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FOOD & BEVERAGE LITIGATION UPDATE

SHOOK HARDY & BACON

FIRM NEWS

Shook Attorneys Review "Regulatory Standoff" on Plant-Based Milks for *Law360*

As plant-based beverages appear on more store shelves, the definition of "milk" has become the center of a dispute involving legislatures, regulators, litigators and industry groups. Shook Partners Katie Gates Calderon and Lindsey Heinz, with Associate Elizabeth Fessler, explain the debate in "Dairy Vs. Plant-Based 'Milks': A Regulatory Standoff."

While Canada and the EU have both ruled that plant-based products cannot be called "milk," the U.S. Food and Drug Administration (FDA) has yet to take determinative action to ensure that products using "milk" contain cow milk, though it does define the term as "obtained by the milking of one or more healthy cows." Although FDA has warned plant-based beverage manufacturers, the agency has not taken enforcement action against such products and has never ruled on a 1997 petition to allow the use of the term "soymilk." Moreover, legislation has been introduced in both houses of Congress (H.R. 778; S.130) that would require FDA to enforce dairy food-labeling regulations, but both bills remain in committee.

"In short, both manufacturers and counsel advising them are left without a clear answer regarding the proper labeling of plant-based milk products," Gates Calderon, Heinz and Fessler explain. "As often happens when a regulatory gray area exists, consumers in California have taken to the courts." In a summary of recent litigation, the authors conclude that courts have tended to allow

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plant-based beverages to use the term “milk,” finding that “qualifiers” such as soy, almond or coconut limit potential consumer confusion.

“With plant-based products continuing to use ‘milk’ without pushback from the FDA, many companies are likely to continue to use the term to describe milk alternatives. Moreover, the longer terms like soymilk, almond milk and coconut milk remain in use, the stronger the argument those terms are the common and usual name of the products as established by common use,” the authors write. “While the term 'milk' will almost certainly be subject to additional legislative and judicial scrutiny, true clarification will require the FDA to either amend its regulatory framework or utilize its enforcement powers to limit the use of 'milk' on plant-based product labels.”

Additional details about the dispute over plant-based products appear in Issues 607, 638 and 643 of this *Update*.

LEGISLATION, REGULATIONS & STANDARDS

FDA Announces Forthcoming Menu-Labeling Guidance

U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb has announced that the agency will provide guidance on menu-labeling requirements before the end of 2017 in advance of the May 2018 compliance date.

"This additional guidance will address concerns that were raised about challenges establishments faced in understanding how to meet their obligations under the new regulations," Gottlieb wrote in an August 25, 2017, statement. "We have been diligently working to address the comments we received, and to establish a sustainable framework for enabling establishments to effectively meet the new menu labeling provisions. These new policy steps should allow covered establishments to implement the requirements by next year’s compliance date."

Agencies Schedule Public Meetings on Codex Positions

The U.S. Department of Agriculture, Food and Drug Administration and the Agricultural Marketing Service will sponsor three meetings in September and October 2017 to provide information and receive comments on U.S. positions to be

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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 inspections, subject to FDA, USDA and FTC regulation.

discussed at upcoming Codex Alimentarius Commission meetings. On September 1, the agencies will discuss U.S. positions for the Committee on Fresh Fruits and Vegetables, which meets in Uganda on October 2-6, 2017. The public meeting to discuss positions for the Committee on Food Labeling is scheduled for September 13, before the committee meets in Paraguay on October 16-20, 2017. Finally, the agencies will hold a public meeting to discuss positions for the Committee of Food Hygiene on October 11, before the committee's meeting in Chicago on November 13-17, 2017.

Domestic Olive Producers Hurt by Spanish Imports, USITC Finds

The U.S. International Trade Commission (USITC) has found a "reasonable indication" that domestic olive production has been injured by imports of Spanish olives sold at less than fair market value. In June 2017, two California olive producers filed a petition alleging that the imported olives, which are subsidized by the Spanish government, have damaged domestic producers. According to the petition, the number of domestic olive producers has fallen from 20 to two over the last few decades. The Department of Commerce initiated an investigation in July, and final determinations of penalties or duties due under the Tariff Act of 1930 are expected in early 2018.

FDA Issues Guidance for Use of Ultrafiltered Milk in Cheese

The U.S. Food and Drug Administration (FDA) has announced the availability of industry guidance titled, "Ultrafiltered Milk in the Production of Standardized Cheese and Related Cheese Products: Guidance for Industry." The guidance advises manufacturers that FDA intends to exercise enforcement in the use of fluid ultrafiltered milk in cheese products.

