FluoroCouncil
Global Industry Council
for FluoroTechnology

October 20, 2017

Ms. Kara Steward
Washington State Department of Ecology
Hazardous Waste & Toxics Reduction Program
300 Desmond Drive SE
Lacey, WA 98503
Submitted via email to kara.steward@ecy.wa.gov

RE: Washington State Chemical Action Plan for Per- and Polyfluoroalkyl Substances (PFAS)

Dear Ms. Steward:

FluoroCouncil appreciates this opportunity to provide comments on the available draft chapters of Washington's PFAS Chemical Action Plan ("PFAS CAP"). FluoroCouncil[1] is a global organization representing the world's leading manufacturers of products based on PFAS. FluoroCouncil has a fundamental commitment to product stewardship and rigorous, science-based regulation, and, as part of its mission, addresses science and public policy issues related to PFAS.

We understand the important issues currently facing Washington regarding elevated levels of certain PFAS found in multiple locations in the state. Further, we appreciate the significant efforts the departments of Ecology and Health have put into drafting these chapters of the PFAS CAP, which can serve as a critical tool in identifying potential actions to address these PFAS contamination issues. It is crucial that Washington takes a science- and risk-based approach grounded in a thorough understanding of the broad family of PFAS in order to develop a set of recommendations that will address these issues in an appropriate and effective manner.

As drafted, however, the PFAS CAP does not clearly articulate the problem it intends to address. Moreover, because it attempts to characterize the extremely broad and diverse group of chemicals referred to as "PFAS" -- including products and substances that are not PBTs and are not relevant to the contamination issues in Washington – the PFAS CAP is technically inaccurate

[1] FluoroCouncil's member companies are Archroma Management LLC, Arkema France, Asahi Glass Co., Ltd., Daikin Industries, Ltd., Solvay Specialty Polymers, The Chemours Company LLC, Dynax (associate), and W. L. Gore & Associates, Inc. (provisional).

and fails to identify and focus on the true sources of concern that should be addressed under the CAP. We recommend that Ecology and Health refine their focus to a more narrow and appropriate scope addressing PFOS and related salts only. Additional work related to other long-chain PFAS, which have been found by regulators around the world to be PBTs, may also be appropriate for inclusion in the PFAS CAP. Stakeholders should be willing to support such a scope and associated recommendations.

Below and attached please find FluoroCouncil's specific comments on the draft PFAS CAP chapters, offered to provide technical accuracy and a more appropriate, focused scope that would support actions to address the PFAS-related issues in Washington. Summary comments on each chapter are provided in Appendix A, along with detailed comments in the accompanying "redl-lined" versions of each chapter.

A. The PFAS CAP should focus on long-chain PFAS.

1. Certain long-chain PFAS have been found in Washington at elevated levels.

The PFAS-related environmental contamination issues currently facing Washington are associated with certain long-chain PFAS, namely PFOS. "Long-chain" and "short-chain" is a distinction that applies to certain PFAS[2] and is recognized by regulators globally.[3] Long-chain PFAS include PFOS, PFOA, and their precursors, including long-chain fluorotelomer-based products.

The distinction between long-chain and short-chain PFAS is based, not purely on chemical structure, but also on hazard characteristics, with long-chains having greater toxicity and higher bioaccumulation potential. By contrast, a substantial body of data demonstrates that short chain PFAS chemicals are not bioaccumulative, are not carcinogenic and generally exhibit low toxicity. Numerous non-polymeric long-chain PFAS, including long chain perfluorocarboxylic acids (PFCAs) such as PFOA and long-chain perfluoroalkane sulfonic acids (PFSAs) such as PFOS, have been classified as PBT substances by regulators around the world. PFOS and its salts are the only long-chain PFAS listed as PBTs in Washington.

Through regulation, the EPA PFOA Stewardship Program and other voluntary initiatives, major manufacturers in the U.S., Europe, and Japan, including FluoroCouncil member companies, worked with regulators to successfully phase out long-chain PFAS (including

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[2] Only non-polymeric PFAS and fluorotelomer-based products can be described as long-chain or short-chain. This description is irrelevant to other PFAS, including fluoropolymers. See Appendix A for a detailed explanation of the family of PFAS chemistry.

[3] Long-chain PFAS are defined by the Organisation for Economic Co-operation and Development (OECD) as:

- PFCAs with carbon chain lengths C8 and higher, including PFOA;
- PFSAs with carbon chain lengths C6 and higher, including perfluorohexane sulfonic acid (PFHxS) and PFOS; and
- precursors of these substances that may be produced or present in products.

See https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/aboutpfass/

precursors), virtually eliminating these chemicals from their products and facility emissions globally. As a result of this phase-out, levels of long-chain PFCAs and PFSAs have been declining in U.S. blood levels.[4] While PFOS, PFOA, and other long-chain PFAS are no longer produced in the U.S., they have not been globally phased out. Production, use, and global trade of these substances and products containing them continues by companies that have not made similar stewardship commitments. This allows products containing long-chain compounds to enter into Washington from abroad, potentially leading to continued exposure and environmental contamination. Recent environmental monitoring and product testing in Washington shows continued presence of long-chain PFAS.

To appropriately address the PFAS-related contamination issues facing Washington, the CAP should focus on recommendations that would target those long-chain PFAS found at elevated levels in the state and their sources, including products containing those substances.

2. The CAP process is designed to address PBT substances.

The regulations that establish and govern the CAP program recognize that PBT substances present unique risk concerns that require a focused regulatory response. As the regulations themselves note:

> Persistent, bioaccumulative toxins (PBTs) are chemicals that pose a unique threat to human health and the environment in Washington State. . . . Because of the unique threat that these PBTs pose, special attention is necessary to identify actions that will reduce and eliminate threats to human health and the environment. . . . The goal of [these CAP regulations] is to reduce and phase-out PBT uses, releases and exposures in Washington.[5]

Thus, the CAP program is specifically intended to address the presence of PBT chemicals in Washington and to mitigate the human health and environmental risks associated with those PBT substances. It is not intended to address non-PBT substances.

