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RE: Draft Rule for Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances, Currently Unavoidable Use (CUU) Designation for Cookware
Issue Overview

Dear Ms. Malinowski Ferris:

Following our testimony on August 21st, you invited our organization to submit any additional written comments to the gaps on issues discussed during that hearing, react to questions raised by panel members of other witnesses who testified, and respond to issues raised by staff in their July 17, 2025 recommendation to deny the CUU proposals for the use of PFAS in cookware and kitchen electric appliances (including coffee makers). This recommendation was based on what staff believed was a lack of evidence that these products meet the statutory definition of “essential for health, safety and the functioning of society” and that “reasonably available alternatives” are readily obtainable by consumers.

This letter will seek to address a number of issues that fit within these categories.

Issue 1: Is PTFE cookware safe?

Per- and poly-fluoroalkyl substances (PFAS) are a large group of compounds composed of fluorinated carbons. Importantly, the physical and chemical properties of the individual chemicals within this large group of compounds vary widely. Their use, how they behave in the environment, and their potential risk to human health vary significantly as well.

Non-stick cookware contains a specific subfamily of PFAS called fluoropolymers. The fluoropolymers used by our industry, primarily polytetrafluoroethylene (PTFE), do not have the same characteristics of non-polymeric PFAS of concern, which should be the focus of environmental and public health policy. Fluoropolymers are extremely large and stable compounds. Today, fluoropolymers used in cookware that come into contact with food are not a concern for human health or the environment for the following reasons:

- They have a decades-long history of safe and essential use, including in the healthcare industry where fluoropolymer coatings are used on medical implantation devices such as pacemakers and catheters.
- They are not water-soluble and potential exposure through drinking water is not a concern.
- Fluoropolymers like PTFE are highly stable and are not shown to degrade under normal conditions of use into their monomeric component chemicals.
- They are no longer manufactured with fluorosurfactants like perfluorooctanoic acid (PFOA), a primary PFAS of concern.

The indiscriminate definition of PFAS in many state's bills or recently signed laws, that include any fluorinated organic chemicals containing at least one fully fluorinated carbon atom, ignores the physicochemical characteristics of fluoropolymers that make the subfamily benign from health effects and environmental impact. Fluoropolymers should not be guilty by association without fair consideration of their chemical-specific properties that make them crucial in modern society, as detailed below.

Government Agencies Have Deemed PTFE Cookware Safe

Since the 1960's, federal regulations at the U.S. Food & Drug Administration (21 CFR 175.300) have authorized specific types of PFAS substances for use in food contact applications. The FDA has determined that PTFE cookware is safe to use due to the "highly polymerized coating bound to the surface of the cookware and studies showing negligible amounts of PFAS in this coating migrating to food, and that polymerized or large molecule PFAS are not absorbed by the human body when ingested." (updated 2024).

Similarly, the European Food Safety Authority (EFSA) has found that PTFE, due to its molecular size, will not likely be absorbed through the gastrointestinal barrier, and therefore concludes it does not present a health hazard (2016).

The properties that make some non-polymer PFAS a concern for human health and the environment include their water solubility and wide-spread environmental occurrence, bioaccumulation potential, and potential toxicity. Fluoropolymers do not have these properties, as detailed below.

- **Fluoropolymers Have No Measurable Bioaccumulation Potential**
  Available empirical data indicates that fluoropolymers such as PTFE, do not bioaccumulate. Bioaccumulation potential is generally assessed on empirical evidence (bioaccumulation factor > 2000) and/or prediction using the octanol-water coefficient (e.g., log Kow > 3). Fluoropolymers such as PTFE are insoluble in octanol and water (Henry et al., 2018). Therefore, the bioaccumulation potential of fluoropolymers cannot be predicted from a log Kow measurement. Measured biota tissue, water, and sediment concentrations indicate that there is no evidence of bioaccumulation in aquatic food webs (Bour et al., 2018; Sfriso et al., 2020).

