should be informed by comprehensive, unbiased, peer reviewed research to ensure that any measures taken are based on the best available data and scientific evidence. A commenter specifically cautioned against the use of non-peer reviewed studies in the Updated Draft State of PFAS Report, as a basis for deciding which PFAS are within the scope of the report.

Response 5: When conducting an assessment under CEPA, Environment and Climate Change Canada (ECCC) and Health Canada (HC) collect information from a variety of sources. This includes consideration of peer-reviewed articles from journals, review papers, electronic databases, and reports from international jurisdictions. Public comments and referenced studies identified in public comments are also considered. Information considered to be most critical to support the lines of evidence for the conclusion were included in the report. In addition, assessments under CEPA are subject to external peer review to ensure soundness of evidence.

Comment summary 6: A commenter suggested that a section on PFAS lab methodology and advancements be added to the State of PFAS Report.

Response 6: A new section on lab methodology and advancement was not added to the State of PFAS Report; however, information on analytical challenges has been expanded and is captured within different sections of the report. For example, additional information on analytical issues (such as extraction, analytical approach, selection of instrument) have been added to Section 5 *Human biomonitoring* of the final report. Multiple sections of the report acknowledge the analytical challenges of measuring PFAS, specifically concerning limit of detection and sensitivity of equipment. Government of Canada research laboratories as well as other jurisdictions have been working on improving analytical detection methods for measuring PFAS in different media. It is acknowledged that analytical methods are improving over time, though, with the exception of non-targeted methods, are currently only available for a small fraction of individual PFAS.

Comment summary 7: A commenter asked for clarification on the criteria used to add substances to the proposed Watch List and cautioned against adding a long list of PFAS to this list. They state that adding PFAS to the Watch List solely based on structural similarities within the class would have a detrimental effect on the supply chain.

Response 7: CEPA specifies when a substance can be added to the Watch List. A <u>public</u> <u>consultation document on the Watch List Approach</u> was published on October 4, 2024. Substances listed on Schedule 1 to CEPA are not candidates for inclusion on the Watch List. As noted in the State of PFAS Report, fluoropolymers are planned for consideration in a separate assessment. Following that assessment, the Minister of the Environment and the Minister of Health will consider whether they are possible candidates for addition to the Watch List under section 75.1 of CEPA.

Comment summary 8: Commenters suggested that PFAS used in situations with low or limited consumer exposure potential (for example, complex equipment, internal electronics) be assessed separately from those that have potential for direct contact.

Commenters also noted that some uses are carried out by trained professionals, thereby reducing exposure.

Response 8: The State of PFAS Report considers many aspects of PFAS including their widespread use, ubiquity in the environment, persistence, impossibility of removing them from the broader environment, and notes that humans are exposed to multiple PFAS. This assessment does not consider individual exposures (by specific use or specific PFAS) but acknowledges potential for cumulative exposure from an unknown mixture of PFAS from various sources. Although some uses of PFAS may have limited opportunity for direct exposure to humans, the lifecycle of PFAS (including PFAS in products) is considered.

Risk management using a class-based approach will help prevent regrettable substitution, that is, the substitution of one regulated PFAS for an unregulated PFAS that possesses similar or more hazardous properties.

Although it is proposed that the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, be added to Schedule 1 of CEPA, this does not in and of itself restrict or prohibit the substances in the class of PFAS; rather, it enables risk management instruments to be developed such as regulations under the Act. Risk management is proposed through a phased approach and will take into consideration factors such as the costs and the benefits, the availability of suitable alternatives and socio-economic considerations. Before taking any risk management actions, information will be gathered to understand the availability of alternatives and the costs of transitioning to those alternatives.

Comment summary 9: A commenter stated that the separation of nanoscale PFAS from the class of PFAS is inconsistent with the class-based, precautionary approach. They note that the response to comment 76 in the <u>Summary of public comments received on the Draft State of PFAS</u> referred to the Nanomaterials webpage, however, this webpage does not have information related to PFAS. The commenter also mentioned that it is not reasonable to defer responsibility to other government programs on nanoforms of PFAS.

Response 9: The definition of PFAS in the State of PFAS Report does not differentiate by form.

The nanoscale issue referenced in the comment refers to a statement found in the Draft State of PFAS Report (published in May 2023), which specifically discussed nanoforms of fluoropolymers. In the State of PFAS Report, fluoropolymers have been excluded from further consideration, which would also exclude nanoscale forms of fluoropolymers. As such, the original statement has been removed from the State of PFAS Report. Fluoropolymers are planned for consideration in a separate assessment.

Comment summary 10: A commenter recommended renaming Section 2.7 to Substitution Trends *and Challenges*, and notes that this section should include a discussion of challenges to have feasible alternatives.

Response 10: The title of Section 2.7 *Substitution trends* of the State of PFAS Report has not been changed. The availability of alternatives to PFAS, in products and the socio-economic impacts of replacing PFAS, including costs and feasibility of replacement will be considered as part of the Risk Management Approach that will be published concurrently with the State of PFAS Report.

Definition and Scope

Comment summary 11: Commenters were supportive of the exclusion of fluoropolymers from the scope of the Updated Draft State of PFAS Report.

Response 11: Noted. Fluoropolymers are planned for consideration in a separate assessment. Their exclusion from the scope of the State of PFAS Report should not be interpreted as meaning they are or are not of concern.

Fluoropolymers are included among the <u>substances proposed as priorities for assessment</u> for the Plan of Priorities to be published under section 73 of CEPA in June 2025. The Plan of Priorities will outline activities to help assess, control, and manage risks to the environment and human health over the next several years. The public and stakeholders will be informed on the expected timing of assessment work on all priorities to be published in the Plan of Priorities.

In support of the separate assessment, additional work on fluoropolymers is either planned or in progress. Data collection (including a notice under section 71 of CEPA in the Canada Gazette) is underway and further work is planned to collect additional information on fluoropolymers to better understand uses, sources of release, and hazards. This information may be used to inform the assessment of fluoropolymers and possibly risk management decisions, if needed.

Comment summary 12: More information (including proposed publication timelines) on the separate assessment of fluoropolymers was requested by commenters, including setting a clear and timely deadline. A commenter mentioned that the "additional work on fluoropolymers" does not create confidence that the Government will address the risks posed by fluoropolymers, using a precautionary and class-based approach.

Response 12: PFAS that meet the fluoropolymer definition in the State of PFAS Report remain a part of the class of PFAS. As noted in the State of PFAS Report, they are planned for consideration in a separate assessment. Their exclusion from this report should not be interpreted as meaning that they are or are not of concern.

Fluoropolymers are included among the <u>substances proposed as priorities for assessment</u> for the Plan of Priorities to be published under section 73 of CEPA in June 2025. The Plan of Priorities will outline activities to help assess, control and manage risks to the environment and human health over the next several years. The public and stakeholders will be informed on the expected timing of assessment work on all priorities to be published in the Plan of Priorities.

Although fluoropolymers are planned for consideration in a separate assessment, the departments will conduct an assessment under the CMP. In assessments conducted under the CMP, key information across multiple lines of evidence is taken into consideration, along with uncertainties when concluding under section 64 of CEPA. The 2023 amendments to CEPA also require consideration of potential cumulative effects on human health and the environment from exposure to multiple substances.

In support of the separate assessment, additional work on fluoropolymers is either planned or in progress. Data collection (including a notice under section 71 of CEPA in the Canada Gazette) is underway and further work is planned to collect additional information on fluoropolymers to better understand uses, sources of release, and hazards. This information can be used to inform the assessment of fluoropolymers and risk management decisions, if needed.

Comment summary 13: A commenter, who supports the exclusion of fluoropolymers from the State of PFAS Report, asserted that no credible scientific documentation was provided to indicate that fluoropolymers require an assessment.

Response 13: Fluoropolymers that meet the definition of PFAS (as used in the State of PFAS Report) are considered to be part of the class of PFAS, however, given the information from a range of sources suggesting their differences in exposure and hazard profiles from other PFAS,

additional work on fluoropolymers is warranted. The exclusion of fluoropolymers from the State of PFAS Report should not be interpreted as meaning that they are or are not of concern.

Public comments and studies referenced in comments on both the Draft and Updated Draft State of PFAS Reports, as well as other information, were considered in the decision to conduct a separate assessment on fluoropolymers. Some of these references are included in the State of PFAS Report (Section 1.1.1 *Polymeric PFAS*).

Fluoropolymers are included among the <u>substances proposed as priorities for assessment</u> for the Plan of Priorities to be published under section 73 of CEPA in June 2025. The Plan of Priorities will outline activities to help assess, control and manage risks to the environment and human health over the next several years. The public and stakeholders will be informed on the expected timing of assessment work on all priorities to be published in the Plan of Priorities. The assessment of fluoropolymers will be subject to a 60-day public comment period, consistent with the assessment process under the CMP.

Comment summary 14: Commenters indicated that fluoropolymers should not be excluded from the report, and that they should be classified with other PFAS as toxic until comprehensive research and risk assessments are completed.

A commenter suggested that since fluoropolymers are a source of PFAS releases and exposures, they must be considered as part of the PFAS class assessment to address the requirement to consider cumulative effects.

Commenters stated that the proposal to remove fluoropolymers from the class lacks transparency and is not a science-based decision. They add that the explanation for the exclusion is inadequate and did not provide sufficient evidence on the environmental and human health impacts of fluoropolymers across their lifecycle. It was also suggested that new evidence on fluoropolymers considered by the Government since May 2023 be made available for consultation through the public comment process. Commenters also suggested that an assessment of fluoropolymers should provide a comprehensive review of PFAS uses and releases throughout the lifecycle of fluoropolymers.

Response 14: PFAS that meet the fluoropolymer definition in the State of PFAS Report remain a part of the class of PFAS. However, given information from a range of sources suggesting their differences from other PFAS, additional work on fluoropolymers is warranted. The exclusion of fluoropolymers from the State of PFAS Report should not be interpreted as meaning that they are or are not of concern.

A variety of sources of information, including peer-reviewed papers, scientific reports, and studies identified by commenters, were considered in the decision to exclude fluoropolymers; some references are included in the State of PFAS Report (Section 1.1.1 *Polymeric PFAS*).

Fluoropolymers are planned for consideration in a separate assessment which will be subject to a 60-day public comment period, consistent with the assessment process under the CMP. Consideration of potential cumulative effects on human health and the environment from exposure to multiple substances in chemical risk assessments has now become a requirement following the recent amendments to CEPA. Thus, as part of the future assessment of fluoropolymers, their potential to contribute to cumulative effects from co-exposure to multiple PFAS in the class will be considered.

Comment summary 15: A commenter noted they do not have any objections to the definition of fluoropolymers chosen in the Updated Draft State of PFAS Report, as it appears to be consistent with other jurisdictions.

Response 15: Noted. Fluoropolymers are defined in the State of PFAS Report as polymers made by polymerization or copolymerization of olefinic monomers (at least one of which contains fluorine bonded to one or both of the olefinic carbon atoms), to form a carbon-only polymer backbone with fluorine atoms directly bonded to it. A similar definition has been used by the European Chemicals Agency (ECHA) and the Organisation for Economic Co-operation and Development (OECD).

Comment summary 16: Commenters suggested that F-gases (such as HFCs, HFOs, HCFOs) and TFA be excluded from the scope of the Updated Draft State of PFAS Report and be evaluated further in a separate risk assessment.

One commenter stated that, given uncertainties around HFOs and TFA, it is prudent to exclude from the scope and conduct a separate assessment. Other commenters mentioned that F-gases and TFA differ significantly (for example, structurally and biologically) from other PFAS. They added that they have a low potential for exposure given their uses and that they are not persistent, bioaccumulative, or toxic. A commenter stated that a risk-based approach to F-gases must consider use, emissions mitigation under existing regulatory frameworks, and degradation products.

Commenters also stated that TFA is easily excreted by animals, does not bioaccumulate, and does not pose a threat to humans or the environment at current environmental exposure levels. It was commented that there is sufficient information on TFA to demonstrate that it does not share the same characteristics as other PFAS of concern.

Response 16: Many HFCs, HFOs and HCFOs, as well as TFA, meet the 2021 OECD definition for PFAS; therefore, they are included in the class of PFAS and are within the scope of the report.

Additional information and studies provided in this round of public comments were reviewed and Section 3.3, *Considerations for hydrofluoroolefins (HFOs) and hydrochlorofluoroolefins (HCFOs)*, of the State of PFAS Report was updated. This section discusses atmospheric degradation and uses of HFOs and HCFOs; sources, occurrence, and effects of TFA; and potential contribution of these substances to cumulative effects of PFAS.

The report acknowledges that TFA is found nearly ubiquitously in the environment. TFA has also been detected in human biomonitoring studies. Section 7 (*Human health hazard*) of the report includes information for TFA, which indicates that exposure of animal models to high doses of TFA has been associated primarily with liver effects (for example, increased liver weight, hepatocellular hypertrophy), although increased kidney weight, decreased white blood cells, reduced weight of reproductive organs, litter loss, reduced body weight of offspring, and malformations have also been observed (ECHA 2023c, 2024). These health effects are generally consistent with those observed for other PFAS in the class. Given the lack of consensus regarding the most sensitive health effects, limited data on the toxicity of PFAS in mixtures and the likelihood of exposure to multiple PFAS at one time, it is not considered appropriate to examine individual PFAS, such as TFA, without considering their potential contribution to cumulative exposure and effects. The potential for cumulative exposure and effects are important considerations as most wildlife and human exposures involve an unknown mixture of PFAS.

Any risk management actions will be developed in alignment with, and complementary to, existing regulations, such as the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* (ODSHAR).

Comment summary 17: A commenter questioned whether the Government of Canada considered information submitted from the previous public comment period on the Draft State of PFAS Report and the UNEP (2023) report in their decision to include HCFOs within the scope of the Updated Draft State of PFAS Report. They also asked whether the Government of Canada would delay the inclusion of HCFOs in the final report, given this information and ongoing research.

Response 17: Public comments received on the Draft State of PFAS Report and information from the UNEP (2023) report were considered and relevant sections of the State of PFAS Report were revised.

The UNEP (2023) report is cited in the State of PFAS Report; however, it should be noted that this report did not consider the cumulative effects of exposure to multiple PFAS in its conclusion, which the State of PFAS Report does. Additionally, while the UNEP report noted the potential for locally elevated TFA concentrations in terrestrial and freshwater systems due to the

short atmospheric lifetimes of HFOs and HCFOs, modeling of increases in environmental TFA concentrations and risk evaluations were only conducted for oceans and terminal sinks. The UNEP report noted the lack of existing models to predict TFA concentrations in surface waters as an uncertainty and identified the need for better local and regional emission inventories as a knowledge gap. The limited availability of toxicity data for marine species, including keystone species, was also noted as an uncertainty.

The 2023 amendments to CEPA require consideration of potential cumulative effects on human health and the environment from exposure to multiple substances. Given the ubiquity of HFO and HCFO uses and TFA presence in the environment, and the likelihood of locally concentrated TFA deposition due to the short atmospheric lifetimes of these substances, there is potential for TFA from HCFOs (as well as HFOs) to contribute to cumulative exposure to unknown mixtures of PFAS from various sources in multiple environmental compartments. As such, HCFOs that meet the definition of the class of PFAS remain within the scope of the final report and conclusion.

Comment summary 18: A commenter suggested that the scope of the Updated Draft State of PFAS Report should align with the mandatory section 71 notice and sought further information as to how the 312 PFAS in the notice were selected.

Response 18: The definition used to identify the class of PFAS captured within the scope of the State of PFAS Report and the Risk Management Approach is broader than the list of PFAS subject to the notice issued pursuant to CEPA section 71.

The intent of the section 71 notice was to collect information on those PFAS likely to be present in Canadian commerce based on their presence on the DSL, that are not currently regulated, and that have not been recently subject to other information gathering initiatives. The purpose of the survey was to collect additional information on uses and sources of release of PFAS which will be used to inform risk management decisions and other activities related to PFAS.

Comment summary 19: Commenters requested the exclusion of perfluoropolyethers (PFPEs) from the report, due to minimal impact on the environment and human health. Some provided information on the physical and chemical properties, behaviour, and end-of-life characteristics of PFPEs.

Specifically, commenters stated that PFPEs generally have a high molecular weight, are stable under a variety of use conditions, display no degradation under environmental conditions, do not contain significant amounts of residual monomer or low molecular weight oligomeric leachables, are negligibly soluble in water, and have a low mobility. Furthermore, because of these properties, commenters added that PFPEs do not bioaccumulate and are not bioavailable and would not be anticipated to pose a significant risk to public health or ecological systems through the release of unwanted byproducts.

Commenters suggested that a separate assessment of PFPEs be conducted. A commenter also suggested PFPEs be included in the future assessment of fluoropolymers.

Response 19: The information submitted was reviewed. References cited by commenters were considered and changes were made to Section 1.1.1 *Polymeric PFAS* of the report, as appropriate.

Section 1.1.1 of the State of PFAS Report indicates that the OECD report on PFPEs notes that many PFPEs have low molecular weight, even below 1000 Daltons in some cases. Molecules with molecular weights less than 1000 Daltons (such as lower molecular weight PFPEs) can be considered bioavailable. These lower molecular weight PFPEs can be volatile and may demonstrate some degree of solubility at ppm levels, indicating potential for mobility in the environment. It is acknowledged that PFPEs are considered to be stable under natural conditions. Under use-related conditions, PFPEs have been shown to degrade at elevated temperatures (such as those that may be encountered in industrial applications) to form non-

polymeric PFAS. It is therefore appropriate to address PFPEs in the State of the PFAS Report using the class-based approach.

Comment summary 20: Commenters requested the exclusion of side-chain fluorinated polymers from the report. Some commenters suggested that a separate risk assessment should be conducted as these substances differ in their physicochemical properties and hazard profiles from other PFAS. Another commenter suggested to focus on non-polymeric PFAS chemistries and include polymeric PFAS as part of the fluoropolymer separate assessment.

Response 20: The State of PFAS Report identifies side-chain fluorinated polymers as polymeric PFAS that do not have fluorinated polymer backbones and are instead composed of variable composition backbones with polyfluoroalkyl (and possibly perfluoroalkyl) side chains. As noted in Section 1.1.1 (*Polymeric PFAS*) of the State of PFAS Report, studies found that these substances can undergo abiotic or biotic degradation to release non-polymeric PFAS (via the cleavage of side chains), which can then transform to stable PFAS (such as PFCAs and PFSAs) that are bioavailable and/or mobile. Given their ability to degrade to stable, bioavailable, and/or mobile PFAS, side-chain fluorinated polymers are considered to contribute to the cumulative effects from co-exposure to multiple PFAS. The potential for cumulative exposure and effects are important considerations as most wildlife and human exposures involve an unknown mixture of PFAS.

Some side-chain fluorinated polymers meet the Schedule 1 definitions of PFOA, LC-PFCAs and PFOS precursors, and, as such, are currently risk managed under CEPA.

Comment summary 21: The commenter stressed that veterinary drugs and biologics are already assessed by the Government of Canada and that food and drug-related compounds can be considered safe until proven otherwise, based on comprehensive study.

Response 21: Through the CMP, the Government of Canada has considered uses of chemical substances that may also be subject to regulatory frameworks other than CEPA. For example, products such as drugs (including natural health products and veterinary drugs) are regulated under the *Food and Drugs Act.* However, substances used in these products are also examined under the CMP as broader considerations may be taken into account, such as exposure via environmental media associated with product lifecycle.

Comment summary 22: A commenter stated that the OECD PFAS definition inadvertently captures some organic pigments that should not be considered PFAS. In addition, the commenter states that a number of organic pigments have been reviewed under the CMP and none have been identified as causing harm to the environment or human health.

The commenter added that PFAS found in pigments that are encapsulated in paint and coatings matrix are not readily available for release in the environment and not likely to degrade.

Response 22: The Government has previously assessed the risk posed by substances referred to collectively as the Pigments and Dyes Group under the CMP (ECCC, HC 2018a,b, 2020). None of these substances meet the definition for PFAS used in the State of PFAS Report (as they do not contain at least one fully fluorinated methyl or methylene carbon atom) and are not a source of release of PFAS.

The OECD definition was developed through a broad community of regulatory authorities and was selected to define the class of PFAS in the State of PFAS Report due to its comprehensiveness. The OECD definition represents the growing and increasingly diverse inventory of PFAS chemicals and includes PFAS that may be developed in the future. Pigments containing a perfluorinated methyl or methylene group meet the OECD definition of the class of PFAS used in the State of PFAS Report.

The broad definition used in this class-based approach also allows consideration of co-exposure to multiple PFAS, which could result in cumulative effects. A precautionary, class-based approach to addressing PFAS is needed to adequately protect the environment and humans.

Comment summary 23: Commenters suggested using modified versions, other definitions, or aligning with other definitions of PFAS, some of which have been identified to focus on PFAS of concern. Examples of definitions, include:

- modifications of the State of Delaware and West Virginia definition (for example, non-polymeric PFAS containing at least 2 fully fluorinated carbon atoms, excluding gases and volatile liquids)
- definition used by the US EPA in TSCA section 8(a)(7) Reporting and Recordkeeping Requirements for PFAS rule
- working definition identified in the US EPA National PFAS Testing Strategy

Some commenters have noted that they would prefer to use Chemical Abstracts Service Registry Numbers (CAS RNs).

Response 23: The OECD definition was developed through a broad community of regulatory authorities and was selected to define the class of PFAS in the State of PFAS Report due to its comprehensiveness. The OECD definition represents the growing and increasingly diverse inventory of PFAS chemicals and includes PFAS that may be developed in the future. The broad definition used in this class-based approach addresses the concern with the stability of the fluorocarbon moiety, which results in persistence in the environment, and allows consideration of co-exposure to multiple PFAS that can contribute to potential cumulative effects. The State of PFAS Report defines PFAS using the OECD (2021) definition of PFAS, which uses chemical structure rather than individual identifiers such as CAS RNs.

Comment summary 24: A commenter indicated that significant differences in the biochemistry and toxicology of PFAS made it scientifically indefensible to regulate them as a class or group and provided peer reviewed papers by the US EPA which illustrated the diversity of PFAS and the challenges of grouping them.

The commenter also provided information indicating that a class assessment of PFAS using relative potency factors (or toxic equivalency factors) was not scientifically appropriate because PFAS act on numerous receptors and cause effects on numerous endpoints.

