Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Lawmakers Call for Investigation into *Listeria* Outbreak

Two members of the U.S. House of Representatives have written a **letter** requesting an investigation and hearing into the recent outbreak of *Listeria monocytogenes* in cantaloupe. Representatives Henry Waxman (D-Calif.) and Diana DeGette (D-Colo.) asked the House Energy and Commerce Committee and its subcommittee on oversight and investigations to conduct a probe into *Listeria* purportedly found at Jensen Farms in Colorado. As of October 3, 2011, the outbreak has reportedly spread to 20 states and killed 18 since it began on or after July 31, according to a CDC **report**.

Calling the event "the nation's deadliest outbreak of foodborne disease in more than a decade," the lawmakers have pressed for Jensen Farm records detailing inspections and communications with federal regulators, documents related to the company's product monitoring, and a description of when and where *Listeria* contamination was first detected. "As the death toll sadly continues to climb, a congressional hearing into this matter would help us identify better ways for government and industry to work together to respond to foodborne illness," DeGette said in a statement. Plaintiffs' law firm Marler Clark has filed a number of lawsuits related to the outbreak. *See Rep. Diana DeGette Press Release,* October 3, 2011*; Marler Clark Press Release,* October 6, 2011.

FTC and Phusion Projects Reach Agreement over Four Loko® Disclosures, Packaging

The Federal Trade Commission (FTC) has entered a 20-year consent order with Phusion Projects, LLC, the maker of Four Loko®, an alcoholic beverage that has generated significant controversy for its "super-size" container and previous inclusion of caffeine, which some allege has led to binge-drinking and adverse health effects. *In re: Phusion Projects, LLC*, No. 112-3084 (FTC). According to an FTC news release, "The marketers of Four Loko have agreed to re-label and repackage the supersized, high-alcohol, fruit-flavored, carbonated malt beverage, to resolve Federal Trade Commission charges of deceptive advertising."

SHB 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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FTC alleged that the company's advertisements, packaging and promotional material misrepresented the amount of alcohol in its products and, in fact, implied that a 23.5-ounce can of the beverage contains the alcohol equivalent of just one or two regular 12-ounce beers. The product actually contains alcohol equivalent to 4.7 regular beers, according to FTC. "As a result, consuming a single can of Four Loko on a single occasion constitutes 'binge drinking,' which is defined by health officials as men drinking five (and women drinking four) or more standard drinks in about two hours."

While Phusion disagrees with FTC's allegations, it has apparently agreed to "clearly and conspicuously" indicate that "This can [or bottle] has as much alcohol as [] regular (12 oz, 5% alc/vol) beers." It has also agreed to offer any flavored malt beverage providing more than 1.5 oz. of ethanol in a resealable container. The consent order, which also proscribes the depiction of any product with more than 1.5 oz. of ethanol "being consumed directly from the container," is subject to court approval. According to a news source, this is the first time that FTC has ordered a beverage maker to express equivalency to the alcohol in "regular beer." *See FTC News Release* and *Advertising Age*, October 3, 2011.

APHIS Proposes Amendments to Bioterrorism Protection Act

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has issued a **proposed rule** that would amend and republish "the list of selected agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products." The Agricultural Bioterrorism Protection Act of 2002 requires APHIS to review the list on a biennial basis and submit revisions as necessary.

Among the criteria APHIS considers when determining the status of an agent or toxin are (i) the effects of exposure on animal or plant health and on the "production and marketability" of an animal or plant product, (ii) the pathogenicity of the agent or toxin, (iii) the ability to treat or prevent any illness caused by the agent or toxin, and (iv) any other factors deemed essential for the protection of animal and plant health. The agency requests comments by December 2, 2011. *See Federal Register,* October 3, 2011.

FDA Issues Draft Proposals on Transparency

The Food and Drug Administration (FDA) has **issued** a **report** as part of a transparency initiative offering eight draft proposals "to make FDA's publicly available compliance and enforcement data more accessible and user-friendly." Based on public comments, an initiative task force will recommend specific draft proposals for FDA Commissioner Margaret Hamburg to consider by January 31, 2012.

