Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Senators Urge U.S. Trade Representative to Resolve Russian Meat Import Ban

U.S. Sen. Debbie Stabenow (D-Mich), who chairs the Senate Committee on Agriculture, Nutrition and Forestry, has joined ranking committee member Thad Cochran (R-Miss.) and 31 other senators in asking U.S. Trade Representative Ron Kirk "to quickly address Russia's new import ban on U.S. beef, poultry and turkey." According to a February 19, 2013, news release, the ban stems "from Russia's zero-tolerance policy regarding ractopamine, a feed additive for livestock approved by both the U.S. Food and Drug Administration and the Codex Alimentarius Commission [CODEX]."

In their **letter** to the trade representative, the senators claim that this "egregious" trade barrier would cost the U.S. economy $600 million annually and amount to an import ban in violation of the World Trade Organization's (WTO's) Sanitary and Phytosanitary Agreement.

"The United States must do everything it can to defend its rights in both the WTO and CODEX and prevent non-science-based trading practices from other trading partners, including Russia," conclude the senators. "[W]e must demonstrate to Russia that its newfound commitment to WTO membership includes adherence to science-based standards, such as the CODEX MRL for ractopamine." Additional details about the ban appear in Issues **465** and **466** of this *Update*.

FDA Seeks Comments on Sweeteners in Flavored Milk

The Food and Drug Administration (FDA) has **announced** that the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) have filed a petition requesting that the agency amend the standard of identity for milk and 17 other dairy products "to provide for the use of any safe and suitable sweetener as an optional ingredient." FDA is seeking comments and other information by May 21, 2013.

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IDFA and NMPF have evidently asked FDA to amend the milk standard of identity to allow optional characterizing flavoring ingredients used in milk—such as chocolate—to be sweetened with any safe and suitable sweetener, including non-nutritive sweeteners such as aspartame. According to IDFA and NMPF, the proposed amendments "would promote more healthful eating practices and reduce childhood obesity by providing for lower-calorie flavored milk products." In particular, the petitioners claim that lower-calorie flavored milk would assist "in meeting several initiatives aimed at improving the nutrition and health profile of food served in the nation's schools," including "state-level programs designed to limit the quantity of sugar served to children during the school day." They also argue that the amended standard of identity would "promote honesty and fair dealing in the marketplace." *See Federal Register,* February 20, 2013.

FDA Extends Comment Deadline on Proposed Hazard Analysis, Produce Safety Rules

The Food and Drug Administration (FDA) has extended the comment periods on two proposed rules related to foodborne illness prevention and produce safety that appeared in the *Federal Register* on January 16, 2013. In response to a request for a 90-extension, the agency has increased until May 16, 2013, the comment periods for the proposed rules titled "**Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**" and "**Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption**."

Under the Food Safety Modernization Act, the two new rules would (i) require both foreign and domestic food manufacturers "to develop a formal plan for preventing their food products from causing foodborne illness," and (ii) establish "science- and risk-based standards for the safe production and harvesting of fruits and vegetables." Additional details about the rules appear in Issue **466** of this *Update*. *See Federal Register,* February 19, 2013.

Mississippi Lawmakers Squash Local Food Regulation

The Mississippi House of Representatives recently passed legislation (H.B. 1182) that aims to prohibit food regulation at the local level. The bill in question would reserve to the state Legislature the power to regulate consumer incentive items, implement menu and vending machine labeling rules, and set other restrictions on the sale of certain foods and beverages where not preempted by federal law.

"If you want to go eat 20 Big Macs, you can eat 20 Big Macs," said Rep. Greg Holloway (D-Hazlehurst), who reportedly argued that the bill would bar municipalities from making their own laws "willy-nilly." The state Senate has also passed a similar measure (S.B. 2687), which must be reconciled with the House version before proceeding to the governor. *See The Associated Press,* February 14, 2013.