The regulations also contain a list of specific PBT chemicals (including groups of chemicals), that are to be addressed under the CAP program. According to the regulations:

> The purpose of the PBT list is to identify toxic chemicals that require further action because they remain ("persist") in the environment for long periods of time where they can

[4] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention "Fourth National Report on Human Exposure to Environmental Chemicals"; Updated January 2017 https://www.cdc.gov/biomonitoring/pdf/FourthReport_UpdatedTables_Volume1_Jan2017.pdf

[5] WAC § 173-333-100

bioaccumulate to levels that pose threats to human health and environment in Washington.[6]

In addition, the regulations specify that Ecology will select chemicals for CAP development from the PBT list, and that any additions to the PBT list will be accomplished through rulemaking after public notice and an opportunity to comment.[7]

Thus, in order to align the PFAS CAP with the purpose and intent of the governing regulations, Ecology must focus the CAP specifically on those PFAS chemicals that are PBT substances, including PFOS.[8]

3. It is not appropriate to include other PFAS in the CAP.

In order to achieve the policy objectives of the CAP program, as spelled out in the regulations, Ecology should focus its efforts on substances that are PBTs, such as PFOS and PFOA. Other categories of PFAS, including fluoropolymers and short-chain PFAS, should not be included in the PFAS CAP because they are not PBTs and they are unrelated to the contamination issues facing Washington.

Because fluoropolymers are too large to be bioavailable, they are neither toxic nor bioaccumulative. Their high stability under all types of environmental conditions means they are not precursors to any PFCAs or PFSAs. Therefore, they should be removed from the scope of PFAS included in the CAP. Discussion of fluoropolymers and their uses is not appropriate for the PFAS CAP.

Short-chain PFAS, including short-chain PFCAs, short-chain PFSAs, and their precursors, should also be excluded from the scope of the PFAS CAP. As part of its charter, FluoroCouncil has been focused on working with regulators around the world to help facilitate the successful global transition from long-chain PFAS of concern to environmentally preferable alternatives. Members of the FluoroCouncil have developed alternative chemistries that include short-chain PFAS that offer similar or superior product performance, but with improved environmental and biological profiles. These short-chain PFAS have been reviewed and approved for use by regulators around the world based on extensive toxicological and environmental testing. The extensive body of research supporting short-chain PFAS shows that, unlike their long-chain counterparts, they are not PBTs. Furthermore they are not precursors for long-chain PFAS.

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6 *Id* at § 173-333-300

7 *Id*. at §§ 173-333-300 and 173-333-340.

8 Indeed, the only PFAS chemical included on the PBT list in the regulations is the group of chemicals referred to as "Perfluorooctane sulfonates," which is defined to consist of PFOS acid and various salts. *See* WAC § 173-333-310. Under the express terms of the regulations the PFAS CAP must focus on this listed group of chemicals and cannot be expanded to include the entire universe of PFAS.

FluoroCouncil and its members are also encouraging the use of best practices to minimize environmental emissions of short-chain PFAS. To date, best practices have been developed for the apparel industry and for users of Class B fire fighting foams.

Short-chain PFAS, namely short-chain fluorotelomer-based products, provide unique properties relied on in numerous applications, including Class B AFFF fluorosurfactants; side-chain fluoropolymer repellants for medical non-wovens, bullet-proof vests, chemical worker, first responder and military gear as well as high performance outdoor wear. Importantly, short-chain PFAS and related products are not substantive sources of long-chain PFAS and are not measurably contributing to the long-chain contamination issues in Washington. Therefore, short-chain PFAS should not be within the scope of the PFAS CAP.

B. PFAS cannot be addressed as a broad class.

PFAS includes a wide variety of chemical substances and polymers with very diverse properties. The term "PFAS" simply means that a substance is highly fluorinated. "PFAS" is too general to be useful for communication purposes and is insufficient to describe a regulatory class. Because there is so much variation among the alleged 3,000+ chemicals in the PFAS category,[9] no scientifically sound rationale exists for treating them all the same as a matter of public policy.

PFAS vary significantly in their hazard profiles. As discussed above, certain PFAS have been classified as PBTs. However, not all PFAS and related products are persistent, bioaccumalative, and/or toxic, particularly at concentrations typically present in the environment. While some PFAS remain in the environment for years, other PFAS are short-lived and convert to other substances in a matter of hours or days. Not all PFAS persist in biological tissues. While some long-chain PFAS have half-lives in humans that extend for years, other PFAS compounds, including short chains, are readily eliminated and do not bioaccumulate.[10] Kinetics studies in animals further demonstrate that the persistence of PFAS compounds decreases with decreasing chain length.[11] All PFAS also do not share a

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[9] *See* KEMI Interim Report "Strategy for reducing the use of highly fluorinated substances, PFASs" 2016. Available at https://www.kemi.se/global/rapporter/2016/report-11-16-strategy-for-reducing-the-use-of-higly-fluorinated-substances-pfas.pdf

[10] Chengelis C.P., J.B. Kirkpatrick, N.R. Myers, M. Shinohara, P.L. Stetson, and D.W. Sved. 2009a. Comparison of the toxicokinetic behaviour of perfluorohexanoic acid (PFHxA) and nonafluorobutane-1-sulfonic acid (PFBS) in cynomolgus monkeys and rats. Reprod Toxicol, 27(3-4):342-351. Gannon S.A., T. Johnson, D.L. Nabb, T.L. Serex, R.C. Buck, S.E. Loveless. 2011. Absorption, distribution, metabolism, and excretion of [1-14C]-perfluorohexanoate ([14C]-PFHx) in rats and mice. Toxicology, 283: 55–62. Iwai H. 2011. Toxicokinetics of ammonium perfluorohexanoate. Drug and Chem. Toxicol. 34: 341–346.