EPA Issues Working Guidance on Nanotechnology Reporting

The U.S. Environmental Protection Agency (EPA) has issued working guidance on its Section 8(a) Information Gathering Rule on Nanomaterials in Commerce for the agency's Final Nanotechnology Reporting and Record-Keeping Requirements Rule, which became effective August 14, 2017. The rule has been

modified to eliminate: (i) exemptions for nanoclays, zinc oxide, nanocellulose and naturally occurring nanomaterials from reporting requirements; (ii) volume cut-offs below which no reporting would be required; and (iii) an exemption for chemical substances manufactured as part of surface films.

Intentional Adulteration Guidance for Small Businesses Available

The U.S. Food and Drug Administration has made available industry guidance titled "Mitigation Strategies to Protect Food Against Intentional Adulteration: What You Need to Know About the FDA Regulation: Small Entity Compliance Guide." Comments on the guidance may be submitted at any time.

Officials Call for Recreational Fishers' Help After Salmon Farm Collapse

Following the collapse of a salmon farm, the Washington Department of Fish and Wildlife has asked recreational fishers to help catch as many Atlantic salmon as possible. Cooke Aquaculture cited "exceptionally high tides and currents coinciding with this week's solar eclipse" as the cause of the damage, which released an unknown number of farm-bred Atlantic salmon into the Pacific Ocean. Initial estimates were that about 5,000 fish escaped, but a Cooke spokesperson reportedly told the *Seattle Times* that the entire farm, which contained more than 300,000 fish, had "totally collapsed." *See* *Seattle Times*, August 24, 2017.

LITIGATION

Quaker Oats Labeling Suit Preempted by FDCA, Court Rules

A federal court has dismissed with prejudice a putative class action alleging that Quaker Oats' use of "100% Natural" on its products misleads consumers, holding that the plaintiffs' claims are expressly preempted by the Food, Drug and Cosmetic Act (FDCA). *Gibson v. Quaker Oats Co.*, No. 16-4853 (N.D. Ill., entered August 14, 2017). The plaintiffs alleged that Quaker's use of "natural" was misleading under several state statutes because the products contained residues of the herbicide glyphosate. The court held that nutritional and food labeling is governed by the

FDCA, preempting the plaintiffs' state law claims, which were "attempting to challenge how food stuffs are marketed." In addition, the court held that the FDCA expressly governs the presence of pesticide and herbicide residues in food, "establishing a clear and manifest purpose that preempts state regulation of food labeling."

The court also found the plaintiffs had no standing to pursue claims related to two Quaker Oats products they had not purchased, rejecting arguments that the products were "similar" to those they had bought. Additional details about other Quaker Oats glyphosate putative class actions appear in Issues 603 and 606 of this *Update*.

Court Dismisses "100% Parmesan" Cheese MDL

A federal court has dismissed multidistrict litigation alleging that several brands' "100% Grated Parmesan Cheese" misled consumers because the products contained as much as 8.8 percent cellulose, finding that the claims were "doomed by the readily accessible ingredient panels on the products that disclose the presence of non-cheese ingredients." *In Re: 100% Grated Parmesan Cheese Mktg. & Sales Practices Litig.*, No. 16-5802 (N.D. Ill., entered August 24, 2017). Additional details about the litigation appear in Issues 595 and 606 of this *Update*.

The court found the cheese's label was ambiguous, noting, "Although 100% Grated Parmesan Cheese might be interpreted as saying the product is 100% cheese and nothing else, it also might be an assertion that 100% of the cheese is parmesan cheese, or that the parmesan cheese is 100% grated. Reasonable consumers would thus need more information before concluding that the labels promised only cheese and nothing more, and they would know exactly where to look to investigate—the ingredient list."

Advocacy Group Sues Agencies Over CAFO Approval

Food & Water Watch has filed a lawsuit against the U.S. Department of Agriculture (USDA) and the Farm Service Agency seeking vacatur of agency decisions that guaranteed loans and allowed construction of a concentrated animal feeding operation (CAFO) in the Choptank River watershed on Maryland's Eastern Shore. *Food & Water Watch v. United States Dep't of Agric.*, No. 17-1714 (D.D.C., filed August 23, 2017). The CAFO is located

upstream from the Chesapeake Bay, where the U.S. Environmental Protection Agency and surrounding states have undertaken extensive agricultural pollution cleanup efforts. Among other allegations, the complaint asserts that USDA's environmental assessment found that the CAFO's density would conform to industry standards but that the actual density is nearly double those standards, resulting in higher-than-average waste concentration, air and water pollution.

The plaintiff argues that the agencies (i) failed to consider adequate alternatives; (ii) failed to address biological resources, groundwater, surface water or air quality; (iii) improperly relied on proposed mitigation measures; (iv) failed to consider the cumulative impacts of the CAFO; and (v) improperly made a finding of no significant environmental impact. In addition to seeking vacatur, the plaintiff also seeks injunctive and declarative relief.

