FluoroCouncil
Global Industry Council
for FluoroTechnology

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FluoroCouncil[1] represents major manufacturers of products based on per- and polyfluoroalkyl substances or "PFAS." PFAS encompass many different classes of chemistry that vary significantly in their physical and chemical properties, hazard profiles, and uses. Because of this variation, it is inappropriate to discuss PFAS as a single class of chemistry.

There has been much attention to PFAS recently because a few specific substances – generally PFOA and PFOS, two perfluoroalkyl acids (PFAAs) - have been found at elevated levels in locations throughout the country. Importantly, PFOA, PFOS, and any similar "long-chain" PFAAs (including PFNA and PFHxS) and their precursors (including long-chain fluorotelomers) have not been manufactured in the U.S. in many years. As a result, blood levels of PFOA and PFOS in the U.S. population have declined by up to 85% since 1999. Their presence in the environment is generally near sites where those chemicals were manufactured or used and locations where older long-chain based Class B (flammable liquid) firefighting foam was used, including military installations, airports, and firefighter training facilities.

Of the many substances in the PFAS family, only some PFAS have actual commercial uses in U.S. commerce, most likely in the hundreds rather than thousands. Two key types of PFAS used today include:

- Fluoropolymers, a type of specialty plastic that provides products with chemical resistance, thermal stability, resilience and are essential to electronics, cell phones, and medical devices. Fluoropolymers are too large to be bioavailable, not toxic, not bioaccumulative, and present no significant risk to human health or the environment. They meet international criteria for polymers of low concern.[2]
- Short-chain fluorotelomers, which provide oil repellency and soil resistance for textiles (including first responder gear and medical garments), upholstery, and specialized paper. They are also critical to Class B firefighting foams and many paint and coating applications. The hazard profile of short-chain fluorotelomers is characterized by their potential breakdown product, perfluorohexanoic acid (PFHxA or C6 acid). PFHxA is well studied with a robust body of data demonstrating it does not present a significant risk to human

[1] FluoroCouncil represents the world's leading manufacturers of fluoropolymers, fluorotelomers, and other fluorinated surfactants and surface property modification agents. FluoroCouncil's member companies are AGC Inc., Daikin Industries, Ltd., Solvay Specialty Polymers, The Chemours Company LLC, Archroma Management LLC (associate), Dynax Corporation (associate), and Tyco Fire Products, LP (associate). FluoroCouncil is administered by the American Chemistry Council.

[2] Henry, B. J., Carlin, J. P., Hammerschmidt, J. A., Buck, R. C., Buxton, L. W., Fiedler, H. , Seed, J. and Hernandez, O. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035

health or the environment. PFHxA is not carcinogenic, mutagenic, or genotoxic, and not an endocrine disruptor. PFHxA is also not a reproductive or developmental toxicant.[3]

It is inappropriate to conflate the characteristics, properties, or potential concerns about long-chain PFAAs like PFOA or PFOS with the types of PFAS manufactured and used today.

Today's PFAS are vital to many products we rely on every day, but much attention has focused on fire fighting foam and food packaging, both of which now use short-chain fluorotelomers.

Of note, the use of PFAS in all food contact applications, including food packaging, is already thoroughly regulated at the federal level by the U.S. Food and Drug Administration. Based on substantial upfront data requirements, FDA concluded that the PFAS currently used in food contact applications are safe for their intended use (based on a standard of "reasonable certainty of no harm"). See Appendix A.

Regarding aqueous film forming foams (AFFF) used to fight Class B flammable liquid fires, industry has transitioned to today's foams that are not based on PFOS or long-chain fluorotelomers. Further, best practices have been developed that call for not using AFFF for training, limited use in testing, but still making these life- and property-saving products available where they are needed to fight fires.

While "fluorine-free foams" are available, they do not meet the performance requirements of military specification, are not fully compatible with each other, require substantially more product in use and testing (up to 60%), and they often require significant equipment changes.

