ISSUE 778 | July 01, 2022

LEGISLATION, REGULATIONS & STANDARDS

Attorneys General Urge FDA, USDA to Take Action on Heavy Metals in Baby Food

The attorneys general of 22 states have submitted a letter to the U.S. Food and Drug Administration (FDA) and Department of Agriculture (USDA) asserting that the agencies "are not sufficiently prioritizing a public health problem long overdue for robust action: children's exposure to neurotoxic heavy metals (lead, arsenic, cadmium, and mercury) through foods specifically designed and marketed for babies and young children." Led by New York Attorney General Letitia James, the group argues that the existing plan to set limits on heavy metals, the Closer to Zero Plan, has "lengthy and vague timelines, which now extend to mid-2024 and beyond," and is "already behind schedule."

"As a result of this and other agency delays, U.S. baby food manufacturers continue to largely self-regulate the amount of lead (and other toxic elements) that is contained within their products. Indeed, it remains up to the manufacturers to decide whether even to test their products for these contaminants. With the continuing absence of FDA action levels and product testing guidance, the lack of transparency about these toxic metals in specific foods brings unnecessary worry and confusion for American families with young children, who continue to face the risks of exposure to heavy metals in the foods marketed to them." The letter argues that issuing immediate guidance to baby food manufacturers would be "the most expedient way for the federal government to reduce toxic heavy metal contamination in the foods eaten by *today's* babies and young children."

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LITIGATION

D.C. Upholds Ban on Raw Butter

The U.S. Court of Appeals for the D.C. Circuit has upheld a lower court's ruling finding a challenge to the U.S. Food and Drug Administration's (FDA's) prohibition on interstate sales of unpasteurized butter to be meritless. *McAfee v. FDA*, No. 21-5170 (D.C. Cir., entered June 10, 2022). A lower court previously dismissed a challenge filed by a dairy farmer who argued that FDA's definition of butter does not require pasteurization and thus the rule banning the sale of unpasteurized butter under the Public Health Service Act (PHSA) made an "unlawful change to butter's statutory definition." FDA had denied the farmer's 2016 petition to exclude butter from the rule requiring pasteurization of milk products, finding that "the ban on raw butter helps prevent the spread of communicable diseases" and that "manufacturing controls intended to ensure safety [] may exist independent of any standards of identity."

The D.C. Circuit was unpersuaded, agreeing that the farmer's argument "rests on the false premise that the pasteurization rule works a change to butter's standard of identity," as the district court held. "That is incorrect: The pasteurization rule did not amend the statutory standard of identity for butter, either formally or functionally," the appeals court stated. "Raw-cream butter, though unpasteurized, is still 'butter' notwithstanding the FDA's determination that its interstate sale would threaten public health."

"[T]he statutory definition at issue here contains no mention of pasteurization nor any other suggestion that undergoing that process prevents a product from qualifying as butter," the court held. "[The plaintiff] may be correct that unpasteurized butter has a distinct taste, texture, and other qualities, but Congress did not speak to those qualities as part of butter's statutory standard of identity. That statutory provision neither references pasteurization nor requires qualities that pasteurized butter lacks. At least in this case, then, the standard-of-identity statute does not extinguish the agency's authority under the PHSA to ensure food safety."

"Italy's #1 Brand of Pasta" Misleads Consumers, Plaintiffs Allege

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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 food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility

Two consumers have filed a putative class action alleging that Barilla America Inc. markets its pasta to incorrectly imply that the products are made in Italy. *Sinatro v. Barilla Am. Inc.*, No. 22-3460 (N.D. Cal., filed June 11, 2022). The complaint asserts that consumers seek "authentic Italian-made pastas" because they "hold a certain prestige and [are] generally viewed as a higher quality product." The plaintiffs argue that Barilla's statement "Italy's #1 Brand of Pasta," which appears prominently on its product packaging, leads consumers to believe that the products are made in Italy rather than New York and Iowa. Further, the company's website describes it as "an Italian family-owned food company" and emphasizes that "Italians know the familiar Blue Box means quality, perfectly al dente pastas every time. That's why Barilla has been an Italian favorite for over 140 years, and continues to be the #1 pasta in Italy today." For alleged violations of California's unfair competition, false advertising and consumer-protection statutes, the plaintiff seeks an injunction, damages, restitution and attorney's fees.

Lawsuit Challenges Cream Content of Coffee Creamer

A consumer has filed a putative class action alleging Danone North America Public Benefit Corp. misleads consumers about the nature of its International Delight coffee creamers by labeling the products as creamers rather than non-dairy creamers. *English v. Danone N. Am. Pub. Benefit Corp.*, No. 22-5105 (S.D.N.Y., filed June 17, 2022). The plaintiff argues that International Delight creamer "lacks cream or dairy ingredients beyond a *de minimis* amount of sodium caseinate" and instead "substitutes water and palm oil, the first and third ingredients, to reduce costs." The complaint notes that consumers "value cream from dairy ingredients for its nutritive purposes," and the plaintiff alleges she would not have purchased the product if she had not been misled by the packaging implying the presence of dairy ingredients. For alleged violations of New York consumer-protection statutes, fraud, unjust enrichment and breach of express warranty, the plaintiff seeks class certification, restitution, damages and attorney's fees.

Clif Bar & Co. to Pay $10.5 Million to Settle Sugar Class Action

Clif Bar & Co. has submitted a settlement agreement to a California federal court seeking approval to settle a class action alleging that Clif Bars are misleadingly marketed as healthy

inspections, subject to FDA, USDA and FTC regulation.

despite containing levels of sugar beyond what consumers would expect healthy foods to contain. *Milan v. Clif Bar & Co.*, No. 18-2354 (N.D. Cal., filed June 23, 2022). In addition to establishing a $10.5-million fund, Clif will "make significant changes to the labeling and packaging of its original Clif Bars and Kid ZBars," according to the agreement. The changes include refraining from use of "nutrition," "nutritious" and "nourishing kids in motion" on Clif Bar packaging "so long as 10% or more of [a bar's] calories come from added sugars." The class includes customers who purchased Clif Bars between April 19, 2014, and June 23, 2022, and claimants will be divided into quintiles with varying levels of awards depending on degrees of use of the product if the court approves the settlement agreement.