FOOD & BEVERAGE LITIGATION UPDATE
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SHOOK HARDY & BACON

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Issues Industry Guidance on "Healthy" Labeling

The U.S. Food and Drug Administration (FDA) has opened a docket and released industry guidance on the use of the term "healthy" in the labeling of human food products. Responding to Kind LLC's citizen petition asking the agency to align its nutrient content claim regulations with federal dietary guidance, FDA invites "public comment on the term 'healthy', generally, and as a nutrient content claim in the context of food labeling."

Current regulations reportedly establish "the parameters for use of the implied nutrient content claim 'healthy' or related terms... on the label or in labeling of a food to suggest that a food, because of its nutrient content, may be useful in creating a diet that is consistent with dietary recommendations, if the food meets certain nutrient conditions, and the claim is made with an explicit or implicit claim or statement about a nutrient." Among other things, the conditions take into account serving-size regulations and set criteria for nutrients to limit—including fat, cholesterol and sodium—as well as those to encourage.

The citizen petition asks FDA to "amend the regulation defining the nutrient content claim 'healthy' with respect to total fat intake and amend the regulation to emphasize whole foods and dietary patterns rather than specific nutrients." In particular, the petition seeks to permit "healthy" claims on foods that meet fat, saturated fat, and cholesterol criteria exclusive of total fat or saturated fat content derived from whole fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood—or foods in these categories that "have been processed in such a way that did not materially degrade their nutrition value."

Meanwhile, FDA has asked stakeholders to weigh in on a number of questions, including: (i) "Is the term 'healthy' most appropriately categorized as a claim based only on nutrient content?"; (ii) "If criteria other than nutrient content (e.g., amount of whole grain) are to be included in the definition of the term 'healthy,' how might we determine whether foods labeled 'healthy' comply with such other criteria for bearing the claim?"; (iii) "What types of food, if any, should be allowed to bear the term 'healthy?'"; (iv) "Is 'healthy' the best term to characterize

foods that should be encouraged to build healthy dietary practices or patterns?; (v) "What nutrient criteria should be considered for the definition of the term 'healthy?'." The agency also seeks input on consumer and industry perceptions regarding a changed definition of "healthy."

In addition, FDA clarifies in its industry guidance that it intends "to exercise enforcement discretion with respect to the implied nutrient content claim 'healthy' on foods that have a fat profile of predominantly mono and polyunsaturated fats, but do not meet the regulatory definition of 'low fat', or that contain at least 10 percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D." *See Federal Register,* September 28, 2016.

FDA Consumer Update Clarifies Maple Syrup Labeling

The U.S. Food and Drug Administration (FDA) has published a September 2016 Consumer Update describing how to determine if a product contains real maple syrup as a flavoring agent. Specifically, the agency urges consumers to look at the ingredient list for the term "maple syrup" and not rely solely on depictions of maple leaves or the word "maple" displayed on the front of packaging.

"Current regulations allow use of terms like 'maple,' 'maple-flavored,' or 'artificially maple-flavored' on the food label without having any maple syrup in the product, as long as it contains maple flavoring," clarifies FDA. "This flavoring could come from a number of sources, including sap or bark from the maple tree. Or it could come from the herb fenugreek, which can impart a maple-like flavor."

Noting that similar rules apply to some fruit flavorings, the agency explains that terms such as "artificial flavors" or "natural and artificial flavors" indicate "that the original source of the flavor may not have been used in the food." As the Director of FDA's Office of Nutrition and Food Labeling Douglas Balentine states, "Ultimately we want consumers to be able to make informed choices about their foods, and FDA's job is to make sure consumers know what they're getting."

OEHHA Adds Furfuryl Alcohol to Prop. 65 List

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) has announced the addition of furfuryl alcohol to the list of chemicals known to the state to cause cancer in accordance with Proposition 65 (Prop. 65) regulations.

OEHHA describes furfuryl alcohol as "formed in foods during thermal processing and as a result of the dehydration of sugars," noting that the

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U.S. Environmental Protection Agency (EPA) has formally identified the chemical as one that causes cancer. In particular, OEHHA cites the 2014 EPA report titled *Cancer Assessment Document, Evaluation of the Carcinogenic Potential of Furfural and Furfuryl Alcohol*, as satisfying "the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations for furfuryl alcohol."