- **Fluoropolymers Show No Evidence of Toxicity**
  Fluoropolymers such as PTFE have not been shown to be toxic to humans. A summary of available data examining the toxicity of PTFE on test animals is provided in Radulovic and Wojcinski (2014). Acute oral toxicity of PTFE in rats is low/negligible with reported LD50 greater

than 11,280 mg/kg. Researchers also found no adverse effects in rats exposed to up to 25% PTFE in their diet for up to 90 days (Naftalovich et al., 2016; Radulovic & Wojcinski, 2014). Additionally, a four-week repeated dose study of PTFE fed to mice in their diet reported no effects at any dose level, and no PTFE was detected in the blood (Lee et al., 2022). The dose level fed to mice without any adverse effects would be equivalent to approximately 9,720 mg/kg for a 60 kg (~132 pounds) adult. Manufacturer material safety data sheets for PTFE indicate that dermal contact with PTFE does not cause skin irritation in humans. PTFE is not genotoxic, and the World Health Organization's International Agency for Research on Cancer concluded that organic polymeric materials (such as fluoropolymers) as a group, are not classifiable as to their carcinogenicity to humans (IARC, 1999).

- **Fluoropolymers Are Not Water Soluble**
  Fluoropolymers are not environmentally mobile. Fluoropolymers such as PTFE are not water soluble (Korzeniowski, et al. 2022) and even if released to the environment, are not likely to result in widespread environmental impacts. Any potential movement of fluoropolymers in the environment will likely occur via mechanical transport.

- **Fluoropolymer Cookware Show No Significant Emissions Upon Disposal**
  Fluoropolymers from food contact applications are unlikely to result in significant environmental emissions during the end-of-life phase. Recycling and treatment of PTFE-treated metal cookware offers the greatest assurance that the used cookware is most properly controlled in the end of life. Incineration at typical temperatures of municipal waste incinerators can result in full mineralization of the fluoropolymers, thereby preventing degradation into non-polymeric PFAS. Landfilling PTFE cookware prevents PFAS emissions due to the stability of the polymer and the absence of high enough temperatures in landfills to cause polymer degradation.

Our Industry is Engaged in Responsible Manufacturing

It is important to acknowledge that since the mid-20th century, PTFE has played a vital role in the technological advancements of many industrial and consumer products. Moreover, over the past several years, PTFE manufacturers have implemented significant changes to their manufacturing processes. Technologies now exist and are implemented to manufacture PTFE without the use of fluorosurfactant processing aids. Also, those manufacturers who may continue to make fluoropolymers via the use of fluorosurfactant processing aids now include additional steps to ensure negligible remaining non-polymer PFAS are entrained in the final fluoropolymer product. These recent developments in the manufacturing process for PTFE and other fluoropolymer cookware ensure that they are not a health effects concern to humans or the environment.

The physicochemical factors and health effects research should lead policymakers to conclude that fluoropolymers in PTFE cookware, even those that come into contact with food being cooked in pots, pans, skillets, and utensils, are NOT appropriate priority product-chemical focus for PFAS ban legislation.

Issue 2: Advocates claim that these statement are false; that industry has not produced any independent studies to support these claims; or, as one advocate said during testimony on August 21st, that the studies were "paid for by industry".

Nothing could be further from the truth. The studies referenced above are independent, refereed, science journal articles or are statements published by the world's leading safety regulatory agencies. They were not commissioned or paid for by any company or industry group:

Améduri, B. (2023). Fluoropolymers as Unique and Irreplaceable Materials: Challenges and Future Trends of These Specific Perfluoroalkyl Substances [Preprint]. Chemistry and Materials Science. https://doi.org/10.20944/preprints202309.0512.v1

Améduri, B., Sales, J., & Schlipf, M. (2023). Developments in fluoropolymer manufacturing technology to remove intentional use of PFAS as polymerization aids (in press). International Chemical Regulatory Law Review, 6(1), 18–28. https://icrl.lexxion.eu/article/ICRL/2023/1/5

Bour, A., Avio, C. G., Gorbi, S., Regoli, F., & Hylland, K. (2018). Presence of microplastics in benthic and epibenthic organisms: Influence of habitat, feeding mode and trophic level. Environmental Pollution, 243, 1217–1225. https://doi.org/10.1016/j.envpol.2018.09.115

European Food Safety Authority (2016). Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2016.4357

Henry, B. J., Carlin, J. P., Hammerschmidt, J. A., Buck, R. C., Buxton, L. W., Fiedler, H., Seed, J., & Hernandez, O. (2018). A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integrated Environmental Assessment and Management, 14(3), 316–334. https://doi.org/10.1002/ieam.4035