[11] Chang S-C, K. Das, D. Ehresman, M.E. Ellefson, G.S. Gorman, J.A. Hart, P.E. Noker, Y-M Tan, P.H. Lieder, C. Lau, G.W. Olsen, and J.L. Butenhoff. 2008. Comparative pharmacokinetics of perfluorobutyrate in rats, mice, monkeys, and humans and relevance to human exposure via drinking water. Tox. Sci. 104: 40-53. Kudo, N., E. Suzuki-Nakajima, A. Mitsumoto, and Y. Kawashima. 2006. Responses of the liver to perfluorinated fatty acids with different carbon chain length in male and female mice: In relation to induction of hepatomegaly, peroxisomal beta-oxidation and microsomal 1-acylglycerophosphocholine acyltransferase. Biol. Pharm. Bull. 29:1952–57. Ohmori, K., N. Kudo, K. Katayama, and Y. Kawashima. 2003. Comparison of the toxicokinetics between perfluorocarboxylic acids with different carbon chain length. Toxicology 184:135–40.

common toxicity profile. For example, toxicity testing on some PFAS substances shows carcinogenic potential (e.g., PFOA, PFOS) while similar testing on other substances (e.g., PFHxA) does not show any evidence of carcinogenicity.[12] In addition, even when toxicity testing of PFAS substances may show some similarity of effects, the doses associated with those effects can vary by orders of magnitude from substance to substance.[13]

Sound science dictates that when multiple chemicals have differing toxicity characteristics they cannot be grouped together for risk assessment purposes. As OECD notes, equating the risks of various chemicals for which there are known differences in toxicity is not "scientifically warranted."[14] Similarly, if analysis of one chemical using information about another does not create "an accurate and credible assessment of the hazards for the substance in question," then it is inappropriate to read-across between the substances.[15] Given the wide variations in toxicities and other hazard characteristics exhibited by different PFAS chemicals, it is scientifically inappropriate to group all PFAS together for purposes of risk assessment, as the draft PFAS CAP currently seems to do.

Additionally, it is important to understand that those PFAS with commercial uses are not used interchangeably. Different PFAS impart different properties. PFAS compounds in the marketplace have been designed for specific uses, making it essential for public policy to be based on the risks associated with exposure to individual substances in particular uses. For example, fluoropolymers are not used to make grease-resistant food wrappers, and fluorotelomers are not used to make plastic parts. The life-cycle impact of any particular compound within the PFAS category can differ by orders of magnitude. Moreover, the broad class of PFAS compounds cited in the KEMI report are not all items of commerce. The broad family of PFAS includes some substances which have been developed and are actually used in commercial applications, but a large number of them have not.

As a result of this significant diversity within the family of PFAS, it is inappropriate to address PFAS as a broad class. Rather, regulatory and policy measures should be substance-specific.

C. The draft chapters need further work to clarify the PFAS CAP scope and support corresponding recommendations.

The family of PFAS is a complex and diverse collection of substances with widely varying chemical structures, properties, uses, and hazard profiles. We appreciate the departments' efforts to tackle the entire family of PFAS in this CAP, however, as drafted, the CAP

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[12] Klaunig, J.E., M. Sinohara, H. Iwai, C. Chengelis, J. Kirkpatrick, Z. Wang, and R. Bruner. 2015. Evaluation of the chronic toxicity and carcinogenicity of perfluorohexanoic acid (PFHxA) in Sprague-Dawley rats. Tox. Pathology 43:209-220.

[13] ATSDR. 2015. Draft toxicological profile for perfluoroalkyls. Agency for Toxic Substances and Disease Registry. U.S. Department of Health and Human Services Public Health Service, August.

[14] *See* http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4& doclanguage=en at 18

[15] http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-116-Category-approaches-Read-across-QSAR.pdf at 44.

chapters fail to clearly articulate a problem formulation statement or objective. For example, the Uses chapter fails to describe all product uses for PFAS and does not address the larger question of current exposure pathways and exposure levels of concern related to these uses. The ability of specific PFAS currently available on the market to be present at levels that may cause negative impact to humans or ecological receptors is not demonstrated. The Regulatory chapter highlights the disparate patchwork of state and federal regulations nationwide and globally, but is out of date and erred in many entries, and does not identify a specific regulatory gap or need that is present in Washington. The Health chapter provides a well-balanced summary of available health information, but does not reach the conclusion that any specific "PFAS" chemicals are toxic to humans or ecological receptors at the environmental exposure levels potentially found throughout the state. The Chemistry chapter does little to provide an accurate or clear description of the various chemistries considered PFAS.

By establishing a clearly defined scope related to PFOS and other long-chain PFAS and refining the supporting CAP chapters to focus on those specific substances, the departments could provide a clear science- and risk-based plan for addressing the PFAS substances of actual concern to the state. Such an approach is also consistent with the overall objective of the CAP process, to address PBT substances. Creating a problem formulation statement could be related to understanding the marketplace transport of long-chain PFAS into the state, as well as global transport into the state environment, and assessing whether levels related to current and foreseeable future releases cause a negative impact to human and/or ecological receptors.

D. Washington should rely on the ITRC PFAS Project

While we applaud Washington's work to compile, synthesize and present numerous technical topics related to PFAS, given the significant challenge and level of effort needed to develop technically accurate and detailed information, it is unclear why Washington is not relying on the experts and resources provided to them via the Interstate Technology and Regulatory Council (ITRC). ITRC's PFAS team will be issuing fact sheets on all of these topics within the next few months, with the more detailed Technical and Regulatory Guidance (Tech Reg) documents to follow by early 2019. The scope of the detailed Tech Reg documents is currently being developed with input from state agencies, such as Washington, solicited. National experts will be compiling the data, with multiple rounds of internal and external peer review to ensure accuracy. Ecology staff members are currently participating on the ITRC PFAS team and can work to ensure that information they deem important is included in the Tech Reg documents.

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FluoroCouncil understands Washington's need to address the PFAS-related contamination issues in the state. It is critical that the approach taken to address those issues be focused on the

chemicals found at elevated levels that are within the scope of the CAP process (PBTs): long-chain PFAS.

FluoroCouncil welcomes the opportunity to work with the departments to refine the draft PFAS CAP chapters to ensure they result in a targeted set of recommendations supported by a scientifically sound foundation.

Sincerely,

Jessica S. Bowman
FluoroCouncil

Enclosures:

- Appendix A: General Comments on Individual PFAS CAP Draft Chapters
- Appendix B: Description of PFAS – "Understanding FluoroTechnology"
- Appendix C: FluoroCouncil Critical Review of Perez, F., et al., Accumulation of perfluoroalkyl substances in human tissues. Environ Int, 2013. 59: p. 354-62.
- Introduction with FluoroCouncil Comments
- Chemistry Chapter with FluoroCouncil Comments
- Health Chapter with FluoroCouncil Comments
- Environment Chapter with FluoroCouncil Comments
- Uses Chapter with FluoroCouncil Comments
- Regulations Chapter with FluoroCouncil Comments

APPENDIX A
General Comments on Individual PFAS CAP Draft Chapters

Introduction

Overall, this chapter does not present a logical or data-driven rationale to support the discussion of all PFAS in the CAP. Washington acknowledges that the PBT criteria apply to PFOS and related salts, but then fails to explain why the CAP is focused on a larger class of chemicals. Their own regulations center on PBTs, and short-chain PFAS are not PBTs. Further, no distinction is made between and long-chain and short-chain PFAS.