In particular, the report recommends that FDA explore (i) "different ways to improve data quality and facilitate more timely data disclosure," (ii) "how to present its compliance and enforcement data graphically and better utilize mobile web

applications," (iii) "whether posting additional data compilations or analysis… would increase transparency," and (iv) "ways to better utilize social media." FDA requests comments by December 2, 2011. *See Federal Register,* October 4, 2011.

FDA Announces 2012-2016 Food and Veterinary Medicine Strategic Plan

The Food and Drug Administration (FDA) recently announced the availability of its draft **Foods and Veterinary Medicine Strategic Plan 2012 – 2016**, which takes into account "all of the activities within the jurisdictions of the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine and includes activities supported by the Office of Regulatory Affairs." According to the executive summary, the Foods and Veterinary Medicine (FVM) Program aims to protect the American food supply by securing high rates of compliance with science-based food safety and labeling standards as well as implementing "integrated, prevention-oriented and risk-based programs."

To this end, the 2012-2016 plan identifies one cross-cutting goal—to "improve effectiveness and efficiency across all levels of the FVM program"—as well as seven program goals: (i) "Establish science-based preventive control standards across the farm-to-table continuum"; (ii) "Achieve high rates of compliance with preventive control standards domestically and internationally"; (iii) "Strengthen scientific leadership, capacity, and partnership to support public health and animal health decision making"; (vi) "Provide accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity"; (v) "Encourage food product reformulation and safe production of dietary supplements"; (vi) "Improve detection of and response to foodborne outbreaks and contamination incidents"; and (vii) "Advance animal drug safety and effectiveness." FDA will accept comments on the draft strategic plan until November 1, 2011.

FDA Releases Fee Guide for Implementation of the Food Safety Modernization Act

The Food and Drug Administration (FDA) has **issued** industry guidance concerning new fee provisions under the Food Safety Modernization Act. The **guidance** aims to provide answers to common questions about FDA's plans for implementing the fees in fiscal year 2012.

In particular, the guidance addresses such topics as fees for import re-inspections and non-compliance of a recall order, and FDA's process for requesting fee reductions. FDA will accept comments at any time. *See Federal Register,* October 6, 2011.

Denmark Taxes Foods High in Saturated Fats

In a move garnering international attention, the Danish government has reportedly approved a new excise tax on butter, cream, cheese, and other foods that contain more than 2.3 percent saturated fat per total weight. According to the

Copenhagen Post, the levy took effect October 1, 2011, and "amounts to a 16 kroner duty per solid kilo of saturated fat," raising the price of a standard butter package to 18 kroner from 15.50 kroner and 500 grams of 45-percent fat cheese to 36 kroner from 34.50 kroner.

This so-called fat tax has already drawn criticism from some retailers and industry groups such as the Danish Agriculture and Food Council, which has estimated the annual cost per family at 1,000 kroner. But the measure has also piqued curiosity abroad, where health advocates are purportedly eager to see whether consumers will alter their diets or pay the higher prices. "It's the first ever fat tax," said one spokesperson for Oxford University's Health Promotion Research Group. "It's very interesting. We haven't had any practical examples before. Now we will be able to see the effects for real." *See the Copenhagen Post,* September 20 and October 4, 2011.

Meanwhile, *New York Times* writer Mark Bittman devoted his October 4, 2011, "Opinionator" column to exploring the logic behind the tax. "By our standards, the Danes aren't even fat: their obesity rate is about nine percent (it could be all that bike-riding), well below the European average of 15 percent and less than a third the rate of Americans," noted Bittman. "More startling, perhaps, is that the tax was introduced by a center-right government that was simply looking for new revenues."

Bittman also surmised that the taxation plan was successful among politicians partly because Danes "do not mind paying taxes as long as they're put to good use" and are more open than Americans to "social engineering." As Jesper Petersen of the Socialist People's Party told Bittman, "It's simply not taboo here. . . . For generations, when we believe something is bad for the population but not so bad that it should be outlawed, we tax it."

