ML STRATEGIES

Congress Intensifies Tampon Safety Efforts and FDA Takes Steps to Respond

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In its August 2024 issue, the journal *Environmental International* published an article called ***Tampons as a Source of Exposure to Metal(loid)s***. The article reports on the results of a recent study by researchers from Columbia, UC Berkeley, and Michigan State that evaluated the presence of metals in different tampons. The research team evaluated 60 samples of tampons, representing 30 unique products from 24 different brands, for the presence of 16 different metals. The researchers found that all the tampons evaluated contained measurable concentrations of each of the 16 metals, including toxic metals such as lead, arsenic, and zinc. In their discussion of the findings, the researchers noted that there are many ways that metals can be introduced into tampons, including during production, such as by contaminated water being used in the manufacturing process; metal compounds may also be intentionally added to the products. The study's authors also indicated that in the regions where the tampons were purchased from (the United Kingdom, the European Union, and the United States), regular product testing for such metals is not required.

This study – whose results were released in pre-publication form earlier in the year – is the first to evaluate the presence of metals in tampons, and its findings have raised the eyes of many stakeholders, including certain lawmakers in Congress. In response to the study's conclusions, Congress has initiated advocacy efforts and has called upon the Food and Drug Administration (FDA) to address the potential risks of metal exposure from tampons and increase tampon safety standards. In this blog post, we examine these Congressional efforts, FDA's regulation of menstrual products and its response to pressure from members of Congress, and current state laws and legislation that seek to increase ingredient transparency and safety for menstrual products.

Congress Reacts and FDA Responds

FDA regulates menstrual products, such as tampons, pads, and menstrual cups, as medical devices. Before a tampon can be sold in the United States, it must go through FDA's 501(k) review and premarket clearance process. FDA's guidance for industry on these products, titled ***Menstrual Tampons and Pads: Information for Premarket Notification Submissions (501(k)s)***, was published in July 2005 (Guidance). The Guidance provides recommendations for the content of 501(k) notifications, including how to describe the product, how to detail potential health risks, labeling requirements, and when clinical studies may be required. However, with respect to potentially harmful chemical constituents, the Guidance only recommends that tampons not contain two dioxin compounds or pesticide residues – there is no discussion of the presence or absence of metals.

Following release of the *Environmental International* research article, members of Congress from both chambers advocated for a thorough safety review by FDA and for appropriate actions to be taken based on the evidence collected. In early September, the Democratic Women's Caucus sent a **letter** to FDA Commissioner Robert Califf, M.D., urging the agency to enhance its current safety standards for tampons in light of concerns over ingredients in tampons and potential adverse health effects they can have on consumers. Additionally, Senator Patty Murray (D-Wash.), Chairwoman of the Senate Appropriations Committee and a senior member on the Senate Health Committee, sent her own **letter** to FDA in July 2024 calling for similar measures and seeking detailed responses about the agency's review process and plans to address these safety concerns.

In just over a month, and on the same day the Democratic Women's Caucus sent their letter, Senator Murray announced that FDA had responded to her inquiry. Then on September 10, 2024, FDA **announced publicly** that it had commissioned an independent literature review to further evaluate the data surrounding the presence of toxic metals in tampons and the associated health impact such contaminants could have on consumers. Additionally, the agency's Center for Devices and Radiological Health will conduct an internal study to assess how much toxic metal enters the bloodstream with regular tampon use, under the Center's existing device biocompatibility and toxicology research program. The results of both FDA initiatives will be made public after undergoing peer review.

Tampon Safety Legislation on the Hill

These recent letters to FDA are just one step Congress has taken on tampon safety. Members of Congress across the aisle have introduced legislation to protect women from harmful menstrual products.

In 2022, Congresswoman Grace Meng (D-N.Y.) led a bipartisan bill with Rep. Debbie Lesko (R-AZ) that would have required menstrual product manufacturers to disclose their ingredients on packaging, including fragrance allergens.

Although Meng, a signatory on the House Democratic Women's Caucus September letter to the FDA Commissioner, has not re-introduced this legislation in the current Congress, she has championed related legislation that would address safety concerns over tampons. Notably, she introduced the Robin Danielson Menstrual Product and Intimate Care Product Safety Act (**H.R. 5957**). This bill would require the National Institutes of Health (NIH) to conduct a study on the presence of chemicals and pigments, such as dioxins, phthalates, and titanium dioxide, in tampons and assess their potential impact on consumers. H.R. 5957 is currently under consideration by the House Energy and Commerce Committee.

State Menstrual Product Laws and Legislation

In addition to the steps being taken at the federal level, several states have enacted or attempted to pass laws geared toward promoting tampon safety over the past several years. Beginning in April 2020, New York law requires all packages or boxes containing "menstrual products" to be labeled with a plain and conspicuous printed list of all ingredients. "Menstrual products" include tampons, pads, and menstrual cups, regardless of whether the product is disposable or reusable. More recently, **Senate Bill S3529A/Assembly Bill 5990** was introduced to amend this law to prohibit menstrual products that contain intentionally added ingredients or certain levels of "restricted substances" from being sold in New York. As of June 2024, the bill was passed in the Senate and is under consideration in the Assembly.

As defined in the pending legislation, an ingredient is determined to have been intentionally added if a manufacturer has intentionally added it to a menstrual product and it has a functional or technical effect in the finished product. This includes intentionally added fragrances, flavoring, and colorants, as well as the intentional breakdown products of an added element or compound that also has a functional or technical effect on the finished product. A "restricted substance" will include, but is not limited to, lead, mercury, formaldehyde, triclosan, toluene, talc, dibutyl phthalate, di(2)exylhexhyl phthalate, butylphenyl methylpropional and isobutyl-, isopropyl-, butyl-, propylparaben, and per- and polyfluoralkyl substances (PFAS).

In June 2024, Vermont followed California's lead and passed a law that prohibits manufacturers from manufacturing, selling, or distributing menstrual products, as well as cosmetics, containing intentionally added PFAS, among other chemicals, in the state. This law will take effect on January 1, 2026. The sale or distribution of menstrual products with intentionally added PFAS will also be banned in Colorado as of January 1, 2026. Other states, like Connecticut, have banned the sale of menstrual products containing PFAS unless the manufacturer of the product provides prior written notification to a regulatory agency, in this case the Connecticut Department of Energy and Environmental Protection. This notification requirement takes effect on July 1, 2026. As these consumer protection-driven laws begin to take effect throughout the nation, we can observe their impact on the marketplace of menstrual products and consumer choice in which products to purchase and use.

Conclusion

Over the past two years, FDA and federal lawmakers have sought to increase the public's insights into the safety of products that are traditionally consumed by women and can impact women's health. Through recent **cosmetic modernization legislation**, for instance, FDA is required to issue regulations regarding fragrance allergens, standardize testing methods to detect asbestos in talc-containing cosmetics, and issue a report on the use of and safety of PFAS in cosmetic and personal care products. Similarly, through regulation, literature review, and scientific studies, FDA is hoping to understand the impact of metal exposure from tampons, which could lead to similar measures in the menstrual product space. In deciding next steps, Congress and policymakers at the agency can look to the states – which have trailblazed ahead in enacting stricter labeling requirements for menstrual products and even enacting bans against tampons containing certain substances, such as PFAS, from being sold in the state – for guidance and inspiration. Advancements made in ingredient transparency and integrity in these products are clearly in the interest of public health.

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