Summary of Public Comments received on PFOA, its Salts and its Precursors.

Comments on the draft screening assessment report for Perfluorooctanoic acid (PFOA), its Salts and its Precursors were provided by Canadian Environmental Law Association and Chemical Sensitivities Manitoba, the Telomer Research Group and Fluoropolymer's Manufacturing Group, Keith R. Cooper, Professor, Rutgers School of Environmental and Biological Sciences, the Environmental Working Group and Environmental Defence.

A summary of comments and responses is included below, organized by topic:

- Scope
- Persistence
- Bioaccumulation
- Exposure impacting human health
- Waste Disposal
- Epidemiology Data
- Margins of Exposure
- Mode of Action
- Carcinogenicity
- Reproductive and developmental effects
- Proposed Risk Management

TOPIC	COMMENT	RESPONSE
Scope	Why was PFOA and its salts not considered to be a high priority for assessment of potential risk to human health following categorization?	Although PFOA and its salts were not considered to be a high priority for assessment of potential risks to human health, based on the information available at that time, a screening assessment has been conducted to assess potential risks from PFOA and its salts to human health.
	References to a long half-life in the synopsis should refer to biological half-life.	The final screening assessment will be revised to provide this clarity.
	The three criteria in Section 64 of CEPA 1999, which defines a substance as toxic should be	The criteria in Section 64 of CEPA 1999 will not be cited in the screening assessment to be consistent with other published

	cited.	assessments.
Persistence	A discussion of potential sources of PFOA in the Arctic is incomplete without a better understanding of the potential for local sources (i.e., presence of military bases and associated activities in the Arctic and near-Arctic areas around the globe).	The assessment includes an extensive discussion identifying a number of theories (i.e., ocean currents, volatile precursors, sea spray, decommissioned military bases) regarding potential sources of PFOA in the Canadian Arctic.
Bioaccumulation	We are concerned that the weight of evidence and the emphasis on biomagnification in aquatic species played a significant role in the final decision of bioaccumulation for PFOA despite the availability of evidence of PFOA in higher tropic levels (mammals and terrestrial animals). We are uncertain if the low levels of PFOA detected in various species of fish were the primary reasons for concluding that PFOA is not bioaccumulative as prescribed by the bioaccumulation criteria in the *Persistence and Bioaccumulation Regulations*, CEPA 1999.	The numeric criteria for bioaccumulation, outlined in the Persistence and Bioaccumulation Regulations of CEPA 1999, are based on bioaccumulation data for freshwater aquatic species (i.e. fish) only as well as for substances that preferentially partition to lipids. As a result, the criteria are of uncertain relevance as indicators of the bioaccumulation potential of PFOA which preferentially partitions in the proteins of liver, blood and kidney in terrestrial and marine mammals. The bioaccumulation potential of PFOA in fish may be low. However, PFOA is considered to accumulate and biomagnify in terrestrial and marine mammals as BMFs ranged from 0.03 to 125 (polar bears) and TMFs ranged from 0.1 – 3.28 (beluga whales).
	Was the weight of evidence approach applied by the assessors adequate to include careful consideration of all degradation or breakdown products, metabolism, and potential synergistic effects of other substances similar to long chain PFCAs or PFOAs, their salts and their precursors?	The key issue considered in this assessment is the bioaccumulation potential of PFOA, rather than the accumulation of individual precursors. While the full range of precursors is less well characterized than PFOA itself, precursors were included as they are expected over time to degrade to PFOA, thereby ultimately contributing to the environmental loading for PFOA. Precursors may also play a key role in the long-range transport and subsequent degradation to PFOA in remote areas.
	We encourage the government to initiate a review of the *Persistence and Bioaccumulation Regulations*, with an aim to strengthen the criteria	In the published assessments for perfluorinated substances such as PFOS, PFOA and the long-chain PFCAs, the Government of Canada has acknowledged that the criteria for bioaccumulation as

