Regulatory Landscape on Food Safety

Policy Memo

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TOPIC: Regulation of PFAS in Food Contact Materials as an Indirect Food Additive

Problem Statement

Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS), also known as "forever chemicals" are a class of highly persistent compounds used in cookware and food packaging. According to the CDC, "nearly all people in the United States have measurable amounts of PFAS in their blood" based on data collected by NHANES since 1999[1]. They are linked to thyroid disease, increased cholesterol levels, liver damage, kidney, prostate and testicular cancer, as well as adverse effects on fetal and child development[2]. Their persistence contributes to widespread environmental contamination affecting soil, plants, animals, and overall wildlife. More concerning, PFAS can be passed intergenerationally, making it challenging for future generations to thrive free of its health risks. Humans are exposed to PFAS in various ways, such as air and drinking water, but food consumption is one of the most common routes of exposure[1]. Food contact materials (FCM) with added PFAS can significantly increase exposure levels. Because the FDA currently oversees food contact materials used in food packaging and food processing equipment, they are uniquely positioned to regulate all types of PFAS as indirect food additives and significantly decrease dietary exposure. To date, the agency's PFAS practices have narrowly focused on paper-based PFAS, such as paperboard food packaging where migration has been recognized as a key source of exposure[3].

Policy Question

How should the FDA leverage its authority over food-contact substances to reduce human exposure to PFAS through food consumption?

Background

PFAS contamination is both environmentally persistent and widespread among Americans. Biomonitoring data from NHANES exhibit the typical American's blood levels contained 4.25ng/mL of PFOS, and 1.42 ng/mL of PFOA in 2017 through 2018, with some individuals and communities measuring higher[1]. Food consumption is a primary exposure route mostly through packaging such as grease resistant paper, fast food wrappers, pizza boxes, and microwave

popcorn bags. Children are especially vulnerable due to their relatively higher food and water intake per body weight. Their hand to mouth behavior also increases their risk of exposure. Additionally, maternal exposure compounds this risk, as PFAS can cross the placenta and reach infants through breast milk, meaning children may be exposed before birth or during infancy[4]. Because PFAS is highly stable, it is difficult for it to break down under environmental and biological conditions, which denotes that even low levels of exposure are concerning as it will accumulate in the body over time and be passed intergenerationally[5]. Therefore, health risks linked to thyroid disease, cancer and developmental are significantly increased just by eating alone.

PFAS came to be in the early in 1940s when industries manufactured the highly stable compounds such as PFOS, PFOA, PFHxS (subclasses of PFAS) giving it non-stick capabilities along with heat and grease resistance[6]. This revolutionary discovery led to its widespread utilization, both nationally and internationally. There were no policies at the time to investigate its risks. By the time the Toxic Substance Control Act (TSCA) was passed in 1976, it had already spread globally, leaving a lag in efforts to contain the problem[7]. It was also used in the Vietnam war to extinguish petroleum-based fires and has since been utilized by firefighters[8]. Today, firefighting sites are contaminated with PFAS that enters the food and water chain by soil absorption[4]. Overall, there is substantial evidence of the risks PFAS poses to humans and the environment, leaving room for policy efforts to take place.

The current FDA regulatory practices authorize PFAS for non-stick cookware coatings, sealing gaskets for food handling equipment, manufacturing aids, and grease-resistant agents added to food paper products. However, as of February 2024 the U.S. market no longer permits selling of grease-proofing chemicals and paper/paperboard products. The FDA claims to lack evidence that other FCMs with PFAS are not of great health concern[3]. Contrasting evidence shows that cookware and grease resistant agents are in fact harmful and found in high concentrations. One study found that 79% of tested non-stick pans coated with PTFE may leach PFAS into food overtime due to wear and tear, often going unreported[9]. Migration has also been detected in plastic food containers where PFAS may unintentionally form due to the use of printing ink additives, and mold-release agents[10]. Beyond the FDA, various efforts have been made. Twelve states have begun to phase out PFAS food packaging including: California, Colorado, Connecticut, Hawaii, Maryland, Minnesota, New Hampshire, New Mexico, New York, Oregon, Rhode Island, and Vermont[11]. Furthermore, fourteen fast food/fast casual dining with over 123,534 locations have committed to eliminating or reducing PFAS from their products[12].

