FOOD & BEVERAGE LITIGATION UPDATE
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SHOOK HARDY & BACON

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Maple Syrup Industry Taps FDA for Action on Allegedly Misbranded Products

Led by the Vermont Maple Sugar Makers' Association (VMSMA), the maple syrup industry has penned a February 15, 2016, letter asking the U.S. Food and Drug Administration (FDA) to take enforcement action "concerning misrepresentative labeling of food products whose labels incorrectly indicate the presence of maple syrup." The signatories—which include the International Maple Syrup Institute and North American Maple Syrup Council, as well as several state organizations—identify several instant oatmeal, natural sweetener and other products that allegedly violate Food, Drug and Cosmetic Act regulations by using the word "maple" in their product descriptions without containing maple syrup.

Drawing parallels to the agency's conclusion that Hampton Creek's Just Mayo® eggless sandwich spread was mislabeled because "mayo" has "long been used and understood as shorthand or slang for mayonnaise," the letter argues that the term "maple" "has long been used and understood to refer to 'maple syrup.'" As VMSMA opines, "This unchecked misbranding has an adverse impact on manufacturers of products containing real maple syrup, as it allows cheaper products not containing premium ingredients to compete with those actually containing maple syrup. Further, it deceives consumers into believing they are purchasing a premium product when, in fact, they have a product of substantially lower quality."

The letter seeks an end to "rampant mislabeling" by prohibiting the use of maple branding on products that do not contain any maple syrup, defined in 21 CFR § 168.140(a) as "substance derived from the heat treatment of sap from the maple tree. Such maple branding may include "vignettes of maple syrup, leaves, and trees" that emphasize the presence of maple syrup.

"As maple syrup purveyors or producers, or parties otherwise invested in a healthy maple syrup marketplace, we have a particular interest in ensuring that products claiming to contain maple are properly labeled

to prevent consumer confusion," concludes the letter, which reportedly drew support from U.S. Rep. Peter Welch (D-Vt.) and U.S. Sen. Patrick Leahy (D-Vt.). "We hope that many companies marketing misbranded products will consider including maple syrup in their products in order to comply with the law, however if they do not, we request enforcement action by the FDA." *See The Associated Press*, February 16, 2016.

Connecticut Senator Poised to Introduce Date-Labeling Legislation

Citing annual costs of $1,500 in wasted food to the average American family, and a "dizzying array of misleading labels," U.S. Sen. Dick Blumenthal (D-Conn.) is reportedly poised to introduce a proposal that would establish uniform national standards for food dating.

"Terms like 'best by,' 'sell by' and 'use by' have no bearing on food safety, leading 90 percent of Americans to throw away food past those dates out of mistaken concern for food safety risks," Blumenthal said in a February 19, 2016, *Facebook* post.

According to the Hartford Courant, Blumenthal's legislation would require labels to indicate the duration of a product's quality by providing dates preceded by "best if used by." The proposal would also mandate that "high-risk foods," including hot dogs and deli meats, to carry labeling with "expires on" dates.

A similar initiative was included in provisions of the Food Recovery Act of 2015 (H.R. 4184), which was referred to the House Subcommittee on Health in December 2015. See Hartford Courant, February 18, 2016.

U.S. Codex Delegates Schedule Food Contaminants Meeting

The U.S. Department of Agriculture's Office of the Under Secretary for Food Safety and U.S. Food and Drug Administration are convening a March 7, 2016, public meeting in College Park, Maryland, to evaluate draft positions for consideration at the 10th Session of the Codex Committee on Contaminants in Food slated for April 4-8 in Rotterdam, The Netherlands.

Agenda items for the March 7 meeting include papers about maximum levels for methylmercury in fish and mycotoxins in spices; and discussions of a draft Code of Practice to prevent and reduce arsenic contamination in rice and proposed draft maximum levels for cadmium in cocoa and cocoa-derived products. *See Federal Register*, February 11, 2016.

Shook offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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If you have questions about this issue of the *Update* or would like to receive supporting documentation, please contact Mary Boyd at mboyd@shb.com.

Cal/EPA Solicits Info About Nickel, PFOA and PFOS for Potential Listing Under Prop. 65

The California Environmental Protection Agency's (Cal/EPA's) Office of Environmental Health Hazard Assessment (OEHHA) has announced the development of hazard identification materials for nickel and nickel compounds, perfluorooctanoic acid (PFOA) and its salts, and pefluorooctane sulfonate (PFOS) and its salts to assist in the agency's consideration of the chemicals for possible listing under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). Food is a major source of nickel exposure, with an average intake for adults estimated to be approximately 100 to 300 micrograms per day (µg/d), while PFOA and PFOS are chemical compounds that have been widely used in commercial and industrial applications, including food packaging and water-resistant coatings.

OEHHA specifically seeks data relevant to assessing the chemicals' reproductive toxicity for evaluation by the Developmental and Reproductive Toxicant Identification Committee. Comments are due by April 4, 2016. *See OEHHA News Release*, February 19, 2016.

EFSA Seeks Input on Exposure Assessments for Food Enzymes

The European Food Safety Authority's (ESFA's) Panel on Food Contact Materials, Enzymes, Flavorings and Processing Aids (CEF) has announced a public consultation on its draft statement on exposure assessment of food enzymes. Recognizing the difficulty in applying current exposure assessment guidelines to food enzymes, which are added during processing of food and food ingredients, the draft statement recommends a tiered approach based on "more realistic" exposure scenarios as opposed to methods that rely solely on upper use levels.

