Before
Environment and Climate Change Canada
Health Canada
Risk management approach for per- and polyfluoroalkyl substances (PFAS), excluding fluoropolymers

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Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide our comments on the proposed Risk management approach for per- and polyfluoroalkyl substances (PFAS), excluding fluoropolymers (the "Approach") developed by Health Canada and Environment and Climate Change Canada ("Canada"). CUC is an association of companies from diverse industries that are interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances. CUC encourages the development of chemical regulatory policies that protect human health and the environment while simultaneously fostering the pursuit of technological innovation. Aligning these goals is particularly important in the context of chemical management policy in a global economy. As stakeholders who have a business interest in the continued use of certain PFAS in highly specialized, critical-use applications, CUC Members have been actively engaged with regulators on PFAS-related legislation and regulation in the United States and we appreciate the opportunity to do so in Canada as well.

General Comments on Overall Approach

CUC appreciates the efforts to provide a phased-in approach to implementing restrictions on PFAS use that are intended to eliminate unnecessary exposures to PFAS. Furthermore, CUC supports the effort made to exclude from the initial Approach certain fluoropolymers. However, CUC believes that adopting a broad, class-based approach to PFAS regulation – the exclusion of certain fluoropolymers notwithstanding – fails to recognize that, as defined in the risk management approach, the term PFAS will encompass thousands of chemical substances that are widely used throughout the world in a broad range of applications.

The Approach uses the PFAS definition utilized by the Organisation for Economic Co-operation and Development ("OECD"): "fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), that is, with a few noted exceptions, any chemical with at least a perfluorinated methyl group ($–CF_3$) or a perfluorinated methylene group ($–CF_2–$) is a PFAS."

Chemically, toxicologically, and physically, PFAS differ widely. Included in the category as PFAS are substances in the solid (e.g., fluoropolymers), liquid (e.g., fluorotelomer alcohols), and gaseous (e.g., hydrofluorocarbon refrigerants) forms. The fundamental physical, chemical, and

biological properties of solids, liquids, and gases are clearly different from one another. In fact, when OECD released its definition of PFAS, they stated that "[a]s PFASs are a chemical class with diverse molecular structure and physical, chemical and biological properties, it is highly recommended that such diversity be properly recognized and communicated in a clear, specific and descriptive manner." Other than fluoropolymers, the Approach fails to recognize that there are significant differences among the unique substances included in the PFAS definition being applied and that many substances implicitly included may not pose a risk of harm to human health or the environment. While CUC appreciates and supports the decision to exclude fluoropolymers from the Approach, CUC believes that the regulatory personnel in Canada should further refine the proposed scope of the specific substances that may become subject to restriction to reflect the substantive differences that exist within the class of PFAS. Canada can use the information gleaned from the PFAS data collection under CEPA 71(1)(b) to refine which PFAS and PFAS uses do not require restriction. CUC recommends that any restrictions being considered on PFAS should be undertaken for individual substances of known concerns, preferably having a specific CASRN for ease of identification and regulatory certainty.

CUC Recommends Expanding the Current Exclusion for Fluoropolymers

As mentioned, the Approach does not address fluoropolymers (although future actions to restrict fluoropolymers are foreshadowed). Fluoropolymers are defined in the Approach as "polymers made by polymerization or copolymerization of olefinic monomers (at least 1 of which contains fluorine bonded to 1 or both of the olefinic carbon atoms), to form a carbon-only polymer backbone with fluorine atoms directly bonded to it." CUC supports the decision to exclude fluoropolymers from the upcoming restrictions. Fluoropolymers generally have well-established safety profiles and are not expected to present significant concerns for human health or the environment. Polymeric, high molecular weight fluoropolymers are often too large to cross biological membranes and therefore present little potential for uptake in humans or environmental exposures of concern. Fluoropolymers are not water soluble and, as a result, are not found in sources of drinking water. Importantly, fluoropolymers are not closely related to PFOA or PFOS or other long-chain PFAS, nor can they readily transform into those substances in the environment. Moreover, as fluoropolymers are used in numerous applications throughout the economy and in many applications for which there are no currently available alternatives, attempting to restrict their use could have severe consequences for the proper functioning of society, including adverse impacts on safety, health, and the economy at large. However, CUC suggests that the definition be expanded to exclude from the anticipated restrictions polymers that are not solely carbon-backbone only, such as perfluoropolyethers and polymers that contain fully fluorinated methyl or methylene atoms in side chains. Such fluoropolymers also are not likely to have the chemical, physical, and toxicological properties as the PFAS that have contributed to existing environmental contamination.