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3 *See* Luz AL, Anderson JK, Goodrum P, Durda J. 2019. Perfluorohexanoic acid toxicity, part I: Development of a chronic human health toxicity value for use in risk assessment. Regulatory Toxicology and Pharmacology. 103:41-55. https://www.sciencedirect.com/science/article/pii/S0273230019300194?dgcid=raven_sd_aip_email. Anderson JK, Luz AL, Goodrum P, Durda J. 2019. Perfluorohexanoic acid toxicity, part II: Application of human health toxicity value for risk characterization. Regulatory Toxicology and Pharmacology. 103:10-20: https://www.sciencedirect.com/science/article/pii/S0273230019300200?dgcid=raven_sd_aip_email. *See* bibliography at https://fluorocouncil.com/health-environment/scientific-studies/

Appendix A

Food Packaging Materials are Subject to Strict Regulation by FDA

- PFAS used in food packaging are regulated as ***food additives*** by FDA

  - Packaging materials that contact food – including coatings and other chemical components of food wrappers, cartons, containers, etc. -- are regulated as "***food additives***" under Section 201(s) of the Federal Food Drug and Cosmetic Act (FFDCA).[1] FDA uses the term "***food contact substance***" to describe food additives from packaging materials.[2]

- Before a food contact substance can be sold or distributed in commerce it must be reviewed by FDA, and under the statute, FDA can only provide authorization for a food contact substance if the agency concludes that there is sufficient scientific data to demonstrate that the substance is ***safe for its intended use*** in packaging.[3]

- In order to demonstrate that a food contact substance is safe for its intended use, FDA requires submission of extensive upfront test data and scientific information regarding:

  - The chemical composition of the food contact substance, including all impurities and potential degradation products;

  - The levels of impurities that may be released from the food contact substance under intended cooking conditions and the potential dietary concentrations of those substances;

  - Toxicity data (and any other relevant health and safety data) on all impurities, degradation products and other components of the food contact substance.[4]

- FDA can withdraw its acceptance of a food contact substance at any time if available data no longer demonstrate that the food contact substance is safe for its intended use.[5] If this occurs (if FDA withdraws its authorization), the food contact substance can no longer be distributed in commerce.

  Note: *FDA traditionally provided approval for food contact substances through a "Food Additive Regulation." However, in 1997 the FFDCA was amended to provide for the use of Food Contact Notifications (FCNs) in lieu of Food Additive Regulations for food contact substances. All modern-day short chain PFAS used as food contact substances have been approved through the FCN process—which is what this document focuses on.*

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1 Section 201(s) of the FFDCA (21 U.S.C. § 321(s)) defines "food additive" to include "any substance intended for use in . . . packaging, transporting, or holding food."

2 Section 409 of the FFDCA (21 U.S.C. § 348) defines "food contact substance" to mean "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food . . ."

3 *See* 21 U.S.C. § 348(h)(1).

4 *See* 21 C.F.R. §170.101; FDA Form 3480 (available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/ucm076880.pdf

5 *See* 21 C.F.R. §170.105(a)

Appendix B

PFHxA Toxicity Information

In order to demonstrate that a food contact substance is safe for its intended use, FDA requires upfront submission of extensive scientific data, including chemical composition, toxicity data, migration data, and other relevant health and safety data under intended conditions of use for the food contact substance, impurities, and potential degradation products.

Consequently, a robust body of data has been developed to characterize the hazard profile of short-chain fluorotelomer products used in today's food packaging. Studies have focused on PFHxA as a primary break down product of today's short-chain PFAS products. These data support the following conclusions:

- Not carcinogenic, not damaging to DNA, not genotoxic or mutagenic
- Not a developmental or reproductive toxicant
- Rapid bioelimination, not bioaccumulative
- Very low incidence of detection and quantification in serum
- Not expected to be harmful to human health or the environment at environmentally relevant concentrations

Below is a list of example studies that support the above conclusions:

- A 2-year rodent cancer bioassay (Klaunig 2015)
- DNA mutation and genotoxicity in vitro assays (NTP 2018, Loveless 2009, Eriksen 2010)
- Chronic systemic toxicity rodent bioassay (Klaunig 2015)
- Reproductive/developmental rodent bioassays (Loveless 2009, Iwai 2014, Iwai et al. 2019)
- Sub-chronic systemic toxicity bioassays (Loveless 2009, Chengelis 2009, Iwai 2014)
- Analysis of endocrine disruption (Borghoff 2018)
- High-throughput molecular in vitro assays (EPA Tox21)
- Toxicokinetic assays in rats, mice, microminipigs, monkeys and humans (many; examples include Chengelis 2009, Iwai 2014, Russell 2013, 2015, Nilsson 2010, 2013, Fujii 2014, Guruge 2015, Gannon 2011, 2016)

A recent critical review of relevant PFHxA data supports the conclusion that PFHxA is not carcinogenic, is not a selective reproductive or developmental toxicant, and does not disrupt hormone (endocrine) activity (Luz 2019). A companion study indicates that PFHxA currently poses minimal risk to the health of the general U.S. population and that human exposure is low and infrequent. In addition, daily intake rates for infants exposed to PFHxA through breast milk, formula and baby food clearly demonstrate very high margins of safety for PFHxA (Anderson 2019). These and additional relevant studies can be accessed at https://fluorocouncil.com/health-environment/scientific-studies/

Furthermore, as a condition of allowing today's short-chain products onto the market, the U.S. Environmental Protection Agency also required manufacturers to conduct long-term carcinogenicity, chronic toxicity, and reproductive effects studies, along with numerous other health and environmental safety studies, generally through Enforceable Consent Agreements.

Appendix C

Additional References

- Fire Fighting Foam Coalition Best Practice Guidance for Use of Class B Firefighting Foams: https://docs.wixstatic.com/ugd/331cad_188bf72c523c46adac082278ac019a7b.pdf

- Fire Fighting Foam Coalition Fact Sheet on AFFF Fire Fighting Agents: https://docs.wixstatic.com/ugd/331cad_fa5766eb867b4a5080330ce96db195fa.pdf

- Fire Fighting Foam Coalition Response to the IPEN Paper on Fluorine-free Foams: https://docs.wixstatic.com/ugd/331cad_073fb784906d4e818d1323c1e10ee8c5.pdf

- Guidance for Best Environmental Practices (BEP) for the Global Apparel Industry: https://fluorocouncil.com/wp-content/uploads/2017/06/FluoroCouncil-Textile-BEP-Guidance-English.pdf

- Information Regarding the Use of PFAS in Food Packaging: https://fluorocouncil.com/applications/food-packaging/

- Interstate Chemicals Clearinghouse Webinar: The PFAS Universe: Uses, Classification, and Degradation (with additional recommended reading): http://theic2.org/ic2_webinar_the_pfas_universe

- PFAS Incineration Publications:
  - Investigation of waste incineration of fluorotelomer-based polymers as a potential source of PFOA in the environment. PH Taylor, T Yamada, RC Striebich, JL Graham, RJ Giraud - Chemosphere, 2014. https://www.sciencedirect.com/science/article/pii/S0045653514002410
  - Thermal degradation of fluorotelomer treated articles and related materials. T Yamada, PH Taylor, RC Buck, MA Kaiser, RJ Giraud - Chemosphere, 2005. https://www.sciencedirect.com/science/article/pii/S004565350500425X
  - Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per-and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. K Aleksandrov, HJ Gehrmann, M Hauser, H Mätzing, D Pigeon, S. Stapf, M Wexler - Chemosphere, 2019. https://doi.org/10.1016/j.chemosphere.2019.03.191
  - Arkenbout, Abel. (2018). Long-term sampling emission of PFOS and PFOA of a Waste-to-Energy incinerator. https://www.researchgate.net/publication/327701467_Long-term_sampling_emission_of_PFOS_and_PFOA_of_a_Waste-to-Energy_incinerator