Petition for Healthier Vending Machines in Massachusetts

Massachusetts lawmakers have proposed a bill (H.B. 2011) to expand access to healthy food choices in vending machines on state property, including "government office buildings, road-side rest stops, state parks and recreation centers, state colleges and universities, and state-supported hospitals." The legislation seeks to set specific nutritional standards for all foods or beverages sold through vending machines located in government buildings or on property owned or managed by the commonwealth.

To this end, the proposed bill would require that all beverage items must be one or a combination of the following: (i) water, including carbonated water, without added caloric sweeteners; (ii) coffee or tea without added caloric sweeteners, provided that condiments offered for these beverages have less fat than cream; (iii) fat-free or 1-percent low-fat dairy milk or calcium- and vitamin-D-fortified soymilk with less than 200 calories per container; (iv) 100 percent fruit juice or fruit juice combined with water or carbonated water in containers that hold 12 fluid ounces or less and do not contain added caloric sweeteners; (v) 100 percent vegetable juice in containers that hold 12 fluid ounces or less, contain 200 milligrams of sodium or less per container and do not contain added caloric sweeteners; and (vi) low-calorie beverages that contain 40 calories or less per container.

For snack items, the proposed rule states that such products must contain (i) no more than 200 calories per item as offered (per package); (ii) no more than 35 percent of calories from fat—packages that contain 100 percent nuts or seeds may contain more than 35 per cent of calories from fat; (iii) no more than 10 percent of calories from saturated fat—packages that contain 100 percent nuts or seeds may contain more than 10 percent of calories from saturated fat; (iv) 0 grams of *trans* fat; (v) no more than 35 percent of calories

from total sugars and a maximum of 10 grams of total sugars per package, with special provisions for fruits, vegetables and yogurt; (vi) no more than 200 milligrams of sodium per item as offered (per package); and (vii) at least one of the following: (a) a quarter cup of fruit, non-fried vegetable, or fat-free or low-fat dairy; (b) one ounce of nuts or seeds or one tablespoon of nut butter; (c) grain ingredients consisting of at least 50 percent whole grain as determined by the product manufacturer listing whole grain as the first ingredient or making a whole grain claim; or (d) at least 10 percent of the daily value of a naturally occurring nutrient of public health concern such as calcium, potassium, vitamin D, or fiber.

The legislation also includes proposed rules for entrée-type items and sandwiches. Under the proposal, violators would face fines of at least $100 for first violations and at least $500 for subsequent violations. Habitual violations would result in a six-month prohibition on the sale of foods and beverages and a fine of at least $1,000.

LITIGATION

First Circuit Rules PACA Appeal Provisions Are Jurisdictional

The First Circuit Court of Appeals has upheld the dismissal of an attempted appeal from an administrative ruling under the Perishable Agricultural Commodities Act (PACA), agreeing with the district court that the company which allegedly failed to pay all of the required purchase price on four truckloads of produce failed to file an appropriate appeal bond within the prescribed period. ***The Alphas Co. v. Kopke*, No. 12-1581 (1st Cir., decided February 13, 2013)**. So ruling, the court affirmed the order of an administrative law judge, acting on behalf of the Secretary of Agriculture, awarding the produce supplier $50,025 plus interest.

The bond that Alphas filed had "three material defects: it was not filed within the prescribed thirty-day appeal period; it was in an amount less than the amount stipulated; and it did not contain appropriate indemnification covenants." Looking to the statute, legislative history and other courts for guidance, the First Circuit concluded, "In this case, all roads lead to Rome: The text of the statute, its context, and its historical treatment point unerringly in the same direction. In line with these signposts, we hold that the bond requirements of the PACA are mandatory and jurisdictional, and that the timely filing of a proper bond is a prerequisite for judicial review of a reparation order."

