FluoroCouncil
Global Industry Council
for FluoroTechnology

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Ms. Harriman:

The purpose of this letter is to provide feedback on the draft "Per- and Poly-fluorinated Alkyl Substances (PFAS): Summary and Introductory Information" (PFAS summary) document, which was circulated at the September 25 Administrative Council meeting, September 27 Advisory Committee meeting, and October 25 Science Advisory Board (SAB) meeting. This document was used by SAB staff to provide background information on PFAS, as well a summary of the SAB's work to date on PFAS chemicals.

A document summarizing PFAS can be useful in educating the Administrative Council and Advisory Committee, who will ultimately decide how to regulate the individual chemistries that the SAB has reviewed under the Massachusetts's Toxic Use Reduction Act (TURA). However, as currently drafted, the PFAS summary document contains many flaws and inaccuracies that misrepresent the science of this complex class of chemistry.

To help provide an accurate and clear summary and introduction on PFAS to the other branches of the TURA process, FluoroCouncil has provided general comments below, as well as specific comments in the attached table.

Overarching Comments

PFAS is a term that describes a wide and diverse array of over 4,000 substances containing fluorine and carbon, including:

- Fluoropolymers (i.e., carbon-only polymer backbone with fluorine directly attached);
- Polymeric perfluoropolyethers (i.e., carbon and oxygen polymer backbone with fluorine directly attached to carbon backbone);
- Side chain fluorinated polymers (i.e., variable composition non-fluorinated polymer backbone with fluorinated side chains; includes both long and short chain fluorotelomer-based polymer products);
- Perfluoroalkyl substances (i.e., non-polymeric compounds for which all hydrogen atoms on all carbon atoms (except for carbons which have been associated with functional groups) have been replaced by fluorine (includes both long and short chain)); and

- Polyfluoroalkyl substances (i.e., non-polymeric compounds for which all hydrogen atoms on at least one (but not all) carbon atom(s) - have been replaced by fluorine (includes both short-chain and long-chain)).

The draft PFAS summary document makes several erroneous blanket statements about all PFAS, which are either not supported or are contradicted by sound science. Because the properties of PFAS vary chemical by chemical, it is inappropriate to make any overarching statement about the entire class.

To date, the SAB has reviewed eight (8) specific PFAS chemicals that all fall within one subset of PFAS chemicals known as perfluoroalkyl substances. More specifically, these 8 substances fall within two of the four subcategories of perfluoroalkyl acids (a non-polymer class of PFAS): perfluoroalkyl carboxylic acids (5 chemicals – PFBA, PFHpA, PFHxA, PFOA, PFNA) and perfluoroalkane sulfonates (3 chemicals – PFOS, PFHxS, PFBS). The SAB has not reviewed substances in any other category of PFAS. The limited data the SAB has reviewed further supports the notion that it is inappropriate for the PFAS summary document to contain unsupported, sweeping statements about all PFAS chemicals.

Additionally, the PFAS summary document oversimplifies a complex group of chemistries, describing categories and classes of PFAS that are not technically appropriate. For example, per- and polyfluoroalkyl ether-based substances are inaccurately categorized as perfluoroalkyl acids (PFAAs). FluoroCouncil appreciates the desire to simplify a complex group of chemistry, especially since simplification is sometimes useful; however, in the case of PFAS, it is critically important to understand the various subclasses and acknowledge the crucial fact that products in each category are often very different from the others. Grouping for convenience, which may make sense in theory, is inappropriate with PFAS, given the vast differences in the properties these compounds have.

Furthermore, the OECD PFAS classification flow chart included in the summary document is inaccurate.[1] While we understand the figure is based on a figure included in a recent OECD document, this document itself suffers from many inaccuracies, including this figure, which re-arranges peer-reviewed categories and classifications without sound scientific rationale. Instead, it is more prudent for the PFAS summary document to incorporate the PFAS classifications and associated figures from validated and accepted sources such as OECD,[2] Buck (2011),[3] or Henry (2018).[4] Each of these sources provide a relatively comprehensive and scientific way to view the complex PFAS group and are attached for your reference.

General Comments – Tables and Appendices

The tables within the draft PFAS summary document also contain inaccuracies and misleading information. In Table 1, there is no mention of risk or dosage, but rather an overly broad statement that the listed PFAS substances cause chronic health effects at any level. This

[1] Both in Figure 1 (P2) and Appendix A (P7)
[2] *See* Figure 1, http://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/aboutpfass/Figure1-classification-of-per-and-polyfluoroalkyl-substances%20-PFASs.pdf.
[3] *See* Figure 4, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3214619/.
[4] *See* Figure 1, https://setac.onlinelibrary.wiley.com/doi/pdf/10.1002/ieam.4035.

statement cannot be substantiated, especially when one considers relevant environmental levels and potential for exposure. Therefore, as drafted, Table 1 is inappropriately misleading.