Response 24: The information submitted was reviewed. It is acknowledged that PFAS within a similar structural category do not always exhibit the same toxicity. Different chain lengths and functional groups may affect the relative toxicity within a grouping. Although few PFAS have been well-studied toxicologically, those that have been studied have been found to be capable of causing adverse effects on some endpoints in animals and/or humans. Amongst those that have been well-studied, there is a degree of consistency in their characteristics in that they are extremely persistent (or degrade into simpler PFAS that are extremely persistent), and they are associated with effects of concern. For this reason, a precautionary, class-based approach to addressing PFAS is needed to protect the environment and people from anticipated adverse effects.

Conclusion

Comment summary 25: Some commenters expressed support for the section 64 proposed conclusion and listing of the class of PFAS, excluding fluoropolymers as defined in the report, on Part 2 of Schedule 1. Other commenters were not supportive of the section 64 proposed conclusion of the Updated Draft State of PFAS Report, specifically due to the exclusion of fluoropolymers.

Response 25: Noted.

Comment summary 26: Commenters suggested that the Government of Canada should only be assessing and risk managing substances in Canadian commerce (that is, those on the Domestic Substances List) and that information from the section 71 notice should be assessed before finalizing the State of PFAS Report.

A commenter suggested that the information from the section 71 notice be used to identify subgroupings, properties, and/or uses to determine which substances should be added to Schedule 1. Other commenters stated that a precise definition, or a list of specific PFAS (for example, using CAS RNs) limited to those that cause harmful effects should be included on Schedule 1. They expressed concerns about the pitfalls of a broad definition, such as in reporting PFAS products and complying with regulations. Another commenter provided references to help define sub-groups.

Response 26: Although few PFAS have been well-studied toxicologically, those that have been studied have been found to be capable of causing effects on animals and/or humans. Amongst those that have been well-studied, there is a degree of consistency in their characteristics in that they are extremely persistent (or degrade into simpler PFAS that are extremely persistent). Given the growing body of scientific evidence suggesting that concerns for health and the environment identified from well-studied PFAS are more broadly applicable to other PFAS, and given their extreme persistence and the expectation that combined exposures to multiple PFAS will increase the likelihood of detrimental impacts, addressing PFAS using a class-based approach is appropriate. For this reason, a precautionary, class-based approach to addressing PFAS is needed to protect the environment and people from anticipated adverse effects.

The use of a class-based approach will also help prevent the substitution of one regulated PFAS for an unregulated PFAS that possesses equally or more hazardous properties, known as regrettable substitution.

The notice under section 71 of CEPA in the Canada Gazette will collect additional information on PFAS to better understand uses and sources of release. This information will be used to inform risk management decisions, the risk assessment of fluoropolymers, and where needed, other activities related to PFAS.

The conclusion in the State of PFAS Report allows a proposal to add the class of PFAS, excluding fluoropolymers, to Schedule 1 of CEPA, but does not in and of itself restrict or prohibit the substances in the class of PFAS; rather, it enables risk management instruments to be developed such as regulations under the Act. The Ministers recommend a substance for addition to Part 1 of Schedule 1 when the substance is toxic as defined in section 64 of CEPA, as well as meeting one or more of the following criteria: a) persistent and bioaccumulative in accordance with the *Persistence and Bioaccumulation Regulations*, inherently toxic (PBiT), present in the environment primarily as a result of human activity, and not a naturally occurring radionuclide or a naturally occurring inorganic substance; b) carcinogenic, mutagenic, or toxic for reproduction (CMR); or, (c) otherwise found to pose the highest risk. The proposed Order to add to Schedule 1 of CEPA, will be published in the Canada Gazette, Part I for a 60-day public comment period.

Risk management is proposed through a phased approach and will take into consideration factors, such as the costs and the benefits, the availability of suitable alternatives and other socio-economic considerations. When considering risk management actions, information will be gathered to understand the availability of alternatives and the costs of transitioning to those

alternatives. There will be additional opportunities to provide input during public consultations on proposed risk management.

Comment summary 27: A commenter expressed concern that there would be no invitation for public comments if risk assessments occur after substances are added to Schedule 1.

Response 27: Assessments conducted under CEPA determine whether a substance is entering or may enter the environment at levels that are or may be harmful to the environment or to human health. When these assessments are finalized, and if the substance(s) is determined to be toxic under CEPA, then a proposed Order can be published to list the substance or group of substances under Schedule 1.

The State of PFAS Report is an assessment under section 68 of CEPA and makes a conclusion under section 64 of CEPA. The Draft State of PFAS Report and the Updated Draft State of PFAS each underwent a 60-day public consultation period in 2023 and 2024, respectively. It is proposed that the class of PFAS, excluding fluoropolymers as defined in the report, be added to Part 2 of Schedule 1 to CEPA. The proposed Order for this addition will have an associated public comment period.

Fluoropolymers are included among the <u>substances proposed as priorities for assessment</u> for the Plan of Priorities to be published under section 73 of CEPA in June 2025. In alignment with the CMP process, a draft assessment of fluoropolymers will also be subject to a 60-day public comment period.

Risk management of the class of PFAS, excluding fluoropolymers, will be developed in phases and there will be additional opportunities for consultation where stakeholders may provide input regarding specific risk management activities.

Comment summary 28: Commenters suggested listing the class of PFAS on Part 1 of Schedule 1. Commenters also suggested that the Government of Canada should fast-track the process to list the class of PFAS on Schedule 1.

A commenter stated that the proposed Part 2 of Schedule 1 listing will not sufficiently address the impacts associated with the class of PFAS. They requested that the Government explain how it concluded the proposed listing on Part 2, since some PFAS are already listed on Part 1.

Another commenter added that the outdated bioaccumulation criteria should not be a barrier for including the class of PFAS on Part 1. It was also recommended that scientific distinctions between PFAS subgroups (that is, variability in the substances' bioavailability via different routes of exposure) be considered in future decisions to move substances to Part 1 of Schedule 1.

Response 28: The proposed Order to add the class of PFAS, excluding fluoropolymers as defined in the report, to Part 2 of Schedule 1 of CEPA, will be published in the *Canada Gazette*, Part I for a 60-day public comment period. The Government uses a standardized process for managing risks of chemical substances under CEPA, including adding substances to Schedule 1. It is to be noted there is no statutory process to fast-track a substance's addition to Schedule 1.

The Ministers recommend a substance for addition to Part 1 of Schedule 1 when the substance is toxic as defined in section 64 of CEPA, as well as meeting one or more of the following criteria: a) persistent and bioaccumulative in accordance with the *Persistence and Bioaccumulation Regulations*, inherently toxic (PBiT), present in the environment primarily as a result of human activity, and not a naturally occurring radionuclide or a naturally occurring inorganic substance; b) carcinogenic, mutagenic, or toxic for reproduction (CMR); or, (c) otherwise found to pose the highest risk. As explained in the report, the class of PFAS are considered to meet the regulatory criteria for persistence, but the bioaccumulation potential of PFAS cannot reasonably be determined according to the regulatory criteria. As such, they are proposed to be listed on Part 2. Given that fluoropolymers have been excluded from this

assessment, they are also excluded from this determination with regard to the Persistence and Bioaccumulation Regulations of CEPA.

Regulations specifying criteria for the classification of substances that pose the highest risk or that are carcinogenic, mutagenic or toxic to reproduction are under development. Once these criteria become available, it is possible that substances may be moved to Part 1 of Schedule 1. However, it should be noted that substances listed on Part 2 of Schedule 1 can also be subject to regulatory prohibitions.

The addition of substances to Schedule 1 enables risk management instruments to be developed, such as regulations under CEPA. Any regulatory measure that prohibits PFAS will take into consideration factors, such as the costs and the benefits, the availability of suitable alternatives and socio-economic considerations.

Comment summary 29: A commenter questioned the use of the term "reasonable to anticipate" in the Updated Draft State of PFAS Report and suggested that it should not be used to rush to final conclusions and any related regulation. The commenter also notes extensive use of the term "potential" in the report.

Response 29: While there are thousands of substances in the class of PFAS with diverse uses, only a limited number of them have been well-studied. Amongst those that have been well-studied, there is a degree of consistency in their characteristics in that they are extremely persistent (or degrade into simpler PFAS that are extremely persistent), and they are associated with effects of concern. The broad use of PFAS, their ability to move locally and over long ranges, and their ubiquitous presence in the environment have resulted in continuous environmental and human exposure to multiple PFAS, with well-studied PFAS demonstrating the potential to affect multiple systems and organs in both humans and wildlife. As a result of the extreme persistence of PFAS, their potential for bioaccumulation in organisms and biomagnification through the food chain, and the impossibility of their removal from the broader environment, presence in the environment and uptake by biota and humans will continue and potentially increase in the absence of intervention. The potential for cumulative effects are important considerations as most wildlife and human exposures involve an unknown mixture of PFAS. These issues were considered, in addition to applying precaution when addressing gaps in information to be protective of the environment and human health.

Comment summary 30: Commenters noticed that the language used in the conclusion for the Updated Draft State of PFAS Report is weaker in comparison to the Draft State of PFAS Report (published in May 2023), as it no longer contains the words "precautionary", "protective", and "hazardous". The language used should be revised to elevate precaution and protection.

Response 30: The use of the terms "precaution/precautionary", "protective", and "hazardous" have been generally consistent between draft and final versions of the report; any changes in this wording does not affect the conclusion of the report.

Impacts on the environment

Comment summary 31: A commenter recommended rewording the State of PFAS Report to note that PFAS is difficult to remove from the environment, but not impossible.

Response 31: Technologies to destroy PFAS in contaminated media continue to be developed, and the State of PFAS Report acknowledges that some PFAS removal treatment technologies exist or are being developed (Section 8.1.4 Contaminated sites of report). See Destruction of PFAS compounds in contaminated media for more information on other remediation technologies that are being developed. However, as noted in Section 2.6.5 (Potential PFAS removal and treatment technologies) of the report, they can only be reasonably applied in specific locations and media such as sites contaminated with PFAS or drinking water treatment facilities. The term "broader environment" from the following statement from the report, "...the removal of PFAS from the broader environment is not possible", is intended to refer to all locations in all environmental compartments (water, sediment, air and soil). Removal from all locations where PFAS are present is not possible. This, in combination with the extreme persistence of PFAS and their potential for bioaccumulation in organisms, will lead to their continued presence in the environment and uptake by biota and humans.

Comment summary 32: A commenter stated that the environmental monitoring and research projects under the Northern Contaminants Program (NCP) have a limited focus in Nunavik, thus PFAS concentrations may be underrepresented within the dataset. The commenter recommended that, if NCP projects are to be used to develop PFAS risk management, it should be supplemented to adequately reflect Nunavik.

Response 32: PFAS are measured as part of wildlife, fish, and environmental monitoring projects across most of the territories and regions of the North. They are also measured in Nunavik as part of human health projects investigating contaminants in beluga and other traditional food sources (for example, NCP Project H-13: Elevated exposure to long-chain perfluoroalkyl acids (PFAAs) in Nunavimmiut adults: concentrations in select country foods and adverse effects on thyroid function).

Previously, there had been samples from Nunavik included in the projects that comprise NCP's core environmental monitoring program; however, this has not been the case in recent years. The NCP Secretariat is currently working with the leaders of the NCP ringed seal monitoring program to re-establish a contaminant monitoring site for ringed seals in Nunavik, which will include PFAS, as do most of NCP's ongoing core monitoring projects. The addition of a Nunavik site to the seal monitoring project is currently in the consultation phase, through discussions with the Nunavik Nutrition and Health Committee (Nunavik Regional Board of Health and Social Services) and other organizations that coordinate wildlife research in the region. Further expansion of contaminant monitoring in Nunavik under the NCP will require prioritization of this activity by the NCP's Management Committee (communicated through the program's annual call for proposals), and will be dependent on available capacity, funding, and submission of proposals that include monitoring activity in this region.

Comment summary 33: Commenters provided additional studies on the occurrence of TFA, its degradation, and information suggesting that concentrations of TFA in deep oceans may originate from natural sources. A commenter stated that the updated draft report overemphasized the contribution of TFA from HFOs relative to the naturally occurring levels of TFA or other sources. A commenter also provided studies indicating that some reports of locally elevated concentrations of TFA are due to industrial sources of TFA, including manufacturing, end-of-life, and pesticide runoff from agricultural land.

Response 33: The studies provided were reviewed and Section 3.3 *Considerations for hydrofluoroolefins (HFOs) and hydrochlorofluoroolefins (HCFOs)* of the report was updated, as suitable. The final report indicates that point source emissions of PFAS/TFA may contribute to locally elevated concentrations of TFA.

Comment summary 34: A commentor requested more information on how ecosystemlevel effects of PFAS can be measured. **Response 34:** Mechanisms by which the impact of PFAS on ecosystems can be measured are summarized in Sections 6.2 (*Ecological Effects*) and 8.1.2.1 (*Planned Future Research, Monitoring, and Surveillance: Ecological*) of the State of PFAS Report.

Comment summary 35: A commenter noted that federal contaminated sites for PFAS identified in the Updated Draft State of PFAS Report are predominately related to aqueous film-forming foam (AFFF) use. The commenter recommended that hot spot identification should include other significant sources of PFAS (such as industrial effluent), and that PFAS be added to the National Pollutant Release Inventory (NPRI).

Response 35: 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. Only the federal contaminated sites with confirmed or suspected PFAS contamination were highlighted in Figure 3 of the final report.

Other PFAS hot spots across the country (associated with sources such as industrial effluent) may come from privately owned or provincially/territorially owned properties. The provinces and territories have jurisdiction over privately owned land and enact laws, regulations and policies regarding the remediation of contaminated sites within their specific jurisdiction. However, the report includes some information on other sources of PFAS as mentioned in Section 2.3 (*Sites Contaminated with Aqueous Film-Forming Foams [AFFF]*): "Most of these sites are associated with past and/or current use of AFFF... Other ways that PFAS may contaminate sites may include migration of landfill leachate or land application of wastewater treatment biosolids contaminated with PFAS, which are discussed in section 2.6".

ECCC has consulted on adding reporting requirements for PFAS to the NPRI, with a key goal being to provide programs with data to support the government activities. All federally designated PFAS hot spots in Canada could be taken into consideration for this purpose. The comment period closed on November 25, 2024. See the following website for more information: Proposed Changes to the National Pollutant Release Inventory. Reporting requirements under NPRI are proposed to apply to all facilities across Canada that manufacture, process or otherwise use PFAS, provided they meet certain thresholds. This may include federal contaminated sites and facilities in other identified hotspots, if they meet reporting requirements. NPRI reporting requirements for PFAS are proposed to take effect as of the 2025 calendar year, that is, facilities will be required to submit PFAS reports for the year 2025 by June of 2026. ECCC intends to provide guidance and tools for facilities to use to fulfill their reporting obligations.

Comment summary 36: A commenter recommended adding a sentence specifying the exclusion of fluoropolymers from the statement stating that the class of PFAS meet the persistence criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

Response 36: Given that fluoropolymers have been excluded from the State of PFAS Report, they are also excluded from the persistence determination with regard to the *Persistence and Bioaccumulation Regulations* of CEPA. The State of PFAS Report has been updated to reflect this.

Comment summary 37: A commenter requested clarity in regard to how the Government intends to apply criteria that would reflect the concern for dietary-based biomagnification.

They mentioned that the proposal that the bioaccumulation potential of PFAS cannot reasonably be determined according to the regulatory criteria set out in the *Persistence and Bioaccumulation Regulations* requires further consultation with stakeholders, as it may have serious impacts on the risk assessment of other substances under the CMP.

Response 37: Although no regulatory criteria exist for biomagnification nor trophic magnification in Canada, this does not prevent the Government from considering well-reasoned and scientifically supported information from the scientific literature regarding these characteristics when making an evaluation of bioaccumulation potential. Such characteristics

can be included in weight of evidence approaches when assessing substances. A weight of evidence approach is a valid scientific methodology, it is a statutory requirement under CEPA, and has undergone consultation with stakeholders in the past.

Comment summary 38: A commenter asserted that the class of PFAS should be considered bioaccumulative, as hundreds of PFAS have been shown to be bioaccumulative. The finding that the bioaccumulation potential of PFAS "cannot reasonably be determined" under the *Persistence and Bioaccumulation Regulations* demonstrates the flaws of the regulations and a need to update them.

Response 38: The domain of applicability of the criteria under the *Persistence and Bioaccumulation Regulations*, originally designed to address whole body lipid-based bioaccumulation, cannot reasonably be applied across this class of substances with confidence. There is a high concern identified for the biomagnification and trophic magnification potential of well-studied PFAS in air-breathing organisms; however, as biomagnification and trophic magnification are out of domain of the regulatory bioaccumulation criteria, additional and alternative bioaccumulation metrics and science must be used to address the totality of PFAS bioaccumulation and its implications for toxic effects. Thus, while the bioaccumulation potential of PFAS can to some degree be characterized scientifically, these evaluations cannot reasonably be compared to the criteria under the *Persistence and Bioaccumulation Regulations* in order to make a *regulatory* determination.

Comment summary 39: A commenter stated that the text in the updated draft report stating that fluoropolymers "do not appear to degrade under natural conditions" ignores the considerations of microplastic pollution.

Response 39: The <u>2020 Science Assessment of Plastic Pollution</u> recognizes that plastic items in the environment break down and fragment into smaller pieces, eventually forming secondary microplastics (categorized as plastic particles less than or equal to 5 mm in size) and notes that polytetrafluoroethylene (a fluoropolymer) has been detected in the environment as microplastics.

Given evidence from a range of sources suggesting their differences from other PFAS, additional work on fluoropolymers is warranted. Thus, this information may be considered when assessing fluoropolymers in the future. The exclusion of fluoropolymers from the State of PFAS Report should not be interpreted as meaning that they are or are not of concern.

Impacts on human health

Comment summary 40: Commenters suggested that it is important to more deeply understand the cumulative effects of PFAS and not qualitatively draw conclusions. It was also noted that there is insufficient human health data to support a human health toxic conclusion across the class of PFAS. Issues include:

- inappropriate to assume that hazards are equivalent across the entire diverse class of PFAS; highlighting issues such as: lack of information regarding mode of action (MOA) across species
- data gaps and variability in the properties of PFAS (for example, bioaccumulation and toxicokinetic differences)
- no analysis on the relative potency of individual PFAS and no suggestions were provided on how to specifically address the wide range of potencies
- no support for the statement: "...on the expectation that combined exposures to multiple PFAS increase the likelihood of detrimental impacts..."

Response 40: The previous response to comments document has acknowledged that compound-specific MOA information is "the gold standard" and that PFAS groupings would "ideally" be based only on common toxic MOAs and/or target organs. However, data such as this are available for only a very limited number of PFAS.

The *Human health hazard* section (Section 7) demonstrates qualitatively that well-studied PFAS are associated with health effects. Although few PFAS have been well-studied toxicologically, those that have been studied have been found to be capable of causing adverse effects in animals and/or humans. It is also acknowledged that not all PFAS will have a similar toxicological potency. However, the toxicity of each PFAS will have the potential to still contribute to cumulative risk. For this reason, a precautionary, class-based approach to addressing PFAS is used to address potential cumulative effects. Using this approach, the intent of Section 7 of the State of PFAS Report was not to conduct individual hazard assessments for each PFAS nor to assess relative potency. Toxicity data gaps amongst many of the individual substances in the class of PFAS have been acknowledged along with acknowledgement that MOA for all PFAS-induced effects are not well understood. However, given the complexity and magnitude of the class of PFAS and the persistence and ubiquity of PFAS, it is reasonable to anticipate that the environment and humans are currently exposed to multiple PFAS and that this will continue in the future.

Comment summary 41: A commenter noted that the updated draft report mentions that Inuit and Indigenous populations were disproportionally affected but did not elaborate on the drivers, which is an important context for the supporting risk management publication.

Response 41: A statement has been added to Section 5.4.2 (*PFAS measured in First Nations [on-reserve] populations, Inuit communities, and other Indigenous or northern communities*) to acknowledge recent research which identifies country food as a potential source of certain PFAAs in Nunavik; however, the authors in this study acknowledge that more work may be done to examine other sources, and they note that drinking water samples will be taken in a follow-up study to measure PFAA concentrations in Nunavik. Additionally, the Government will continue to support health, environmental and community-based monitoring studies that address the research needs of northern communities. The environmental and human health objectives for the class of PFAS are to reduce releases to the environment and exposure to the general population. Proposed risk management will take into consideration those groups of individuals within the Canadian population who, due to greater exposure, may be disproportionately impacted.

Comment summary 42: A commenter noted that the updated draft report does not identify the major sources of exposure to the Canadian population, including vulnerable populations with higher exposure. They recommended that this knowledge gap be filled to enable the effective targeting of restrictions on PFAS uses, however, this should not delay the regulation of non-essential uses.

Response 42: This assessment considers many aspects of PFAS including their widespread use, ubiquity in the environment, persistence, impossibility of removing them from broader environment and notes that humans are exposed to multiple PFAS. For the general population, the assessment does not consider individual exposures (by specific use or specific PFAS) but acknowledges potential for cumulative exposure from an unknown mixture of PFAS from various sources. People living in Canada may be exposed to PFAS from various sources such as in food and food packaging materials, cosmetics, products available to consumers (including textiles such as carpets, furniture, and clothing), ambient and indoor air, dust, and drinking water. The relative importance of each exposure source can vary across different populations, by PFAS and over time. Furthermore, variable concentrations of PFAS in exposure media, differences in duration and frequency of exposures, and consideration of PFAS precursors (which can transform into more persistent PFAS) can all impact the relative contribution of exposure sources. Canadian-specific information on the contribution of sources to the exposure of Canadian to PFAS is also limited. Research continues to grow in this area.

A statement has been added to Section 5.4.2 (*PFAS measured in First Nations [on-reserve] populations, Inuit communities, and other Indigenous or northern communities*) to acknowledge research which identifies country food as a potential source of certain PFAAs in Nunavik; however, the authors in this study acknowledge that more work may be done to examine other sources, and note that drinking water samples will be taken in a follow-up study to measure PFAA concentrations in Nunavik.

The risk management objective for the class of PFAS is to achieve the lowest levels of environmental and human exposure that are technically feasible, taking into consideration socio-economic factors. Risk management is proposed through a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams, and then managing other uses or sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

Comment summary 43: A commenter indicated that the updated draft report does not take into account the impact of unchecked climate change on the health of Canadians, in a world without HFOs and HCFOs.

