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FOOD & BEVERAGE LITIGATION UPDATE

SHOOK HARDY & BACON

LEGISLATION, REGULATIONS & STANDARDS

FDA Issues First Warning Letter for FSMA Foreign Supplier Program

The U.S. Food and Drug Administration (FDA) has issued the first warning letter enforcing the Food Safety Modernization Act (FSMA) Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals. The letter targeted a company importing tahini that was recalled after purportedly causing a *Salmonella* outbreak.

"Moving forward, the FDA will take more steps to ensure compliance with FSVP, including reinspecting importers that had deficiencies in previous inspections and by acting immediately when FSVP deficiencies are found that pose an imminent public health risk," the agency's announcement stated.

Guidance Released on Converting Vitamin Measures for Nutrition Label

The U.S. Food and Drug Administration's Office of Nutrition and Food Labeling has released guidance providing "step-by-step instructions to manufacturers of retail food products marketed in the United States on how they may convert the previous units of

measure for certain nutrients to the new units in the updated Nutrition Facts label." The guidance also "provides information that can help manufacturers understand and comply with relevant labeling requirements," according to the agency's announcement.

OEHHA Releases Agenda for Symposium on Synthetic Food Dyes

California's Office of Environmental Health Hazard Assessment (OEHHA) has released the agenda for its September 19-20, 2019, symposium on synthetic food dyes. OEHHA is "conducting a risk assessment of the potential impacts of synthetic food dyes," focusing on dyes batch-certified by the U.S. Food and Drug Administration (FDA). The symposium, which can be attended in person or via webinar, will feature discussions of the toxicological studies used by FDA to evaluate synthetic food dyes as well as exposures to dyes in American adults' and children's diets.

LITIGATION

Advocacy Groups Sue FDA for Inaction on Foodborne Illness Programs

The Center for Food Safety and Center for Environmental Health have filed a lawsuit seeking to compel the U.S. Food and Drug Administration (FDA) to promulgate rules for a program to improve foodborne-illness detection as required under the Food Safety Modernization Act (FSMA). *Ctr. for Food Safety v. Azar*, No. 19-5168 (N.D. Cal., filed August 19, 2019). The organizations allege that FDA failed to create a laboratory accreditation program "whereby an increased number of accredited laboratories following model standards developed by the agency would be in place 'to rapidly detect and respond to foodborne illness outbreaks and other food-related hazards.'"

"FDA's failure to implement FSMA's laboratory accreditation provisions by their statutory deadlines is an abdication of the agency's fundamental responsibilities," the complaint asserts. "Moreover, the agency's unlawful withholding and unreasonable delay is putting millions of lives at continued risk from

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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.

contracting foodborne illnesses, contrary to Congress's commands. This lawsuit therefore seeks to require FDA to complete the laboratory accreditation actions FSMA requires by Court-established deadlines."

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 inspections, subject to FDA, USDA and FTC regulation.

Creamery Targeted with Designation of Geographic Origin Lawsuit

A plaintiff has filed a putative class action alleging Tillamook County Creamery Association misleadingly markets its products as sourced from cows in Tillamook County. *Bohr v. Tillamook Cty. Creamery Ass'n*, No. 19-36208 (Ore. Cir. Ct., Multnomah Cty., filed August 19, 2019). The complaint alleges that consumers "increasingly seek out and are willing to pay more for products that they perceive as being locally and ethically sourced—better for the environment, more humane."

Tillamook allegedly sought to capitalize on this consumer preference by advertising its products as "made with four ingredients, patience, and old-fashioned farmer values in Tillamook, Oregon," despite producing its cheese and ice cream with ingredients obtained from "the largest and most industrialized dairy factory farm in the country," a "complex of cement-floored production facilities and barren dirt feedlots, where cows are continuously confined, milked by robotic carousels, and afflicted with painful udder infections."

The complaint cites a "recent consumer survey of Pacific Northwest consumers" purportedly finding that "the majority of Tillamook dairy purchasers believe, from Tillamook's representations, that Tillamook sources milk from small-scale family farms and not large industrial dairy farms." The plaintiff alleges unjust enrichment and seeks class certification, injunctive relief, attorney's fees and costs.

Coconut Milk "Healthy" Suit Dismissed

A California federal court has dismissed a putative class action complaint alleging that Danone U.S. Inc.'s So Delicious Coconut Milk is misleadingly marketed as healthful. *Andrade-Heymsfield v. Danone U.S. Inc.*, No. 19-0589 (S.D. Cal., entered August 14,

2019). Danone argued that the challenged statements were not health or nutrient content claims, and the court assessed each statement. "The 'Maximum Calcium Absorption' statement . . . is a permissible structure/function claim as permitted under the [U.S. Food and Drug Administration's (FDA's)] own guidance to its regulations. FDA guidance even lists 'calcium helps build strong bones' as a permitted structure/function claim, not a health claim," the court found.

Similarly, "Nutrition in Every Sip" is a "permissible structure/function claim" and "is not made in connection with an explicit or implicit claim or statement about a nutrient as required by the regulation for implied nutrient content claims such as the cited example, 'healthy, contains 3 grams of fat.' [] The FDA has clarified that general references to 'healthy' do not suggest a nutritional profile of the food, and consumers possess the ability to discern when the word 'healthy' is being used to convey that a food has a particular nutrient profile." Accordingly, the court dismissed the plaintiffs' claims with prejudice.