Federal Criminal Charges Filed Against Peanut Corp. Owner and Employees

In a 76-count indictment, four individuals formerly associated with the Peanut Corp. of America (PCA), which was the source of a nationwide *Salmonella* outbreak in 2009, have been charged with conspiracy, mail and wire fraud, obstruction of justice and other counts involving the distribution of adulterated or misbranded food. ***United States v. Parnell,* No. 13-12 (U.S. Dist. Ct., M.D. Ga., Albany Div., filed February 15, 2013)**. A fifth individual employed by PCA has entered a guilty plea to charges filed against him. ***United States v. Kilgore*, No. 13-7 (U.S. Dist. Ct., M.D. Ga., Albany Div., filed February 11, 2013)**.

The outbreak was traced to the Blakely, Georgia, plant owned by defendant Stewart Parnell. The other defendants are Michael Parnell, who was employed as a food broker on behalf of PCA, Samuel Lightsey, the Blakely plant's operations manager from July 2008 through February 2009, and Mary Wilkerson, who worked in a number of positions from April 2002 through February 2009, including as quality assurance manager. Daniel Kilgore served as PCA operations manager in Blakely from June 2002 through May 2008; he has pleaded guilty to "one count of conspiracy to commit fraud, one count of conspiracy to introduce adulterated and misbranded food into interstate commerce, eight counts of introducing adulterated food into interstate commerce with the intent to defraud, six counts of introducing misbranded food into interstate commerce with intent to defraud, eight counts of interstate shipment fraud, and five counts of wire fraud."

According to a U.S. Department of Justice news release, Stewart Parnell, Michael Parnell, Lightsey and Kilgore "misled PCA customers about the existence of foodborne pathogens, most notably salmonella, in the peanut products PCA sold to them [and] did so in several ways—for example, even when laboratory testing revealed the presence of salmonella in peanut products from the Blakely plant, [they] failed to notify customers of the presence of salmonella in the products shipped to them."

The charging documents also allege that they "participated in a scheme to fabricate certificates of analysis (COAs) accompanying various shipments of peanut products. COAs are documents that summarize laboratory results, including results concerning the presence or absence of pathogens. . . . [O]n several occasions these four defendants participated in a scheme to fabricate COAs stating that shipments of peanut products were free of pathogens when, in fact, there had been no tests on the products at all or when the laboratory results showed that a sample tested for salmonella." DOJ further claims that the defendants, including Wilkerson, "gave untrue or misleading answers to . . . questions" posed by Food and Drug Administration (FDA) inspectors after the outbreak, which sickened more than 700 people.

According to Stewart Parnell's attorneys, the charges will be vigorously defended. They said, "There is little doubt that as the facts in this case are revealed, it will become apparent that the FDA was in regular contact with PCA about its food handling policy and was well aware of its salmonella testing protocols. Representatives of State and Federal agencies made regular visits to the PCA facility in Georgia over the years and months prior to the salmonella outbreak and such agencies were aware of and made no objections to the testing policies or protocols in place." They also said that "as this matter progresses it will become clear that Mr. Parnell never intentionally shipped or intentionally caused to be shipped any tainted food products capable of harming PCA's customers."

FDA Commissioner Margaret Hamburg said, "The charges announced today show that if an individual violates food safety rules or conceals relevant information, we will seek to hold them accountable." The defendants could face prison terms of up to 20 years if they are convicted. *See Gentry Locke Rakes & Moore LLP Press Statement, NPR.org,* and *DOJ News Release*, February 21, 2013.

OTHER DEVELOPMENTS

Lancet Article Assesses Role of Industry in Non-Communicable Disease Policy

An article recently published in *The Lancet* has apparently concluded that industries promoting so-called "unhealthy commodities" "should have no role in the formation of national or international NCD [non-communicable disease] policy." Rob Moodie, et al., "Profits and pandemics: prevention of harmful effects of tobacco, alcohol, and ultra-processed food and drink industries," *The Lancet,* February 2013. Writing on behalf of *The Lancet's* NCD Action Group, researchers examined the purported influence of transnational tobacco, alcohol and food and beverage companies in low- and middle-income countries, as well as "the effectiveness of self-regulation, public-private partnerships, and public regulation models of interaction with these industries."