Response 43: Many HFOs and HCFOs, as well as the breakdown product TFA, meet the 2021 OECD definition for PFAS. TFA is considered to contribute to the potential for cumulative effects of PFAS as it is detected nearly ubiquitously in the environment. Therefore, HFOs, HCFOS, and TFA are included in the scope of the report. As stated in the Risk Management Approach, any risk management actions on PFAS will be developed in alignment with, and complementary to, existing regulations, such as those under the Paris Agreement on climate, as well as the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* (ODSHAR) which is intended to contribute towards Canada's efforts to combat climate change.

Any risk management measures to address HFOs or HCFOs will also take into consideration socio-economic factors and the availability of suitable alternatives, including the costs and benefits of switching to those alternatives. Information gathering to fully understand the feasibility of alternatives and the costs of transitioning to alternatives would also take place before risk management actions are taken.

Comment summary 44: Commenters noted the variability in the inhalation and dermal routes of exposure, discussed the relative importance of exposure pathways, and provided references. A commenter discussed that the significance of dermal and inhalation routes of exposure was not properly acknowledged.

Response 44: The information submitted was examined. Some references were added to Section 7.1 (*Toxicokinetics*) of the State of PFAS Report. In addition, a 2024 report that was commissioned by the Government of Canada to summarize the most recent available health data, including data on the absorption of PFAS through the dermal and inhalation routes was added to Section 7.1. Certain references provided by commenters were considered as part of this report.

Wording in Section 7.1 has been updated to note that the absorption by different routes may vary amongst PFAS. Relative to oral data, the data on dermal and inhalation absorption of and exposure to PFAS is very limited.

Comment summary 45: To support people who may be disproportionately impacted, such as people living near sites contaminated with PFAS, a commenter suggested that high quality, disaggregated biomonitoring data continue to be collected and that opportunities to further disaggregate existing data be considered.

Response 45: The Government of Canada has been validating methods to disaggregate biomonitoring and associated demographic data to identify populations that may be highly exposed or more susceptible to the adverse health effects, and hence disproportionately impacted by chemical exposures. Notably, using data collected under the Canadian Health Measures Survey (CHMS), the Government of Canada has recently been able to produce reliable estimates of blood and urinary concentrations and/or time trends of certain priority chemicals (including limited analyses for select PFAS) for several subpopulations of interest including racial and Indigenous identity populations, and for populations living in broad geographic regions such as Quebec, Ontario, and the Prairies. The findings from these analyses have been recently published (see: Karthikeyan et al. 2024; Valcke et al. 2020; Alberta Environmental Public Health Information Network [AEPHIN] c2022).

Comment summary 46: A commenter suggested that the Government should explore how existing programs (within government and industry) can support Indigenous rights in the context of CEPA, in efforts to support those who may be disproportionately exposed to higher levels of PFAS.

Response 46: The Government recognizes that every individual in Canada has a right to a healthy environment under the CEPA as amended by Bill S-5 (SC 2023, Ch.12) and has begun public consultation on the development of a right to a healthy environment implementation framework. The draft framework was published on October 4, 2024, includes a section on Indigenous rights which recognizes that respect for section 35 rights is essential to protecting a right to a healthy environment as provided under CEPA. The draft framework proposes guiding considerations related to Indigenous rights and priorities that can be applied in CEPA decision-making. The draft framework also proposes to work with Indigenous partners on a new Indigenous Knowledge Policy Framework which could provide guidance to CEPA decision-makers on opportunities and approaches to Free Prior and Informed Consent, where applicable, and on bridging, braiding, weaving, Indigenous knowledge with western science in their work. In the broader context of CEPA, the Government is also engaging with people living in Canada on environmental justice and racism to address the fact that certain communities have been disproportionately affected by environmental hazards, like pollution, toxic waste, and waste disposal sites.

Comment summary 47: A commenter noted that national biomonitoring results in the United States (National Health and Nutrition Examination Survey [NHANES]) show declines. Commenter also notes very different half-lives of PFHxA compared to PFOS, PFOA and PFHxS.

Response 47: The State of PFAS Report has noted declining trends in biomonitoring levels in the general public in Canada for certain, well-studied PFAS (most of which are regulated, for example, PFOA and PFOS). The report has been updated to note similar declining trends in the general population of the United States. The report has also noted differences in biological half-lives amongst PFAS..

Comment summary 48: A commenter suggested that the implementation of some form of critical appraisal process would ensure that scientific evidence related to human health is reliable and robust, which would enhance the credibility and effectiveness of proposed guidelines.

Response 48: The purpose of the *Human health hazard* section (Section 7) is to provide an overview of recurrent health effects observed amongst PFAS to get a better understanding of

key endpoints, organs, and systems affected by PFAS. Consequently, a critical evaluation and presentation of every available scientific study is not included in the State of PFAS Report. The data in the Human health hazard section effectively demonstrates qualitatively that well-studied PFAS are associated with health effects as observed in animal and epidemiological studies. Should quantitative health-based guidelines be developed, the scientific evidence for the health endpoint of concern would be critically evaluated to ensure that the appropriate point of departure is identified.

Comment summary 49: Commenters requested further research and investment on topics including monitoring the effects of PFAS on human health including:

- individual PFAS
- mixtures
- · low concentrations, and
- cumulative effects

Response 49: Toxicology research is being conducted to better understand the potential human health effects of exposure to certain PFAS, including their potential contribution to metabolic diseases, such as obesity and type II diabetes, and their impacts on the immune system and neurological diseases. The Government of Canada also continues to examine the potential health effects of PFAS in populations that may be more susceptible or highly exposed (including pregnant people and children) through means that include leveraging the MIREC Research Platform. In addition, to continue to improve the understanding of PFAS, Health Canada is leading a collaborative case study (working with other jurisdictions and academics including the United States, Singapore, University of Ottawa, and the University of Birmingham) under the international government initiative Accelerating the Pace of Chemical Risk Assessment (APCRA). In this case study, transcriptomic points of departure were derived from human liver microtissues exposed to PFAS and PFAS mixtures in order to characterize potency and additivity.

Information on the planned and future research associated with human health and PFAS is summarized in Section 8.1.2.2 (*Human health*) of the report.

Comment summary 50: Commenters encouraged the continued collection and expansion of PFAS monitored through CHMS to help understand trends over time, identify at-risk populations, examine impacts of regrettable substitutions, and assess potential impacts of regulations.

Response 50: Although a thorough understanding of the contribution of target analytes to the potential PFAS burden is still limited, the number of PFAS analytes being monitored in biomonitoring studies, including Canadian biomonitoring studies (for example MIREC ENDO, Cartagene), is expanding. In general, well-studied PFAS (for example, PFOA, PFNA, PFHxS and PFOS) continue to demonstrate the highest concentrations and detection frequencies compared to other PFAS analytes.

Monitoring and surveillance activities, such as those conducted through the CHMS, the MIREC longitudinal study, and biomonitoring studies funded under the Northern Contaminants Program, are continuing to collect and analyze biospecimens for historically used and replacement PFAS and their precursors and metabolites. Legacy, alternative and precursor PFAS (approximately 40 PFAS analytes) are planned to be assessed in CHMS cycle 6 (2018–2019) biobank samples covering population aged 3 to 79 years. The analysis to be conducted on 2,500 samples will ensure that the results (expected to be available in 2026) are representative of the Canadian population. This data can also be used to identify potentially disproportionately impacted populations. The same set of PFAS will also be measured in CHMS cycle 8 (2025-2027) enabling an assessment of potential changes in exposure in the Canadian population over time for several PFAS previously not measured in the population of Canada. Analyses of the PFAS data collected as part of MIREC will help to identify what, if any, adverse effects may occur in pregnant people, infants, children and adolescents. Through a competitive process, the Northern Contaminants Program can support biomonitoring studies of PFAS and health outcomes, if such projects are a priority for community and regional partners.

In addition to optimizing methods to identify a larger scope of PFAS, methods are under development to address the knowledge gap between known analytes and unidentified PFAS that may contribute to the overall burden. Other matrices (for example, urine) are also being identified as potentially informative for levels of certain PFAS.

Many considerations such as these may be taken in account when considering future monitoring through CHMS or other biomonitoring work.

Comment summary 51: A commenter suggested that the cumulative impacts from mixtures containing PFAS and their impact on vulnerable populations be carefully considered in risk management decisions. They recommended that all consumer products manufactured or imported into Canada be regulated and that there be substantial public engagement when considering certain exemptions.

Response 51: As outlined in the Risk Management Approach, the proposed environmental and human health objectives for the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, are, respectively, to reduce releases of these substances to the Canadian environment so as to avoid adverse effects; and to reduce exposure of the general population, including disproportionately impacted populations, to these substances to protect human health.

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 feasible, taking into consideration socio-economic factors. The class-based approach for the risk management of PFAS is intended to address the potential for cumulative effects resulting from exposure to a mixture of PFAS. Furthermore, additional opportunities for public and stakeholder engagement will be provided during the subsequent risk management activities.

Comment summary 52: A commenter noted that rigorous scientific studies that prove cumulative effects (with common endpoints) should be advanced and used to tailor risk management actions to address the potential for cumulative effects from co-exposure to unknown and variable groups of PFAS and to protect vulnerable populations.

Response 52: This assessment considers many aspects of PFAS including their widespread use, ubiquity in environment, persistence, impossibility to remove from broader environment and notes that humans are exposed to multiple PFAS. The State of PFAS Report also provides an overview of recurrent health effects observed to be caused by multiple PFAS to get a better understanding of key endpoints, organs and systems affected by PFAS.

Given the lack of consensus regarding the most sensitive health effects, limited data on the toxicity of PFAS in mixtures and the likelihood of exposure to multiple PFAS at one time, even with lack of information, it is considered appropriate to consider the potential contribution of cumulative exposure and effects of PFAS.

The class-based approach for the risk management of PFAS is intended to address the potential for cumulative effects resulting from exposure to a mixture of PFAS in order to protect the general population, including disproportionately impacted populations.

Comment summary 53: A commenter noted that certain biomonitoring studies related to TFA had analytical or methodological issues and should be disregarded. It was also noted that data related to TFA in serum was not corrected for possible confounding of TFA, that is exposure from other sources such as pharmaceuticals.

Response 53: Additional text has been added or modified in Section 5 of the State of PFAS Report (Human biomonitoring) to acknowledge methodological complexities associated with analytical methods for TFA. Some references have been removed; in other cases, the limitations of studies have been more clearly identified. In the State of PFAS Report, exposure from multiple PFAS from various sources was considered. Examination of biomonitoring data representing PFAS from a range of sources (including pharmaceuticals) is consistent with this approach of considering cumulative exposure.

Comment summary 54: A commenter provided information related to the health impacts of TFA and noted calls for applying a precautionary approach from non-governmental organizations.

Response 54: The submitted information was examined. This information was considered as appropriate in updating the State of PFAS Report.

Comment summary 55: A commenter noted that the Updated Draft State of PFAS Report provided a distorted picture of effects of TFA in animal studies. The commenter also provided information that indicates that TFA does not have similar toxicological properties to PFAS of toxicological concern.

Response 55: The data provided by the commenter was considered and the information on health effects associated with TFA in Section 7 (*Human health hazard*) of the report was modified to clarify that animals in which liver effects were observed were exposed to relatively high doses of TFA. It is acknowledged that not all PFAS will have a similar toxicological potency. However, the intent of Section 7 of the State of PFAS Report was not to conduct individual hazard assessments for each PFAS nor to assess relative potency. Given the lack of consensus regarding the most sensitive health effects, limited data on the toxicity of PFAS in mixtures and the likelihood of exposure to multiple PFAS at one time, it is not considered appropriate to examine individual PFAS, such as TFA, without considering their potential contribution to cumulative exposure and effects.

Comment summary 56: A commenter provided data on the non-clinical safety assessment of HFO-1234ze (E), which indicate that HFO-1234ze (E) is not considered to be a risk to patients and supports its further development as a medical device inhaler propellant.

Response 56: It is acknowledged that available toxicological information may indicate low hazard for some HFOs, however, the potential degradation of HFOs to TFA has been a primary lifecycle consideration for the continued inclusion of HFOs in the class of PFAS.

Information gathered through the various stages of consultation will help inform any risk management options to be developed. Risk management is proposed through a phased approach and will take into consideration factors such as the costs and the benefits, the availability of suitable alternatives and socio-economic considerations.

Comment summary 57: A commenter suggested rewording a statement found in the *Executive Summary*, Section 7 (*Human health hazard*), and Section 9 (*Findings*) of the Updated Draft State of PFAS Report, specifically to recognize that other PFAS have been studied and noted to be "less bioavailable".

Response 57: The text proposed by the commenter refers to a US EPA report (<u>Multi-Industry Per- and Polyfluoroalkyl Substances (PFAS) Study – 2021 Preliminary Report</u>) and it appears that the term "less bioavailable" refers to a section of the US EPA report in which it is noted that certain high-molecular weight fluoropolymers are "less bioavailable". Fluoropolymers are planned for consideration in a separate assessment.

Occupational exposure

Comment summary 58: Commenters recommended that the measurement of PFAS levels in the blood of Canadian firefighters be conducted, concrete timelines for this work be provided, and that firefighters and their association, be engaged in the process. A commenter highlighted the issue of cancer as the most significant health threat facing firefighters, and that PFAS are pervasive carcinogens and toxicants resulting in firefighters' exposure daily.

A commenter included information on firefighters working on installations on federally controlled lands contaminated with PFAS.

Response 58: The State of PFAS Report summarized biomonitoring information on international firefighters. In addition, the association between exposure to PFAS and the occurrence of cancer is described in the section on *Carcinogenicity* (Section 7.2.9) of the report, including the classification of PFOA and PFOS by the International Agency for Research on Cancer classification as "carcinogenic" and "possible carcinogenic" to humans.

Specific research activities conducted by Government of Canada scientists related to firefighting gear and PFAS in dust collected at fire stations are ongoing or recently completed and may contribute to better understanding of firefighter exposure. The recommendation for more work related to biomonitoring in Canadian firefighters has been noted. The Government of Canada also aims to stay informed of other research at Canadian academic institutions related to firefighters in Canada and PFAS.

In addition, in June 2023 the <u>National Framework on Cancers Linked to Firefighting</u>
<u>Act</u> received Royal Assent. This Act compels the Minister of Health to establish a national framework designed to raise awareness of cancers linked to firefighting with a goal of improving access for firefighters to cancer prevention and treatment. Work is ongoing under this Act.

As stated in the Risk Management Approach, the Government of Canada is planning a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams.

Comment summary 59: A commenter noted that activities identified within the Firefighter Action Plan (2021) and the National Framework on Cancers Linking to Firefighter Act do not address the issue of PFAS within the fire service, nor do they identify funded government instruments to be actioned. The commenter also requested funding to develop and transition to safer turnout gear.

Another commenter was supportive of the research being done to protect firefighters.

Response 59: As part of research under the <u>Firefighter Action Plan</u>, Health Canada has recently published a study related to PFAS emissions from firefighter turnout gear. A reference to this study has been added to the State of PFAS Report (Section 5.6 *Occupational HBM data-Firefighters*) which indicates that PFAS have been intentionally used, detected in or released from firefighters' protective clothing.

At this time, no funding is currently available for external research work on PFAS in firefighters.

Comment summary 60: A commenter provided information on the release of PFAS from firefighting garments.

Response 60: The information was examined and Section 5.6 (*Occupational HBM data – Firefighters*) of the final report was revised to add this reference.

Comment summary 61: A commenter provided information on two biomonitoring studies in Australian firefighters, which indicated that the PFAS found in the highest concentrations were legacy PFAS. Since the detection frequency and concentration of non-legacy PFAS was low, the commenter indicated that no further study was justified.

The commenter also indicated that these PFAS are already widely restricted under the Stockholm Convention and referenced 2 reports to suggest that in some cases there were not significant associations with cholesterol and kidney function and that there were little differences in the studied outcomes between highly exposed PFAS communities and communities without exposure.

Response 61: The data provided by the submitter has been considered. It is acknowledged that the PFAS identified as appearing to be elevated in international firefighters in the State of PFAS Report are "legacy" PFAS as identified by the commenter. As indicated in Section 7 (*Human health hazard*) of the report, multiple organs and systems have been found to be affected by both "legacy" and "non-legacy" PFAS.

It is acknowledged that several legacy PFAS are currently restricted under the Stockholm Convention, that is, PFOA, PFOS, and PFHxS, their salts and related compounds. In 2023, long-chain PFCAs were recommended for listing.

Although restrictions are currently in place for certain legacy PFAS in firefighting foams, the Government of Canada is planning to manage PFAS in a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams.

Comment summary 62: A commenter noted that spray polyurethane foams (such as those containing HFOs) are solely applied by professional contractors (using supplied air) therefore there is very little potential of exposure during installation.

R1233zd is also not available for contact with humans because it has a low boiling point and will evaporate rapidly when sprayed under pressure.

Response 62: R1233zd, like certain other HFOs and HCFOs, meets the 2021 OECD definition for PFAS, and is therefore included in the class of PFAS and within the scope of the report.

Although direct exposure to applicators may be managed via personal protective equipment, the State of PFAS Report considers the broad uses of PFAS, the potential release of PFAS to the environment, the ability of certain PFAS to break down to other, persistent PFAS, and the mobility of PFAS resulting in potential exposure through other pathways.

Drinking water

Comment summary 63: Commenters suggested that Canada should establish enforceable limits on PFAS in drinking water. A commenter also noted that the drinking water guideline of 30 ppt is not protective enough. Guidelines that are in the range of 0-4 ppt, as recommended by the US EPA, should be pursued.

Response 63: HC plays a leadership role in science and research on drinking water and derived the objective for PFAS in drinking water in collaboration with the Federal-Provincial-Territorial Committee on Drinking Water. However, setting regulatory standards for drinking water, and putting such standards into place, is primarily the responsibility of provinces and territories.

The objective value of 30 ng/L (ppt) is for the sum of 25 PFAS; this group approach is considered protective, and cannot be compared to the US EPA approach, which addresses 6 PFAS individually. The value for the objective for PFAS in drinking water is based on analytical detection and treatment achievability. The purpose of the objective is to reduce exposure (along with potential health risks) while the full guidelines are being re-evaluated. HC acknowledges that as more toxicity data are published, an increasing number of health effects are being associated with exposure to PFAS, and at lower levels. Consequently, in the objective, HC has included a recommendation to keep concentrations in drinking water as low as reasonably achievable (ALARA). HC will continue to monitor the science and will incorporate the results of new toxicology studies in the full reassessment of the Canadian guidelines for PFAS in drinking water.

Comment summary 64: A commenter questioned how the Government of Canada envisions the drinking water guidelines being integrated into management plans when many isolated Northern communities are already struggling with aging and/or failing drinking water infrastructure.

The commenter also asked how the government can expect Northern regions to incorporate PFAS guidelines into their current water treatment activities and policies, given issues with accessing safe drinking water in many Indigenous communities. They requested more information on the support that will be provided, such as access to testing, systematic reviews, capacity building and funding.

Response 64: HC plays a leadership role in science and research on drinking water and has established an objective of 30 ng/L for a sum of 25 specific PFAS. HC recognizes the challenges of implementing the drinking water objective for PFAS and will continue to work closely with provinces, territories and other government departments to provide health guidance, advice on testing protocols and water treatment strategies moving forward.

Indigenous Services Canada will continue to support First Nations to upgrade their water and wastewater systems under the First Nations Water and Wastewater Enhancement Program (FNWWEP). The program is delivered under the terms and conditions of the Department's Capital Facilities and Maintenance Program (CFMP), which is the main program for federal investments in infrastructure on First Nations reserves. Indigenous Services Canada is responsible for supporting the planning, design, construction, operation and maintenance of water and wastewater systems under the authorities of the CFMP. North of the 60th parallel, First Nations communities in the Yukon and two First Nations communities in the Northwest Territories (Salt River and K'atlodeeche) are eligible for the CFMP. Service delivery in Nunavut and most communities in the Northwest Territories has been transferred to territorial governments. In Nunavik, infrastructure service delivery has been transferred. Inuit communities in Nunavik, like municipalities within the Province of Quebec, are not eligible for ISC funding.

Comment summary 65: Commenters provided information on TFA concentrations in water in Europe, showing TFA to be:

- rapidly increasing
- measured as the dominant PFAS in German drinking water, and
- present in tap-water, bottled mineral and bottled spring water in several European countries

A commenter noted that fluorine gases are creating significant TFA drinking water contamination issues.

Response 65: The issue of drinking water contamination with TFA has been updated in section 3.3 (Considerations for hydrofluoroolefins [HFOs] and hydrochlorofluoroolefins [HCFOs]), including references, to indicate that referenced studies show that both the detection and concentrations of TFA found in drinking water are increasing.

New risk assessment information and data

Comment summary 66: Commenters provided research papers demonstrating health effects related to exposure to PFAS.

Response 66: The references have been examined. Several references had already been considered or included in the State of PFAS Report. The new information was considered within Section 7 (*Human health hazard*) and references were added to Section 7.2.9 (*Carcinogenicity*) as well as the supporting information in Appendix E.

Comment summary 67: Commenter provided testing results of certain PFAS in winter gloves for children purchased in Canada.

Response 67: The submitted information was examined but was noted to have limitations due to lack of information in areas such as sample handling, sample preparation and analytical methodology.

Comment summary 68: Commenters provided information on fluoropolymers, including use information, physical-chemical properties, bioavailability of high molecular weight fluoropolymers, fluoropolymers present as microplastics in various human tissues and end-of-life considerations; as well as important considerations for their risk management.

Response 68: Information related to fluoropolymers will be considered as part of the fluoropolymer assessment. Fluoropolymers are included among the <u>substances proposed as priorities for assessment</u> for the Plan of Priorities to be published under section 73 of CEPA in June 2025. The Plan of Priorities will outline activities to help assess, control and manage risks to the environment and human health over the next several years. The public and stakeholders will be informed on the expected timing of assessment work on all priorities to be published in the Plan of Priorities. The exclusion of fluoropolymers from the scope of the State of PFAS Report should not be interpreted as meaning they are or are not of concern.

Comment summary 69: A commenter noted that a now-approved research project is underway in Ontario to examine the lifecycle of PFAS present in biosolids of existing municipal wastewater treatment systems and then applied to farmland.

Response 69: The Government is aware of and acknowledges this research project. No changes were made to the report since the final results of this study have not yet been reported publicly nor published.

Comment summary 70: A commenter provided a poster containing degradation data in soil for a substance that meets the OECD PFAS definition, to demonstrate that not all PFAS are stable. They propose that PFAS with certain functional groups should be excluded and considered separately.