Policy Options

In addition to the status quo, there are two alternative options to consider:

Policy 1: The FDA regulates PFAS as an indirect food additive where no amount of PFAS is considered safe, thereby prohibiting its intentional use in food contact materials (FCMs) altogether. This could significantly reduce human exposure through food consumption. Seeing that many states are already acting on such a decision proves some degree of feasibility and acceptability. The NHANES study demonstrates company voluntary phase-outs and use of PFAS subtypes led to an 85% or more reduction in PFOS, and over 70% for PFOA in American blood

levels[15]. While this was not a direct result of limiting food packaging, it illustrates the impact policy level bans could have in improving the overall public health. On the contrary, because PFAS regulation uses a chemical-by-chemical approach to ban each type of PFAS singularly, it creates opportunity for companies to simply replace one subtype with another. For this policy to be effective, PFAS must be treated as one class given the 15,000 known types that exists[16]. If PFAS is treated as a class of compounds, undiscovered PFAS subtypes will be prohibited from entering the environment before they are identified.

Policy 2: The FDA regulates PFAS as an indirect food additive by establishing maximum thresholds levels for PFAS in food contact materials if intentionally added. This would be a less disruptive approach that may be more appealing to manufacturers for both financial and legal feasibility. Since 2020 companies, states like Washington and Minnesota set requirements for companies to maintain a threshold of 100 ppm for total organic fluorine (TOF) while using third party organizations for testing[13,14]. While the policy attempts to limit PFAS, the problem lies in appropriately quantifying and reporting total organic fluorine which is not typically added, thus may not need to be reported. This issue leaves companies and consumers with a false sense of safety and raising it to a federal level requirement is likely to have limited positive impact on health. Although the current outcomes as seen with the NHANES demonstrate some existing positive impact, this policy would still fall short given the bioaccumulative properties of PFAS that amount to serious health consequences from small incremental exposure.

Criteria for Evaluating Options

Criterion 1: Improved Public Health – this criterion would investigate how the policy would further reduce exposure through food consumption.
Criterion 2: Acceptability to industry – this would help answer the question "would manufacturers and consumers be willing to adopt the changes that came with the policy?".
Criterion 3: Affordability – explores how cost-effective it is to implement and enforce the policy.

Evaluating the Options

	Criterion 1: Improved public health	**Criterion 2: Acceptability to industry**	**Criterion 3: Affordability**
Status Quo	0	0	0
Policy 1: Full PFAS Ban in FCMs	++	--	---
Policy 2: Maximum Threshold Regulation in FCMs	---	+	++

Matrix Explanation

Policy 1: When it comes to improving public health fully banning PFAS from food contact materials has a positive impact as it would decrease exposure and potentially decrease PFAS in blood levels of the average American. However, when considering acceptability and affordability, this policy could face resistance given its expensive and disruptive effects on manufacturers and their supply chain.

Policy 2: As for setting a maximum threshold, acceptability and affordability would be highly positive in comparison to the fully banning PFAS from FCMs as these are practices already adopted and required in some states. However, from the perspective of improving health, this policy could continue and even prolong exposure through food given the testing nuances of PFAS.

Recommendation

Despite the ease for implementing policy 2, I recommend policy 1 based on the strong evidence supporting human and environmental health risks. Since this policy option requires large scale change, I advise deploying this ban in phases to give companies and consumers time to restructure supply chains and internal protocols. Funds may also be granted to encourage the efforts and offer a bonus to organizations that pivot timely and effectively while leveraging them to create a blueprint for other companies. Whether policy 1 or 2 is chosen, the most important effort should be centered around streamlining regulation for all PFAS FCMs, as a chemical-by-chemical approach is proven ineffective.

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