In particular, the CEF Panel notes that food enzyme guidance adopted in 2009 stipulates that, "Potential human exposure to the food enzyme and to any other constituent or by-product of concern should be assessed considering all proposed uses. A conservative technique such as the 'budget method' should be used … assuming that they (i.e. foods and beverages) always contain the food enzyme at its proposed upper use level." This budget method apparently makes several assumptions regarding (i) food and beverage intake, (ii) the percentage of food and beverage that are processed, and (iii) the percentage of processed food and beverage containing the food additive. A margin of exposure (MoE) is then calculated "based on the estimated dietary exposure from use of the food enzyme and the no-observed-adverse-effect level (NOAEL)."

Because the budget method when applied to food enzymes "can lead to a considerable overestimation of exposure," a tiered approach would use the budget method without the use of standard factors as an initial screening step for all food enzymes. Only in those cases "where calculated MoE according to Tier 1 is insufficient" will the exposure assessment be further refined in one of two ways. Tier 2a assessments will cover cases in which there is available information about the occurrence of the food enzyme in foods/beverages as consumed that "allows for a calculation of the exposure using specific food categories in the EFSA Comprehensive European Food Consumption Database." All other cases will undergo Tier 2b assessment, which will use the budget method with factors specific to the respective enzymes and derived "using all available information (e.g. the use of the enzyme during food processing, the proportion of processed food and the presence of the food enzyme therein)."

"As each safety assessment is performed on a case-by-case basis requiring expert judgment of the entire toxicological database and information related to the intrinsic properties of specific food enzyme, no generally acceptable value can be established for MoE," concludes the CEF Panel, which seeks public feedback by March 31, 2016. "As a first indication, a MoE of 300 (Factor 10 for inter-species difference, factor 10 for intra-species difference and factor 3 for the extrapolation from short-term studies to chronic studies, EFSA Scientific Committee, 2012) may be regarded as sufficient provided the data are complete and the quality of the data is acceptable."

LITIGATION

Cheese Company Pleads Guilty to Food Adulteration Charge, FDA Vows Continued Collaboration with DOJ on Food Safety

A Delaware cheese company and two individual defendants have pled guilty to a misdemeanor violation of the federal Food, Drug, and Cosmetic Act for distributing adulterated ricotta, queso fresco and fresh cheese curds in several neighboring states. *U.S. v. Roos Foods, Inc.*, No. 16-0013 (D. Del., information filed January 22, 2016). Roos' cheese was connected to a 2014 outbreak of *Listeria* that caused five adults and three newborns to contract listeriosis. The criminal information alleged the company produced the cheese in unsanitary conditions, including the "[f]ailure to clean food-contact surfaces as frequently as necessary to protect against contamination of food" and "failure to store raw materials or ingredients in a manner that protects against contamination."

In their agreement with the U.S. Food and Drug Administration (FDA), the defendants agreed to an injunction preventing them from processing or distributing food products until they undergo an FDA inspection and facility testing by an independent laboratory. The defendants must also hire a sanitation expert to prepare a sanitation-control program for employee training, environmental monitoring and remedial actions.

"The FDA will not tolerate food companies that fail to provide adequate safeguards and place the public health at risk by producing and shipping contaminated products," an FDA official said in a January 22, 2016, press release. "We will continue to work with the Department of Justice to use the full force of our justice system against those that place profits over the health and safety of American consumers."

Advertising Group Files Amicus Brief in San Francisco Sugar-Sweetened Beverage Case

The Association of National Advertisers, Inc. (ANA) has filed an amicus brief in a case challenging San Francisco's health code provisions requiring advertisements on sugar-sweetened beverages (SSBs) notifying the public of alleged health risks associated with SSB consumption. *Am. Beverage Ass'n v. City of San Francisco*, No. 15-3415 (N.D. Cal., San Francisco Div., amicus brief filed January 22, 2016). The brief focuses on First Amendment arguments against requiring private parties to include government speech on their product labels.

"The City of San Francisco's imposition of the Warning Mandate in reaction to potential over-consumption of sugar-sweetened beverages by its citizens, whatever the merits of that concern, takes regulatory Nannyism to new levels and is wholly incompatible with First Amendment protections afforded to commercial speech," the brief argues. "If this Court were to uphold the Board of Supervisors' conscription of sugar-sweetened beverage ads to convey government views on health issues there would be virtually no limit to similar efforts targeting other products, at any level of government. Every sugary, fatty, salty, processed, or other food disfavored by the science of the moment would be susceptible to having a significant portion of its advertising turned into a placard for government hectoring with which the advertiser not only disagrees, but for which there may be data controverting the government position."

Details about the American Beverage Association's lawsuit challenging the ordinance appear in Issue 573 of this *Update*, and information about the repealed ad ban on city property appears in Issue 586.

Lawsuit Challenges Use of *Trans* Fat in Kellogg's Mother's Cookies®

A consumer has filed a putative class action against Kellogg Co. alleging the company produces Mother's Cookies® with partially hydrogenated oil (PHO), which contains *trans* fat, in violation of the U.S. Food and Drug Administration's (FDA's) ban on the ingredient. *Hawkins v. Kellogg Co.*, No. 16-0147 (S.D. Cal., filed January 21, 2016). The plaintiff asserts FDA "determined that PHO is unsafe for use in food" in 2015, and alleges as a result that Kellogg is prohibited from using the food additive in its cookies. "Today there is no question about the scientific consensus on trans fat," the complaint argues, in describing several studies examining the alleged human health effects of PHO consumption. For alleged violations of California consumer-protection statutes, nuisance and breach of implied warranty, the plaintiff seeks class certification, restitution, an injunction, a corrective advertising campaign 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.