LITIGATION

Cruz-Alvarez and Rameshwar Detail Dismissal of Challenge to Abbott Labs' Organic Infant Formula

Shook Partner Frank Cruz-Alvarez and Associate Ravika Rameshwar have authored an article for the Washington Legal Foundation's *Legal Pulse* discussing a New York federal court's dismissal of a class action centered on infant formula marketed as organic. The complaint alleged that Abbott Laboratories, Inc. represented its Similac® Advance® as organic despite containing ingredients prohibited in organic products by the U.S. Department of Agriculture (USDA).

Cruz-Alvarez and Rameshwar provide an overview of the case and detail the relevant provisions of the Organic Foods Production Act of 1990, which establishes that a product can be labeled "organic" if a USDA-accredited agency certifies it as such. The court compared the infant formula allegations to a U.S. Court of Appeals for the Eighth Circuit case challenging the organic label of milk and reached an analogous conclusion: the state laws supporting the complaint challenged the federal law's certification determination and were thus preempted. Accordingly, the court dismissed the plaintiff's complaint but granted leave to amend.

Additional details on the dismissal appear in Issue 615 of this *Update*.

Court Adopts EPA's Language Admitting Failure to Set Perchlorate Limits

In a lawsuit brought by the Natural Resources Defense Council (NRDC) alleging failure to meet a deadline to set limits on perchlorate levels in drinking water, a New York federal court has issued an order adopting the U.S. Environmental Protection Agency's (EPA's) preferred language to admit the failure. *Nat. Res. Def. Council v. EPA*, No. 16-1251 (S.D.N.Y., order entered September 19, 2016).

An EPA attorney reportedly admitted in court that the agency had missed the deadline of February 11, 2013, to set limits on perchlorate in drinking

water after announcing its intention to propose regulations two years prior. NRDC and EPA then submitted proposed orders admitting the failure, and the court adopted EPA's language without further discussion. *See Law360*, September 20, 2016.

The court's order finds that (i) EPA triggered a non-discretionary duty to propose a maximum contaminant level goal by February 11, 2013; (ii) EPA failed to propose that goal by the deadline; and (iii) the inaction "constituted a failure to perform a non-discretionary act or duty under the Safe Drinking Water Act."

EPA, Whole Foods Reach $3.5-Million Settlement in Hazardous-Waste Action

The U.S. Environmental Protection Agency (EPA) has announced a settlement with Whole Foods Inc. after a year-long investigation into the company's hazardous-waste disposal at facilities in five states. According to EPA, the investigation uncovered that Whole Foods did not properly make hazardous waste determinations—as required by the Resource Conservation and Recovery Act—and mishandled spent lamps. Under the settlement terms, Whole Foods will correct the violations, pay $3.5 million and "promote hazardous waste compliance in the retail industry as part of a supplemental environmental project." That project will aim to educate Texas retailers—"particularly smaller businesses"—about hazardous waste laws and the importance of maintaining compliance.

"All companies must follow the law and be responsible stewards of their hazardous waste, from generating it to safely disposing of it," an EPA administrator was quoted as saying in a September 20, 2016, press release. "Whole Foods is correcting these violations and will ensure their stores and facilities continue to comply with environmental regulations. They will also look into launching an innovative hazardous waste tracking system that we hope becomes the industry standard."

Kind Litigation on Hold as FDA Decides "Natural" Definition

A New York federal court has stayed a proposed class action alleging Kind LLC misleads consumers by describing its products as "all natural" and free of genetically modified organisms. *In re Kind*, No. 15-2645 (S.D.N.Y., order entered September 15, 2016). The court noted that the U.S. Food and Drug Administration (FDA) requested comments on the use of the term "natural" in food labeling in November 2015 and closed the comment period in May 2016, suggesting that FDA is "prepared to address the core issues in this case."

The plaintiffs voluntarily dismissed their claims that Kind's use of "healthy" on its labels was misleading following FDA's determination that it would permit Kind to use the term as the agency considers redefining it. Details on that determination appear in Issue 604 of this *Update*.

Consumer Targets Dave's Gourmet Pasta Sauces in ECJ Lawsuit

A consumer has filed a putative class action against Dave's Gourmet, Inc. alleging the company deceives its customers by listing evaporated cane juice (ECJ) on its sauce labels rather than the U.S. Food and Drug Administration's (FDA's) preferred term, sugar. *Kazemi v. Dave's Gourmet, Inc.*, No. 16-5269 (N.D. Cal., filed September 14, 2016). The complaint asserts that the plaintiff and other members of the putative class "would have paid less for the Products or would not have purchased the Products had they known that the Products' listing of ECJ as an ingredient claim was false, misleading, and deceptive." For alleged violations of California's and Florida's consumer-protection statutes, the plaintiff seeks class certification, injunctions, restitution, damages and attorney's fees.

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.