Any economic analyses must consider the impact of restrictions on short-chain PFAS (should short-chains be included) and the adverse impact of non-fluorinated alternatives as substitutes that may or may not work in some critical applications.

Chemistry

The chemistry of PFAS products is a complex subject that requires both significant discussion and understanding to appreciate its full scope.

PFAS as a name and a broad category is really neither defining nor descriptive enough to use broadly and/or generally. All PFAS are not the same and grouping is inappropriate and incorrect. One should be specific and avoid general grouping and categorizations. Specificity is important and necessary.

Using the OECD definition, many of the long chain legacy PFAS chemicals (and their related higher homologues and precursors) such as PFOS and PFOA are classified as PBTs. At the same time, the new generation of short-chain PFAS chemistry using PFBS (ECF) and 6:2 FTOH (telomer manufacture) are not PBTs; therefore it is inappropriate to grouped short-chains with the legacy (long-chain) chemistry.

The major global manufacturers (FluoroCouncil member companies) have all transitioned (by year-end 2015) to the new short-chain chemistry and no longer produce and sell long-chain chemistry products.

The legacy chemistry from both ECF and telomer manufacture contains mixtures of homologues and, in the case of ECF, both odd/even and branched/linear mixtures. Today's products are much simpler and significantly cleaner and purer (largely single homologs, i.e., C4 in ECF and C6 in telomerization).

The reader and those attempting to understand this class of chemistries must recognize that there are several critical categories of end-products and they are not the same in structure, function, end-use, manufacture and behavior. Consider:

- Perfluoroalkyl acids such as PFOA and PFNA and perfluoroalkyl sulfonates such as PFOS and PFHxS
- Fluoropolymers (Fluoroplastics and Fluoroelastomers)

- Side-chain fluorinated polymers: acrylates, methacrylates, urethanes, oxetanes
- Perfluoropolyethers
- Fluorosurfactants: fluoroalkyl, ether products and ether carboxylates

The toxicological and environmental properties of the various classes of PFAS products can be vastly different and should be understood prior to any classification.

The carbon-fluorine bonds in these molecules impart unique properties to this class of chemistry. These fluorinated products are used because they provide unique and irreplaceable functionality in their chosen end-uses. The abilities of side-chain fluorinated polymers to repel oil and water and grease and soil, of fluorosurfactants to lower surface tension and film-form, and of fluoropolymers to provide chemical resistance and high temperature resistance are unmatched with other chemistries.

As a general comment, from a readability standpoint, the chapter would benefit from having organized topics with headers to present information more clearly and concisely.

Health

The Health chapter covers a broad range of topics, including human exposure pathways, occurrence studies (both serum measurements and environmental surveys), toxicology, epidemiology, and regulatory standards. The information from the literature is compiled and summarized, but in most cases stops short of providing an independent opinion or assessment for the state. The chapter focuses primarily on PFOA and PFOS, but includes some information for PFHxS, PFNA, PFBA, PFBS, PFHxA as well. Washington currently relies on USEPA's 2016 Health Advisories for PFOA and PFOS (0.07 µg/L), separately and as a sum.

This chapter, like other chapters in the document, will benefit from a clearer chemical classification scheme, providing a clearer description of the PFAS compounds that are covered, and those that are not because they fall outside the scope of the CAP. This will improve the accuracy of some of the global statements made with regarding to exposure, absorption, and retention of PFAS.

The Health chapter's summary is comprehensive in the sense that it covers the key literature through early 2017, yielding an impressive 385 citations in its reference list. The few instances where a key publication is not cited are included in detailed comments on this chapter. The presentation is balanced, particularly in the summary of toxicological endpoints, and limitations associated with extrapolation from animal study results to humans. In addition, the inconsistency in findings of human health effects across the epidemiologic studies is well presented. The occurrence study information is intended to present the available empirical data on paired serum and water measurements, however, key limitations in how these data are used in setting standards are absent; there is no analysis other than a cursory presentation of summary statistics relative to NHANES findings.

- The chapter would be greatly strengthened in clarity and understandability using clear, specific and descriptive terms and acronyms as often as possible. The acronym “PFAS” is used throughout the draft. Because this term describes a large and complex universe of substances that are different from one another in physical form and properties, many sentences using “PFAS” as the central noun are factually incorrect.
- A central message should be that perfluoroalkyls acids (PFAAs, i.e., PFOS and PFOA) and their potential precursors are key substances of focus.
- The terms “long-chain” and “short-chain” should only be applied to PFAAs and their potential precursor substances.
- The document starts by acknowledging that there are 3,000 PFAS and then states that there is little toxicity data available. The next 96 pages describe PFOA, PFOS data without distinguishing between any classes of PFAS.
- The strong implication is that all PFAS should be considered to have the effects and risk of PFOA or PFOS because there is little data on most PFAS. This implication is not correct. For example, fluoropolymers are highly stable, not water soluble, and too large to be bioavailable. Also, there is a substantial body of data demonstrating that short chain PFAS chemicals are not bioaccumulative, are not carcinogenic and generally exhibit low toxicity.
- Statements that might be true for a specific PFAS become incorrect when applied broadly. For example:
    - "Humans excrete PFAS slowly such that years are required to reduce body burden levels." Page 2
    - "PFAS in your water can contribute significantly to body burden levels. It is well established that serum PFAS concentrations are elevated in communities with PFAS in drinking water compared to the general population." Page 3

We suggest these broad changes:

1. Whenever possible, be more specific than "PFAS". Use PFOA when making statements about perfluorooctanoic acid. Use PFOS when referring to perfluorooctyl sulfonic acid.
2. Start with the Buck et al., 2011 terminology that PFAS are a diverse group of many chemicals, including polymer and non-polymer categories. Tie the PFAS that are within the scope of the CAP to one of the 5 categories of PFAS shown on Buck Figure 4 (polymeric PFAS: fluoropolymers, perfluoropolyethers, side chain fluorinated polymers; and non-polymeric: perfluorinated and polyfluorinated substances).
3. Add a definition of mobile/mobility and an explanation that high molecular weight fluoropolymers are neither water soluble nor bioavailable and thereby not toxic.
4. See the FluoroCouncil science web page studies on fluorotelomer-based polymers (also known as side-chain fluorinated polymers). (https://fluorocouncil.com/Resources/Research)

Environment

The Environment chapter provides both general information about potential sources and pathways, as well as a compilation of some of the PFAS study data specific to Washington. Environmental matrices addressed include: surface water, sediment (from freshwater and marine systems), groundwater (and drinking water), waste water treatment plant (WWTP) effluent, and biological tissues (fish and osprey eggs). Samples were collected in the period 2008 – 2016, and in some cases include multiple sampling events over time. Please add a brief discussion of the relevance of changes in target analytes and/or analytical detection limits to the interpretation of trends.