Petersen further explained that "seeing the strategy as health-related rather than simply income-generating" leaves the door open for similar taxes on a range of products. "These taxes will work," he was quoted as saying, "and they'll become the trend. Health problems from lifestyle diseases are big in every European country—and even more in the United States—and everyone will be watching us. They'll see that this can help us control health care expenses—which will help us control the economy—and make people healthy and allow them to live longer and better lives. We'll also pressure industry to create products that are healthier."

OEHHA to Consider Inclusion of BPA on Prop. 65 List

The Carcinogen Identification Committee of California EPA's Office of Environmental Health Hazard Assessment (OEHHA) will **meet** October 12-13, 2011, to consider, among other matters, whether bisphenol A (BPA) should be designated as a high priority for preparation of hazard identification materials and further considered for inclusion on the state's list of chemicals known to cause cancer (Prop. 65). Among those filing comments on the proposal are the Polycarbonate/

BPA Global Group of the American Chemistry Council, North American Metal Packaging Alliance, Grocery Manufacturers Association, and Toy Industry Association. They contend that BPA should be designated as a low priority.

OEHHA Proposes Changes to No Significant Risk Level for 4-MEI

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has issued a **notice** indicating that it has changed the proposed regulation establishing a No Significant Risk Level (NSRL) for 4-MEI and augmented the record with additional references.

The new proposed NSRL is 29 micrograms per day, increased from the proposed 16 micrograms per day level. The chemical, 4-Methylimidazole, has been identified as a by-product of fermentation, heating or roasting in certain foods and beverages, such as coffee, some carbonated beverages, beer and wine, soy sauce, molasses, and crackers. Comments are requested by October 24, 2011.

LITIGATION

MDL Court Releases Several Defendants from Egg Products Antitrust Litigation

A federal multidistrict litigation (MDL) court has granted several motions to dismiss in consolidated actions alleging a conspiracy by egg producers and trade associations to restrict the domestic supply of eggs. *In re: Processed Egg Prods. Antitrust Litig.*, MDL No. 2002 (U.S. Dist. Ct., E.D. Pa., decided September 26, 2011). Among other allegations, the plaintiffs contend that the defendants agreed over a period of years to reduce the size of egg-laying flocks and require larger cages to reduce overall hen densities as part of an alleged collective plan to keep egg prices high.

In their motions to dismiss, the defendants argued that while the second amended complaint alleged sufficient facts to support the antitrust conspiracy claim as to some of the defendants, "the pleading is deficient with respect to each of the movants by failing to allege facts that they specifically were parties to the conspiracy." Examining each motion in turn, the court dismissed the claims as to four defendants, but denied the motions to dismiss filed by the remainder. The dismissal was without prejudice to allow the plaintiffs the opportunity to amend their complaint. Additional details about the case appear in **Issue 352** of this *Update*.

Court Finds Honey Importers Improperly Served, Quashes Summonses

A federal court in Illinois has determined that the government did not allege facts sufficient to pierce the corporate veil of related U.S. and foreign corporations and thus could not bring the foreign corporations before the court on charges of avoiding $80 million in customs duties on honey imported into the United States

between 2002 and 2009. *United States v. Alfred L. Wolff GMBH*, No. 08 CR 417 (U.S. Dist. Ct., N.D. Ill., E. Div., decided September 26, 2011).

A federal grand jury indicted the foreign defendants and a U.S. corporate entity on 44 counts in August 2010. The U.S. entity's attorneys voluntarily accepted service on its behalf and on behalf of its parent and then appointed, via a shareholder resolution, a limited-authority corporate representative to appear before the court and enter a not-guilty plea for the U.S. defendants. This representative did so, and, immediately after the arraignment, the government served the representative with summonses for each of the foreign defendants. They moved to quash the summonses, and the court obliged, finding that the government could not effect service of the foreign defendants this way. According to the court, "Nothing in the indictment, in Special Agent Gauder's affidavit, or in the materials filed under seal by the government, suggests that any of the Foreign ALW Defendants formed ALW USA 'to perpetrate a fraud on the United States,' as the government now contends."