Table 2 shares similar shortcomings to Table 1, as it does not provide the information in the context of risk. Table 2 also lists all substances as bioaccumulative, which is inaccurate.[5] It also has undeclared redundancy with bioaccumulation and presence in biota, resulting in the table being misleading. Furthermore, it is important to note that mere presence in the environment and/or biota is not informative without an indication of levels that present risk.

Inaccuracies in Table 1 stem from its more developed form in Appendix B. As FluoroCouncil has previously noted,[6] the SAB has selected articles to support its position that do not present a balanced picture of the science. The FluoroCouncil Response letter, which was submitted to the SAB in February, provides many examples of where the SAB did not take into proper consideration all of the facts, particularly regarding PFHxA. Furthermore, in several instances, studies cited in the draft PFAS summary come to the opposite conclusions arrived at by the SAB. Because of this, PFHxA is incorrectly categorized in Appendix B (and consequently, Table 1).

Finally, although the full set of references consulted by the SAB is shown in the SAB's bibliography, it would be prudent to include the citations to all the studies listed within Appendix B (or SAB's bibliography), as the short reference is insufficient to locate the actual reference article in several instances.[7]

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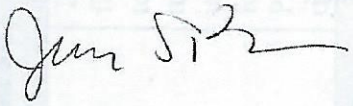
Thank you for your consideration of this information. Please contact Jessica Bowman (202-249-6737 or jessica_bowman@fluorocouncil.org) with any questions.

Sincerely,



Jessica S. Bowman
Executive Director

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[5] Conder, Jason M., et al. Are PFCAs bioaccumulative? A critical review and comparison with regulatory criteria and persistent lipophilic compounds. Environmental science & technology 42.4 (2008): 995-1003.

[6] FluoroCouncil Response to the MA TURA "List of PFAS Concerns from January 10, 2018 SAB Meeting (Feb. 21, 2018) [*hereinafter* FluoroCouncil Response letter].

[7] See e.g., Ren X-M, Zhang Y-F, Guo L-H, Qin Z-F, Lv Q-Y, Zhang L-Y. 2015. Structure-activity relations in binding of perfluoroalkyl compounds to human thyroid hormone T3 receptor. *Arch Toxicol* 89:233–242; Rosenmai AK, Taxvig C, Svingen T, Trier X, van Vugt-Lussenburg BM, Pedersen M, et al. 2016. Fluorinated alkyl substances and technical mixtures used in food paper-packaging exhibit endocrine-related activity in vitro. *Andrology* 4:662–672; Wolf, Cynthia J., et al. Activation of mouse and human peroxisome proliferator– activated receptor alpha by perfluoroalkyl acids of different functional groups and chain lengths. *Toxicological Sciences* 106.1 (2008): 162-171.

Attachments:

- FluoroCouncil's Specific Comments on Draft PFAS Summary Document.
- General Classification of PFAS – reproduced and updated from OECD (2013), OECD/UNEP Global PFC Group, *Synthesis paper on per- and polyfluorinated chemicals (PFCs)*, Environment, Health and Safety, Environment Directorate, OECD.
- Buck, et al. (2011), "*Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins*," Integr Environ Assess Manag.; 7,4:513-41.
- Henry, et al. (2018), "*A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers*," Integr Environ Assess Manag.; 14,3:316-34.
- FluoroCouncil Response to the MA TURA "List of PFAS Concerns" from January 10, 2018 SAB Meeting (Feb. 21, 2018).
- Borghoff, et al. (2018), "*A hypothesis-driven weight-of-evidence analysis to evaluate potential endocrine activity of perfluorohexanoic acid*," Regul. Toxicol. Pharmacol.; 99:168-81.
- Iwai, et al. (in submission), "*Addendum to Iwai and Hoberman 2014 – Reassessment of Developmental Toxicity of PFHxA in Mice*," submitted to Intern J Tox.
- FluoroCouncil's response to the SVHC proposal for PFHxA (October 19, 2018)
- Luz, et al. (in review), "*Perfluorohexanoic Acid Toxicity, Part I: Development of a Chronic Human Health Toxicity Value for Use in Risk Assessment*," submitted to Regul. Toxicol. Pharmacol.
- Anderson, et al. (in review), "*Perfluorohexanoic Acid Toxicity, Part II: Application of Human Health Toxicity Value for Risk Characterization*," submitted to Regul. Toxicol. Pharmacol.