The chapter reads mostly like a "state of the available data," with just a brief discussion of data gaps. It is unclear what the goal of the data gaps discussion is, but presumably Washington has an interest in prioritizing future investigation or literature compilation efforts.

Readers would benefit from an executive summary of the key findings from the available study data, organized by matrix. An example is provided in detailed comments on the chapter.

There is cross-over between topics in this chapter and topics covered in the Uses/Sources chapter and the Health chapter. Recommendations for streamlining and reorganizing information are provided in detailed comments on the chapter.

Uses

This draft chapter of the CAP is somewhat unclear and incomplete. The single greatest issue contributing to this lack of clarity is the attempt to characterize the production, use and release of PFAS materials as if PFAS is a clearly defined category of materials that is easily reduced to simple definitions and characterization. PFAS is an extremely broad category of materials that represent an incredibly diverse range of material forms, performance characteristics, hazard characteristics, end uses, and environmental presence and release. The use of this broad terminology applied to this diverse set of materials leads to confusion, inaccuracy, incomplete information and, in many cases, errors in the statement of facts and figures.

Our recommendation, therefore, is to narrow the scope of this chapter to a discussion of materials of concern to Washington (long-chain PFAS) based on their PBT characteristics and to clearly define these materials in the body of the text to ensure accuracy and clarity in the report.

Additionally, the methodologies used to estimate Washington-specific PFAS uses and releases are new to us and seem to mix information regarding historic and current releases of materials. This information is difficult to follow. It is recommended that this section be reviewed and clarified with respect to methodology and accuracy of current versus past emissions.

More detailed comments are included in the draft and summarized as follows:

- Consider a summary of key findings relevant to Washington (similar to other chapters that provide a summary in the beginning)

- Content of the introductory paragraph is not consistent with the content of the following chapters as the following paragraphs on "Production" only provide information on the production of a subset of PFAS substances, namely specific long-chain PFAAs and fluorotelomers.
- A section on POSF-based substances (and their shorter chain homologs) production is missing and should be included as these substances are mentioned in this report (see, e.g., Table 2) and might be relevant as they might be precursors to PFOS and other PFSA.
- Please consider including a section on "Rest of the World Production" as imports of finished goods and/or substances might be relevant to Washington's economy.
- Please consider structuring the "PFAS Uses" chapter similar to the "PFAS Production" chapter as this will greatly help the reader.
- The section on "PFAS Uses" is incomplete. For example, discussions of key uses are missing, such as protection of medical garments/surgical gowns, protective wear for fire fighters, workers in the chemical and petroleum industry, law enforcement and the military. Furthermore, the benefits the chemistry provide are not always mentioned. For example, a) finishing medical gowns and drapes with side-chain fluorinated polymers creates a barrier that provides life-saving protection against infections and transmission of diseases in hospitals; b) Clothing utilizing side-chain fluorinated polymers offers life-saving protection to workers in chemical and pharmaceutical manufacturing, to workers in the petroleum refining industry and to first responders, whether by helping bulletproof vests maintain their functionality or by maintaining performance of protective gear in the extreme environment of a fire.
- The section on "PFAS Uses" do not always reflect on the benefit provided and why specific PFAS are used in these applications. For example, in chrome plating, the plating bath consists of chromic acid (H_2CrO_4, often referred to as Cr(VI) acid). Cr(VI) is a known human carcinogen and therefore Cr(VI) emissions are regulated to protect workers from occupational exposure and to protect the environment. Amounts of Cr(VI) in the ambient air of plating facilities need to be controlled by utilizing a chemical mist suppressant and add-on air handling and air scrubbing devices. California maintains a list of approved fume suppressants which have undergone testing to meet hexavalent chromium emission standards (CA EPA 2016: California Environmental Protection Agency, Air Resources Board, September 21, 2016: List of approved fume suppressants which have undergone testing to meet hexavalent chromium emission standards. https://www.arb.ca.gov/toxics/chrome/cfs.htm andhttps://www.arb.ca.gov/toxics/chrome/fumesuppresslistfinal9.21.16.pdf
- The section on "Biosolids" in "PFAS Uses" seems misplaced. Please consider moving the entire chapter the draft CAP Chapter "Environment".
- The last section on waste emissions should be structured to clearly separate on-going emissions from legacy emissions.

Regulations

Overall, this chapter contains out of date and/or inaccurate information and is not well organized or clear regarding the intent and purpose. It is not clear how this chapter will be of benefit to Washington's stakeholders. At the very least, effort should be made to update the entries in the table and clearly acknowledge that due to the dynamic nature of regulations, information within this chapter will need to be verified from the original source. Washington should include hyperlinks and full references to all original sources of information for users to check for updates.

In addition to updating the PFAS Regulations Summary Table with all current information, each specified numerical limit should be earmarked as "requirement, guidance, proposed or otherwise noted". This should be a "living" table as specific values change.

Regulations have been implemented, proposed and planned primarily on long-chain PFAS products (and their related salts) such as PFOS, PFOA, PFHxS and PFNA.

The focus on regulation globally (state, federal, international) has been on PBT PFAS substances that have a history of direct manufacture, use and emissions into the environment.

All of the major global manufacturers of PFAS chemistry (EPA 2010/2015 VSP signees) have transitioned away from the historical long-chain chemistries noted above and now only manufacture and sell short-chain PFAS-based intermediates and products.