Response 70: While the study indicates the potential for degradation of the substance to non-PFAS in one matrix, further studies would be needed to allow this possible fate process to be more clearly understood. This would still be of a very limited scope and would not be sufficient to exclude a substance from the class-based approach. Addressing the large number of PFAS using a class-based approach is appropriate given the growing body of scientific evidence suggesting that concerns for health and the environment identified for well-studied PFAS are more broadly applicable to other PFAS, and the expectation that combined exposures to multiple PFAS will increase the likelihood of harmful impacts.

Comment summary 71: Commenters provided new studies on the bioaccumulation potential of PFAS.

Response 71: The information submitted was examined. Additional references that were cited by the commenter were considered and changes were made to the final report, Section 6.1 (*Bioaccumulation*), as appropriate.

Sources and uses

Comment summary 72: Commenters provided information on the use of PFAS in various applications, including:

- high-voltage switchgear
- foam blowing applications
- closed cell spray foam
- · frost protected shallow foundations
- protected membrane insulation
- · some industrial mining processes/functions
- marine, industrial machinery, food production
- · organic pigments and dyes
- production of green hydrogen, electric vehicle batteries, and solar panels
- lithium-ion battery technology

Some commenters indicated that there are no technically or economically feasible alternatives.

Response 72: This information has been noted and will be considered during the development of any risk management actions in relation to these uses and sectors.

Comment summary 73: A commenter stated that the Updated Draft State of PFAS Report places undue focus and bias on the land application of biosolids as a potential pathway of PFAS exposure, when there are various sources of exposure.

Response 73: The State of PFAS Report acknowledges that there are multiple pathways for PFAS release and exposure. Section 2 (*Uses and sources of exposure*) of the State of PFAS Report summarizes numerous uses, sources and pathways of exposure, including sites contaminated with aqueous film-forming foam, drinking water, indoor air and dust, food, and waste/end of life product management including wastewater treatment systems and biosolids. As mentioned by the commenter, given public interest and media attention, biosolids and their potential as a pathway of PFAS to the environment needs to be identified in this report. However, it is recognized that biosolids are a pathway of release and not a source of PFAS, as PFAS are present in the influent received by wastewater treatment systems.

Comment summary 74: A commenter stated that their company monitors and controls PFAS emissions in their manufacturing processes and takes responsibility for minimizing any potential impact on the environment. In addition, only highly trained personnel, who follow defined operating procedures, have access to critical parts and specific equipment.

Response 74: This information will be taken into consideration for any future risk management activities.

Comment summary 75: A commenter suggested that fluoropolymers in food contact materials remain a route of hazard and exposure and cited a study examining the presence of PFAS in food contact materials. The commenter suggests that fluoropolymers should be a regulatory priority for phase out.

Response 75: The information submitted was examined. As identified in the Risk Management Approach, PFAS used in food packaging materials, food additives, and non-industrial food contact products are being proposed as a priority for the second phase of prohibition of the class of PFAS, excluding fluoropolymers. Fluoropolymers are planned for consideration in a separate assessment and information related to fluoropolymers will be considered in this future assessment. The exclusion of fluoropolymers from the State of PFAS Report should not be interpreted as meaning they are or are not of concern.

Comment summary 76: A commenter noted that the use of hydrofluorocarbons (HFCs) as a medical propellant in metered dose inhalers to treat respiratory diseases may cause additional negative health impacts and that urgent attention should be given to finding and implementing use of a safe propellant.

Response 76: Substances used in metered dose inhalers, undergo a thorough assessment prior to their approval for use in Canada. This process includes an assessment of any negative health effects that may result directly or indirectly from the use of the product. Marketed metered dose inhalers using HFCs have been found to be acceptable from a human health perspective.

Comment summary 77: A commenter noted that the Executive Summary of the Updated Draft State of PFAS Report failed to identify firefighter turnout gear (PPE) as a source of PFAS exposure to firefighters (as it does with AFFF).

Response 77: A published study in Section 2.1 (*Uses of PFAS*) of the State of PFAS Report identified more than 200 current uses of PFAS. The State of PFAS Report included a list of major PFAS uses, such as textiles and clothing. An additional reference for PFAS releases from firefighter protective clothing was added to Section 5.6 (*Occupational HBM data – Firefighters*) of the final report. Furthermore, as indicated in the Risk Management Approach, PFAS in textile uses, including personal protective equipment such as firefighter turnout gear, are being proposed as a priority for the second phase of prohibition of the class of PFAS (excluding fluoropolymers).

Comment summary 78: Commenters indicated that PFAS play vital roles in several applications of the transportation sector, with no viable alternatives. They requested that a number of specific applications, such as lithium-ion batteries, electric vehicles, hydrogen-based energy, vehicle electrical and electronic systems, and vehicle systems seals, hoses, and lubricants, be exempt from PFAS restrictions.

Another commenter noted that although there are many parts within a vehicle, the maximum amount of all PFAS within a vehicle is less than 0.1% by weight.

Response 78: Noted. This information will be taken into consideration for any future risk management activities. Owing to their properties, PFAS have a wide range of uses in products available to consumers, industrial applications, and other specialized applications, including certain firefighting foams, food packaging materials, drugs (including natural health products and non-prescription drugs), medical devices, cosmetics, pesticides, textiles, vehicles, and electronics. Information gathered through the various stages of consultation will help inform any risk management options to be developed. Risk management is proposed through a phased approach and will take into consideration factors, such as the costs and the benefits, the availability of suitable alternatives and socio-economic considerations.

Comment summary 79: Commenters recommended that the State of PFAS Report address the use of PFAS in pesticides. They also noted that PFAS are intentionally added to some pesticides, but that it is difficult to determine the pesticide products that contain PFAS. They recommended that pesticides with PFAS be addressed under the *Pest Control Products Act* (PCPA) and Regulations (PCPR).

Response 79: Pesticides were identified in the Updated Draft State of PFAS Report in the list of products that may be a source of exposure to PFAS. This has not changed in the State of PFAS Report.

Pest control products are regulated in Canada under the *Pest Control Products Act* and Regulations and undergo a rigorous health and environmental assessment prior to being registered for sale and use in Canada.

Collaboration and coordination with other government branches and departments will take place during future risk management development to ensure effective, coordinated, and consistent risk management decision-making. Future PFAS regulations under CEPA are meant to be complementary with existing Acts and regulations in order to avoid duplication or conflict.

Comment summary 80: Commenters recommended that the scope of the State of PFAS Report be broadened to include uses that were not captured in the updated draft report to ensure that there is a balanced portrayal of all industries and have specifically highlighted the mining and pulp and paper industries.

Response 80: The State of PFAS Report provides an overview of the sources, fate, occurrence, and potential impacts of PFAS on the environment and human health. It does not purport to capture every potential source of PFAS. Section 2.1 (*Uses*) of the State of PFAS Report acknowledges that "PFAS are used in many industrial sectors". Mining is an industrial sector that may use PFAS; however, information on the significance of this PFAS use relative to other sectors is limited. There are gaps in the currently available information on industrial uses of PFAS in Canada. The results from the <u>section 71 mandatory information gathering notice</u> will be helpful in providing additional information on Canadian industrial uses of PFAS.

Comment summary 81: A commenter stated that the vast majority of PFAS used in textiles fall within the category of fluoropolymers and given that the Government acknowledges that fluoropolymers have different exposure and hazard profiles when compared to other PFAS, it is interpreted that these substances may be less of a concern. The commenter also stated that nothing in the report suggests that the hazards associated with PFAS in textiles are excessive or problematic.

Response 81: PFAS meeting the definition of fluoropolymers are planned for consideration in a separate assessment. Their exclusion from the State of PFAS Report should not be interpreted as meaning that they are or are not of concern.

The report identifies textiles as products potentially containing PFAS and identifies risk management taken by other jurisdictions. The report does not examine single uses or sectors but considers potential for cumulative exposure from an unknown mixture of PFAS from various sources. This information will be taken into consideration for any future risk assessment activities of fluoropolymers and risk management activities.

Comment summary 82: A commenter noted that the Government of Canada intends to continue to monitor PFAS in food through the Total Diet Study (TDS) but also noted that the TDS does not analyze PFAS concentrations in country or traditional food sources. The commenter asked if there will be future consideration of testing of PFAS in country or traditional food sources given their cultural importance and essentiality in mitigating Northern food insecurity.

Response 82: While the Total Diet Study is focused on retail foods, Health Canada also has the capacity to perform targeted surveillance to address specific exposure questions. Specifically, the Department has the expertise to analyze/quantify a variety of PFAS in various foods and is considering the feasibility of expanding this capacity to relevant country or traditional foods.

The Northern Contaminants Program (NCP) supports monitoring and research of contaminants in country or traditional food sources. Further expansion of contaminants monitoring in Nunavik under the NCP will require prioritization of this activity by the program's Management Committee (communicated through the program's annual call for proposals), and will be dependent on available capacity, funding, and submission of proposals that include PFAS monitoring activity in this region.

Comment summary 83: A commenter noted that the report and Risk Management Scope did not consider all the potential sources of PFAS in the agriculture sector, such as fertilizers other than biosolids.

Response 83: Under Section 2.1 (*Uses of PFAS*), the State of PFAS Report mentions that more than 200 uses of PFAS have been identified. While the report aims to present the major uses of PFAS and give a sense of the breadth of use, this section is not meant to be an exhaustive listing that captures all possible uses. While new information on PFAS is being generated rapidly, the literature searches in support of the final report did not reveal fertilizers, other than biosolids, as a significant source of PFAS in the agricultural sector.

Comment summary 84: A commenter stated that fluoropolymers and fluorine gases are among the largest groups of PFAS in terms of production, and that other PFAS, such as PFOS and PFOA are used as fluoropolymer processing aids.

Response 84: PFAS meeting the definition of fluoropolymers are planned for consideration in a separate assessment. Their exclusion from the State of PFAS Report should not be interpreted as meaning that they are or are not of concern. The information provided on fluorine gases will be considered in future stages of risk management.

Comment summary 85: Commenters supported the focus on firefighters in moving ahead with risk management measures and a commenter urged for prohibitions.

Response 85: Noted. As indicated in the Risk Management Approach, the Government of Canada is considering a phased approach.

As a first phase, a regulation under CEPA to prohibit PFAS not currently regulated in firefighting foams. In addition, PFAS in textile uses, including personal protective equipment such as firefighter turnout gear, are being proposed as a priority for the second phase of prohibition of the class of PFAS (excluding fluoropolymers).

There will be additional opportunities for consultation where stakeholders may provide input regarding specific risk management activities. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed.

Consultation

Comment summary 86: Commenters suggested limiting consultation with industry and other jurisdictions to avoid perceived conflicts of interest and undue influence on Canada's decision-making for risk assessment and management of chemicals substances, such as PFAS.

Response 86: The Government conducts scientific research, assesses and manages the risks of chemical substances when they are determined to pose a risk to human health or the environment.

The Government aims to safeguard human health and the environment in a global context while supporting economic growth (sustainable development). Consulting with a wide range of interested and implicated parties including NGOs, academia, Indigenous partners as well as industry, is an important element of the risk assessment and management of chemical substances.

Comment summary 87: A commenter offered to provide ECCC with a demo of their reporting product and to meet to better understand ECCC's future reporting plans to support producers with complying with their environmental compliance and reporting obligations.

Response 87: This information will be considered in future stages of risk management.

Comment summary 88: Commenters had specific questions related to performance measurement and evaluation of the effectiveness of the risk management actions, including how data-poor regions will be taken into account. Another commenter was supportive of the performance measurement framework to ensure that risk management actions for PFAS are effective in achieving their objectives. A commenter was supportive of the performance measurement framework to ensure that risk management actions for PFAS are effective in achieving their objectives.

Response 88: The Government of Canada plans to measure the effectiveness of the risk management actions by collecting and analyzing data such as the presence of 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, to establish a baseline and in the future to evaluate the performance of risk management actions.

In addition, data collected from the recent section 71 notice with a deadline of January 29, 2025, will help determine the current Canadian situation to inform future risk management actions for PFAS. This information may also serve as a baseline for the Government of Canada to be able to evaluate the performance of any future risk management actions for PFAS.

Comment summary 89: Commenters stated that it will be crucial for the Government to work with potentially impacted sectors to ensure risk management does not have unintended consequences, such as impacts on uses that does not represent known exposure pathways.

A commenter suggested that the Government collaborate with industry to avoid regulatory contradictions, especially in sectors such as transportation as it moves towards electrification.

Response 89: As stated in the Risk Management Approach, the Government of Canada is proposing to manage the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, through a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to

PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

There will be additional opportunities for consultation where stakeholders may provide input regarding specific risk management activities. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed.

Potential actions

Comment summary 90: Commenters recognized the need for actions on PFAS to protect public health and the environment. They support the adoption of a balanced, phased, prioritized, and/or science-based approach to regulating PFAS that will reduce the chance of regrettable substitution and reduce future environmental and human exposure. They recommend focusing initial efforts on products containing PFAS that are intentionally added.

Some commenters suggested the need for exemptions for certain PFAS or uses and advocate for incremental and sustainable measures that allow those impacted sufficient time to adapt their operations and identify suitable alternatives.

A commenter stated that risk management actions on products used in manufacturing and production equipment would not have benefits in reducing environmental/human health exposure.

A commenter requested that cost, feasibility and timelines be taken into consideration if restrictions are put in place, because when transitioning to alternatives that are technically feasible, substitutions are generally implemented on a long-term basis.

A commenter also stated that prohibitive costs of replacing the class of PFAS in a small number of parts and the potential for parts to be sourced from jurisdictions where PFAS can still be obtained need to be considered.

A commenter requested that product bans should only be implemented as a last resort, only after other management tools are used.

Response 90: As stated in the Risk Management Approach, actions are being considered for the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report. These risk management actions are being considered through a phased approach starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

There will be additional opportunities for consultation where stakeholders may provide input regarding specific risk management activities. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed.

Comment summary 91: A commenter supports the prohibition of PFAS in products to prevent contamination at the source thus avoiding the need for management and remediation.

Another commenter indicated that regulation-making and prohibition-establishing tools available under CEPA are more comprehensive and impactful to deal with all sources of PFAS instead of using a scoped risk management solution that does little to solve the PFAS problem in the marketplace.

Response 91: Reduction of contaminants at the source is often the most efficient and costeffective way to prevent harmful impacts and remediation costs of pollution and adverse human health.

As stated in the Risk Management Approach, the Government of Canada is planning to manage PFAS in a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

Comment summary 92: Commenters were supportive of strong regulations on the class of PFAS with clear timelines for implementation to protect the environment and human

health. Another commenter mentioned that a phased approach could spur the development of safer alternatives.

Response 92: Noted. As stated in the Risk Management Approach, the Government of Canada is planning to manage PFAS in a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

Comment summary 93: Commenters suggested banning the use of PFAS in nonessential applications with short effective timelines and provided a list of what they believed to be non-essential uses including: cosmetics, food packaging, textiles, children's products, carpets, upholstery, and ski waxes.

Response 93: As indicated in the Risk Management Approach for PFAS, the Government of Canada is considering the following prioritized phased approach: starting with a regulation under CEPA to prohibit PFAS not currently regulated in firefighting foams, and then managing under CEPA other uses and sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

There will be additional opportunities for consultation where stakeholders may provide input regarding specific risk management activities. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed.

Comment summary 94: Commenters were supportive of a regulatory framework that excludes essential uses of PFAS. They provided examples of "essential uses" from other jurisdictions and recommended consultations be held to define essential uses in the Canadian context. They felt that any alternatives would need to be better than the restricted product in terms of safety, quality, performance, durability, reliability requirements, and environmental effects as demonstrated by comparative cost-benefit analyses.

Response 94: As indicated in the Risk Management Approach for PFAS, the Government of Canada is considering the following prioritized phased approach: starting with a regulation under CEPA to prohibit PFAS not currently regulated in firefighting foams, then managing under CEPA other uses and sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

Any risk management actions will consider all information available, including data collected via the <u>section 71 notice for PFAS</u>.

There will be additional opportunities for consultation where stakeholders may provide input regarding specific risk management activities. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed.

Comment summary 95: A commenter recommended that the Government of Canada delay implementation of the risk management activities on PFAS until information from the recent mandatory notice under section 71 of CEPA is fully analyzed to develop informed regulations.

Response 95: Any risk management actions will consider all information available, including data collected via the section 71 notice for PFAS.

Comment summary 96: A commenter requested that the delay in the publication of the mandatory notice under section 71 of CEPA does not delay implementation of the risk management activities on PFAS. The commenter stated that the regulatory instruments do not require the characterization of PFAS in the marketplace to proceed.

Response 96: Gathering data is essential to inform the development of relevant and efficient risk management actions prior to their implementation. As part of its proposed actions to address the class of PFAS, the Government of Canada is gathering key information on certain PFAS from various sources. This includes information on use quantities and types, import, manufacture including for mixtures, products and manufactured items containing these substances through a mandatory section 71 notice under CEPA. The purpose of the survey is to help inform the development of risk management actions for PFAS, by collecting information on certain PFAS considered likely to be in Canadian commerce, as well as for a separate assessment that is planned for PFAS meeting the definition of fluoropolymers.

Comment summary 97: A commenter recommended that risk management tools be implemented only for individual PFAS, in the context in which they are used and released. The commenter added that these tools be implemented only for those with well-established analytical methods.

Response 97: As stated in the Risk Management Approach, actions are being considered for the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report. These risk management actions are being considered through a phased approach starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

Comment summary 98: A commenter stated that limiting the Revised Risk Management Scope to high exposures to firefighting foams ignores other widespread PFAS sources that can pose a risk to humans and the environment.

Response 98: Firefighting foams have been identified as the first use to be addressed due to their high potential for environmental and human exposure. As stated in the Risk Management Approach, other uses and sectors will be managed in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

Comment summary 99: A commenter asked for clarification on what types of risk management may be undertaken, whether there would be the opportunity for public consultation on this risk management document, and how risk management will adopt changes to CEPA under Bill S-5.

Response 99: The Risk Management Approach outlines the proposed risk management actions under consideration for the management of PFAS through a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then prioritizing other uses and sectors in relation to PFAS to those based on factors such as socio-economic considerations and the availability of feasible alternatives. The Risk Management Approach is published for a 60-day public comment period. Additional formal and informal opportunities for stakeholder and interested party engagement will also be provided during the subsequent development of specific risk management actions.

Proposed risk management actions take into account the amendments to CEPA under Bill S-5.

Comment summary 100: Commenters suggested that PFAS regulations should be coordinated across federal branches and departments to prevent setbacks in their own economic, environmental, and social objectives as a result of potential supply chain disruptions.

Response 100: Collaboration and coordination with other government branches and departments will take place during future risk management development to help ensure effective, coordinated, and consistent risk management decision-making. Future PFAS regulations are meant to be complementary with existing Acts and regulations in order to avoid duplication or conflict.

Comment summary 101: Commenters stated that consideration should be given in the planned regulations to exemptions for the incidental presence of PFAS, including the use of *de minimis* concentration thresholds. They recommended that these thresholds be applicable at the manufacturer level and not to retailers. A commenter stated that there remain significant unknowns regarding unintentionally added PFAS in products, including in recycled material, and it would be challenging to determine the appropriate thresholds.

Response 101: Any regulatory measures that prohibit PFAS will take into consideration the availability of suitable alternatives, including the costs and benefits of switching to those alternatives. Information gathering to fully understand the availability of alternatives and the costs of transitioning to alternatives will also take place before certain risk management actions are taken. Consideration would also be given to whether certain concentration thresholds, and/or exemptions for incidental presence may be needed in any risk management instruments for PFAS.

Comment summary 102: Commentors suggested that future regulations of PFAS must account for conditions of use in Canada and emissions related to those conditions of use as the foundation for a risk-based approach.

Response 102: The Government of Canada is gathering information to better understand patterns of use and release of PFAS in Canada. This information will be taken into account in the development of future risk management.

Comment summary 103: Commenters analyzed the timelines of the Government of Canada activities on PFAS and concluded that the controls promised on more PFAS could be in place by 2030. They stated that this is too slow considering the problems posed by these chemicals and the 2021 announcement to address the class.

Response 103: The Government of Canada understands that people in Canada may be concerned with the potential impacts of PFAS on the environment and their health and is considering the information gathered through the various stages of consultation in determining the most effective and feasible timelines for taking action on PFAS as outlined in the Risk Management Approach.

As stated in the Risk Management Approach, the Government of Canada is proposing to manage PFAS through a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

Voluntary risk management actions between the Government and industry sectors with common goals to address PFAS are also being considered to achieve early results as a complement to the proposed regulatory instruments.

Comment summary 104: A commenter supported the use of a finite list of reportable PFAS in the section 71 notice and suggested this approach be employed for future risk management actions. The commenter cited the additional complexities and the higher costs of implementing requirements when dealing with suppliers for substances defined based on their structures, particularly for substances that are confidential or trade secrets.

Response 104: The State of PFAS Report defines PFAS using the OECD (2021) definition of PFAS, which uses chemical structure rather than individual identifiers such as CAS RNs. As generally done in the risk management of class-based approaches, non-exhaustive lists of CAS RNs are provided to assist companies with their regulatory compliance and to facilitate communication within the supply chain.

Comment summary 105: A commenter requested that the impacts in terms of safety performance and durability of PFAS alternatives should be considered as part of the risk management decisions. Another commenter stated that the Revised Risk Management Scope continues to underestimate the time and cost of identifying suitable alternatives and releasing them on the market.

A commenter recommended adopting collaborative approaches to managing chemical alternatives and substitutions, on an individual substance basis, in collaboration with industry to ensure economic aspects and potential future concerns are considered. The commenter cited additional challenges with identifying suitable alternatives for a class of substances in comparison to individual substances.

Response 105: As stated in the Risk Management Approach, 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. The Risk Management Approach is subject to a 60-day public comment period and there will be additional opportunities for consultation on future risk management actions. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed.

Comment summary 106: A commenter recommended addressing current regulatory gaps and completely prohibit PFOA use in manufactured items under the *Prohibition of Certain Toxic Substances Regulations*, 2012.

Response 106: "In Canada, the *Prohibition of Certain Toxic Substances Regulations, 2012* prohibiting manufacture, use, sale and import of the perfluorooctanoic acid, which has the molecular formula C₇F₁₅CO₂H, its salts and precursors (PFOA), with some 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 final Regulations are anticipated for publication in Spring 2025.