Focusing on the alleged financial ties between transnational corporations and public-health policymakers, the article ultimately argues that the food and beverage industries "use similar strategies to the tobacco industry to undermine effective public health policies and programs." In particular, the authors find "no evidence to support the effectiveness or safety" of industry-backed initiatives such as self-regulation or public-private partnerships. Instead, the article proposes, among other things, that (i) "discussions with unhealthy commodity industries should be with government only and have a clear goal of the use of evidence-based approaches by government"; (ii) "funding and other support for research, education, and programs should not be accepted

from the tobacco, alcohol, and ultra-processed food and drink industries or their affiliates and associates"; (iii) "evidence-based approaches such as legislation, regulation, taxation, pricing, ban, and restriction of advertising and sponsorship should be introduced"; and (iv) "a new scientific discipline that investigates industrial diseases and the transnational corporations that drive them, should be developed."

"Public regulation and market intervention are the only evidence-based mechanisms to prevent harm cause by the unhealthy commodities market," opine the article's authors. "Regulation, or the threat of regulation, is the only way to change transnational corporations." Additional details about the work of lead author Rob Moodie appear in Issue 460 of this *Update*.

Monster Energy to Reclassify Products as Beverages

According to media sources, Monster Energy Corp. has announced plans to re-label its energy drinks as beverages regulated by the Food and Drug Administration (FDA) as opposed to dietary supplements. The company reportedly told industry publication *Beverage Digest* that it will update product labels to include "Nutritional Facts" rather than "Supplement Facts", as well as information about the caffeine content. The change will purportedly take effect with the introduction of new products and packaging.

"The Company saw no reason to continue being subjected to erroneous and misguided criticism that its Monster Energy drinks are being marketed as dietary substances to avoid FDA regulation," read a statement that the corporation sent to *ABC News*. Monster Energy and other energy drink manufacturers have faced increased scrutiny and litigation over claims allegedly linking the products to fatalities in susceptible individuals. Additional details about ongoing investigations by FDA and members of Congress appear in Issues 463 and 467 of this *Update*. *See CBS News,* February 14, 2013; *ABC News,* February 16, 2013.

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SCIENTIFIC/TECHNICAL ITEMS

Researchers Examine Soybean Uptake of Nanoparticles from Soil

A recent study has purportedly found that soybean plants can uptake widely-used industrial nanoparticles (NPs) from the soil, raising concerns about potential effects on the food chain and the next generation of crops. Jose Hernandez-Viezcas, et al., "*In Situ* Synchrotron X-ray Fluorescence Mapping and Speciation of CeO2 and ZnO Nanoparticles in Soil Cultivated Soybean (*Glycine max*)," *ACS Nano,* February 2013. Researchers apparently used microscopic synchrotron X-ray beams on soybean plants grown in soil contaminated with zinc oxide (ZnO) and cerium dioxide (CeO_2) NPs to trace "the potential storage of these NPs or their biotransformed products in edible/reproductive organs of crop plants."

Although x-ray absorption spectroscopy studies evidently did not find intact ZnO NPs within the plant tissues, micro-X-ray absorption near end structure (μ-XANES) data did identify "O-bound Zn, in a form resembling Zn-citrate, which could be an important Zn complex in soybean grains." The μ-XANES data also reportedly showed "that Ce remained mostly as CeO_2 within the plant."

"To our knowledge, this is the first report on the presence of cerium dioxide and zinc compounds in the reproductive/edible portions of the soybean plant grown in farm soil with cerium dioxide and zinc oxide nanoparticles," conclude the study's authors. "In addition, our results have shown that cerium dioxide NPs in soil can be taken up by food crops and are not biotransformed in soybeans. This suggests that cerium dioxide NPs can reach the food chain and the next soybean plant generation, with potential health implications." *See ACS Nano Press Release,* February 6, 2013.

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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.

SHB 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.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.