Court Dismisses Liquor Co.'s Suit Aiming for Approval to Market with Health Claims

A D.C. court has dismissed Bellion Spirits LLC's lawsuit aiming to compel the Alcohol and Tobacco Tax and Trade Bureau (TTB) to permit the company to market its products as containing "NTX, a proprietary blend of ingredients that they contend mitigates alcohol's damage to DNA." *Bellion Spirits LLC v. United States*, No. 17-2538 (D.D.C., entered August 1, 2019). TTB denied Bellion's application to make the health claims because it purportedly found inadequate substantiation after consulting with the U.S. Food and Drug Administration (FDA). Bellion filed suit, arguing that TTB could not work with FDA without express statutory authority. The court disagreed, finding that TTB has exclusive regulatory authority to make final decisions on alcohol, but nothing prohibits the agencies from consulting with each other. The court also dismissed Bellion's First Amendment argument, which maintained that its claims about NTX are true; the court noted that it must be deferential to TTB's finding that the claims are unsubstantiated.

Clif Bar Added Sugar Suit to Continue

A California federal court has denied Clif Bar & Co.'s motion to dismiss a putative class action alleging that its Clif bars contain high levels of sugar but are misleadingly marketed as healthful. *Milan v. Clif Bar & Co.*, No. 18-2354 (N.D. Cal., entered August 20, 2019). The court disagreed with Clif's argument that the plaintiff's claims were preempted by federal laws on the display of nutritional information on food packaging, finding the provisions "of no moment here because plaintiffs are not challenging the nutrition information on the Clif bars' label." Further, the court declined to consider whether a "reasonable consumer would know that the challenged products contained added sugars" given the flavor names—including Chocolate Chip, Chocolate Brownie and Iced Oatmeal Cookie—because "the motion to dismiss stage is not the place to decide these questions of fact."

"Clif is alleged to have marketed its bars using words and imagery designed to convey to consumers that the bars are 'healthy or are conducive to good health and physical well-being,'" the court stated. "This marketing is alleged to have been deceptive because 'as much as 37% of the calories in' these products come from added sugar. [] The fact that this could theoretically be consistent with the [U.S. Food and Drug Administration]'s Daily Value and the [American Heart Association]'s daily recommendation for added sugars—*if the consumer ate very little else that day*—is hardly a basis for kicking these claims out at the motion to dismiss stage. Plaintiffs have laid out in painstaking and voluminous detail how this substantial percentage of added sugars in Clif's products can contribute to excessive sugar consumption, which in turn has been linked to many diseases and detrimental health conditions. [] At this stage of the proceedings, the Court takes these allegations as true, and taken as such, the Court concludes that plaintiffs have stated a claim and, 'given the opportunity, . . . could plausibly prove that a reasonable consumer would be deceived by' the Clif bars' packaging."

Bombay Sapphire Contains Illegal Botanical, Complaint Alleges

A consumer has filed a putative class action alleging that Bacardi U.S.A. Inc.'s Bombay Sapphire is made with grains of paradise, amounting to adulteration under Florida law. *Marrache v. Bacardi U.S.A. Inc.*, Filing No. 93932678 (Fla. Cir. Ct., 11th Jud. Cir., filed August 9, 2019). The complaint cites a Florida statute deeming the inclusion of grains of paradise—along with several other substances described as "poisonous or injurious to health," including opium, capsicum, laurel water and cochineal—in any liquor intended for consumption to be adulterated, amounting to a felony of the third degree. The plaintiff notes that the Bombay Sapphire bottle features an etching of 10 botanicals, including grains of paradise—which "has been used in other parts of the world for medicinal purposes including, without limitation, to treat impotence and to stimulate miscarriages when a pregnancy was unwanted."

MEDIA COVERAGE

NPR Compares Allergy Accommodations in US, UK

NPR has published a writer's comparison of his experiences eating at restaurants in the United States and the United Kingdom while living with a peanut allergy. "Restaurants in the United Kingdom are generally far more vigilant, in this regard, than restaurants in the United States," the author observes. He recounts his experience being turned away from a U.K. restaurant after answering the server's question about food allergies by receiving a card explaining that the restaurant does "not operate in a surgical environment" and therefore could not guarantee that any of its menu items did not contain peanuts. "In America, the onus typically falls more on diners themselves," the author notes. "It's not routine, as it is in England, for servers to ask their customers proactively." The writer credits coverage of a U.K. teenager's death after eating a sandwich from Pret A Manger that was not labeled as containing sesame for the establishment of routine allergen questions in U.K. restaurants as well as the passage of a law that will require additional allergen labeling when it takes effect in 2021.

The perspective follows up on NPR's previous reporting on a JAMA Network Open study purportedly finding that sesame allergies may be more widespread than researchers and regulators previously understood, affecting as many as 0.49% of Americans—1.6 million people—rather than 0.2% as previously thought. Sesame labeling has become a focus for many legislators; Illinois enacted a law requiring labeling of the allergen, while the U.S. Food and Drug Administration and U.K. Food Standards Authority have initiated investigations into the prevalence and effects of sesame allergies.