Comment summary 107: A commenter urged the Government of Canada to act swiftly in restricting PFAS in water, air, food, and other consumer and health products and to enhance its support for municipalities through targeted funding, practical implementation timelines, and harmonized regulations.

Response 107: HC plays a leadership role in science and research on drinking water and has established an objective of 30 ng/L for a sum of 25 specific PFAS. HC recognizes the challenges of implementing the drinking water objective for PFAS and will continue to work closely with provinces, territories and other government departments to provide health guidance, advice on testing protocols and water treatment strategies moving forward.

As stated in the Risk Management Approach, actions are being considered for the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report. These risk management actions are being proposed through a phased approach starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives. All information provided about the uses of PFAS, and their alternatives (or lack of) will be considered during the development of future risk management.

At this time, no federal government funding is allocated to support municipalities with PFAS-specific initiatives.

Comment summary 108: A commenter requested that legacy clauses be included in future risk management actions on PFAS to allow industry time to deplete current inventory.

Response 108: This information will be considered in the future steps of risk management development. Information gathered through the various stages of consultation would help inform the risk management actions to be developed.

Comment summary 109: A commenter stated that Canadian provinces should avoid implementing stricter PFAS requirements.

Response 109: Provinces and territories are consulted about proposed activities under CEPA. However, the Government of Canada does not dictate what actions and measures provinces and territories see fit to take within their jurisdictions.

Comment summary 110: Commenters provided information about their industry's contribution to the Canadian economy and how restrictions on PFAS could cause potential supply chain disruptions and economic impact.

Response 110: Noted. This information will be taken into consideration for any future risk management activities.

Comment summary 111: Commenters urged that the various levels of government work together to ensure regulatory efficiency in risk management decisions.

Response 111: Noted. This information will be taken into consideration for any future risk management activities.

Socio-economic factors and international alignment

Comment summary 112: Commenters recommended that a thorough cost benefit analysis be carried out when considering the prohibition of PFAS uses. Factors identified for consideration included critical uses of PFAS, costs to industry, the consumer and the public sector as well as costs borne by society and the environment. A commenter shared their analysis and modelling of the potential costs attributable to various drinking water treatment levels and compared them to their benefits.

Response 112: Any federal regulatory measure is subject to a cost and benefit analysis. The availability of suitable alternatives and other socio-economic considerations are also considered when developing risk management measures. These considerations are elaborated in the Regulatory Impact Analysis Statement published for public comment with the proposed measure, in application of the Cabinet Directive on Regulation.

Comment summary 113: A commenter requested that any future proposed measures on PFAS be notified to the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Committee with a comment period of at least 60 days to take WTO stakeholder comments into consideration in the development of any final measures.

Response 113: As a signatory of certain international trade agreements, Canada complies with international law it is a signatory to, including with notification of proposed regulations where there is a requirement to do. These publications are open for a public comment period of 75 days.

Comment summary 114: A commenter recommended that socio-economic factors related to extending product lifetimes, ensuring safety, and improving energy efficiency should be considered as part of the risk management approach for certain PFAS.

Response 114: There will be additional opportunities for consultation where stakeholders may provide input regarding specific risk management activities. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed. Risk management is proposed through a phased approach and will take into consideration factors, such as the costs and the benefits, the availability of feasible alternatives and other socio-economic considerations.

Comment summary 115: Commenters requested that an economic analysis should also consider any potential trade barriers that could emerge and the potential impacts to Canada's competitiveness, critical infrastructures and security.

Commenters stated that addition of the class of PFAS to Schedule 1 could be problematic for different aspects of the Canadian economy, such as trade flow. They also assert that the potential economic impact of a proposed Schedule 1 listing should be estimated, and potentially affected stakeholders should have an opportunity to comment.

A commenter stated that risk management measures on PFAS will reduce the number of manufacturing jobs. The commenter also stated that insurance companies may refuse to insure manufacturing facilities and businesses selling products containing PFAS due to potential liabilities.

Response 115: The addition of substances to Schedule 1 does not in and of itself restrict or prohibit the substances; rather, it enables risk management instruments to be developed, such as regulations under CEPA.

Any regulatory measure that prohibits PFAS will take into consideration factors, such as information on the costs and the benefits, the availability of feasible alternatives and socioeconomic considerations. The analysis of these considerations is summarized in the Regulatory Impact Analysis Statement that is published with the proposed regulations. In addition, stakeholders are always consulted at every stage of the process prior to the publication of the proposed regulations.

Comment summary 116: Commenters provided further information on activities on PFAS in other jurisdictions and made recommendations for Canada to align its actions with actions taken in other jurisdictions to mitigate potential trade disruptions in their sectors, including:

- leveraging various existing forums to coordinate efforts, like the Canada-US Regulatory Cooperation Council (RCC) and USMCA Free Trade Commission
- aligning with the EPA's regulations pursuant to the American Innovation and Manufacturing (AIM) Act and the Significant New Alternatives Policy (SNAP) Program
- using a comparable approach to regulations as the US by PFAS that have demonstrated persistence, bioaccumulation potential, and toxicity

Response 116: As stated in the Risk Management Approach, actions taken in other jurisdictions, including the US, are being taken into consideration in the development of risk management for PFAS in Canada, with the possibility of aligning, where appropriate, given different regulatory contexts and authorities. Existing forums for consultation will be leveraged where possible. Note that some existing programs in the US and Canada share similar goals, for example, the Significant New Activity provisions in Canada and the US EPA SNUR program and the Chemicals of Mutual Concerns under the Great Lakes Water Quality Accord.

Comment summary 117: A commenter stated that companies will only be able to prevent obsolescence and support the right-to-repair and repairability initiatives by continuing to be readily given continued access to functional product components or parts that contain PFAS.

Response 117: The risk management of PFAS will take into consideration socio-economic factors and the availability of feasible alternatives while aiming to reduce PFAS over time to achieve the lowest levels of environmental and human exposure that are technically feasible.

Comment summary 118: Commenters noted that adopting the definition of PFAS used by the US EPA for its TSCA Reporting and Recordkeeping requirements for PFAS would reduce regulatory burden and promote cooperation with the US. An example was given of paint pigments that would be considered to be PFAS in Canada, but not by the US EPA.

Response 118: There is no universally accepted definition of PFAS across jurisdictions. The Government of Canada uses the OECD 2021 PFAS definition, which is comprehensive and was developed through a broad community of regulatory authorities and experts. The OECD 2021 PFAS definition is similar to that used by the EU as well as some US States.

The Government of Canada is taking into consideration actions by other jurisdictions, including measures taken in the US. Alignment will be considered where appropriate, taking the Canadian context into consideration.

Comment summary 119: Commenters from various sectors provided information on the challenges of replacing PFAS-containing firefighting foams with alternatives for emergency uses in specific high hazard applications. Some commenters are concerned that the performance of current fluorine free foam (F3) alternatives is inferior to AFFF and that AFFF remain critical to maintain adequate emergency response readiness and minimize the risk of any catastrophic fires from occurring. Some commenters also recommended that transitional periods and permitting frameworks be considered as part of the phase out of these foams.

Response 119: All information submitted will be considered when developing a regulation under CEPA to prohibit PFAS not currently regulated in firefighting foams. Any regulatory measure that prohibits PFAS would take into consideration factors such as the costs and the benefits, the availability of feasible alternatives and other socio-economic considerations. The analysis of these considerations is summarized in the Regulatory Impact Analysis Statement that is published with any proposed regulations. In addition, stakeholders are always consulted

at every stage of the process prior to the publication of the proposed regulations. The Government of Canada will notify implicated stakeholders of future consultation opportunities.

Comment summary 120: A commenter indicated that imposing a phase out of PFAS-containing firefighting foams and requiring their disposal could place some Canadian industries at a competitive disadvantage. They requested that consideration should be given to compensating these industries for any costs with this phase out.

Response 120: All information submitted will be considered when developing a regulation under CEPA to prohibit PFAS not currently regulated in firefighting foams. Any regulatory measure that prohibits PFAS would take into consideration factors, such as the costs and the benefits, the availability of feasible alternatives and socio-economic factors. There will be additional opportunities for consultation on future risk management actions. The Government of Canada will notify implicated stakeholders of future consultation opportunities.

Comment summary 121: A commenter recommended that instead of a regulatory instrument, an Act of Parliament should be put in place to minimize the risk associated with the continued use of the PFAS-containing foams during emergencies only.

Response 121: An Act of Parliament is not required to put in place controls for substances if they are found to be toxic to the environment or human health under section 64 and listed to Schedule 1 of CEPA. Regulations can be made under CEPA to put in place prohibitions or restrictions for toxic substances, such as PFAS, excluding fluoropolymers, once listed to Schedule 1.

Adding PFAS, excluding fluoropolymers, to Schedule 1 to CEPA and developing a regulation for PFAS not currently regulated in firefighting foams under that authority is the proposed approach.

There will be additional opportunities for consultation on future risk management actions. The Government of Canada will notify implicated stakeholders of future consultation opportunities.

Comment summary 122: Commenters expressed their support for the development of a regulatory instrument that would prohibit all remaining PFAS from use in firefighting foam. Commenters indicated the broad availability of effective alternatives, some of which are already in use at major international airports around the globe as well as industrial and petrochemical facilities and storage installations. A commentator indicated that these foams should not be considered essential, including for the protection of facilities at high risk of large-volume fuel fires.

Response 122: Noted. All information submitted will be considered when developing a regulation under CEPA to prohibit PFAS not currently regulated in firefighting foams. There will be additional opportunities for consultation on future risk management actions. The Government of Canada will notify implicated stakeholders of future consultation opportunities.

Comment summary 123: A commenter indicated that a US State elected to purchase back old-fluorinated firefighting foams as a means to prevent their release into the environment.

Response 123: Noted. The Government of Canada is taking into consideration actions by other jurisdictions, including measures taken in the US at both the federal and State level. Alignment will be considered where appropriate, while taking into consideration the Canadian context.

Comment summary 124: A commenter shared their concerns that changes to exemptions for PFOA and LC-PFCAs under the proposed *Prohibition of Certain Toxic Substances Regulations 2022* would prevent the use of C6 AFFF.

Response 124: The proposed *Prohibition of Certain Toxic Substances Regulations, 2022* proposed to set quantitative concentration thresholds of 1 ppm for the incidental presence of PFOA and LC-PFCAs (including their salts and precursors) in firefighting foams and to lower the current one for PFOS from 10 ppm to 1 ppm (including their salts and precursors). Comments and information that were received indicated that trace levels of PFOS, PFOA and/or LC-PFCAs

may be present above 1 ppm in certain fire-fighting foams as impurities in other PFAS (for example, those used in C6 AFFF) and/or as remaining contaminants from firefighting equipment where these substances were historically used. This information is being taken into consideration in the development of the final Regulations.

Comment summary 125: A commenter requested a phase-out period for C8 AFFF of 2 years under the final *Prohibition of Certain Toxic Substances Regulations* to allow adequate time to transition to alternatives of these foams.

Response 125: The time-limited exemptions proposed under the proposed *Prohibition of Certain Toxic Substances Regulations, 2022* for C8 AFFF put Canada, over time, in a position to ratify the PFOA listing under the Stockholm Convention on Persistent Organic Pollutants (POP). Comments and information that were received in response to the proposed Regulations are being taken into consideration in the development of the final Regulations.

Comment summary 126: A commenter was pleased that the intent of the government is to restrict the use of firefighting foams; however, the options proposed seem unrealistic to achieve the environmental and human health objectives without a complete ban on the import, manufacture, distribution, and sale of PFAS-containing fire-suppressing foam products.

Response 126: As stated in the Risk Management Approach, any regulatory measure that prohibits PFAS, including in firefighting foams, will take into consideration factors, such as the costs and the benefits, the availability of feasible alternatives and socio-economic considerations.

Comment summary 127: A commenter stated that if the OECD PFAS definition is adopted, which encompasses HFOs, Canada will essentially restrict the closed cell spray foam market.

Response 127: The addition of substances to Schedule 1 does not in and of itself restrict or prohibit the substances; rather, it enables risk management instruments, such as regulations, to be developed under CEPA.

Any regulatory measure that prohibits PFAS will take into consideration factors, such as the costs and the benefits, the availability of feasible alternatives and other socio-economic considerations.

Comment summary 128: Commenters indicated that their products may contain fluorinated gases, such as HFOs, for critical applications and have no feasible alternatives. Commenters are concerned that the State of PFAS Report conclusion could eventually lead to a ban on HFOs and HCFOs, which are critical for use across many industrial sectors including closed cell spray foam market. A commenter said that HFOs and HCFOs are the only viable substitute in certain applications due to low flammability potential and other safety and health concerns. A commenter stated that regulating HFOs and HCFOs will negatively impact their sector as well as the Canadian economy.

Another commenter suggested that risk management actions should focus on large sources of PFAS, such as those used in agrochemicals, rather than implicating HCFOs and HFOs.

Response 128: Any regulatory measures that prohibit PFAS will take into consideration factors, such as the availability of feasible alternatives, including the costs and benefits of switching to those alternatives. The addition of substances to Schedule 1 does not in and of itself restrict or prohibit the substances; rather, it enables risk management instruments, such as regulations, to be developed under CEPA. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed.

As stated in the Risk Management Approach, any regulatory measure that prohibits PFAS will take into consideration factors such as the costs and the benefits, the availability of feasible alternatives and socio-economic considerations.

Comment summary 129: Commenters recommended to align new PFAS regulations with previous environmental protection initiatives, such as those on HFCs, by avoiding restrictions on alternatives like HFOs and HCFOs, which were developed in response to earlier regulations. They stated that this approach will safeguard existing investments and progress made in terms of efficiency and safety, as well as continue to support climate and environmental commitments.

A commenter requested that HFOs and HCFOs should be regulated under the ODSHAR to avoid conflicting requirements.

In addition, some commenters stated any additional controls on HFCs are unnecessary, beyond, or in parallel of current ODSHAR regulations and in alignment with the US American Innovation and Manufacturing (AIM) Act. A commenter indicated that HFCs are already managed via Refrigerant Management Canada (RMC), which focuses on recovery and emission reductions of refrigerant gases and could be expanded to HFOs and HCFOs.

Response 129: As stated in the Risk Management Approach, any risk management actions on PFAS will be developed in alignment with, and complementary to, existing regulations, such as the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* (ODSHAR), the Pollution Prevention (P2) Planning Notice for Halocarbons, and other commitments such as the climate goals. During the selection of the risk management instrument(s), existing regulations and alignment with other jurisdictions will be taken into account, when possible.

As stated in the Risk Management Approach, the selection and development of future risk management instrument(s) will take into account the existing regulations and alignment with other jurisdictions, when goals and timelines converge.

Comment summary 130: A commenter suggested that the Revised Risk Management Scope for PFAS should include prohibiting the use of F-gases as it would be a regrettable substitution for ozone-depleting substances. They state that regulatory emphasis on the transition to safer PFAS-free alternatives for refrigeration and blowing agents is needed and would implement climate solutions.

Response 130: Fluorinated gases that meet the definition of PFAS are in the scope of the Risk Management Approach. Any regulatory measure that prohibits PFAS will take into consideration factors, such as the costs and the benefits, the availability of feasible alternatives and socioeconomic considerations.

Comment summary 131: A commenter indicated that the US EPA has deemed HFOs and HCFO blowing agents as "acceptable" replacements for HFC blowing agents under the Significant New Alternatives Policy (SNAP) program. They noted that the US EPA determined that HFO foam blowing agents "reduce overall risk to human health and the environment compared to other substitutes for the particular end-use." The commenter added that the US EPA SNAP aligns with both the Montreal Protocol on ozone depleting compounds and the US AIM Act on HFCs.

Response 131: As stated in the Risk Management Approach, the selection and development of future risk management instrument(s) will take into account the existing regulations and alignment with other jurisdictions, when goals and timelines converge.

The government acknowledges the US EPA SNAP review of HFOs and HCFOs and will consider information when developing relevant risk management. Section 8 (*Domestic and international actions on PFAS*) of the State of PFAS Report has been updated to include information on the US SNAP and the assessment of HFOs as an alternative to HFCs for certain uses.

Comment summary 132: Commenters indicated that natural refrigerants, such as carbon dioxide (R744), ammonia (R717), propane (R290) and isobutane (R600a), are viable alternatives to PFAS refrigerants, while offering excellent performance and having low global warming potential.

Another commenter noted the drawbacks of using carbon dioxide and propane as alternatives to PFAS refrigerants. They added that carbon dioxide does not meet the cooling requirements in warmer climates and cannot yet be used in systems driven mechanically by compressors. Moreover, propane is associated with flammability concerns. They stated that the global warming potential of alternatives needs to be considered in determining the viability of alternatives.

A commenter specifically called for Canada to restrict PFAS refrigerants in mobile air conditioners.

Response 132: This type of information is useful to inform the development of future risk management and to fully understand the availability of feasible alternatives and the costs of transitioning to alternatives.

Comment summary 133: A commenter stated that alternatives to PFAS blowing agents present negative characteristics that would make them very difficult to use, such as pentane which is highly flammable and cannot be processed with standard equipment. They added that removing HFOs from spray polyurethane foam will result in reducing the thermal properties of the foam, which would ultimately reduce the insulation properties of Canadian buildings.

Response 133: This type of information is useful and participation of the commenters and other stakeholders in future consultations to inform the development of future risk management will be welcomed.

Comment summary 134: A commenter recommended to avoid a separate regulation for refrigerants that are currently subject to the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* (ODSHAR). A commenter requested to have more information ahead of any regulatory action regarding how HFOs and HFO containing blends might be regulated complementary to existing regulations, such as the ODSHAR.

Response 134: As stated in the Risk Management Approach, any risk management actions on PFAS will be developed in alignment with, and complementary to, existing regulations, such as the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* (ODSHAR) and other commitments such as the Climate goals.

Information gathering to fully understand the availability of alternatives and the costs of transitioning to alternatives would also take place before risk management actions are taken.

Comment summary 135: A commenter expressed support for adding HFOs to the ODSHAR and the P2 plan but recommended requiring all imports (HFOs and HFCs) to be part of the industry program run by Heating, Refrigeration and Air Conditioning Institute of Canada (HRAI) called Refrigerant Management Canada (RMC). They stated that regulating under ODSHAR and P2 would reduce releases of HFOs by ensuring that HFOs are offered for sale in refillable packages to prevent venting of heels and HFOs have a pollution prevention plan in place.

Response 135: As stated in the Risk Management Approach, the selection and development of future risk management instrument(s) will take into account the existing regulations, such as the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* (ODSHAR) or the *Pollution Prevention (P2) Planning Notice for Halocarbons*, and alignment with other jurisdictions, when goals and timelines converge.

Future potential risk management of PFAS will follow the standard process to manage risks which includes several factors such as socio-economic considerations and the availability of

feasible alternatives. Participation of the commenters and other stakeholders in future consultations to inform the development of future risk management will be welcomed.

Comment summary 136: Commenters stated that the US EPA has excluded most HFCs and HFOs from their PFAS definition and decided that they be dealt with in the context of climate change and air quality policies. A commenter suggested that Canada should follow the US EPA's approach.

Response 136: As stated in the Risk Management Approach, the selection and development of future risk management instrument(s) will take into account the existing regulations and alignment with other jurisdictions, when goals and timelines converge.

Future potential risk management of PFAS will follow the standard process to manage risks which includes several factors such as socio-economic considerations and the availability of feasible alternatives.

Comment summary 137: Commenters recommended that ECCC and HC articulate the priority products for PFAS phaseouts in the Risk Management Scope and move forward with regulatory measures to reduce the growing risks of the PFAS class to the environment and human health, including vulnerable populations.

A commenter stated that the Risk Management Approach must clearly demonstrate how the Government will protect the right of every individual in Canada to a healthy environment and that this duty compels action without delay.

Response 137: The Risk Management Approach describes the proposed risk management options for the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, through a phased approach.

As a first phase, due to their high potential for environmental and human exposure, a regulation under CEPA to prohibit PFAS not currently regulated in firefighting foams will be developed. Other uses or sectors in relation to PFAS will be risk managed in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives.

The Risk Management Approach is subject to a 60-day public comment period and there will be additional opportunities for consultation on future risk management actions. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed.

Comment summary 138: A commenter requested that PFAS processing aids and monomers used in the manufacture of fluoropolymers be excluded from Schedule 1, given the lack of currently available alternatives and the potential impact this may have on medical devices. They also requested that medical devices, pharmaceuticals, and in vitro diagnostic products be exempt from PFAS prohibition and cited examples of other jurisdictions considering such exemptions.

Response 138: Processing aids and monomers that are used in the manufacture of fluoropolymers and which meet the definition of PFAS, excluding fluoropolymers, are within the scope of report and the proposed Schedule 1 listing.

As indicated in the Risk Management Approach for PFAS, prioritization for prohibition of uses of concern may be based on factors such as socio-economic considerations, and the availability of feasible alternatives. There will be additional opportunities for consultation on the proposed risk management actions.

The Government of Canada also considers actions taken in other jurisdictions (for example, the US and Europe) and is closely following international developments to help inform the risk management approach for addressing the class of PFAS. The Risk Management Approach outlines that alignment with other jurisdictions will be considered, where appropriate, to avoid trade barriers for Canadian companies and disruption to the supply chain.

The Risk Management Approach is subject to a 60-day public comment period and there will be additional opportunities for consultation on future risk management actions. Information gathered through the various stages of consultation (including the information already submitted) will help inform the risk management actions to be developed.

Comment summary 139: A commenter indicated that regulated product types must be clearly defined. They recommend that the Government consider ways to assist industry stakeholders in identifying them and when they are prohibited for sale by using existing product classifications, when possible.

Another commenter stated that the reporting of products containing PFAS is expected to create confusion and administrative burdens to their struggling industry.

Response 139: The Risk Management Approach outlines the prioritized phased approach to risk manage the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report. The Risk Management Approach strives to clearly identify the product types to be regulated using existing product classifications and definitions when possible.

Note that stakeholder participation is essential to obtain accurate and precise information, such as submissions in response to section 71 notices and public comments received during consultations. Stakeholder input is key to the development of clearly defined risk management regulations.

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.

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 <u>Cabinet Directive on Regulation</u>.

Comment summary 140: A commenter stated that PFAS are used in many parts, that it would be impossible to manufacture key complex articles without them and requested that the use of PFAS be exempted indefinitely.

