

The Cookware Sustainability Alliance (the CSA) was created to express strong concern about the policy and scientific misinterpretations behind legislative proposals to ban products containing per- and poly-fluoroalkyl substances (PFAS). Importantly, fluoropolymers and nonstick cookware are approved for use in food prepraration by the U.S. Food & Drug Administration (U.S. FDA), European regulatory bodies, as well as decades of sound scientific research.

The CSA is made up of companies with a significant stake in the nonstick cookware category, aimed at setting the record straight and emphasizing the science that underpins fluoropolymer cookware safety.

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 contains a specific subfamily of PFAS called fluoropolymers. The fluoropolymers used by our industry, primarily polytetrafluoroethylene (PTFE), do not have the same characteristics of nonpolymeric 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

References

- Améduri, B. (2023). Fluoropolymers as Unique and Irreplaceable Materials: Challenges and Future Trends of These Specific Perfluoroalkyl Substances [Preprint]. Chemistry and Materials Science. <u>https://doi.org/10.20944/preprints202309.0512.v1</u>
- 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.
- 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. <u>https://doi.org/10.1016/j.envpol.2018.09.115</u>
- 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. <u>https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2016.4357</u>
- 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. <u>https://doi.org/10.1002/ieam.4035</u>
- 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.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. <u>https://doi.org/10.3390/polym14112220</u>
- 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. <u>https://doi.org/10.1177/1932296815626726</u>
- 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-contactapplications