Biscotti Maker Targeted in "All Natural" Lawsuit

California residents have filed a putative class action against Nonni's Foods, LLC, alleging that the company falsely represents its "All Natural" biscotti products by failing to disclose that ingredients, such as cocoa processed with alkali, glycerin, monocalcium phosphate, and diglycerides, are synthetic. *Larsen v. Nonni's Foods, LLC*, No. 11-4758 (U.S. Dist. Ct., N.D. Cal., filed September 23, 2011). Seeking to certify a nationwide class and statewide subclass, the plaintiffs allege common law fraud; unlawful, unfair and fraudulent business practices; false advertising; and violation of the state's Consumers Legal Remedies Act.

They request restitution; compensatory, statutory and punitive damages; declaratory and injunctive relief; attorney's fees; costs; interest; and an accounting and imposition of a constructive trust on money the company received as a result of its conduct. The plaintiffs essentially contend that they did not receive the benefit of their bargain when purchasing the product and "lost money as a result in the form of paying a premium for Nonni's biscotti because it was purportedly all natural."

Certified Organic Beef Ranchers Sue Government for Herbicide Spraying

Alleging that a government contractor sprayed an herbicide on their property as part of transmission-line maintenance, the owners of a state-certified organic beef farm in Skagit County, Washington, have sued the U.S. government and the contractor for damages incurred by the contamination of their property. *Benson v. United States*, No. 11-01619 (U.S. Dist. Ct., W.D. Wash., Seattle, filed September 28, 2011). According to the complaint, the plaintiffs have a contract with the government "with regards to all maintenance on the power lines and providing recovery of any resulting damages." In 2008, the plaintiffs were allegedly notified that spraying would take place, and they spoke with a government representative explaining that their property could not be sprayed. They were allegedly assured

that this would be noted in the paperwork and that no herbicide would be sprayed on their property.

Despite the assurances and despite a "no spray" sign on the access gate to the plaintiffs' property, herbicide was sprayed on the property in 2009. They claim that they had to sell their existing herd on the regular market, which resulted in insufficient income "to pay off the operating capital loan needed to run the farm in 2009." They also allegedly lost a contract for the purchase of 100 cows per year for ten years. The contamination of 2½ acres of their ranch also purportedly required the plaintiffs to preserve the remaining cattle that had not been exposed, "which resulted in the loss of use of approximately 60 acres of their farmland for three years following contamination."

Alleging negligence, strict liability, nuisance, breach of contract, intentional interference with business expectancy, statutory waste and damage to land and property, and common law trespass, the plaintiffs seek damages for emotional distress; loss of reputation, credibility and brand; special damages including past and future lost earnings and profits; increased expenses; and property damages. They also request permanent injunctive relief, treble damages, costs, attorney's fees, and interest.

Greek Yogurt Company Challenges Denial of Trademark Registration

Fage Dairy Processing Industry, S.A. has filed a lawsuit seeking to overturn the Trademark Trial and Appeal Board's refusal to register the yogurt maker's "Fage Total" trademark and a declaration that its use of the mark does not infringe any claimed right of General Mills, which makes Total® breakfast cereals. *Fage Dairy Processing Indus., S.A. v. General Mills, Inc.*, No. 11-01174 (U.S. Dist Ct., N.D.N.Y., filed September 30, 2011). According to the complaint, the board's ruling is replete with factual errors. The complaint also asserts that Total® cereal and Fage Total yogurt co-existed in U.S. markets for 13 years "without a single instance of actual confusion arising from the parties' use of their respective marks." Fage alleges that the defendants, "suddenly and without warning" brought a federal trademark infringement lawsuit against it in mid-September, "seeking draconian damages." That suit was apparently filed two days after the board refused to register Fage's marks.