Response 140: The Government of Canada is committed to preventing pollution in order to protect the environment and human health. In cases where harmful releases cannot efficiently be prevented by users, regulatory measures have to be taken with consideration given to socioeconomic factors and feasibility of alternatives.

Comment summary 141: A commenter pointed out that when a PFAS product is considered for removal from the market, the potential benefit must be balanced with the consequences of higher risks and overall environmental impact.

Response 141: Listing a substance on Schedule 1 of CEPA means that, pursuant to subsection 90(1) of CEPA, the Governor in Council is satisfied that the substance is a toxic substance. The substance generally requires implementation of risk management actions in order to help prevent and control risks and protect human health and the environment throughout its lifecycle which includes the manufacture, importation, sale, use and disposal of the substance and products containing it. The proposed risk management objective outlined in the Risk Management Approach, is to, over time, achieve the lowest levels of environmental and human exposure that are technically feasible, taking into consideration socio-economic factors. Stakeholder input is key to the development of clearly defined risk management regulations that appropriately weigh the pros and cons.

Comment summary 142: A commenter requested that any regulatory changes do not adversely impact the availability of products to Canadian consumers, particularly where products can be purchased online.

Response 142: The Government of Canada is committed to preventing pollution in order to protect the environment and human health.

As stated in the Risk Management Approach, socio-economic considerations, including sectors specificity, and the availability of feasible alternatives will be taken in consideration during the development of the phased approach for risk management of PFAS.

Comment summary 143: A commenter suggested to specify a due diligence standard in any actions taken with respect to PFAS in manufactured items, which would allow complying entities to rely on supplier declarations and limit the scope of due diligence that manufacturers would be expected to undertake with suppliers. They suggest that the Government use a reporting standard such as the "known to or reasonably ascertainable by" (KRA) standard from the US EPA.

Response 143: This information will be considered in future phases of risk management.

Comment summary 144: A commenter requested an exemption for spare parts and used products from the scope of any future PFAS restriction. They note that an exclusion for spare parts would implement the "repair as produced" principle that is commonly incorporated into material restrictions, including under RoHS and REACH.

Response 144: This information will be considered during the subsequent phases of risk management.

Comment summary 145: A commenter asked if there will be opportunities to comment on the prioritization process as risk management is developed to prohibit various uses or sectors. The commenter cited experience in which "data-poor" regions, such as the Arctic, had approaches applied from "data-rich" regions that did not work well for their context and realities.

Response 145: Interested parties are invited to participate and provide information pertaining to their reality during the public comment period for the Risk Management Approach.

Additional opportunities for interested party engagement will also be provided during the subsequent development of specific risk management actions.

Comment summary 146: A commenter recommended that the Risk Management Approach should consider the applications of products containing PFAS and their associated risks and exposure pathway.

Response 146: As stated in the Risk Management Approach, the Government of Canada is proposing to manage PFAS through a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to PFAS in subsequent phases based on socio-economic considerations and the availability of feasible alternatives.

Comment summary 147: A commenter stated that if the PFAS listed in the section 71 notice are eventually subject to risk management measures, it would remove expanded and extruded polystyrene foam insulation products from the marketplace in Canada.

Response 147: The section 71 notice results provide important additional information on PFAS uses in Canada, which is critical to informing the development of future risk management measures.

As stated in the Risk Management Approach, the Government of Canada is proposing to manage PFAS through a phased approach, starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to PFAS in subsequent phases based on socio-economic considerations and the availability of feasible alternatives.

Comment summary 148: A commenter requested that the Government of Canada should clearly categorize and identify priority levels for groups of PFAS through a risk management matrix and proceed with multistakeholder consultations, similar to what was done in the previous phases of the CMP.

Response 148: The Risk Management Approach does include a prioritization process of uses based upon factors such as the need for the protection of health, safety or the environment, taking into consideration socio-economic factors and whether alternatives to PFAS exist. Firefighting foam is the first use to be prioritized and addressed. Other uses will be addressed in a phased approach based on factors such as socio-economic considerations and the availability of feasible alternatives.

Comment summary 149: A commenter stated that it is imperative to exclude non-problematic PFAS like fluoropolymers and PFPEs from the Revised Risk Management Scope for PFAS, as they are vastly different from other PFAS. They stated that PFPEs are irreplaceable parts of critical products that are essential to society, circular economy and climate neutrality goals. They provided a list of various applications where PFPEs are used and cannot be substituted.

Response 149: As stated in the Risk Management Approach, actions are being considered for the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report. However, PFPEs continue to be addressed as part of the class-based approach due to concerns outlined in the State of PFAS report, and other responses to comments included in this table. These risk management actions are being proposed through a phased approach starting with prohibiting the use of PFAS not currently regulated in firefighting foams and then managing other uses and sectors in relation to PFAS in subsequent phases based on factors such as socio-economic considerations and the availability of feasible alternatives. All information provided about the uses of PFAS, and their alternatives (or lack thereof) will be considered during the development of future risk management.

Comment summary 150: A commenter stated that it is essential for Canada to be more active in removing or remediating the existing sources of PFAS releases in the environment, such as landfills, drinking water, and wastewater treatment plants.

Response 150: The Government of Canada continues to take action through the <u>Federal Contaminated Sites Action Plan (FCSAP)</u> to reduce environmental and human health risks from known 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.

Comment summary 151: A commenter expressed concern that the first significant risk management for the class of PFAS pertains to biosolids, which may risk increasing negative public perceptions of land application of biosolids. They also emphasized that a balanced risk management perspective must consider that any reduction in the use of biosolids as fertilizers risks increasing the use of commercial fertilizers that include phosphates and other chemicals.

Response 151: The proposed risk management for the class of PFAS as outlined in the Risk Management Approach is prohibition of the class of PFAS in phases, beginning with AFFF.

The interim standard for PFAS in biosolids was developed by the Canadian Food Inspection Agency as a related, but separate risk management action. This standard is designed to mitigate the potential risks to human health and the environment associated with land application of heavily contaminated biosolids sold as commercial fertilizer. Additional information, as well as contact information, is available here: Notice to industry: Implementation of an interim standard for per- and polyfluoroalkyl substances (PFAS) in commercial biosolids - inspection.canada.ca.

Comment summary 152: A commenter suggested putting a focus on upstream management for reducing PFAS concentrations in the ambient environmental media into guidance or when developing future regulatory actions on sites contaminated with PFAS.

Response 152: All information provided will be considered during the development of future risk management.

Also, the focus on the upstream reduction of PFAS concentrations is coherent with the risk management objective proposed in the Risk Management Approach.

Comment summary 153: A commenter noted that limiting PFOS to less than 50 ppb in biosolids ensures that the land application of these materials is safer; however, the interim measures may limit the availability of biosolid fertilizers and increase operational costs.

Response 153: The interim standard for biosolids was developed by the Canadian Food Inspection Agency (CFIA) after careful consideration of its impact on the waste diversion sector. Available data shows that at least 92% of Canadian biosolids would pass the interim standard, which should cause minimal disruption to waste-diversion efforts across Canada.

Comment summary 154: A commenter noted that Canadian biosolids are not land applied to any crops that are directly consumed as food and noted that the reasons for actions being taken by the Government appear to be in response to contaminated biosolids that were imported into Canada from contaminated sites.

Response 154: The CFIA has indicated that, of the estimated approximately 1 million dry tonnes of biosolids produced in Canada annually, available data indicates that approximately 59% are applied to land used for food production (including both crop production and grazing land), with the remainder being disposed of through landfilling, incineration or other means. The fates of biosolids produced in Canada vary, with legislation respecting application to agricultural land differing by province and territory.

Comment summary 155: A commenter noted that the CFIA announced the implementation of an interim standard for PFOS, in which public consultations ended in February 2024, however, it is not known when CFIA will finalize these guidelines on biosolids. They also mention that communities have no information about the level of PFAS in biosolids and whether biosolids are regularly tested for PFAS contamination.

Response 155: On October 18, 2024, the CFIA began enforcing an interim standard for PFAS in biosolids imported or sold in Canada as fertilizers. This standard is designed to mitigate the potential risks to human health and the environment associated with land application of heavily contaminated biosolids sold as commercial fertilizer. Additional information is available from Notice to industry: Implementation of an interim standard for per- and polyfluoroalkyl substances (PFAS) in commercial biosolids - inspection.canada.ca.

Comment summary 156: A commenter recommended that the provincial and territorial response to proposed guidelines to address PFAS in biosolids, drinking water, and air should be undertaken without delay and suggested that public reporting be carried out on an annual basis. The commenter also noted that the Revised Risk Management Scope for PFAS should include details on how the provinces and territories comply with measures to address the class of PFAS.

Response 156: The Government is considering the addition of 131 PFAS to the National Pollutant Release Inventory (NPRI). If added to the NPRI, then facilities in Canada, including wastewater treatment plants, will be required to report PFAS releases annually. This information may be useful for measuring the performance of risk management objectives.

For drinking water, an objective for Canadian drinking water quality was developed by Health Canada in collaboration with provincial and territorial governments. Activities such as monitoring and regulating PFAS in drinking water are primarily the responsibility of provinces, territories, and municipalities, and in general, the federal government does not have the mandate to enforce drinking water requirements. The objective represents a benchmark for all jurisdictions to strive towards. However, achieving it may take time given the complexities of measuring and managing PFAS.

Comment summary 157: A commenter recommended using Federal-Provincial-Territorial infrastructure negotiations to discuss harmonizing water quality guidelines across the country. In addition, the commenter recommended that new funding options should be included to support municipal compliance.

Response 157: Health Canada plays a leadership role in science and research on drinking water and derived an objective for PFAS in drinking water in collaboration with the Federal-Provincial-Territorial Committee on Drinking Water. The objective aims to reduce Canadians' exposure to PFAS and thus to lower the risk to health. While HC developed the objective in collaboration with the Federal-Provincial-Territorial Committee on Drinking Water, setting regulatory standards for drinking water, and putting such standards into place, are primarily the responsibility of provinces and territories.

HC recognizes the challenges of implementing the drinking water objective for PFAS and will continue to support provinces and territories through health guidance and providing advice on testing protocols and water treatment strategies moving forward.

Comment summary 158: A commenter requested that the class of PFAS be designated as hazardous substances under *Cross-border Movement of Hazardous Waste and Hazardous Recyclable Material Regulations* to be able to implement a Prior Informed Consent requirement.

Response 158: A review of the definitions of hazardous waste and hazardous recyclable material under the *Cross-border Movement of Hazardous Waste and Hazardous Recyclable Material Regulations* is expected in the future. This will include an examination of substances controlled under these regulations.

Comment summary 159: Commenters encouraged the Government of Canada to take a leadership position and work with its provincial, territorial, and municipal partners to address PFAS contamination sources and waste management challenges, such as waste regulations, across the country.

A commenter indicated that provinces have deferred to federal jurisdiction, in response to industry calls for harmonized action on this and other chemicals of concern.

Another commenter noted that the lack of specific regulations for the acceptance and disposal of PFAS-containing waste at the provincial or territorial level is a significant problem in the management of PFAS.

A commenter recommended that new funding options should be included to support municipal compliance.

Response 159: Provinces and territories can legislate in relation to the approval, licensing, and monitoring of waste management facilities, such as landfills, as well as establishing specific requirements for waste management, including waste containing PFAS and their definitions, and programs to divert waste from disposal. Municipal governments are responsible for collection and diversion, such as composting and recycling, as well as the disposal of solid waste within their jurisdiction.

Given the shared responsibility for waste management in Canada, the Government of Canada works collaboratively with its provincial, territorial, and municipal partners under the auspices of the Canadian Council of Ministers of the Environment, to address waste issues of mutual interest, and to improve waste reduction policies and practices across Canada. Partnerships will be considered during the development of future risk management while noting the respective mandate of each jurisdiction.

It should be noted that the most efficient method to reduce PFAS concentrations in many receiving media, and the only method to reduce PFAS concentrations in ambient environmental media, continues to be upstream management and minimization.

Comment summary 160: A commenter stated that concerns with the release and disposal of products containing PFAS should be addressed through applicable water discharge and waste management laws.

Response 160: Public wastewater treatment plants are not designed to treat chemicals from industrial processes. In addition, they are not the generator of the substance but rather a conduit into the environment.

Provinces and territories can legislate in relation to the approval, licensing, and monitoring of waste management facilities, such as landfills, as well as establishing specific requirements for waste management, including the scope of waste containing PFAS, and programs to divert waste from disposal. Municipal governments, generally speaking, are responsible for collection and diversion, such as composting and recycling, as well as the disposal of solid waste within their jurisdiction.

Comment summary 161: A commenter indicated that the National Research Council Canada is leading a PFAS Destruction challenge through Innovative Solutions Canada to find solutions for removal and treatment of PFAS from Canadian small and medium enterprises.

Response 161: ECCC and HC are aware of and have contributed expertise to the development of the Innovative Solutions Canada challenge on PFAS (<u>Destruction of PFAS compounds in contaminated media</u>).

Comment summary 162: A commenter noted that in October 2020, Canada and the United States reached an agreement concerning the environmentally sound management of non-hazardous waste and scrap that are transported across their borders. The arrangement specifically covers waste and scrap materials that are not included under the OECD Decision (OECD/LEGAL/0266) or the Canada-US Agreement on the Transboundary Movement of Hazardous Waste.

The commentor adds that since PFAS can be found in various types of plastic products, it is important for companies to guarantee that using plastic as an alternate fuel will not result in toxic emissions. They suggest that companies should provide the federal, state, and local governments with documents explaining how they plan to address this.

Response 162: In Canada, the federal government can enact legislation regarding the international and interprovincial movements of hazardous waste and hazardous materials. For international movement, any hazardous waste or hazardous recyclable material under the *Cross-border Movement of Hazardous Waste or Hazardous Recyclable Material Regulations* is subject to the reporting requirements under the regulations, including notification of proposed imports or exports, movements documents to track shipment and confirmation of disposal or recycling.

The Canada-U.S. Arrangement on non-hazardous waste and scrap affirms that Canada and the United States manage such waste in an environmentally sound manner and intend to maintain measures to provide for the environmentally sound management of such waste and scrap to protect human health and the environment.

Comment summary 163: A commenter stated that several members of their sector have adopted voluntary policies to ensure that all customer-facing food packaging materials do not contain intentionally added PFAS.

Response 163: This effort is acknowledged and welcomed and will be considered during the development of future risk management.

Comment summary 164: A commenter requested clarification on the proposed voluntary initiatives under consideration under Section 3.4 (*Additional complementary risk management actions*) of the Revised Risk Management Scope.

Another commenter also indicated that industry consultation on these voluntary initiatives and their impact on the healthcare sector needs to be carefully assessed.

Response 164: Voluntary initiatives considered in the Risk Management Approach are usually understood as early actions undertaken by an industry sector in response to concerns voiced by their members or customers. It may result in an awareness campaign, establishment and implementation of new standards or labelling of products. In the case of PFAS, this type of initiative has been taken by companies in the textile sector in Europe. Canadian companies adopting globally recognized standards may gain a competitive edge for their products on the global market. As for any risk management measures, stakeholders are consulted.

Comment summary 165: A commenter was supportive of voluntary actions pertaining to the disclosure of PFAS information (such as using QR codes or e-labels) that would enable consumers and importers to identify products containing certain PFAS. However, they recommend that such an initiative should be a voluntary engagement with manufacturers and marketers. They also cautioned that this type of labelling may be considered an environmental claim that would be subject to the new amendments of the *Competition Act*, where companies may need to provide a justification for these claims.

Response 165: This suggestion will be considered during the development of future risk management. Any risk management actions will be developed in alignment with, and complementary to, existing regulations and Acts.

Comment summary 166: Commenters recommended improving the disclosure and traceability for products containing PFAS. One commenter was supportive of the labelling of products option proposed in the Revised Risk Management Scope. It was also suggested that product packaging could be labelled to indicate the presence of PFAS during a transition period until PFAS are banned.

Response 166: The Risk Management Approach includes exploring opportunities to increase disclosure of information (such as through labelling) regarding chemicals of concern, that would enable consumers and importers to identify products containing PFAS.

Comment summary 167: A commenter suggested the development of a government-supplied template letter for restaurants to send to suppliers requesting information around the inclusion of PFAS in their goods and food processing equipment to better promote data sharing.

Response 167: This suggestion will be considered during the development of future risk management activities.

Information gathering

Comment summary 168: Some submissions of public comments during the 60-day public comment period on the Updated Draft State of PFAS Report and the Revised Risk Management Scope included questions regarding the section 71 notice on PFAS (available at: Canada Gazette, Part I: Vol.158, No.28 – July 13, 2024) which is beyond the scope of this public comment period.

Response 168: These questions were re-directed to be addressed through the Substances inquiry process to facilitate timely compliance with the section 71 notice, which was due January 29, 2025.

Comment summary 169: A commenter sought clarification regarding why fluoropolymers are within the scope of the mandatory section 71 notice but have been excluded from the conclusion of the Updated Draft State of PFAS Report. They also recommended that perfluoropolyethers be excluded from the survey.

Response 169: Fluoropolymers are excluded from the State of PFAS Report and will be addressed in a separate assessment. Their exclusion from the State of PFAS Report should not be interpreted as meaning they are or are not of concern.

Fluoropolymers are included among the <u>substances proposed as priorities for assessment</u> for the Plan of Priorities to be published under section 73 of CEPA in June 2025. The Plan of Priorities will outline activities to help assess, control and manage risks to the environment and human health over the next several years. The public and stakeholders will be informed on the expected timing of assessment work on all priorities to be published in the Plan of Priorities.

The notice under section 71 of CEPA in the *Canada Gazette* will collect additional information on PFAS, including fluoropolymers and perfluoropolyethers, to better understand uses, sources of release, and exposure. This information is intended to be used to inform the planned assessment of fluoropolymers, risk management decisions, if needed, and other activities related to PFAS.

Comment summary 170: Commenters stated that compliance with section 71 reporting is difficult and complex, given that facilities will not have access to information aside from what is provided from the manufacturer. In particular, safety data sheets (SDSs) do not require the inclusion of PFAS present at concentrations below 1% and accredited testing methods are not available for all PFAS.

Response 170: Stakeholders subject to the notice under section 71 of CEPA in the *Canada Gazette* are required to provide information that is in their possession or to which they may reasonably be expected to have access. Stakeholders are not required to conduct tests to comply with the notice; however, they should make reasonable efforts to obtain information through their supply chain, especially if they know or suspect that PFAS is present in their goods. This will help the Government of Canada ensure that all information is considered which will enable timely and appropriate risk management decisions.

Comment summary 171: A commenter noted that although the report is only in the draft stage, the section 71 notice is already live with the earliest reporting deadline for PFAS internationally. They requested reasonable timelines based on information readily available for reporting and that these timelines start only once the regulations are in place. They indicated that reporting requirements should be effective no sooner than 2026 to align with other jurisdictions.

Response 171: The information collected during the notice under section 71 of CEPA in the *Canada Gazette* is required to determine the current Canadian situation to inform future risk management actions.

Stakeholder participation in the notice is essential for the Government of Canada to obtain important information that reflects the current situation of PFAS use in Canada. This input is critical for the development of clearly defined risk management actions for PFAS, including

regulations, and to mitigate risks to the environment and human health without undue delay. The notice reporting period ensures timely collection of necessary data. In addition, the information collected now may serve as a baseline for the Government of Canada to be able to evaluate the performance of any future risk management actions.

Stakeholders subject to the notice are required to provide information that is in their possession or to which they may reasonably be expected to have access. The information needed to meet reporting obligations is usually available from suppliers, especially if it is suspected that PFAS may be present, based on the type of goods. Stakeholders requiring additional time had the option to submit a written request for additional time to respond to the notice. Extension requests were reviewed on a case-by-case basis.

Comment summary 172: Commentors indicated that information gathering activities, like section 71 notices, should require reporting for a period going forward or to start in the future rather than retroactively, without giving industry sufficient time to prepare.

Response 172: The notice under section 71 of CEPA in the Canada Gazette will collect information to establish baseline commercial use data and support future activities related to PFAS. It will only collect information for the 2023 calendar year.

Risk management is based on current data to determine a baseline and future objectives to manage risks associated with PFAS.

Comment summary 173: A commenter recommended that reporting requirements should take a practical approach and focus on the sources, such as chemical producers.

Response 173: Risk management aims at limiting sources of exposure and of release. However, some exposure may happen during the use of products or from release to the environment when a product is discarded. Thus, risk management must consider every stage of the substance use, whether in an industrial setting or from a final product available to consumers.

Comment summary 174: A commenter stated that the reporting mechanism under section 71 appears to allow companies to report the amounts of PFAS that are used as zero if suppliers refuse to provide chemical information required by law in Canada. The commenter asked what steps will be taken to address this, especially in cases where products originate from jurisdictions with differing mandates and regulations concerning PFAS disclosure.

Response 174: Stakeholders subject to the notice under section 71 of CEPA in the *Canada Gazette*, are required to provide information that is in their possession or to which they may reasonably be expected to have access. The information needed to meet reporting obligations is usually available from suppliers, especially if it is suspected that PFAS may be present, based on the type of goods. It is in the interest of stakeholders to inquire about the presence of PFAS in their supply chain and to report it during consultations and data gathering exercises. Without data, it would be difficult to justify exemptions for substances in certain uses where their presence is currently unavoidable.

Comment summary 175: A commenter noted that any information gathering initiative should consider the challenges that many sectors themselves face with respect to determining whether PFAS are present in their purchased products and subsequent processes.

Response 175: Stakeholders subject to the notice under section 71 of CEPA in the *Canada Gazette* are required to provide information that is in their possession or to which they may reasonably be expected to have access. Stakeholders are not required to conduct tests to comply with the notice, however they should make reasonable efforts to obtain information through their supply chain, especially if they know or suspect that PFAS is present in their goods. This will help the Government of Canada ensure that all information is considered before taking any further action.

Stakeholders requiring additional time had the option to submit a written request for additional time to respond to the notice. Extension requests were reviewed on a case-by-case basis.

Comment summary 176: A commenter is concerned that the current reporting processes do not adequately consider the operational realities of facilities. They note that PFAS concentrations below 1% are not required to be listed on SDSs and that there is a limited capacity to test for PFAS at a concentration threshold of 0.1% in Canadian laboratories. The commenter also questions whether the threshold is proportionate to the risks posed by these trace levels.

Response 176: Stakeholders subject to the notice under section 71 of CEPA in the *Canada Gazette* are required to provide information that is in their possession or to which they may reasonably be expected to have access. Stakeholders are not required to conduct tests to comply with the notice, however, they should make reasonable efforts to obtain information through their supply chain, especially if they know or suspect that PFAS is present in their goods. This will help the Government of Canada ensure that all information is considered when making decisions on suitable actions.