	applied for persistence and include the consideration of bioaccumulation in terrestrial animals and mammals. The government should acknowledge that certain substances such as those that are ionizable may not exhibit the bioaccumulative potential as required under the *Persistence and Bioaccumulation Regulations*. The *Persistence and Bioaccumulation Regulations* should be more encompassing and ensure that the determination of bioaccumulation potential for these types of substances can be undertaken.	stated in the *Persistence and Bioaccumulation Regulations* may not fully account for accumulation of substances that partition to non-lipid tissues. The appropriateness of revisions to the *Persistence and Bioaccumulation Regulations* will be further considered.
	While the screening assessment noted that the measures for TMFs and BMFs may note the differences found in the food webs of these organisms, they may not determine the bioaccumulation potential for PFOA. Nevertheless, we note the importance of using these measures to inform the decisions by government on bioaccumulation for PFOA.	There are various uncertainties associated with the bioaccumulation of perfluorinated compounds, such as PFOA, and these are recognized and described in the screening assessment. However, if substances have been shown in field studies to biomagnify through the food web (through measures such as BMFs and TMFs), it is considered that this provides weight of evidence that the substance can significantly accumulate in biota.
	We have great concern as there is limited information on the toxicology of PFOA precursors, the potential for combined or synergistic effects with PFOA, and the toxicology and potential for combined or synergistic effects of PFOA with other perfluoroalkyl acids. With variability in analytical results between individual laboratories, this raises more concern as to the confidence level in the data collected.	It is recognized that other perfluoroalkyl compounds and precursors to PFOA may contribute to the overall additive or synergistic impact of PFOA and that precursors contribute to the ultimate loadings of PFOA. However, the assessment did not consider the combined effects of PFOA, all its precursors and other perfluorinated compounds. The key issue considered is the bioaccumulation potential of PFOA, rather than the accumulation of individual compounds. However, the screening assessment does recognize the various uncertainties and data gaps associated with the evaluation of ecological risks of perfluorinated compounds, such as PFOA.
	It is not scientifically appropriate to ascribe causation to PFOA for potential observed effects where a causative relationship has not been established (even if a statistical association has	Causation to PFOA was not stated for potential observed effects if a causative relationship was not clearly established for studies described in the screening assessment. For example, causation to PFOA was not stated for the study on liver lesions in East

	been observed).	Greenland polar bears and for the study on inflammation and immunity parameters in bottlenose dolphin.
	The ecological exposure, effects and risk assessments do not focus on exposure concentrations to the same extent, but rather seems to infer the importance of potential exposure concentrations based solely on the persistence of PFOA and detection of PFOA at typically very low concentrations.	The exposure and risk characterization of PFOA is based on the available data in Canada. The risk quotients for some types of fish indicate a low likelihood of risk from exposures at current concentrations in the environment.
	There are no studies using environmental samples collected since 2000 that suggest that there is an on-going, increasing trend in PFOA concentrations in any species.	The Government of Canada identified three studies showing temporal trends of PFOA up to 2002 and 2006 (i.e, 1972–2002, 1984–2006, and 1992–2002) for polar bears and sea otters.
	The evaluation of "biomagnification" (and perhaps bioaccumulation) based on extrapolations from liver residues in one organism to liver residues in another organism at the next higher position in the food chain is inappropriate because it assumes undemonstrated similarities in uptake processes and organism physiology.	From a physiological perspective, it is the concentration of a substance at the site of toxic action within the organism that determines whether a response is observed, regardless of the external concentration. In the case of PFOA, the site of toxic action is often considered to be the liver. However, when the potential for toxicity in consumer organisms is being determined, it is the concentration in the whole body of a prey item that is of interest, since the prey is often completely consumed by the predator (including individual tissues and organs, such as the liver and blood). Since perfluorinated substances partition to liver and blood, most field measurements for these substances have been performed on those individual organs and tissues. This is especially true for organisms at the higher trophic levels (e.g., polar bear), where whole-body analysis is not feasible. Thus, from a toxicological perspective, BCFs, BAFs and BMFs based on concentrations in individual organs, such as the liver, may be more relevant when the potential for direct organ-specific toxicity (i.e., liver toxicity) is being predicted.

Exposure impacting human health	Adequate consideration should be given to vulnerable populations and occupational exposure.	The screening assessments are based on consideration of the available data and include various conservative exposure scenarios considered to account for both general and vulnerable populations in Canada. Information on specific subpopulations, including those occupationally exposed and exposures to children living in Northern Canada was considered in the assessment. Information developed through the Chemicals Management Plan process may be used to inform decisions regarding additional actions to minimize exposure to workers.
	The screening assessments of long chain PFCAs and PFOAs, their salts and their precursors should include consideration of the cumulative and synergistic impacts of PFCs, based on the findings of ski wax technicians.	The biomonitoring data used in the current assessment represents aggregate exposure from all routes and sources, including precursors. Consideration of cumulative and synergistic effects is not precluded from screening assessments, when sufficient information to undertake such an analysis is available.
	There should be a switch to products that do not result in the off-gassing or migration of such PFOA and precursors. Also information on the inhalation during treatment of clothing scenario should be clarified.	Biomonitoring data used in the assessment represents exposure from all routes and sources, including inhalation exposure during use of consumer products. The margins of exposure are considered adequate to be protective of human health and to address the uncertainties in the health effects and exposure databases. Inhalation exposure during the treatment of clothing has been clarified in the final screening assessment.
	There is available new biomonitoring data from the Canadian Health Measures Survey (CHMS) and epidemiology data indicating associations between PFOA exposure and reduced birth weight.	The assessment has been updated with new biomonitoring data, including data from the CHMS. The epidemiology data examining reduced birth weight were addressed in the screening assessment. The changes in birth weight are within normal range of variation, As well, in other epidemiological studies, no association between PFOA exposure and birth weights were identified, including the studies from highly exposed populations. Additionally, developmental toxicity was selected as one of the endpoints for risk characterization. The margins of exposure are considered adequate to be protective of human health and to address the