IARC. (1999). Re-evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide (Part 1, Part 2, Part 3) (Vol. 71). https://www.ncbi.nlm.nih.gov/books/NBK498701/

Korzeniowski, Stephen H., Robert C. Buck, Robin M. Newkold, Ahmed El kassmi, Evan Laganis, Yasuhiko Matsuoka, Bertrand Dinelli, et al. 2022. "A Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers." Integrated Environmental Assessment and Management, August. https://doi.org/10.1002/ieam.4646

Lee, S., Kang, K.-K., Sung, S.-E., Choi, J.-H., Sung, M., Seong, K.-Y., Lee, J., Kang, S., Yang, S. Y., Lee, S., Lee, K.-R., Seo, M.-S., & Kim, K. (2022). In Vivo Toxicity and Pharmacokinetics of Polytetrafluoroethylene Microplastics in ICR Mice. Polymers, 14(11), Article 11. https://doi.org/10.3390/polym14112220

Naftalovich, R., Naftalovich, D., & Greenway, F. L. (2016). Polytetrafluoroethylene Ingestion as a Way to Increase Food Volume and Hence Satiety Without Increasing Calorie Content. Journal of Diabetes Science and Technology, 10(4), 971–976. https://doi.org/10.1177/1932296815626726

Radulovic, L. L., & Wojcinski, Z. W. (2014). Encyclopedia of Toxicology; PTFE (Polytetrafluoroethylene; Teflon) (Vol. 3). Elsevier Inc. https://www.sciencedirect.com/science/article/abs/pii/B9780123864543009702?via%3Dihub

Sfriso, A. A., Tomio, Y., Rosso, B., Gambaro, A., Sfriso, A., Corami, F., Rastelli, E., Corinaldesi, C., Mistri, M., & Munari, C. (2020). Microplastic accumulation in benthic invertebrates in Terra Nova Bay (Ross Sea, Antarctica). Environment International, 137, 105587. https://doi.org/10.1016/j.envint.2020.105587

U.S. Code of Federal Regulations. Title 21, Part 175, Section 175.300. Resinous and Polymeric Coatings. https://ecfr.io/Title-21/Section-175.300

U.S. Food and Drug Administration (updated 2024). Authorized Uses of PFAS in Food Contact Applications.
https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications

Issue 3: There was a challenge to my testimony on August 21st that ceramic cookware could be ten times more expensive that non-stick cookware. Note that my testimony was about a 10-piece set of non-stick cookware vs. a 10-piece set of ceramic cookware (which is why I mentioned the price of the latter could easily exceed $1,000).

The advocate who testified pulled up random pricing on her phone, claiminig ceramic cookware was on par with or even cheaper than non-stick cookware. It's certainly easy to scroll through Amazon, for example, and cherry pick the cheapest ceramic cookware made in China vs. top-of-the line non-stick cookware made in the United States to support such a claim. The best way to show the *average* price of both types of cookware is through Prudent Reviews (prudentreviews.com). Prudent Reviews is a trusted, independent testing site of consumer goods. Below are some examples of both ceramic-coated and Teflon-coated cookware. Prudent reviews had this to say about the cost difference between non-stick and ceramic cookware:

Ceramic-Coated Cookware:

GreenPan Paris 8 Inch Ceramic Non-Stick Fry Pan (check price on Amazon) [$69.99]

Caraway 10.5-Inch Ceramic Fry Pan (check price on CarewayHome.com) [$115]

Ozeri Professional Series Earth Ceramic 8-Inch Fry Pan (check price on Amazon) [$59.99]

Teflon-Coated Cookware:

OXO Good Grips Non-Stick Open Frypan 8 Inch (check price on Amazon) [$39.99]

Cuisinart 12-Inch Non-Stick Skillet (check price on Amazon) [$59.95]

Rachael Ray 12.5-Inch Non-Stick Frying Pan (check price on Amazon) [$39.87]

In summary, given the wide range of products available to today's Maine consumer, costs vary. However the trend line is clear – and this, coupled with the proven fact that ceramics last much shorter periods of time, and therefore are discarded and replaced much more frequently than PTFE non-stick cookware – supports the notion that this replacement is *more expensive* than the product potentially being banned.

Sincerely,

Stephen D. Burns, President