The 1 ppm threshold in the notice under section 71 of CEPA in the *Canada Gazette* is based on the current knowledge of concentration of PFAS used in products and takes into consideration actions taken by other jurisdictions. This threshold is consistent with the approach that the Government is taking to address PFAS as a class, given the expectation that cumulative effects may occur from exposure to multiple PFAS.

Under the NPRI, reporting requirements are proposed to apply to facilities that meet the employee threshold and that manufacture, process or otherwise use one kilogram or more of a listed PFAS at a concentration of 0.1% by weight or more. The 0.1% level was selected to align with the requirements for disclosing substances on SDSs which are used by many facilities to calculate and report quantities of NPRI substances. Substances in mixtures that are health hazards, like some PFAS, must be disclosed on SDSs if they occur in concentrations of 1% or more, unless they are carcinogenic, mutagenic, or toxic to reproduction, like some PFAS, in which case they must be disclosed in concentrations of 0.1% or more.

Comment summary 177: A commenter stated that it is imperative to recognize that NPRI is one of the tools to collect information on PFAS from all users of PFAS. They add that the purpose of the NPRI needs to be considered and that the information for uses such as discharges from AFFF needs to be collected differently.

Response 177: CEPA has several tools to collect information. The NPRI is one of the tools which data is publicly accessible. Notices under section 71 are another means to gather information at certain points in time and can inform the development of risk management. Reporting under both tools is mandatory. Future risk management will assess which tool is more appropriate to achieve its data collection objectives.

Comment summary 178: A commenter recommended that all consultations regarding any proposed changes to the NPRI related to PFAS be given sufficient time to develop clear guidance and allow industries to set up systems to track and monitor PFAS. They added that there is no available data on PFAS as a class in products and testing methods are undefined, therefore, companies cannot properly assess PFAS content in products or releases.

Another commenter requested that any requirements relating to industrial releases to air, water or soil must be designed in such a way as to limit the administrative burden and set achievable targets given the technologies available.

Response 178: ECCC publicly consulted on adding reporting requirements for PFAS to the NPRI. The comment period closed on November 25, 2024. See the following website for more information: <u>Proposed changes to the National Pollutant Release Inventory.</u>

Reporting requirements are proposed to apply to facilities that meet the employee threshold and that manufacture, process or otherwise use one kilogram or more of a listed PFAS at a

concentration of 0.1% by weight or more. The 0.1% level was selected to align with the requirements for disclosing substances on SDSs which are used by many facilities to calculate and report quantities of NPRI substances. Substances in mixtures that are health hazards, like some PFAS, must be disclosed on SDSs if they occur in concentrations of 1% or more, unless they are carcinogenic, mutagenic, or toxic to reproduction, like some PFAS, in which case they must be disclosed in concentrations of 0.1% or more.

NPRI reporting requirements for PFAS are proposed to take effect as of the 2025 calendar year (that is, facilities will be required to submit PFAS reports for the year 2025 by June 2026). ECCC intends to provide guidance and tools for facilities to use to fulfill their reporting obligations.

The Government of Canada is committed to a phased prioritization approach for risk management based on factors such as socio-economic considerations and availability of feasible alternatives. The Risk Management Approach outlines the proposed risk management actions under consideration for the management of PFAS. The State of PFAS Report notes that upstream management and minimization is the most efficient method to reducing releases of to the environment.

References

[AEPHIN]. Alberta Environmental Public Health Information Network. <u>AEPHIN Human</u>
<u>Biomonitoring of Environmental Chemicals in Canada and the Prairies</u>. c2022. [accessed 2024 Oct 16].

[ECCC, HC] Environment and Climate Change Canada, Health Canada. 2018a. Rapid Screening of Substances with Limited General Population Exposure. Ottawa (ON): Government of Canada.

[ECCC, HC] Environment and Climate Change Canada, Health Canada. 2018b. <u>Screening Assessment: Substances Identified as Being of Low Concern using the Ecological Risk Classification of Organic Substances and the Threshold of Toxicological Concern (TTC)-based Approach for Certain Substances. Ottawa (ON): Government of Canada.</u>

[ECCC, HC] Environment and Climate Change Canada, Health Canada. 2020. <u>Screening assessment – Pigment and Dyes Group.</u> Ottawa (ON): Government of Canada.

Karthikeyan S, Pollock T, Walker M, Khoury C, St-Amand A. 2024. <u>Analysis of chemical exposures in racial populations in Canada: An investigation based on the Canadian health measures survey. International Journal of Hygiene and Environmental Health</u>. 260:114406. [accessed 2024 Oct 16].

[OECD] Organisation for Economic Co-operation and Development. 2021. Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances OECD Environment, Health, and Safety Publications Series on Risk Management, No. 61. Paris (FR): Environment Directorate, Chemicals and Biotechnology Committee. [accessed 2021 Nov 24]. Report No.: ENV/CBC/MONO(2021)25.

[UNEP] United Nations Environment Programme. 2023. <u>Environmental effects of stratospheric ozone depletion, UV radiation, and interactions with climate change: 2022 assessment report of the Environmental Effects Assessment Panel [PDF].</u> UNEP Nairobi, Ozone Secretariat. [accessed 2023 Aug 8].

Valcke M, Karthikeyan S, Walker M, Gagné M, Copes R, St-Amand A. 2020. Regional variations in human chemical exposures in Canada: A case study using biomonitoring data from the Canadian Health Measures Survey for the provinces of Quebec and Ontario. International Journal of Hygiene and Environmental Health. 225:113451. [accessed 2024 Oct 16].

ANNEX: Summary of public comments received on the Updated Draft State of Per- and Polyfluoroalkyl substances (PFAS) Report and the Revised Risk Management Scope for PFAS that were considered to be similar to previously submitted comments on the Draft Report and Risk Management Scope

A number of comments on the Updated Draft State of PFAS Report and Revised Risk Management Scope (published July 13, 2024) were received that were the same or very similar to those submitted during the previous public comment period (that is, on the Draft State of PFAS Report and Risk Management Scope, published May 20, 2023). Comments and responses considered consistent to those included in the previous public comment period and found in the Summary of public comments published on July 13, 2024, have been updated and are provided in this annex.

Summarized public comments and responses are provided below, organized by topic:

On this page

- General comments
- Definition and scope
- Conclusion
- Sources and uses
- Impacts on the environment
- Impacts on human health
- Drinking water
- Potential action
- Consultation

General comments

Comment Summary A-1: Commenters asked for further detail on the evaluation of new chemical substances. They enquired about what the Government of Canada can do to ensure that substances like PFAS do not enter the market again.

Response A-1: The <u>New Substances Notification Regulations (Chemicals and Polymers)</u> (NSNR) help protect people living in Canada and the environment, as they allow new chemicals and polymers to be assessed prior to being imported or manufactured in Canada above prescribed quantity thresholds. Following a New Substances Notification (NSN), ECCC and HC follow a joint assessment process to determine whether there is a potential risk to the environment and human health. When potential risks are identified, the Government of Canada imposes risk management measures. Additional information on the NSNR can be found on the New substances: Chemicals and polymers webpage.

As noted in the State of PFAS Report, about one-third of the approximately 290 PFAS notified under the new substances regime since 1994 were subject to actions intended to mitigate the risks to human health and/or the environment.

Since the publication of the Draft State of PFAS Report (published in May 2023), the New Substances program has considered the information included in the report, including the potential of combined exposure to multiple PFAS and the proposed class conclusion. The New Substances program will continue to consider updated information, and will inform notifiers about potential actions on PFAS, referencing the State of PFAS Report and associated risk management documents, as appropriate.

Comment Summary A-2: Commenters requested clarification on how the Government of Canada plans to identify and measure new PFAS under the New Substances program, given that analytical methods have been developed for only a few PFAS.

Response A-2: Under CEPA, the assessment of a new substance that is proposed to be imported or manufactured in Canada begins once the Government of Canada receives a complete New Substances Notification from the importer or manufacturer of the new substance. The New Substances Notification package must contain all required information prescribed in the NSNR (more information available at the New Substances program webpage). The New Substances program is not responsible for generating the required information prescribed in the NSNR, nor for measuring PFAS in the environment (other programs in the Government of Canada conduct monitoring activities as described in Sections 4, Environmental occurrence, and 5, Human biomonitoring, of the State of PFAS Report). Importers and manufacturers of new PFAS are responsible for providing information, including test results (for example, from physical-chemical data tests), on new substances to be imported or manufactured in Canada. This is supplemented by information in the scientific literature and from other sources, all of which are used by the Government to assess the human and environmental health risks of the individual substance at the time of notification. The New Substances program will continue to consider updated information and will inform notifiers about potential actions on PFAS, referencing the State of PFAS Report and associated risk management documents, as appropriate.

Comment Summary A-3: Commenters would like the Government of Canada to ban the use of laboratory animals for PFAS toxicity studies.

Response A-3: In 2023, the <u>Food and Drugs Act</u> was amended to ban cosmetic animal testing in Canada, which came into force in December 2023. Beyond cosmetics, HC and ECCC are working with the international scientific and regulatory community to develop, validate and implement effective alternatives to animal testing. In June 2023, several amendments across the *Canadian Environmental Protection Act* (CEPA) were made to support replacing, reducing, or refining the use of vertebrate animals in toxicity testing. On September 14, 2024, HC and ECCC published a <u>draft strategy to replace, reduce or refine vertebrate animal testing</u> under CEPA for a 60-day public consultation period. The final strategy is expected to be published alongside the Plan of Priorities by June 2025.

Comment Summary A-4: Commenters stated that the representation of new approach methods (NAMs) in the Updated Draft State of PFAS Report are superficial. The use of NAMs should be enhanced and explored further.

Response A-4: The intent of this section of the report is to acknowledge that these tools are becoming increasingly important in toxicological testing and assessing many data-poor chemicals, including PFAS. It is recognized that PFAS pose unique challenges when implementing NAMs, and strategies are currently being explored within this chemical space in Canada and internationally. Although this is an active area of research and development, a comprehensive review regarding NAMs and their application is considered to be outside the scope of the State of PFAS Report.

Comment Summary A-5: Commenters requested that the Revised Risk Management Scope clearly indicate the right of every individual in Canada to a healthy environment. They stated that the Revised Risk Management Scope objectives do not align with the duty to protect the right of every individual in Canada to a healthy environment and uphold the related principles, which include upholding environmental justice and avoiding adverse effects that disproportionately affect vulnerable populations.

Other commenters mentioned that it is inappropriate to make conclusions related to new CEPA provisions, such as the right to a healthy environment, before consultations have taken place.

Response A-5: CEPA requires the development of an implementation framework setting out how a right to a healthy environment as provided under CEPA will be considered in the administration of the Act. A <u>draft of the implementation framework</u> was published in October 2024 for a 60-day public comment period. The draft framework elaborates on principles, such as environmental justice, including the avoidance of adverse effects on populations who may be disproportionately impacted by pollution. published by June 2025. As the implementation framework has not been finalized, a right of every individual in Canada to a healthy environment as provided under CEPA was not specifically referenced in the Risk Management Approach. However, the human health objective of the Risk Management Approach is to reduce exposure for all people in Canada including those that may be disproportionately impacted, and any risk management activities under CEPA after June 2025 will be guided by the final implementation framework.

Definition and scope

Comment Summary A-6: Commenters are in opposition to a class-based approach. Several recommended conducting assessments for subgroups or individual PFAS. They stated that there is limited information on most substances in the class to apply a class-based approach.

These commenters added that not all PFAS chemicals possess the same hazard profile. The class of PFAS is comprised of thousands of individual substances with diverse molecular structures, which are highly varied in physical and chemical properties, health and environmental profiles, toxicological properties, uses, and benefits.

Response A-6: A precautionary, class-based approach to addressing PFAS is needed to protect the environment and people from anticipated adverse effects. While it is acknowledged that only a small number of PFAS have been the focus of the majority of studies, there is a growing body of evidence suggesting that concerns identified for these well-studied substances are more broadly applicable to other PFAS than previously believed. Amongst those that have been well-studied, there is a degree of consistency in their behaviour in that they either are extremely persistent or degrade into simpler PFAS that are persistent, and they are associated with effects of concern. To be protective of the environment and human health, and to apply precaution when addressing gaps in information, it is reasonable to anticipate that concerns identified for PFAS that have been well studied may also be inherent in other substances in the class. The use of a class-based approach will also prevent the substitution of one regulated PFAS for an unregulated PFAS that possesses similar hazardous properties, known as regrettable substitution.

Comment Summary A-7: Commenters stated that the Updated Draft State of PFAS Report does not follow a scientific and risk-based approach that identifies the critical exposures that are of primary concern based on actual data.

Some commenters were not supportive of the toxic conclusion for the class of PFAS. They commented that the documents failed to demonstrate that concentrations or quantities of PFAS in Canada are associated with health or ecological effects, as per section 64 of CEPA.

They also mentioned that the work completed by the departments has not satisfied the statutory requirements to add a substance or a group of substances to Schedule 1. For instance, a risk assessment has not been performed. Until a risk assessment is completed, it is inappropriate to make any conclusions under CEPA section 64. Additionally, the conclusions of the Updated Draft State of PFAS Report do not reflect the full weight of evidence of the available science as information is only available for a small number of PFAS.

Response A-7: The State of PFAS Report is an assessment and makes a conclusion that the class of PFAS, excluding fluoropolymers, meets one or more of the criteria set out in section 64 of CEPA. The State of PFAS Report considers information on potential adverse effects of PFAS to human health and the environment and weighs it against information on exposure to determine the potential for harm. Unlike quantitative assessments that consider risk metrics such as risk quotients or margins of exposure among other lines of evidence, this report uses multiple lines of evidence, based on the latest science available, in a qualitative approach.

Exposure is informed by environmental monitoring and biomonitoring data that indicate widespread detection of certain PFAS in humans, biota, and environmental media, including exposure to multiple PFAS at the same time. Certain PFAS may bioaccumulate and biomagnify in food webs to an extent that can cause adverse effects in biota at low environmental concentrations.

This information is considered in combination with the knowledge that PFAS are associated with broad uses and are extremely persistence in the environment. Certain PFAS may

bioaccumulate and biomagnify in food webs to an extent that can cause adverse effects in biota at low environmental concentrations. The information is also considered alongside the evidence that organisms are typically exposed simultaneously to multiple PFAS in the environment, which has the potential to increase detrimental impacts. Recent amendments to CEPA also require consideration of potential cumulative effects on human health and the environment from exposure to multiple substances.

Given the growing body of scientific evidence suggesting that concerns for health and the environment identified from well-studied PFAS are more broadly applicable to other PFAS, and given the expectation that combined exposures to multiple PFAS will increase the likelihood of detrimental impacts, addressing the large number of PFAS using a class-based approach is appropriate.

Of note, conclusions for the ecological components of screening assessments for PFOS, PFOA, LC-PFCAs, and their salts and precursors were based on a similar qualitative approach.

Comment Summary A-8: Commenters expressed support for a class-based approach. These commenters stated that by addressing PFAS as a class, the Government of Canada is adopting a proactive and precautionary approach. They added how a class approach is imperative to avoid "regrettable substitution", address the impact of PFAS mixtures on human health and reduce human and environmental exposure to the broader class of PFAS.

Response A-8: Noted.

Comment Summary A-9: Commenters provided recommendations for subdividing the class of PFAS based on chemistry (for example, polymeric vs. non-polymeric, acid vs. non-acid chemistries). Some commenters also provided recommendations for dividing polymeric PFAS into subgroups for regulatory purposes.

Response A-9: Section 1.1 (*Chemical Scope*) of the State of PFAS Report clearly identifies the definition of PFAS and identifies common types of polymeric PFAS.

Only a small number of PFAS have been the focus of the majority of studies. To be protective of the environment and human health, and to apply precaution when addressing gaps in information, it is reasonable to anticipate that the concerns identified for PFAS that have been well-studied may also be inherent in other substances in the class. The use of a class-based approach will help prevent the substitution of one regulated PFAS for an unregulated PFAS that possesses equally or more hazardous properties, known as regrettable substitution. A class-based approach also allows to take into consideration co-exposure to multiple PFAS which could result in cumulative effects.

It is concluded that the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, meets 1 or more of the criteria set out in section 64 of CEPA. Thus, it is proposed that the class of PFAS, excluding fluoropolymers, is added to Schedule 1 of CEPA. However, this does not in and of itself restrict or prohibit the substances in the class of PFAS; rather, it enables risk management instruments, such as regulations, to be developed under the Act. Risk management instruments would be tailored to sectors and uses depending upon the information received and socio-economic factors. Before taking any risk management actions, information would be gathered to fully understand the availability of alternatives and the costs of transitioning to those alternatives.

Comment Summary A-10: Commenters stated that ECCC and HC have already assessed the risk posed by certain fluorinated gases and determined, prior to listing them on the Domestic Substances List (DSL), that they do not pose a threat to the environment or human health. They claimed that substances that have previously been assessed as not toxic prior to entry into the Canadian marketplace should not have been arbitrarily designated as CEPA-toxic because they meet OECD's broad definition for PFAS.

Response A-10: CEPA sets out several ways to initiate the assessment of a substance. In respect of the substances mentioned by the commenters, some were added to the DSL

following submission under the NSNR. Others were manufactured or imported during the transition period (that is, between January 1, 1987, and July 1, 1994) and were added to the DSL following a risk assessment by ECCC and HC. One of the substances was in commerce in Canada between 1984 and 1986, so it was included on the original DSL without assessment. The presence of a substance on the DSL does not preclude it from further assessment. The State of PFAS Report includes PFAS that have been previously assessed individually.

Comment Summary A-11: A commenter stated that the majority of substances that are captured by the OECD 2021 definition for PFAS are not in Canadian commerce and therefore cannot meet the Schedule 1 definition since there is no possibility of exposure.

Response A-11: Although the majority of PFAS captured by the OECD 2021 definition are not manufactured in, or imported into, Canada on a commercial scale (that is, on the DSL), this does not preclude their potential exposure to humans and biota in Canada. Some PFAS are capable of undergoing long-range transport in the atmosphere or global ocean currents, as shown by their widespread distribution around the world, including in remote regions.

Additionally, PFAS may be present in manufactured items that are imported into Canada and may be a source of PFAS in Canada. As highlighted in Sections 4 and 5 (*Environmental occurrence* and *Human biomonitoring*, respectively) of the State of PFAS Report, environmental monitoring and Canadian human biomonitoring has shown that PFAS are routinely detected in various environmental samples (including wildlife) collected across Canada and that certain PFAS are present in the blood of the Canadian population. Some PFAS that are present in monitoring data in Canada may be transformation products of PFAS that are in commerce in Canada or elsewhere.

Conclusion

Comment Summary A-12: Commenters stated that the Government of Canada should assess substances under CEPA by first gathering information, then publishing a state of science report or science approach document for stakeholder input, if needed, to identify any missing information, and then publishing a risk assessment with a proposed conclusion. The Updated Draft State of PFAS Report proposed a conclusion under CEPA before appropriately gathering information, consulting with stakeholders (including on the scope of the definition and appropriate sub-groups) and assessing risk.

Response A-12: The State of PFAS Report included steps such as data gathering of information and the publication of draft reports for public comment and stakeholder input. A search for available information was conducted, the information relevant to the conclusion under section 64 of CEPA was synthesized in the report and limitations in the availability of data were indicated. Both the Draft and Updated Draft State of PFAS Reports (published in May 2023 and July 2024, respectively) were subject to 60-day public comment periods. Public comments and studies identified in public comments were considered when finalizing the report. It should be noted that fluoropolymers are planned for consideration in a separate assessment.

Comment Summary A-13: A commenter stated that persistence alone cannot support a toxic conclusion, and that persistence is not synonymous with toxicity.

Response A-13: The State of PFAS Report draws upon multiple lines of evidence, which are not limited to persistence, to reach its toxic conclusion under section 64 of CEPA. Some of the key lines of evidence include monitoring data, the extreme persistence of PFAS, their potential for bioaccumulation and biomagnification through the food chain, the ability of PFAS to move locally and over long distances, toxicological studies on humans and wildlife as well as human epidemiological information, and in particular, the consideration of the potential for cumulative effects as most wildlife and human exposures involve an unknown mixture of PFAS. To be protective of the environment and human health and to apply precaution when addressing gaps in information, it is reasonable to anticipate that the concerns identified in well-studied PFAS may also be inherent in other substances in the class.

Sources and uses

Comment Summary A-14: Commenters provided additional information on products that may contribute to exposure to PFAS.

Response A-14: Additional information received on products that may be sources of exposure to PFAS was considered. The products identified in public comments are broadly captured by the general description of the wide range of industrial uses and products described in the State of PFAS Report. The information gathered thus far and at other stages of consultation will be used to help inform any risk management actions to be developed.

Comment Summary A-15: Commenters stated that more focus needs to be put on identifying alternatives for PFAS.

Response A-15: The OECD Global Perfluorinated Chemical Group published several reports about potential alternatives to PFAS in various sectors. Reports are available from <u>Alternatives - OECD Portal on Per and Poly Fluorinated Chemicals</u>.

Any risk management measures to control certain uses of PFAS would take into consideration the availability of suitable alternatives, including the costs and benefits of switching to those alternatives. Before taking any risk management actions, information would be gathered to fully understand the availability of alternatives and the costs of transitioning to those alternatives.

Impacts on the environment

Comment Summary A-16: Commenters suggested that contaminated sites that are impacted by PFAS (for example, military bases and airports) should be remediated and that specific action plans must be developed in consultation with those affected. Additionally, the current Federal Contaminated Sites Action Plan (FCSAP) should provide more funding for further assessment.

Response A-16: The priority to clean up federal contaminated sites follows an established prioritization process aimed at reducing environmental risks, human health risks, and associated federal financial liabilities. When contaminants migrate off-site, federal departments coordinate with local health services to communicate the risks.

FCSAP funds the assessment, remediation, and risk management of federal contaminated sites. Funding is provided to departments, agencies and consolidated Crown corporations that have accepted responsibility for the contamination. Please see Funding of federal contaminated sites for more information. There are federal contaminated sites that are contaminated with PFAS, and available FCSAP funding is provided to custodians to conduct assessments, provide remediation, and hold risk management activities at eligible sites based on the potential risks to human health and the environment.

Information on FCSAP sites is available online at Federal Contaminated Sites Inventory.

