January 28, 2025

Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333-0017
Submitted via email: rulecomments.dep@maine.gov

**Re: Chapter 90 Draft Rule: Products Containing perfluoroalkyl and Polyfluoroalkyl Substances**

To whom it may concern:

The Cookware Sustainability Alliance (CSA) appreciates the opportunity to submit comments to the Maine Department of Environmental Protection's ("DEP") Chapter 90 Draft Rule to implement certain provisions of the Maine PFAS in Products law, P.L. 2024, c. 630. We represent a diverse membership of cookware manufacturers who are committed to promoting sustainable practices and ensuring compliance with regulatory standards. Specifically, we write to support the Department's efforts to clarify the definition of "cookware" in the draft rules and to recommend revisions that explicitly exclude polymer-coated durable items from this definition. Such clarification is critical to ensure the final rules align with the law's intent, provide regulatory certainty for industry stakeholders, and avoid unintended burdens on products that do not pose the types risks to human health and the environment for which the PFAS in Products law was enacted to address.

**Issue Overview**
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 is made using a specific subfamily of compounds called fluoropolymers, primarily polytetrafluoroethylene ("PTFE"). Fluoropolymers are characterized as a PFAS under Maine's expansive definition, i.e., any fluorinated organic compound containing at least one fully fluorinated carbon atom. However, unlike non-polymeric PFAS of concern, fluoropolymers are extremely large and stable compounds that do not pose the same risks to human health or the environment. Extensively studied and approved for use in food preparation by the U.S. Food & Drug Administration and various European regulatory bodies, fluoropolymers have a decades-long record of safety supported by sound scientific research.

CSA was established to address misconceptions surrounding fluoropolymers and ensure that policies targeting PFAS focus on substances of actual concern, rather than safe and well-regulated products like non-stick cookware 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 healthcare where fluoropolymer coatings are used on medical implantation devices like pacemakers and catheters.
- They are not water-soluble, thus potential exposure through drinking water is not a concern.
- PTFE and similar fluoropolymers are highly stable and are not shown to degrade under normal use conditions.

- Fluoropolymers are no longer manufactured with fluorosurfactants like perfluorooctanoic acid (PFOA), a primary PFAS of concern.

Including cookware in Public Law 2023, c. 630 disregards the unique physicochemical characteristics of fluoropolymers that make the subfamily benign with respect to potential health effects and environmental impact. Policies aimed at prohibiting certain PFAS compounds deemed harmful to human health and the environment, along with the rules implementing them, must fairly evaluate chemical-specific properties and carefully avoid inadvertently regulating compounds like fluoropolymers, which are essential to modern society and have been demonstrated through scientific research to be safe for use in consumer products such as non-stick cookware.

**Accordingly, we submit the following limited proposed amendments to portions of the Chapter 90 Draft Rule pertaining to the definition of cookware and the prohibition on the sale of cookware containing intentionally added PFAS:**

> **2. Definitions.**
> **Cookware product.** "Cookware product" as defined at 38 M.R.S. § 1614(1)(A-10) is limited to houseware intended to be in direct contact with food or beverage. Cookware does not encompass items intended for use in and market exclusively for use in commercial, industrial, or institutional settings, nor does it include any polymer-coated durable items which the United States Food and Drug Administration authorizes for food contact.
>
> **5. Prohibition on sale of products containing intentionally added PFAS.** This subsection governs sales of products containing intentionally added PFAS.
> C. Except as provided in subsection H and section 9(B), effective January 1, 2026, a person may not sell, offer for sale or distribute for sale in the State of Maine:
>
> (2) A cookware product surface that is intended to be in direct contact with food or beverage while cooking and containing intentionally added PFAS. This prohibition under this subparagraph does not include polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), and perfluoroalkoxy alkane (PFA) used on food contact surfaces of cookware.

**Supporting Data**

1. **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 the following further details.

2. **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).

3. **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).

4. **Fluoropolymers Are Not Water Soluble**
   Fluoropolymers are not environmentally mobile. Fluoropolymers such as PTFE are not water soluble and even if released to the environment, are not likely to result in widespread environmental impacts (Korzeniowski, et al. 2022).

5. **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.

In sum, 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 chemical focus areas for regulation under the Chapter 90 Draft Rule.

Sincerely,

Stephen D. Burns

Stephen D. Burns
President, Cookware Sustainability Alliance

**References**


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/data/article/18899/pdf/icrl_2023_01-006.pdf.

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).

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.

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.

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