Important Considerations When Making Risk management Decision

In noticing the Approach, Canada requested information on the availability of alternatives to PFAS. CUC recognizes the need for such information in regulatory decision making. However, "availability" encompasses many criteria that CUC recommends be considered. For example, the

fact that an alternative substance may serve an equivalent purpose in some applications does not mean it will have equivalent functionality to a given substance in all use applications. To be a truly compatible alternative, a substance must perform its intended function in the same fashion (i.e., with the same technical and performance capabilities) as the original substance. The use of an alternative must be such that its use does not create problems for the manufacturing or processing of the product in which it will be used and the performance capabilities of the end product must not be diminished in any way. Furthermore, the use of an alternative must not pose any new safety concerns.

Additionally, many products have stringent technical requirements that must be satisfied to ensure acceptable levels of performance, reliability, safety, and utility for the end-user. An alternative must satisfy these requirements to be considered a true substitute. The process of testing/qualifying a substitute in those situations may take many years and considerable resources to be successful. Further, there is no guarantee that a potential alternative would successfully replace a PFAS until the replacement process has been completed. It is also important to consider that the existence of an alternative does not equate to its availability – either due to economic or supply issues.

For the foregoing reasons, it is challenging on a "class-wide" basis to determine whether there are alternatives to PFAS and to identify them on anything other than a one-to-one chemical and use-specific basis.

Similarly, Canada requested information on the socio-economic impacts of replacing PFAS. Although alternatives to PFAS may exist, they could be potentially cost-prohibitive. Requiring the use of an alternative could lead to a manufacturer deciding to cease manufacturing a product because it is now simply too expensive, and consumers will not purchase it. The economic consequences of such decisions must be carefully weighed.

CUC further recommends that Canada, as part of the socio-economic impact analysis, consider whether the restriction of a PFAS would result in a significant increase in negative healthcare outcomes, an inability to mitigate significant risks to human health or the environment, or significantly interrupt the daily functions on which society relies. Canada must understand the impact of restriction on the availability or effective use of products or product components that are essential for health, safety, or the functioning of society, such as those needed for climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, aerospace, aeronautics, public safety, security and defense, and construction. Thus, CUC Members recommend when making regulatory determinations, the regulatory authorities in Canada take care to assess the socio-economic impacts of a restriction on chemical and use-specific bases.

Comments on Specific Proposed Phases

CUC supports the approach of phasing in targeted prohibitions as a last resort to adequately control risks where no other feasible options (e.g., pollution controls) have been identified. This allows both Canada and the regulated community to learn from the experience of each phase and make improvements as further phases are implemented.

- The Approach describes the scope of phase 2 as "Uses of PFAS (excluding fluoropolymers) not needed for the protection of health, safety or the environment, with a particular focus on consumer applications where alternatives are known to exist." The Approach provides examples of such uses/products, such as:
    - cosmetics
    - natural health products and non-prescription drugs
    - food packaging materials, food additives, non-industrial food contact products such as paper plates, cups and bowls
    - paint and coating, adhesive and sealant and other building materials available to consumers
    - consumer mixtures such as cleaning products, waxes and polishes
    - textile uses (including personal protective equipment such as firefighting turnout gear)
    - ski waxes

  CUC understands that Canadian authorities intend to adopt an approach that focuses on non-essential uses of PFAS. CUC supports this approach. However, when closely analyzing the list above, the criteria that Canada will be using to determine what "is not needed for the protection of health, safety of the environment" are not readily apparent to the reader. While health care-related products and non-prescription drugs can definitely protect human health, other products provide societal benefits as well. Examples can include certain food packaging that not only serves to keep food fresh but also can be critical to prevent contamination from bacteria and other microorganisms and pests. Some cleaning products may contain PFAS and often serve important functions related to keeping important spaces (e.g., food preparation areas, hospitals, medical offices) free from potential contaminants, allergens, and microbes. CUC suggests that Canada add greater clarity and detail to the criteria for a use that is "needed for the protection of health, safety or the environment." This would also include uses that are essential to national defense and security purposes.

  Furthermore, when deciding on the risk management approach for these products, Canada must ensure that it has a complete understanding of the purposes served by the PFAS components in these products. Care should be given to assessing whether PFAS enables or enhances the technical and performance functionality of the product, and whether the product would be as effective should PFAS use in the product be prohibited. Additionally, as mentioned above, the fact that an alternative substance may serve an equivalent purpose generally does not equate to equivalent functionality of the substance. The performance capabilities of an alternative must be carefully understood to determine the impact of prohibiting the use of PFAS. Such an analysis is needed to truly ascertain if a certain PFAS is essential or non-essential.