Impacts on human health

Comment Summary A-17: Commenters stated that certain HFOs and HFCs have been heavily studied, rigorously regulated, and identified as not of toxicological concern in various repeat dose studies.

Response A-17: It is acknowledged that certain HFOs may be regulated under various legislation (for example, US EPA and California Air Resource Board) and that available information may indicate low hazard for some HFOs.

However, as part of the consideration of PFAS as a class, the lifecycle of HFOs has been taken into consideration. It is noted that these substances contribute to the overall presence of low molecular weight PFAS in the environment which may result in human exposure (for example,

TFA in surface water). Health effects information for TFA is found in Section 7 (*Human health hazard*) which outlines that exposure to high doses of TFA in animal models has been associated primarily with liver effects (increased liver weight, hepatocellular hypertrophy, increased ALT), although increased kidney weight, decreased white blood cells, reduced weight of reproductive organs, litter loss, reduced body weight of offspring, and malformations have also been observed (ECHA 2023c, 2024). It is concluded that the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, meets 1 or more of the criteria set out in section 64 of CEPA. Any risk management actions would be developed in alignment with, and complementary to, existing regulations, such as the ODSHAR.

Comment Summary A-18: Commenters stated that more information and training are needed to inform people living in Canada and health professionals about the risks of PFAS and what people can do to minimize exposure to these substances. Commenters also recommended a government-run sustained public education campaign for military service members. Suggestions indicated that guidance on PFAS (for example, for clinical testing and levels in people) would be helpful.

Response A-18: The Government of Canada is working to inform people in Canada of the concerns associated with PFAS. Information on PFAS in products may be found on some ingredient lists on some labels or information may be available from the product manufacturer. While there are currently no requirements to specifically identify PFAS in most products, the Government of Canada has outlined proposed risk management options under consideration. It is concluded that the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, meets 1 or more of the criteria set out in section 64 of CEPA. A Risk Management Approach was developed, that considered information from public comments and other sources.

HC also works with provinces, territories, and other federal departments, to provide accurate and relevant information to municipalities and homeowners concerned about the health effects of PFAS in drinking water.

Requests for public campaigns have been noted and may be considered. Information on how people in Canadia can reduce their exposure to PFAS is available on the Government of Canada's <u>PFAS</u> website.

In the United States, the Agency for Toxic Substances and Disease Registry has published PFAS Information for Clinicians.

Comment Summary A-19: Commenters expressed that the development of the federal management strategy on PFAS as a class should prioritize the impacts of PFAS on vulnerable groups and communities and ensure that information is actively disseminated to the impacted communities.

Specific action plans must be developed in consultation with groups and communities that were affected to remediate the environments harmed by PFAS and to reduce the exposure to PFAS in communities at high risk. High-risk environments include military bases, airports, firefighting areas, and landfills.

Commenters stated that the needs of vulnerable populations may not have been adequately addressed in the Updated Draft State of PFAS Report.

Response A-19: In the State of PFAS Report, certain subpopulations that may experience greater susceptibility or greater exposure have been identified, including specific Indigenous populations that may experience higher levels of exposure to certain PFAS compared with similar populations sampled in the Canadian Health Measures Survey (CHMS).

PFAS-impacted contaminated sites are also identified as representing hot spot areas. In addition, information on children and pregnant people are considered. It is concluded that the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, meets 1 or more of the criteria set out in section 64 of CEPA. The federal government will aim to reduce releases of PFAS to the Canadian environment and to reduce exposure of these substances to the general population, including disproportionately impacted populations, to protect human

health. The development of risk management tools will involve cooperation with other departments and programs. The Risk Management Approach document outlines the proposed risk management options under consideration for the class of PFAS, excluding fluoropolymers.

There will also be additional opportunities for consultation on future risk management actions.

Drinking water

Comment Summary A-20: Commenters asked that the federal government convene multiple government-level working groups to ensure that precautionary drinking water standards are put into place at the provincial and territorial level.

The federal government must enhance funding to ensure that municipalities and municipal wastewater treatment plants are not burdened with financial costs associated with adoption of technologies for PFAS removal.

Canada should provide support for baseline monitoring needed for implementation planning and prioritization.

Response A-20: HC plays a leadership role in science and research on drinking water and derived an objective for PFAS in drinking water in collaboration with the Federal-Provincial-Territorial Committee on Drinking Water. The objective aims to reduce Canadians' exposure to PFAS and thus to lower the risk to health. While HC developed the objective in collaboration with the Federal-Provincial-Territorial Committee on Drinking Water, setting regulatory standards for drinking water, and putting such standards into place, are primarily the responsibility of provinces and territories.

HC recognizes the challenges of implementing the drinking water objective for PFAS and will continue to support provinces and territories through health guidance and providing advice on testing protocols and water treatment strategies moving forward.

Comment Summary A-21: Commenters stated that standard sampling and measurement methods in water, wastewater and biosolids are needed.

Response A-21: While validated and standardized analytical methods are currently available for a combined total of 29 PFAS in drinking water and 40 PFAS in aqueous and biosolid samples, new methods that will measure a greater number of compounds are under development by regulatory authorities, academics and independent laboratories in many countries. In addition, Government of Canada research laboratories have been working on improving analytical detection methods for PFAS in different exposure media, including drinking water.

Potential action

Comment Summary A-22: Commenters asserted that a more comprehensive ban on PFAS needs to take place, especially with respect to cleaning up existing contamination and preventing future exposures.

Response A-22: The Risk Management Approach outlines the proposed risk management options under consideration for the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, at a broad level. As stated in the Risk Management Approach, the Government of Canada's objective in managing the risks 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.

The Federal Contaminated Sites Inventory shows more than 24 000 suspected, active, and closed federal contaminated sites (as of November 2024), of which there are over 100¹ sites with active or suspected PFAS contamination. 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 most common sources of PFAS at federal contaminated sites are associated with the use of AFFF and include activities such as firefighting training and the 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.

Comment Summary A-23: Commenters asserted that the Government of Canada must ban all PFAS substances immediately and needs to impose stricter regulations on companies. There should be no phase-out period for PFAS.

Response A-23: PFAS possess traits that are useful in a broad spectrum of applications. Thus, there is a wide variety of sources of releases and exposure to take into consideration in managing the risks. As outlined in the Risk Management Approach, the federal government will aim to reduce releases of the class of PFAS excluding fluoropolymers as defined in the State of PFAS Report, to the Canadian environment and to reduce exposure of the general population, including disproportionately impacted populations, to these substances to protect environmental and human health. Risk management actions may be tailored to sectors and uses in order to allow specific uses that are currently without technically or economically feasible alternatives.

Comment Summary A-24: Commenters stated that respective industries should be responsible for the cleanup costs of any PFAS contamination in the Canadian environment and held accountable for the exposure of Canadians to PFAS and the intentional withholding of information on PFAS use in Canada. The commenters added that Governments should also be fully accountable and transparent in communicating to the public their knowledge of PFAS manufacture, use and import by industries. Other commenters recommended that the Government of Canada should take legal action against the manufacturers of PFAS.

Response A-24: In the Risk Management Approach, the Government of Canada has proposed actions to reduce releases of PFAS with the aim of reducing exposure of the Canadian environment and people living in Canada, including those groups of individuals within the Canadian population who, due to greater exposure, may be disproportionately impacted, to these substances. Risk management actions may be tailored to sectors and uses depending upon the information received, demonstrated absence of suitable alternatives and socioeconomic factors. Information on manufacture, use and import of PFAS is summarized in the State of PFAS Report. In addition, data collection initiatives (including the mandatory CEPA section 71 notice in the *Canada Gazette*) are aimed at collecting additional information on PFAS, which will be

¹ The Federal Contaminated Sites Inventory (FCSI) does not currently contain all the PFAS-Contaminated Sites as this category was newly developed in the 2024-2025 fiscal year. The inventory will be updated yearly to ensure that all the sites with confirmed PFAS contamination are entered in the database. As of November 6, 2024, there were 81 PFAS-contaminated sites registered in FCSI.

used to inform future risk assessment and risk management decision making and other activities related to PFAS. PFAS were considered for addition to the publicly available NPRI. The Government of Canada aims to provide a high degree of public participation, openness and transparency in decision making, yet it also has an obligation to protect confidential business information. Government officials work to promote public participation and transparency while protecting confidential information. Additional information obtained by the Government of Canada may be shared in future risk management documents.

Comment Summary A-25: Commenters stated that the Government of Canada should exclude HFOs, HCFOs and/or HFCs, and their uses from the Schedule 1 listing.

Response A-25: The Government of Canada takes note of the challenges posed by the limited alternatives to HFCs, following the coming into force of the controls under the ODSHAR. Although many HFOs, HFCs and HCFOs are part of the class of PFAS in the State of PFAS Report, risk management measures may be tailored to specific sectors and uses depending upon the information received through various stages of consultations, relevant socio-economic factors, and in consideration of concerns to the environment and human health that have been identified.

Any risk management measures to address HFOs or HCFOs would take into consideration the availability of suitable alternatives, including the costs and benefits of switching to those alternatives. Information gathering to fully understand the availability of alternatives and the costs of transitioning to alternatives would also take place before risk management actions are taken.

Should risk management actions on HFOs and HCFOs be considered, they would be developed in alignment with, and complementary to, existing regulations with controls on PFAS, such as the ODSHAR.

Comment Summary A-26: Commenters recommended not to duplicate existing listings in any Schedule 1 listing(s) that result from addressing PFAS as a class.

Response A-26: The recommendation is to add the class of PFAS, excluding fluoropolymers, to Schedule 1. Note that existing listings of certain PFAS on Schedule 1 does not prevent the addition of the broader class to the Schedule. The addition does not in and of itself restrict or prohibit the substances; rather, it enables risk management instruments to be developed, such as regulations under CEPA.

Any risk management actions considered will be developed in alignment with, and complementary to, existing regulations.

Comment Summary A-27: Commenters recommended excluding certain PFAS, such as HFOs, from a Schedule 1 listing of CEPA. Others recommended not to add PFAS to Schedule 1 of CEPA until assessments are conducted for subgroups or individual PFAS.

Other commenters recommended adding the entire class of PFAS to Schedule 1 of CEPA.

Response A-27: The State of PFAS Report concluded that the class of PFAS, excluding fluoropolymers as defined in report, meets 1 or more of the criteria set out in section 64 of CEPA. The Risk Management Approach recommends adding to Schedule 1 the class of PFAS, excluding fluoropolymers, as defined in the State of PFAS Report. Note that adding a substance to Schedule 1 of CEPA does not in and of itself restrict or prohibit the substance; rather, it enables risk management instruments to be developed such as regulations under the Act.

Risk management instruments may be tailored to sectors and uses depending upon the information received and socio-economic factors for *a*ny regulatory measure that would address PFAS, including HFOs, will take into consideration the availability of suitable alternatives, including the costs and benefits of switching to those alternatives. Before taking any risk management actions, information will be gathered to fully understand the availability of alternatives and the costs of transitioning to those alternatives.

There will be additional opportunities for consultation on future risk management actions.

Comment Summary A-28: Commenters recommended clarifying the use of the risk management instruments and the scope of the risk assessment and risk management. The scope should not include substances that are addressed by other regulations; it should include an exhaustive list of substance identifiers (that is, Chemical Abstracts Service Registry Numbers [CAS RNs]) and be limited to substances on the DSL.

Other commenters added that manufacturers do not have the background to interpret complex chemical definitions or identify chemical structure diagrams, making it difficult for them to identify PFAS from only a chemical structural definition. A list of CAS RNs would help to streamline and simplify reporting.

Response A-28: The State of PFAS Report defines PFAS using the OECD (2021) definition of PFAS, which uses chemical structure rather than individual identifiers such as CAS RNs. It should be noted that while they are part of the class, PFAS meeting the definition of fluoropolymers as described in the State of PFAS Report are planned for consideration in a separate assessment.

Risk management actions considered would be developed in alignment with, and complementary to, existing regulations. The proposed approach is therefore to address parent compounds and potential transformation products.

The following external resources are non-exhaustive lists of PFAS:

- OECD comprehensive global database on PFAS [xlsx]
- List of PFAS chemicals with structures (US EPA)
- <u>List of PFAS chemicals without explicit structures polymers and other UVCB chemicals</u> (US EPA)

Note that the US EPA uses a different definition of PFAS than the OECD and thus does not capture the same number of substances.

Comment Summary A-29: Commenters recommended that the Government of Canada invest more in the research and monitoring of PFAS. Some suggestions include:

- · improved analytical testing and sampling methods
- more research on the toxicological effects of PFAS and various PFAS at different concentrations, including mixtures
- monitoring to understand PFAS trends, to capture a wider range of PFAS and examine releases within Canada, and
- developing and conducting targeted monitoring, including targeted biomonitoring, to inform the public of the potential for PFAS contamination

Response A-29: The Government of Canada conducts a variety of monitoring programs and research studies to understand trends in PFAS occurrence in Canada.

As the analytical methods for PFAS have improved over the years, a larger number of PFAS, including newer generation compounds, are included in monitoring programs. The data generated from these monitoring programs are routinely published on the Government of Canada's Open Data Portal. Research on the toxicology of PFAS is also ongoing. More information on planned and future research, monitoring, and surveillance projects is highlighted in Section 8.1.2 (*Planned and future research, monitoring, and surveillance*) of the State of PFAS Report.

Comment Summary A-30: Commenters supported efforts to identify PFAS uses that should be targeted for restriction. They also recommended that more work needs to be done to identify key product categories leading to direct and indirect PFAS human and ecosystem exposure.

Response A-30: Data collection initiatives (including a notice under section 71 of CEPA in the *Canada Gazette*) are aimed at collecting additional information on PFAS to better understand uses and sources of release and may be used to inform risk management decisions and other activities related to PFAS.

Risk management instruments may be tailored to sectors and uses depending upon the information received, socio-economic factors. Any regulatory measure that would address PFAS would take into consideration the availability of suitable alternatives, including the costs and benefits of switching to those alternatives. Information gathering to fully understand the availability of alternatives and the costs of transitioning to alternatives would also take place before risk management actions are taken.

Additional opportunities for stakeholder and interested parties engagement would be provided during the subsequent development of risk management actions.

Comment Summary A-31: Commenters requested that the environmental objectives of the Risk Management Scope should also be expanded to specify the need to reduce the use and release of PFAS substances to levels that are not harmful to biodiversity. This aligns with Canada's commitments under the Kunming-Montreal Global Biodiversity Framework.

They recommend that the Risk Management Scope environment objectives should be revised to: "Reduce releases of these substances to the Canadian environment so as to not cause adverse effects, including immediate and long-term harmful effects on biological diversity.

Response A-31: The State of PFAS Report concluded that the class of PFAS, excluding fluoropolymers as defined in the report, meets the criteria 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 effects on the environment or its biological diversity, and that constitute or may constitute a danger in Canada to human life or health. It is thus understood that the environmental objective also includes biological diversity.

Comment Summary A-32: Commenters requested that Canada implement a robust regulatory framework for continuous evaluation and review of hazardous chemical products.

Response A-32: Canada's approach to chemicals management includes information gathering, risk assessment, risk management, compliance promotion and enforcement, performance measurement and evaluation, and reporting. For more information please consult Canada's approach on chemicals.

Comment Summary A-33: Commenters requested that the Government of Canada establish a centre to undertake research and work directly with companies to substitute toxic chemicals and harmful pollutants in products.

Response A-33: This will be considered during future steps of risk management.

When developing risk management documents, substitutes and alternatives are considered whenever possible and when adequate and relevant information is available on the economic, social and environmental implications for Canada. The Government of Canada is also exploring ways to advance responsible replacement of chemicals of concern, including ways to apply informed substitution to support chemicals management.

Comment Summary A-34: Commenters recommended maintaining the current regulatory approach for veterinary medicines at HC's Veterinary Drugs Directorate and CFIA, as well as conducting an assessment on potential impacts of regulatory approaches for PFAS on veterinary medicine and animal health.

Response A-34: The Veterinary Drugs Directorate and the CFIA were kept informed of developments leading to the publication of the State of PFAS Report and will be directly consulted regarding any risk management activities that may affect their programs.

Consultation

Comment Summary A-35: Commenters requested to be engaged in future consultations and discussions regarding PFAS, including risk management actions.

Response A-35: It is concluded that the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, meets 1 or more of the criteria set out in section 64 of CEPA. Please note that there will be additional opportunities for consultation on future risk management actions. The Government of Canada will notify implicated stakeholders of future consultation opportunities.

To receive the latest news on actions to assess and manage chemical substances under the CMP, please consult the <u>Latest News about the CMP</u> website.

Comment Summary A-36: Commenters recommended forming an expert working group comprised of academics, industry representatives, US industry counterparts, and other agencies and organizations to develop a PFAS approach and address current data gaps as required. This expert group could conduct more coordinated reviews and develop risk management actions.

Response A-36: It is concluded that the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, meets 1 or more of the criteria set out in section 64 of CEPA. Thus, this suggestion will be considered in the risk management process.

International alignment

Comment Summary A-37: Commenters asserted that Canada's approach to PFAS should not be a blanket approach, but rather it should align with actions taken in other jurisdictions and follow the examples of various countries that provide approaches and regulations suited to each reasonable subclass of material.

Response A-37: The Government of Canada is considering actions taken in other jurisdictions, including measures taken in the EU and the US. Alignment with other jurisdictions will be considered where appropriate and provided that the measures are consistent with the Canadian context.

Comment Summary A-38: Commenters stated that PFAS is a global issue, but each jurisdiction appears to be developing its unique approach and not aligning efforts. Commenters recommended that Canada should collaborate with its counterpart agencies to compare scope definitions and requested that the definition of PFAS align with key trade partners, particularly the US and Europe. Commenters also suggested that the Government of Canada align its actions with actions taken in other jurisdictions, including work by the US EPA and through the Great Lakes Water Quality Agreement. They recommended that the Government of Canada consider measures taken in the US on PFAS to ensure consistency with our trade partner.

Several commenters noted that risk management must avoid regulatory policies that are barriers to free trade and advocated for a harmonized North American PFAS approach. Failure to align with the US EPA could lead to supply chain disruptions and impact the availability of products in Canada.

Other commenters recommended alignment with California AB 1817 with regards to risk management.

Response A-38: The Government of Canada is taking into consideration actions taken in other jurisdictions (for example, the US and Europe), including measures proposed by the US EPA, and is closely following international developments to help inform the approach it will take in addressing the class of PFAS.

The State of PFAS Report uses the definition developed by the OECD (Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD 2021). This is a broad chemical definition developed by a working group consisting of several international regulatory authorities and other experts.

Under the Great Lakes Water Quality Agreement, 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. 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. 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.

Canada is a party to the Stockholm Convention on Persistent Organic Pollutants (POPs), an important international agreement that requires that measures be taken to prohibit or restrict a number of PFAS, including PFOA, PFOS, and PFHxS. Recently, Canada nominated LC-PFCAs for addition to the Stockholm Convention, which is currently under review. If the review is successful, LC-PFCAs could be considered for listing under the Stockholm Convention as early as 2025.

In addition, the Risk Management Approach outlines that alignment with measures in other jurisdictions will be considered, where appropriate.

New information and data

Comment Summary A-39: Commenters identified uses of PFAS where there is no known alternative or the alternative is not technically, economically, or otherwise feasible. Uses mentioned included the following:

- medical devices (including metered dose inhalers or MDIs) and processing aids for essential uses (in vitro diagnostic products), as well as medicinal products and medicinal product packaging
- high-voltage switchgear
- hydrogen energy-related products, especially fuel cells
- seals, hoses, custom wires and cables, hydraulic systems, refrigerants, and alternative power technologies (batteries and hydrogen fuel cells)
- engines, vehicles, and equipment
- new coating technologies, including uses in front and back-sheet materials for solar panels, uses that are critical for ultraviolet (UV) light and corrosion resistance, and uses to protect critical private and public infrastructure such as bridges and various metal constructions.
- veterinary products and veterinary product packaging
- certain fertilizer manufacturing processes
- printed circuit boards, lithium-ion batteries, and other internal parts of home appliances
- products and their respective new and replacement parts in the aerospace and defense sectors

Response A-39: The Risk Management Approach has taken into consideration the information received to the extent possible. Information gathered through the various stages of consultation will continue to inform the risk management actions to be developed. These actions may be tailored to sectors and uses depending upon the information received, demonstrated absence of feasible alternatives and socio-economic factors.

Comment Summary A-40: Commenters provided information on the potential impacts of a ban on PFAS. Products and sectors anticipated to be impacted include:

- firefighting foams, and their replacement, disposal and clean-up
- medical devices
- transportation, agriculture, construction and industry
- international trade
- pharmaceutical products

Response A-40: It is concluded that the class of PFAS, excluding fluoropolymers as defined in the State of PFAS Report, meets 1 or more of the criteria set out in section 64 of CEPA. AS Report, meets 1 or more of the criteria set out in section 64 of CEPA. The Risk Management Approach has taken into consideration the information received to the extent possible. Information gathered through the various stages of consultation will continue to inform the risk management actions to be developed. These actions may be tailored to sectors and uses depending upon the information received, demonstrated absence of suitable alternatives, socioeconomic factors, and consideration of health and environmental concerns.

Comment Summary A-41: Commenters provided technical information on the function and uses of certain PFAS in products, some of which was identified as confidential business information.

Response A-41: The Risk Management Approach has taken into consideration the information received to the extent possible. Information gathered through the various stages of consultation will continue to inform the risk management actions to be developed. These actions may be tailored to sectors and uses depending upon the information received, demonstrated absence of suitable alternatives and socio-economic factors.

Comment Summary A-42: Commenters stated that there are missing elements for agricultural ecosystems such as information on the characterization of agricultural sites, the impacts of PFAS on the agricultural environment and the possible water treatments for contaminated water for different uses.

Response A-42: The State of PFAS Report does not have a specific section on agricultural lands, however, this information is captured within different sections of the report. For example, the uptake of PFAS into crops/livestock through irrigation and soil contamination is relevant to soil, biosolids and irrigation water (although fodder is not explicitly addressed). The characterization and management of PFAS contaminated agricultural sites would follow the same methodologies used to characterize and manage other PFAS contaminated sites with different land uses (for example, residential, parklands, commercial, industrial, etc). In addition, the CCME PFOS Soil Quality Guideline includes information related to agricultural land uses which is referenced in the State of PFAS Report. Land application of biosolids and use of PFAS- impacted irrigation water on plants are also referenced in the report.