The FluoroCouncil and its members support regulation of the historical long-chain chemistries and any and all regulatory efforts to eliminate imports of products and/or treated articles containing these PFAS chemicals into the United States. This will also have the direct impact of minimizing on-going exposure from any long-chain PFAS chemicals.

The focus on any future regulation should be on the understanding, control and elimination of sources of long-chain chemistry regardless of their origins.

APPENDIX B
[Understanding FluoroTechnology]

FluoroCouncil
Global Industry Council for FluoroTechnology

Fluoropolymers Product Group
PlasticsEurope
Association of Plastics Manufacturers

Understanding FluoroTechnology

Per-and polyfluoroalkyl substances (PFASs) is a term that describes a wide and diverse array of chemistry containing fluorine and carbon. This class of chemistry is sometimes inaccurately called "PFCs." Specific interest and concern from regulators, environmental groups, the media and other stakeholders is focused on a subset of PFAS chemistry: Long-chain perfluoroalkyl acids (PFAAs) and substances that may degrade to form them (known as "precursors"). It is often incorrect to make general statements about properties of the broad family of PFASs, particularly when discussing their safety and environmental impacts.

This document explains some key FluoroTechnology terms and depicts those in an overview visual:

- Long-chain PFAAs
- Short-chain PFAAs
- Non-polymeric and Polymeric Fluorotelomer-based Products
- Fluoroplastics and Fluoropolymers

LONG-CHAIN PFAAS

Long-chain PFAAs include:

- perfluoroalkane sulfonic acids (PFSAs) with carbon chain lengths of 6 and higher, including perfluorohexane sulfonic acid (PFHxS) and perfluorooctane sulfonic acid (PFOS).
- perfluorocarboxylic acids (PFCAs) with carbon chain lengths of 8 and higher, including perfluorooctanoic acid (PFOA).

Precursors of these substances may be produced or present in products. Examples are long-chain perfluoroalkyl sulfonyl fluoride-based raw materials and long-chain fluorotelomer-based raw materials.

The focus of regulators in many regions of the globe, manufacturers and downstream users is action on long-chain PFAAs and substances or products that may degrade to form them (precursors). Through the U.S. EPA 2010/15 PFOA Stewardship Program, major manufacturers in the U.S., Europe, and Japan have globally phased out long-chain PFAAs and their precursors, moving to alternatives such as, but not limited to, short-chain fluorotelomer-based products. Major downstream users have followed suit. Production and use of long-chain PFAAs continues outside those regions by companies that have not made such stewardship commitments.

SHORT-CHAIN PFAAS

Short-chain PFAAs include:

- PFSAs with carbon chain lengths of 5 and lower, including perfluorobutane sulfonic acid (PFBS)
- PFCAs with carbon chain lengths of 7 and lower, including perfluorohexanoic acid (PFHxA).

Precursors of these substances may be produced or present in products. Examples are short-chain perfluoroalkyl sulfonyl fluoride-based raw materials and short-chain fluorotelomer-based raw materials.

With the phase out of production and use of long-chain PFAAs, responsible industry and downstream users have transitioned to alternatives, including short-chain products that cannot degrade to form long-chain PFAAs. Regulators have held industry to high standards and increased data requirements to ensure that the alternatives are well studied and safe for their intended use. Consequently, short-chain alternatives are some of the most robustly studied new chemicals introduced to the market. Substantial toxicity and environmental testing data have been generated over several years and submitted to regulators.

FLUOROTELOMER-BASED PRODUCTS

Fluorotelomer-based Products can be non-polymeric or polymeric, and can be based on long- or short-chain intermediates. Fluorotelomer-based raw materials are considered precursors to PFAAs. For example, a long-chain fluorotelomer-based raw material can degrade to form a long-chain PFAA. Stewardship Program participants offer only short-chain fluorotelomer-based products.

Non-Polymeric Fluorotelomer-based Products are fluorotelomer-based derivatives, such as fluorinated surfactants used in firefighting foams and as coatings additives, and fluorotelomer-based raw materials used as feedstock to produce polymeric fluorotelomer-based substances.

Polymeric Fluorotelomer-based Products are also known as "side-chain fluorinated polymers." These products consist of hydrocarbon backbones with polyfluoroalkyl side chains that stick out like teeth on a comb. These polymers are used to treat textiles, carpets, nonwovens and paper to provide water, soil, oil and stain resistance. The polymers are of a sufficient molecular weight that they are not readily bioavailable or biodegradable, similar to other polymers such as polyethylene. The short-chain polymeric fluorotelomer-based products are safe for their intended uses, and offer a significantly improved health and environmental profile over the long-chain fluorotelomer-based products.

FLUOROPLASTICS AND FLUOROPOLYMERS

Fluoropolymers are polymers that have a carbon backbone and contain fluorine atoms directly attached to these carbons. They are specialty plastics, elastomers and liquid polymers used in applications such as wire and cable coatings; linings for pipes, tanks and equipment in chemical and pharmaceutical manufacturing; lubricants; and non-stick cookware. In these applications, they provide important properties such as heat and chemical resistance, and non-stick and unique dielectric properties.

Examples of solid fluoropolymers (fluoroplastics) are PTFE (polytetrafluoroethylene) and PVDF (polyvinylidene fluoride) whereas liquid fluoropolymers are (per)-fluoropolyethers.

Typically, fluoropolymers are of a sufficient molecular weight that they are not bioavailable. They are extremely stable and not biodegradable under normal environmental conditions, similar to other polymers such as polyethylene, etc. Therefore, fluoropolymers themselves have not been the focus of regulatory efforts.

Additionally, any use of a fluoropolymer in a food contact application, such as cookware, is reviewed by regulators, such as the U.S. Food and Drug Administration and the European Food Safety Authority, which have all confirmed that fluoropolymers are safe for their intended uses in nonstick cookware coatings and certain food packaging materials.

ABOUT THE FLUOROCOUNCIL:

The FluoroCouncil is a global membership organization representing the world's leading manufacturers of fluoropolymers, fluorotelomers, and other fluorinated surfactants and surface property modification agents. Its member companies are Archroma Management LLC, Arkema France, Asahi Glass Co., Ltd., Daikin Industries, Ltd., Solvay Specialty Polymers, The Chemours Company LLC, Dynax Corporation (*associate*), and WL Gore (*provisional*).