- The Approach describes Phase 3 as "Uses of PFAS (excluding fluoropolymers) for which currently there may not be feasible alternatives and requiring further evaluation of the role of PFAS." The Approach provides examples of such products/uses, such as:

- fluorinated gas applications such as spray-foam insulation and refrigeration
- prescription drugs (human and veterinary)
- medical devices
- industrial food contact materials
- industrial sectors such as mining and petroleum
- transport and military applications

While the published approach acknowledges that further study of the uses of PFAS in these products is required, it is important to recognize that some of the example uses are already subject to regulation in Canada. Fluorinated gas applications are regulated by the Ozone-depleting Substances and Halocarbon Alternatives Regulations under the Canada Environmental Protection Act. These regulations implemented Canada's obligations under the *Montreal Protocol on Substances that Deplete the Ozone Layer*, including the Kigali Amendment, and their role is to control ozone-depleting substances and introduce restrictions on hydrofluorocarbons. Attempting to focus on PFAS content in gases has the potential to frustrate progress under these regulations.

Additionally, Health Canada already regulates the approval and use of prescription drugs and medical devices. There are already robust regulatory regimes that regulate the safety, efficacy, and quality of these products. Again, narrowing a regulatory focus to one substance of concern – PFAS – runs counter to the holistic reviews that are already performed on these products before they are allowed on the marketplace. Accordingly, CUC recommends that products that are already subject to regulatory approvals not be the focus for PFAS specific regulatory action.

Specific Recommendations Concerning Sales Restrictions

Should Canada decide to restrict the sales of products containing PFAS as part of its risk management program, Canada should consider the following recommendations:

- CUC recommends that sales prohibitions not extend to previously manufactured products (i.e., existing stocks produced before the effective date of any regulatory requirement), spare/replacement parts for existing products, and materials needed to maintain and repair existing products (such as machinery and other durable equipment). These parts are often not newly manufactured. Rather, when a new product is manufactured, spare and replacement parts are manufactured and maintained in accordance with either contractual or regulatory requirements so that the product can be continuously used and need not be replaced solely because a replacement part is not available. If these parts are not newly manufactured, it may be difficult for the entity selling the parts in any specific state to ascertain PFAS content due to the lapse of time since manufacture. The availability of spare/replacement parts would also allow for the continued use and maintenance of existing products, thereby preventing the accumulation of unnecessary waste including e-waste.
- The presence of PFAS should only be prohibited if it is intentionally added. CUC suggests that "Intentionally added" be defined as "PFAS known to have been added to a

and remain in a product or one of its product components in order to provide a specific characteristic, appearance, or quality for the product as manufactured or to perform a specific function in the final product. Products containing intentionally added PFAS include products that consist solely of PFAS. Intentionally added PFAS does not include PFAS that is reasonably believed to be present in the final product as a contaminant, byproduct, or intermediate."

- Although we understand that regulatory personnel in Canada, prior to proposing restrictions, will be studying the availability of alternatives, CUC nonetheless recommends that any sales prohibitions include a waiver from such restrictions for "currently unavoidable uses of PFAS." The "currently unavoidable" phrase has been used in a number of PFAS-related legislative actions taken in several US states and is gaining familiarity within the regulated community. The use of the term, however, should be accompanied by the establishment of a transparent, predictable, and efficient waiver process, so that manufacturers will not need to risk noncompliance and consumers can continue to have access critical products on which they may depend. Canadian procedures would need to include objective standards for what constitutes a currently unavoidable use, what information and/or data is required to support such a finding, and the process (including limits on processing time) needed to obtain such waivers. Such a waiver process should also specify that use can continue until a waiver decision has been rendered.

Additional Risk Management Actions

The Approach also contains suggestions for complimentary, voluntary risk management actions. One such initiative is labelling. While CUC recognizes that the labeling Approach is meant to be of a voluntary nature, authorities in Canada should be aware of the following considerations:

- Labelling should only be promoted for items that meet some de minimis threshold for PFAS content, such as PFAS present at 0.1% by product weight or greater. The de minimis level of 0.1% is practical and is generally understood by the manufacturers and distributors of manufactured articles that move among various international markets because the level aligns with the level imposed in the European Union for "substances of very high concern" when present in articles. This would ensure that labeling is not promoted for products that may have an insignificant (trace) amount of PFAS (including impurities), for which exposure to the PFAS is highly unlikely, and that would pose minimal risk over the product lifecycle.
- Labeling initiatives can disproportionately affect small businesses that may lack the resources and expertise to comply. Costs, such as redesigning labels and printing new packaging, can be a significant financial burden. This could hinder small businesses' ability to compete with larger corporations and may result in reduced product diversity and market competition. Accordingly, alternative methods for PFAS content disclosure should be considered.
- Labeling PFAS-containing components is challenging if not completely impossible in complex manufactured goods. Even utilization of alternative methods may prove to be

difficult, due to the number of individual components that may be within a finished good (for example, an automobile). Additionally, it is possible that the fact that a distinct component in a complex finished good contains PFAS may be a trade secret, and therefore might not be known or readily revealed to the manufacturer of a finished product and could not readily be disclosed through labeling.

Conclusion

CUC appreciates your consideration of these comments. CUC looks forward to additional opportunities to respond to any questions you might have and to discuss these above comments with the appropriate regulatory officials in Canada.