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FOOD AND BEVERAGE LITIGATION AND REGULATORY UPDATE

SHOOK HARDY & BACON

FIRM NEWS

Johnson to Present a Year in Review on Food and Dietary Supplement Regulations

Shook Of Counsel John Johnson III will co-present "Food and Dietary Supplement Regulation Year-in-Review" on Wednesday, March 30, 2022, at the Food and Dietary Supplement Safety and Regulation Conference. The conference, which takes place March 30-31, will be presented virtually by the Food and Drug Law Institute.

"This session will recap the most significant recent developments in food and dietary supplement regulation and enforcement, including updates on FDA and United States Department of Agriculture (USDA) inspections, FDA and Federal Trade Commission (FTC) warning letters and enforcement, and compliance challenges faced by manufacturers and retailers," according to the conference agenda. "Panelists will also discuss the extent to which federal regulation and enforcement may have impacted private litigation over the past year."

LEGISLATION, REGULATIONS & STANDARDS

FDA to Research Use of "Healthy" Symbol

The U.S. Food and Drug Administration (FDA) has announced that it will conduct quantitative consumer research on the use of

Mark Anstoetter
816.559.2497
manstoetter@shb.com

"voluntary symbols that could be used in the future to convey the nutrient content claim 'healthy.'" The agency is simultaneously "developing a proposed rule that would update when manufacturers may use the 'healthy' nutrient content claim on food packages."

"Updating labeling and making it more accessible helps empower consumers," the constituent update states. "In particular, claims and symbols can help consumers better understand nutrition information and identify foods that contribute to a healthy eating pattern. Manufacturers may also reformulate products to improve their nutritional value so they can use the claim."

Yogurt Standard of Identity Updated to Allow for Technological Advancements

The U.S. Food and Drug Administration (FDA) has issued a final rule amending the acceptable qualities of food labeled as yogurt. Under the rule, the standards of identity for lowfat and nonfat yogurt will be combined with the general definition; in addition, the list of allowable ingredients has expanded to include additional substances such as agave. "Additionally, the final rule supports the many innovations that have already been made in the yogurt marketplace, including continuing to allow manufacturers to fortify yogurts, such as adding vitamins A and D, as long as they meet fortification requirements," according to the constituent update. "The rule also allows various styles or textures of yogurt as long as they meet requirements in the standard of identity."

Codex Meeting on Food Contaminants Scheduled

The U.S. Department of Agriculture has announced a public meeting scheduled for April 19, 2022, to discuss U.S. positions for the meeting of the Codex Committee on Contaminants in Foods of the Codex Alimentarius Commission. Issues to be discussed include:

- "Maximum level for cadmium in cocoa powder (100% total cocoa solids on a dry matter basis)";
- "Code of practice for the prevention and reduction of cadmium contamination in cocoa beans";
- "Maximum levels for lead in certain food categories";
- "Maximum levels for total aflatoxins in certain cereals and cereal-based products including foods for infants and young children";

M. Katie Gates Calderon
816.559.2419
kgcalderon@shb.com

Lindsey Heinz
816.559.2681
lheinz@shb.com

James P. Muehlberger
816.559.2372
jmuehlberger@shb.com

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

- “Sampling plans and performance criteria for total aflatoxins in certain cereals and cereal-based products including foods for infants and young children”;
- “Maximum level for total aflatoxins in ready-to-eat peanuts and associated sampling plan”;
- “Maximum levels for total aflatoxins and ochratoxin A in nutmeg, dried chili and paprika, ginger, pepper and turmeric and associated sampling plans”; and
- “Methylmercury in fish.”

inspections, subject to FDA, USDA and FTC regulation.

LITIGATION

Ninth Circuit Upholds Injunction on California Acrylamide Warning

The Ninth Circuit Court of Appeals has found that the district court did not abuse its discretion in granting a preliminary injunction blocking a requirement to warn California consumers about the presence of acrylamide in food and beverage products. *Cal. Chamber of Com. v. Council for Education and Research on Toxics*, No. 19-2019 (9th Cir., entered March 17, 2022). Filed by the California Chamber of Commerce, the suit alleges that requiring the warning for products containing chemicals listed under the state’s Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65) on products with acrylamide would violate the organization’s members’ “First Amendment rights to not be compelled to place false and misleading acrylamide warnings on their food products.”

The district court held that the state did not show the Prop. 65 acrylamide warning was “purely factual and uncontroversial.” “[D]ozens of epidemiological studies have failed to tie human cancer to a diet of food containing acrylamide,” the district court found. “[T]he safe harbor warning is controversial because it elevates one side of a legitimately unresolved scientific debate about whether eating foods and drinks containing acrylamide increases the risk of cancer.”

The appeals court agreed, finding support for the district court’s holdings in the record. “In 2019, the American Cancer Society stated that ‘dietary acrylamide isn’t likely to be related to risk for most common types of cancer,’” the court noted, then went on to list similar statements from the National Cancer Institute and additional studies before noting three organizations on the opposite side of the argument. “Given this robust disagreement by reputable scientific sources, the court did not abuse its discretion in concluding that the warning is controversial.”

The district court was also justified in finding that "the warning is misleading," the appeals court held, because the safe-harbor Prop. 65 warning, which states that a substance is "known to the State of California to cause cancer," does not convey the meaning of the word "known." "Under Prop. 65, a 'known' carcinogen carries a complex legal meaning that consumers would not glean from the warning without context," the appeals court held. "Thus, use of the word 'known' is misleading—as the [Food and Drug Administration] acknowledged the warning might be. Even the State of California has stipulated that it 'does not know that acrylamide causes cancer in humans, and is not required to make any finding to that effect in order to list the chemical under Proposition 65.'"

Chocolate Lawsuit Preempted by FDCA, Court Rules

An Illinois federal court has dismissed a lawsuit alleging Dreyer's Grand Ice Cream Inc. misled consumers by describing its ice cream bars as coated in milk chocolate when the chocolate contained coconut oil. *Zurliene v. Dreyer's Grand Ice Cream Inc.*, No. 21-0747 (S.D. Ill., entered March 17, 2022). The complaint, brought under the Illinois Consumer Fraud and Deceptive Business Practices Act, asserted that the Häagen-Dazs ice cream bars' label confused the plaintiff because she understood the term "milk chocolate" to describe "a product made from the cacao bean without chocolate substitutes, such as coconut oil."

The claim "is preempted by the Food, Drug, and Cosmetic Act (FDCA)," the court held. "The FDCA prohibits states from 'directly or indirectly establish[ing] under any authority . . . any requirement for a food which is the subject of a standard of identity . . . that is not identical to such standard identity or that is not identical to the requirement of section 343(g)."

"[N]either the name nor the ingredients of the product 'milk chocolate and vegetable fat coating' must be stated on the ice cream bars' front label. The front label must include 'a statement of the identity of the commodity,'" the court explained. "Here, the commodity is not milk chocolate and vegetable fat coating, but ice cream bars, of which milk chocolate and vegetable fat coating are ingredients. . . . The [Food and Drug Administration (FDA)] regulations require Defendant to list the ingredients of milk chocolate and vegetable fat coating (specifically, coconut oil) either on the front of the package *or* on the side of the package where the ingredients are normally listed."

The court noted that the plaintiff conceded that coconut oil is listed as an ingredient but argued that it should also appear on the front of the package. “This requirement would be one step beyond FDA regulations and is therefore preempted,” the court held.