		uncertainties in the health effects and exposure databases.
Waste Disposal	Most of the assessments conducted through the Chemicals Management Plan do not take into consideration all issues related to waste disposal. The continuing absence of this consideration creates significant gaps in the assessment approach.	The Government of Canada considers waste disposal activities such as landfill, wastewater and recycling. Releases of the substance to sewer (before sewage treatment plants) are estimated from recycling activities as they are for industrial activities when applicable and, depending on a substance's properties (e.g. if it is expected to partition to solids), resulting concentration in sewage sludge can be estimated based on these quantities released to sewer. Further investigation on disposal method for the sewage sludge (e.g. land application, landfill) can be considered when relevant and available. Recycling activities and their resulting potential releases to the environment are also considered.
Epidemiology Data	The Government was not sufficiently precautionary. Adverse health effects, including excess of cancers in multiple locations, hormone disruption, and developmental abnormalities were observed among workers in fluorochemical plants and exposed individuals who live nearby.	Available epidemiology data have been reviewed and incorporated, as appropriate, in the final screening assessment. The overall weight of evidence does not indicate consistent or causal relationships between PFOA exposure and observed adverse effects. The margins of exposure are considered adequate to be protective of human health and to address the uncertainties in the health effects and exposure databases.
	The Draft Screening Assessment report does not contain many relevant published studies on immunotoxicity, neurobehavioral effects, and mode of action. Additional epidemiology studies should be included in the SAR to address associations with cancer endpoints.	The screening assessment does not list or describe each individual study, but rather highlights key relevant studies which cover the relevant human exposure, epidemiology, toxicology, and mode of action studies. To our knowledge, all available and relevant data on the potential human health effects related to PFOA were considered in the draft screening assessment. Recent published epidemiology studies have been reviewed and incorporated, as appropriate, into the final screening assessment.
Margins of Exposure	The calculated margins of exposure should be based on the most sensitive animal studies.	All available and relevant data on the potential human health effects related to PFOA were considered in the screening assessment. The margins of exposure derived in the assessment were based on the most sensitive effects and species and therefore considered adequate to be protective of human health and to

		address the uncertainties in the health effects and exposure databases.
Mode of Action (MOA)	Based on the current evidence, the human relevance of the MOA for immune, developmental and neurobehavioral effects cannot be excluded.	The screening assessment acknowledges that there are uncertainties associated with MOA of PFOA and its human relevance. The margins of exposure are considered adequate to be protective of human health and to address the uncertainties in the health effects and exposure databases.
Carcinogenicity	The Government of Canada should reconsider its review of PFOA cancer data.	The evidence on cancer associated with the elevated PFOA levels in humans is still unclear. However, tumors in PFOA exposed rats occur at higher dose levels than other health effects. Therefore, the margins of exposure generated for critical health effects are considered to be protective of human health from tumors.
Reproductive and developmental effects	Several mice studies demonstrate that exposure to PFOA during critical developmental periods affect mammary gland development. Mammary gland development is a more sensitive endpoint than increased liver weight or decreased body weight.	The mammary gland developmental effects reported at low exposure levels in the most recent study were not considered appropriate for use in risk characterization due to evidence of strain sensitivity, lack of repeatability of the endpoint at low exposure levels, lack of understanding of MOA, and the relevance of this endpoint for humans. Furthermore, the study does not provide sufficient evidence that these effects are permanent and therefore adverse. Hence, the margins of exposure are considered adequate to be protective of human health and to address the uncertainties in the health effects and exposure databases .
Proposed Risk Management	We believe that a regulatory program to implement risk management actions for PFOA, its salts and its precursors is appropriate, provided the regulation is workable and is consistent with and takes into consideration the actions, and timing of such actions, that are being implemented under the Performance Agreement as well as other programs. We welcome the opportunity to work with the Government of Canada to develop science-based, workable and predictable regulations that are consistent with responsible product stewardship practices and	The Government of Canada will continue to engage and consult with stakeholders as we move forward in the development of proposals for risk management actions with respect to PFOA and long-chain PFCAs.

	that foster innovation.	