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LEGISLATION, REGULATIONS & STANDARDS

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FDA Receives Approval for Reorganization Creating Unified Human Foods Program

The U.S. Food and Drug Administration (FDA) has received approval for a reorganization proposal seeking to create a unified Human Foods Program and restructure its field operations. The agency announced the reorganization in January 2023 after reviewing the findings and recommendations of a Reagan-Udall Foundation evaluation, an internal review of its infant formula response, and feedback from stakeholders. FDA indicated it will implement the reorganization on October 1, 2024.

Shook offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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LITIGATION

Court Grants Class Certification in Barilla Pasta Labeling Suit

A federal court has granted class certification for plaintiffs alleging Barilla America, Inc. misleads consumers with "Italy's #1 Brand of Pasta" labeling. *Sinatro v. Barilla Am., Inc.*, No. 22-3460 (N.D. Cal., issued May 28, 2024). The plaintiffs allege such labeling deliberately misleads consumers into believing the



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products are made in Italy, with ingredients sourced in Italy, when the products are made in the United States with ingredients from outside of Italy. Barilla told the court that it has since removed the labeling from 34 of 54 products at issue and argued that the label changes would make it impossible to determine injured parties. The court disagreed, calling Barilla's argument "meritless," and granted class certification.

East West Tea Co. Sued Following Pesticide-Related Recall

A New York consumer has filed a proposed class action alleging East West Tea Co. failed to disclose that consumers drinking its Echinacea Immune Support Tea may increase their risk of ingesting pesticides. *Kaatz v. East West Tea Co., LLC*, No. 24-03996 (S.D.N.Y., filed May 24, 2024). The defendant recalled the product in March 2024 after finding pesticide residue levels were detected above action levels. The plaintiff alleged the recall is "designed to reach very few people and designed to benefit very few of the consumers who purchased the Product," and asserted a class action is the superior remedy for consumers.

Proposed Class Action Claims Malt-Based 'Chi-Chi's Margarita' Misleads

A group of New York residents has filed a proposed class action alleging Sazerac Co.'s Chi-Chi's Original Margarita product sold in mini bottles misleads consumers into thinking the product has tequila and triple sec when it has a malt-beverage base. *Bethea v. Sazerac Co. Inc.*, No. 24-3747 (E.D.N.Y., filed May 24, 2024). The plaintiffs allege the malt version was manufactured and designed to look and taste like its full-size counterpart, but because it has a malt-alcohol base instead of distilled spirits, it can be sold in more locations. Sazerac has faced similar lawsuits involving other malt-based beverages packaged in mini bottles.

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ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged foodborne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.





S. Martinelli & Co. Sued for Arsenic in Apple Juice Following Recall

A New York woman has brought a proposed class action alleging S. Martinelli & Co. failed to inform consumers that consuming its apple juice may increase the risk of ingesting arsenic. *Seaman v. S. Martinelli & Co.*, No. 24-3944 (E.D.N.Y., filed May 31, 2024). The suit follows a voluntary recall after Martinelli determined that one lot of its apple juice sold in one-liter bottles contained elevated levels of inorganic arsenic. The plaintiff asserts that the product's packaging does not identify arsenic as an ingredient or warn about its inclusion in the product, which allegedly "leads reasonable consumers to believe the Product does not contain, and is not at risk of containing, Arsenic."

Lawsuit Challenges Poppi Soda's Prebiotic, Gut-Health Marketing Claims

VNGR Beverage LLC faces a proposed class action alleging the company makes misleading health claims about its Poppi soda products. *Cobbs v. VNGR Beverage, LLC*, No. 24-3229 (N.D. Cal., filed May 29, 2024). The plaintiff alleges that Poppi marketing asserts that the soda maintains the sweetness of traditional sodas while providing prebiotics for gut health. The plaintiff alleges that the soda only contains two grams of prebiotic fiber, an amount too low to cause meaningful health benefits from one can. She asserts that a consumer would need to drink more than four Poppi sodas in one day to realize any potential benefits from prebiotic fiber and that any such benefit would be negated by the product's sugar content, which she alleges "would offset most, if not all, of these purported gut health benefits."

Tacos Are Sandwiches, Indiana Court Holds

An Indiana court has reportedly ruled that The Famous Taco can open a location in a development that limits food businesses to those selling "made-to-order' and 'subway-style' sandwiches," holding that "tacos and burritos are Mexican-style sandwiches." The restaurant's owner sued the Fort Wayne Plan Commission after it denied a proposed amendment that would have extended the sandwich limitation to include tacos and other Mexican-style food products. The court ruled that the commission's denial was not an abuse of discretion but found that the proposed amendment was unnecessary because the restaurant company was not limited by the sandwich stipulation. The written commitment did not restrict potential restaurants to only American-style sandwiches, the court reportedly found, and in addition to Mexican-style tacos and burritos, "made-to-order Greek gyros, Indian naan wraps or Vietnamese banh mi" would have also been acceptable under the restriction.

SCIENTIFIC / TECHNICAL

Study Finds Link Between Xylitol, Cardiovascular Event Risk

A team of researchers from the Cleveland Clinic has found that higher amounts of xylitol, a sugar alcohol, are associated with increased risk of cardiovascular events. Witkowski et al., "Xylitol is prothrombotic and associated with cardiovascular risk," European Heart Journal, June 6, 2024. The researchers purportedly found that high levels of circulating xylitol were associated with an elevated three-year risk of events such as heart attacks or strokes, according to a news release.

Consumer Reports Conducts Study on Lead in Baby Food Puffs

Consumer Reports has published its <u>findings</u> from research into levels of lead in cassava- and sorghum-based vegetable puffs.

The researchers purportedly found lead levels in one product

that exceeded California's maximum allowable dose level as well as some products that contained more than half the dose allowable in California.

The report identified cassava and other root vegetables as potentially containing high lead levels because the naturally occurring lead in the soil can accumulate in plants' root systems. The organization noted that processing cassava into flour "to bake it into crackers, chips, or snack foods can potentially concentrate the lead more than eating it fresh."

"Our current tests, combined with our previous ones, show the FDA needs to act with urgency on its Closer to Zero initiative, which is meant to reduce childhood exposure to these environmental contaminants," a spokesperson for *Consumer Reports* said. "The risk to children will only increase if the agency allows this work to languish."

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