Two Classes Certified in Olive Oil Lawsuit

A California federal court has certified two classes alleging that Deoleo USA Inc., importer of Bertolli and Carapelli olive oils, misleadingly labeled its products as "extra virgin" and "imported from Italy." *Koller v. Med Foods, Inc.*, No. 14-2400 (N.D. Cal., entered August 24, 2017). Details on the court's denial of a motion to dismiss appear in Issue 550 of this *Update*.

The court held that the question is whether the manufacturer "breached any legal obligation to take reasonable steps to ensure its oils meet the standards at least until the 'best by' date" on the bottle, a question that is subject to determination on a class-wide basis and predominates over any individual issues.

Kellogg's Breakfast Cereals Sugar Lawsuit to Proceed

A California federal court will allow to proceed a suit alleging that Kellogg's breakfast cereals and bars are unhealthy because of excess added sugars, finding that the labeling and packaging of 24 named products "contain at least one statement that is not preempted, non-misleading or puffery as a matter of law." *Hadley v. Kellogg Sales Co.*, No. 16-4955 (N.D. Cal., entered August 10, 2017). The court rejected Kellogg's argument that the company accurately disclosed the ingredients of its products and complied with U.S. Food and Drug Administration (FDA) labeling guidelines..

The court also found that because FDA "expressly decided" not to set a level for sugar that would disqualify a product from making health or nutrient-content claims, any allegation that Kellogg's product labeling was misleading because of a certain amount of added sugar was preempted by the Food, Drug and Cosmetic Act. However, the court refused to preempt a claim based on "No High Fructose Corn Syrup" labeling, reasoning that preemption did not apply because the representation related to the type of sugar in the product rather than the amount.

Red Bull Asserts Trademark Ownership of Sideways Bull Image

Red Bull GmbH has filed a notice of opposition with the Trademark Trial and Appeal Board (TTAB) alleging that a mark used by Bull By The Horns Fitness is too similar to its own name, mark and logo. *Red Bull GmbH v. Bull By The Horns Fitness*, No. 91236158 (TTAB, filed August 16, 2017). The fitness club applied for a mark that shows a man holding a sideways-facing charging bull, while Red Bull's marks also show a sideways-facing charging bull. Red Bull argues that its mark has been extensively used in sports and fitness promotion and training services and opposes the application for likelihood of confusion, dilution and false suggestion of a connection.

Jelly Belly ECJ Suit Limited to Monetary Damages

A California federal court has limited relief to monetary damages in a lawsuit alleging that Jelly Belly Candy Co. misleads consumers into believing its Sport Beans do not contain sugar because the term "evaporated cane juice" (ECJ) appears on the label instead. *Gomez v. Jelly Belly Candy Co.*, No. 17-0575 (C.D. Cal., entered August 18, 2017). Additional details about the case appear in Issues 629 and 638 of this *Update*.

The court found that to pursue California consumer-protection claims, the plaintiff must establish that she had no adequate remedy at law, but she failed to do so in an amended complaint. The only injury the plaintiff alleged was that she "lost money" because she purchased the product, the court stated, limiting her relief to that alleged loss.

SCIENTIFIC/TECHNICAL ITEMS

Study Finds Association Between "Good" Cholesterol and Premature Death

University of Copenhagen researchers have apparently found that extremely high levels of "good" cholesterol, or high-density lipoprotein (HDL), may be associated with premature death rates. Christian M. Madsen, et al., "Extreme high high-density lipoprotein cholesterol is paradoxically associated with high mortality in men and women: two prospective cohort studies," *European Heart Journal*, August 21, 2017. The medical community has generally accepted that higher levels of HDL may protect against cardiovascular disease and that "bad" cholesterol, or low-density lipoprotein (LDL), contributes to atherosclerosis, leading to increased risk of heart disease and stroke.

The study followed more than 116,000 people for an average of six years and found that men with extremely high levels of HDL had a 106 percent higher chance of dying prematurely than men with normal levels, while women with high levels had a 68 percent higher chance of premature death. Extremely high levels were defined as ≥3.0 millimoles per liter of blood for men and ≥3.5 millimoles for women. Mortality rates for men with "very high" levels of HDL were 36 percent higher than men with medium levels, which were defined as 1.9 millimoles per liter.

The study authors noted that they "could not determine if the association between extreme high HDL cholesterol and higher mortality was causal." Moreover, because both studies observed subjects who were included because of "previous contact with the health care system that included obtainment of a lipid panel," the authors noted that the "results of these studies are not necessarily representative for the general population."