cc: Dan Sieger, EEA Assistant Secretary
Rich Bizzozero, Executive Director TUR Administrative Council
Michael Ellenbecker, Director TURI
TURA SAB Members
TUR Administrative Council Members
TUR Advisory Committee Members

FluoroCouncil's Specific Comments on Draft PFAS Summary Document

Section	Text (location)	FluoroCouncil Comment
Overview		
	PFAS "constitute a large category of chemicals, all of which share certain characteristics of concern." (P1¶1)	This is patently false, as not all PFAS have characteristics of concern. For example, fluoropolymers are high molecular weight plastics that are extremely stable, too large to be bioavailable or toxic, and cannot dissolve in water. Furthermore, fluoropolymers meet all thirteen of OECD's Polymer of Low Concern criteria. Therefore, it is inaccurate to state that all PFAS have characteristics of concern. It is more appropriate for most uses of the term "PFAS" in the document to be substituted with the term PFAA (perfluoroalkyl acids), as that appears to be the focus of the SAB and the extent of the substances reviewed by the SAB to date.
Category description		
	"OECD has developed a broad categorization of PFAS, dividing them into perfluoroalkyl/per- and polyfluoroalkylether acids (PFAAs), PFAA precursors, and other PFASs." (P1¶4)	OECD has not made any such division of the PFAS class. OECD's PFAS class division is much more nuanced,[8] lending to its accuracy. Specifically, it divides PFAS in to polymers and non-polymers, and further divides those categories into structure-specific classes.
	"perfluoroalkyl/per- and polyfluoroalkylether acids (PFAAs)" (P1¶4)	PFAA is an acronym for "perfluoroalkyl acid" (not perfluoroalkyl/per- and polyfluoroalkylether acids).[9] The widely accepted definition of PFAA does not include per- and polyfluoroalkyl ether-based substances. Attempting to lump these separate classes together is scientifically inappropriate, as they differ significantly in structure and properties. Creating a new definition for an already widely used acronym facilitates confusion, contradicting the purpose of the PFAS summary document, which is to minimize confusion.
	"PFAS are often identified by the length of the fluorinated carbon chain." (P1¶6)	Only perfluoroalkyl carboxylic acids (PFCAs), perfluoroalkane sulfonic acids (PFSAs), and their precursors are typically identified by their fluorinated carbon chain length. Fluoropolymers are not typically identified by their chain lengths, as they can have variable chain lengths, most of which can be very long.
	"OECD and EPA have also developed an approach to categorizing PFAS into 'long chain' and 'short chain.'" ((P1¶6)	It would be useful to explain the distinction and why that distinction has been made. It is not merely an arbitrary cutoff based on chain length.

[8] *See* Figure 1, http://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/aboutpfass/Figure1-classification-of-per-and-polyfluoroalkyl-substances%20-PFASs.pdf.
[9] ITRC's "Naming Conventions and Physical and Chemical Properties of Per- and Polyfluoroalkly Substances (PFAS)" fact sheet, to which the draft PFAS summary document cites (fn 1), utilizes the appropriate PFAA acronym.

Section	Text (page)	FluoroCouncil Comment
Category description (cont.)		
	"…the science described in this document refers to the carboxylic and sulfonic acids, which have been widely identified as contaminants in the environment." (P2¶7)	The SAB's review of these substances focused on hazard, not environmental presence or risk. As noted above, the mere presence of a substance in the environment is not informative without an indication of levels that present risk.
Summary of Scientific Information: PFAAs		
Summary	"…all of these chemicals pose some degree of bioaccumulation concern" (P2¶3)	This is an overstatement. There is likely no "zero" bioaccumulative value for the PFAS compounds (smaller molecules). While the SAB has not reviewed any fluoropolymers, it should be noted that they are not bioavailable.
	"…shorter-chain chemicals also bioaccumulate, at least in plants." (P2¶3)	While some of these compounds do end up in food (lab studies and some field work), it has yet to be shown that the dose/level poses any risk whatsoever from an Estimated Dietary Intake (EDI) or (Tolerable Daily Intake) TDI viewpoint.
SAB approach	"It was not necessary to review the literature on PFOS and PFOA as their hazards are well understood and they have been studied by authoritative bodies." (P3¶2)	It should be noted that while PFOS and PFOA have been studied by authoritative bodies, not all of these bodies have reached consistent conclusions.[10]
	"…the literature on [PFOS and PFOA] was used for context in evaluating other substances." (P3¶2)	This approach is scientifically inappropriate and unsupportable, as the properties of PFAS chemistries, including their toxicity profiles, differ from chemical to chemical.
	"Longer-chain substances … have been studied in greater depth than shorter-chain substances." (P3¶3)	While this statement is not patently false, it is misleading, as there is a large body of peer-reviewed, published data on PFHxA, much of which FluoroCouncil summarized and provided to the SAB.[11]
C8 substances	"This information [from the C8 Health Project] added important additional context for understanding the range of health impacts of PFAS of other lengths as well." (P3¶4)	As noted above, it is scientifically inappropriate and unsupportable for the SAB to have used C8 PFAS health impacts to determine those of other PFAS, as the properties of PFAS chemistries, including their toxicity profiles, differ from chemical to chemical.