For more information about the FluoroCouncil, visit www.fluorocouncil.org or contact Jessica Bowman at +1 (202) 249-6737 or Jessica_Bowman@fluorocouncil.org.

ABOUT THE FLUOROPOLYMER GROUP OF PLASTICSEUROPE:

The Fluoropolymer Product Group of PlasticsEurope is a professional representative body for the European fluoropolymers manufacturers in Europe. Its member companies are AGC Chemicals Europe ltd., Chemours International Operations sarl., WL Gore & Associates GmbH, Solvay Specialty Polymers SPA., Dyneon GmbH., Arkema, Daikin Chemical Europe GmbH.

For more information about the Fluoropolymer Product Group of PlasticsEurope, visit www.plasticseurope.org or contact Patricia Vangheluwe at +32 (0) 2 676 17 32 or patricia.vangheluwe@plasticseurope.org.

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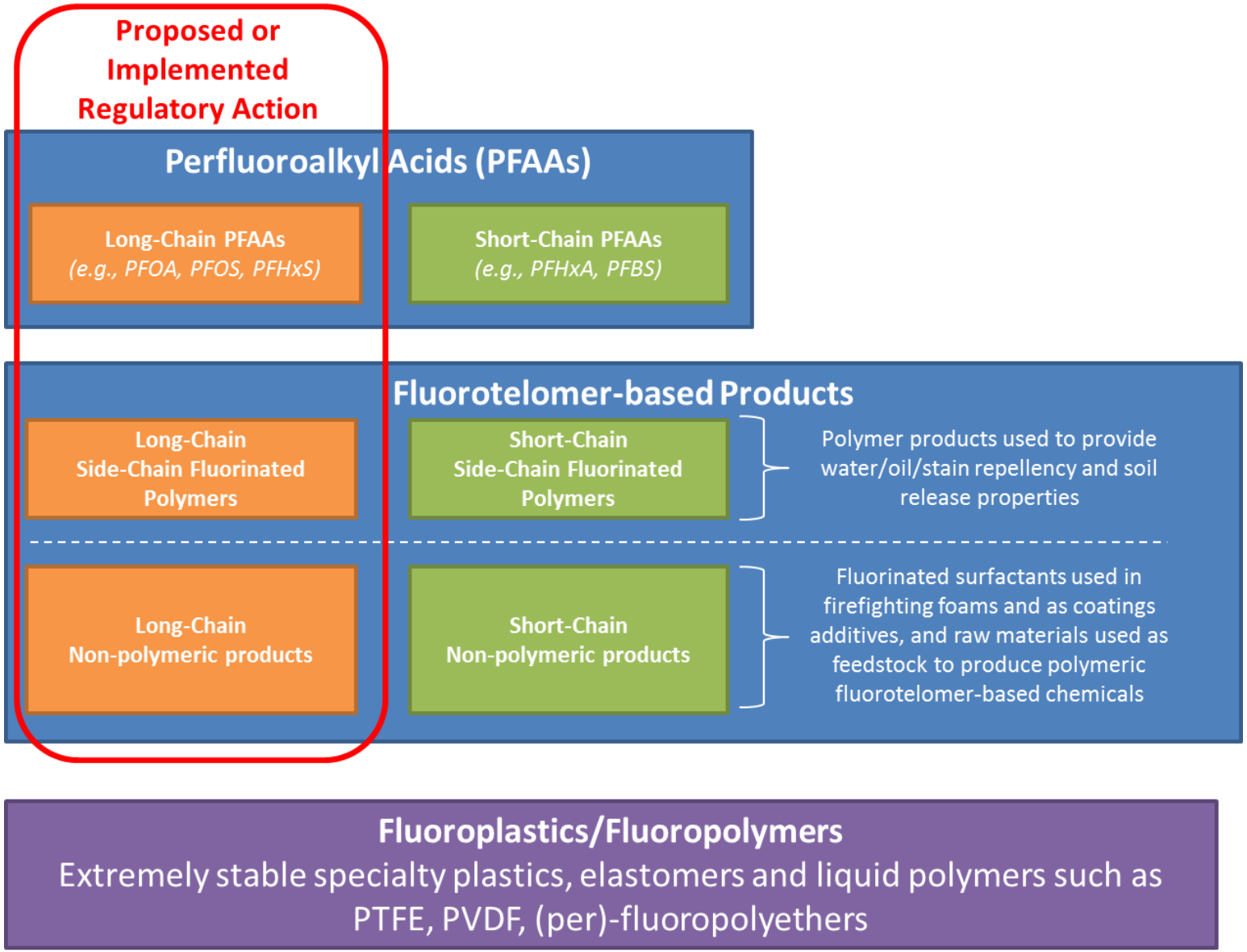
PFAS Overview



APPENDIX C
FluoroCouncil Critical Review

"Accumulation of Perfluoralkyl Substances In Human Tissues" *Environment International* 59 (2013) 354–362
Authors: Francisca Pérez, Martí Nadal, Alícia Navarro-Ortega, Francesc Fàbrega, José L. Domingo, Damià Barceló, Marinella Farréa

Pérez et al. reported levels of perfluorohexanoic acid (PFHxA) in limited numbers of autopsied samples of human tissues, including brain, liver, lung, bone and kidney, with highest levels being reported in liver and brain. When analyzing the data, individual samples do not appear internally consistent or within the range of published literature. For example, a liver sample from one individual had a relatively high concentration of PFHxA, but the brain sample from the same individual had a low concentration of PFHxA. In addition, data presented in the Pérez et al. paper on levels of PFHxA would, overall, be an outlier within current literature reporting levels of PFHxA in various human matrices. The article, as published, has several analytical method shortcomings. Specifically, the authors use an analytical method - turbulent flow chromatography - that has not been validated for human tissue analysis. This method has been used by the pharmaceutical industry to analyze human fluid samples, urine and plasma, on a large scale, but not solid tissues. In validating this method, the Perez et al. lab used pig tissue instead of the human tissue, which is the matrix of the study, and failed to report the recovery data in the publication. Recovery data in the range of 80-120% is considered of scientific value and publishable in this type of experiment, but there is no way to know whether or not this range has been respected. Overall, the data reported by Pérez et al. can be considered an anomaly and further research is needed before any definite conclusion can be made as to whether PFHxA accumulation occurs in human tissues.