[10] *See* Australian Department of Health Expert Health Panel for Per and Poly-Fluoroalkyl Substances (PFAS). Available at www.health.gov.au/internet/main/publishing.nsf/Content/ohp-pfas-expert-panel.htm, Health Canada. Perfluorooctanoic acid (PFOA) in drinking water. Document for public consultation (2016a). https://www.canada.ca/en/health-canada/programs/consultation-perfluorooctanoic-acid-pfoa-in-drinking-water/document.html, and Health Canada. Perfluorooctane Sulfonate in Drinking Water. Document for public consultation. Prepared by the Federal-Provincial-Territorial Committee on Drinking Water (2016b). https://www.canada.ca/en/health-canada/programs/consultation-perfluorooctane-sulfonate-pfos-in-drinking-water/document.html.

[11] *See* FluoroCouncil Response letter.

Section	Text (page)	FluoroCouncil Comment
Summary of Scientific Information: PFAAs (cont.)		
C7 and lower	They all "have long half-lives in the human body." (P3¶5)	This is an incorrect statement that is much too broad and should be revised with accurate data. The half-lives of the short-chain PFAAs are generally significantly shorter than the long-chain PFAAs. Furthermore, there is no clear definition of what constitutes a "long half-life."
	"…their [C7 and lower PFAS] presence in the environment creates the potential for on-going exposures." (P3¶5)	The fact that certain PFAS have been found in the environment does not mean that those PFAS present a hazard. Presence alone does not equate to risk, as is currently asserted.
	"…the SAB's literature review found evidence of a range of chronic health effects…"	In many cases, the evidence relied on by the SAB found from the literature review was derived incorrectly or from poor studies with weak associations. It should also be noted that convincing evidence was presented to the SAB that contradicts this chronic health effects evidence, especially for PFHxA. Further clarification should be provided so that it does not appear as though all health effects apply to all "C7 and lower" PFAS chemistries.
	"…while the shorter-chain substances are not as bioaccumulative in air-breathing organisms as the longer-chain substances, they do bioaccumulate in plants." (P3¶6)	As noted above, while some of these compounds do end up in food (lab studies and some field work), it has yet to be shown that the does/level poses any risk whatsoever from an Estimated Dietary Intake (EDI) or (Tolerable Daily Intake) TDI viewpoint.
	"PFAS binds to proteins". (P4¶1)	This blanket statement about all PFAS is not true. The significance of protein binding is an area of ongoing study and discussion, and not all PFAS bind to the same degree to the same proteins.
Regulatory context: preliminary overview		
	"EPA is working to address selected PFAS under its Unregulated Contaminant Monitoring Rule 3…"	The UCMR program only serves to collect data on the presence of certain substances in public drinking water systems. It does not include measures to address substances that are present. Further, the collection of data on six (6) PFAS substances was completed in 2012-15 and is not ongoing.
	"For PFOS and PFOA, EPA has developed a health advisory of 70 ppt … for the sum of PFOS and PFOA in public drinking water." (P5¶6)	As written, the statement is misleading, as the 70 ppt health advisory is for lifetime exposure. This clarification should be added.
	re: CT and MN PFAS regulatory activity (P6¶2)	Additional clarification should be provided to note that both CT's Drinking Water Action Levels and MN's Health Risk Limits are guidance values and not enforceable.
	"'an additive toxicity approach be used for these compounds [PFOA, PFOS, PFNA, PFHxS, and PFHpA] when they occur together,' because they have similar effects." (P6¶3)	There is no sound science to support grouping these chemistries together for regulatory purposes.