FluoroCouncil Comments

Perez et al. report for the first time PFASs accumulation in various human tissues from the same subjects. The authors present data on 21 different PFASs in 99 samples of autopsy human tissues, including brain, liver, lung, bone and kidney from 20 different individuals. All subjects were reported to have lived in Tarragona (Catalonia, Spain) for at least 10 years prior to death and ranged in age from 28 to 83 years. Sample collection was reported to occur within 24 hours of death and samples were stored at -20°C, but there is no information on the state or preservation of cadavers prior to sample collection. Further details were unknown regarding sample collection.[1] The samples were initially solvent extracted and followed by online purification by turbulent flow chromatography and were then analyzed by liquid chromatography coupled to tandem mass spectrometry. Using this method the authors most notably reported maximum median levels of perfluorobutanoic acid (PFBA) in kidney and lung at concentrations of 263 and 807 ng/g respectively, PFHxA in liver and brain at 68.3 ng/g (range: 353 – DL) and 141 ng/g (range: 486-10), respectively, while the highest levels of perfluorooctanoic acid (PFOA) were reported in bone at 20.9 (234- DL) ng/g.

[1] Because these tissues were collected post-mortem and complete autopsy details are missing, it is unclear whether the reported accumulations in the tissues actually occurred in the tissues or the result of blood in the tissues. After death the vasculature breaks down and the maintenance of blood vessels is lost. Thus, the results may simply reflect blood levels of the compounds rather than accumulation of the material. This is particularly suspect in the brain values where it is unknown whether the breakdown of the blood brain barrier occurs after death and if so, the "accumulation" of PFASs reported in the brain may be the result of breakdown of the vasculature and not the result of accumulation. Additionally the section(s) of the brain analyzed were not indicated in the paper. While the brain is a highly vascularized organ, certain regions are more vascular than others.

In regards to sample acquisition and storage conditions, the paper does not discuss specific conditions around tissue collections or storage prior to acquiring the samples. In addition, there was a discrepancy in the paper in regards to storage temperature of the samples.

In a previous publication, using the same method, the lab used two enrichment columns including the Thermo Fisher Scientific: Cyclone (50 mm×0.5 mm, 60 μm particle size, 60 Å pore size) and C18 XL (50 mm×0.5 mm, 60 μm particle size, 60 Å pore size), connected in tandem (Llorca, 2012). However, the analytical procedure published in the Pérez et al. paper indicated the use of one column.

From the details of the analytical procedure stated in the Pérez et al. paper, the accuracy and precision of the analytical method is not clear. In a previous publication by the same working group, the analytical method and recovery, along with accuracy and precision data are provided in much more detail (Llorca, 2012). The method used for the sample purification step in this publication, turbulent flow chromatography (TFC), has not previously been published as a method to analyze human tissue samples. The method has been used mainly by the pharmaceutical industry to analyze human urine and plasma samples on a large scale. The paper by Pérez et al. states that the lab used only pig tissue for standardization and recovery experiments given the small volume of human tissue available (2 g per sample, ½ gram for each analysis). No validation experiment was performed with human control tissues. Given the differences in these two matrices, using pig tissue to quantify data for human tissue samples could lead to inappropriate interpretation of data.

Typically, recovery data in the range of 80-120% is considered of scientific value and publishable in this type of experiment. The authors failed to report on recovery data in the publication.

The Principal Component Analysis (PCA) conducted using the data generated in this paper attempted to compare concentration levels of different substances. The data set had a small sample size (20 individuals) and, therefore, was insufficient and inconclusive. Also, this type of analysis is typically used on soil and sediment values, not tissue sample concentrations.

More specifically, and in regards to the actual data, the concentrations of PFHxA reported for brain and liver tissues of the same individuals in the Pérez et al paper do not reflect consistent results for PFASs accumulation in human tissues. When comparing ratios of brain- to liver- concentrations reported in the paper per individual subject, there is a 1000-2000 fold difference among individuals. The data indicate instances in which individual liver samples had a relatively high concentration of PFHxA, but the brain sample from the same individual had a low concentration of PFHxA and vice versa. Samples from individuals Nr. 5, 9, and 11 had no detectable PFHxA in liver, but had the highest levels in brain in this study. One would not expect such large differences of PFHxA concentrations in liver and brain tissues from the same individual.

The data presented in the Pérez et al. paper, specifically, levels of PFHxA-seem not to be consistent with current literature reporting levels of PFHxA in various human matrices. For example, Erisson et al (2007) published a pilot study measuring PFHxA in human blood samples of individuals living within Catalonia, Spain, the same target region of Spain within the Pérez paper, but did not find any detectable PFHxA in any sample. In a 2011 publication by Pérez, the author did not report detectable levels of PFHxA in human hair samples, and in only 3 out of 30 human urine samples was PFHxA detectable.

Pérez et al. discuss dietary exposure as a major route of human exposure to PFASs within the Catalonia region. However, Domingo et al (2012) conducted a study that calculated total intake of PFHxA from food sources in Catalonia, Spain, and showing only 2 out of 12 analyzed food groups with any detectable PFHxA level. The levels of PFHxA Pérez et al. reported in liver, kidney lung, brain and bone does not correlate with aforementioned studies of food sources in the same region.

Perez et. al. indicated that the data presented in this article "…should be beneficial for the development of theoretical PBPK models, whose validation is still incomplete" (p.258). The data presented by Perez et al., however, only shows a snapshot of PFASs in human post mortem tissue at best. In order to perform PBPK studies blood levels and data from fresh tissue are needed. Therefore, the statement by Perez et al. is misleading in that it infers that the data presented is useful in developing human models for the compounds. (See also Fabrega 2015 and FluoroCouncil's critical review of Fabrega et al.)

Overall, the data reported by Pérez et al. can, at best, be considered an anomaly. Several issues of unresolved analytical uncertainties have become obvious. Based on the small sample size, use of a technique with limited validation and inconsistent findings, and compared to the previous publications, the data for PFHxA presented in this paper are unrealistic and cannot be considered valid documentation for the potential for PFHxA to accumulate in human tissues. Further, the small volume of human tissue used in this study per sample and the lack of proper standardization and recovery data shed major doubt on the values reported. Further research is needed before any definite conclusion can be made in particular as to whether PFHxA accumulation occurs in human tissues.

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