Artist Claims "Beautiful Blonde" Ale Maker Infringed Her Copyright

A woman who allegedly created a design for Knee Deep Brewing Co. to use on its beer tap handles has sued the company for breach of contract and copyright infringement after they could not apparently come to terms over a price for her design and the company began using a similar design on its product labels. *Sylvers v. Knee Deep Brewing Co., LLC,* No. 11-00714 (U.S. Dist. Ct., D. Nev., filed October 4, 2011). The disputed design is purportedly being used on the company's "Beautiful Blonde" Ale; it features a woman posing before a panorama of downtown Reno, Nevada, with mountains in the background. The plaintiff, who allegedly registered the "Girl Over Reno" design with the U.S. Copyright Office, seeks preliminary and

permanent injunctive relief, compensatory damages and restitution, interest, costs, and attorney's fees.

Nicaraguan DBCP Exposure Claims Settled by Dole

Dole Food Co. has reportedly signed a definitive settlement agreement that could conclude five U.S. lawsuits and 33 lawsuits filed in Nicaragua by banana plantation workers purportedly exposed to the agricultural chemical DBCP (1,2-Dibromo-3-chloropropane). At stake are potential alleged damages in excess of $9 billion. According to Dole's October 3, 2011, news release, the company "will not fund the settlement by making any payments until specific conditions are satisfied, including receiving a signed release from each plaintiff, dismissals of cases and judgments, and a good faith settlement determination by the Los Angeles Superior Court that is presiding over four of the U.S. cases."

Insurer Seeks Declaration in Coverage Dispute over Diacetyl Litigation

Arch Specialty Insurance Co. has filed a declaratory judgment action in a New York state court against a company identified as a distributor of food product ingredients, including the butter-flavoring chemical diacetyl. *Arch Specialty Ins. Co. v. Citrus & Allied Essences, Ltd.*, No. 652670/2011 (N.Y. Sup. Ct., N.Y. County, filed September 29, 2011). The insurance company contends that it has no obligation to defend or indemnify the defendant in the personal injury actions "asserted by numerous claimants against Citrus & Allied in several jurisdictions around the country."

Among other matters, the insurer claims that the events giving rise to the underlying claims did not occur during the policy period; the claims involve "damages or injuries which were expected, intended or non-fortuitous from the standpoint of Citrus & Allied"; the claims fall within a pollution exclusion clause or arise from a recall as defined by the policy; and the insured failed to timely notify the carrier about the underlying claims. The personal injury actions referred to in the complaint involve the claims of food-industry workers who have alleged that occupational exposure to diacetyl caused a debilitating lung injury, bronchiolitis obliterans, often referred to as "popcorn lung."

ELF Sues Food and Beverage Companies for Lead in Products for Babies

An environmental and public-health advocacy organization has filed a Proposition 65 lawsuit against numerous food and beverage producers in a California state court, alleging failure to warn the public that their baby and toddler foods and fruit juices contain lead, a chemical known to the state to cause reproductive toxicity or cancer. *Envtl. Law Found. v. Beech-Nut Nutrition Corp.*, No. 11597384 (Cal. Super. Ct., Alameda County, filed September 28, 2011). Alleging one count of violating Proposition 65, the plaintiff seeks injunctive relief and civil penalties of $2,500 per day for each violation of the law, as well as attorney's fees and costs. According to the complaint, the plaintiff notified the companies about the alleged violation in 2010

and provided the required notice to the state attorney general, who is not apparently prosecuting an action involving this claim.

OTHER DEVELOPMENTS

Center for Food Safety Petitions FDA for GE Food Labels

The Center for Food Safety (CFS) has filed a **legal petition** on behalf of the "Just Label It" campaign with the Food and Drug Administration (FDA), "demanding that the agency require the labeling of all food produced using genetic engineering [GE]." Representing health-care, consumer, agricultural, and environmental organizations, the campaign has urged the public to submit comments on the petition to FDA and to question why GE foods are patented for novelty but remain unlabeled.

The petition specifically calls on FDA to rescind its 1992 Statement of Policy: Foods Derived from New Plant Varieties, which evidently determined that GE foods do not require special labeling because they "are substantially equivalent to foods produced through conventional methods." Instead, the petitioners want FDA to issue "a new policy declaring that a production process is 'material' under FFDCA [the Federal Food, Drug and Cosmetic Act] section 201(n) if it results in a change to a food at the molecular or genetic level because a significant share of consumers would find it relevant to their purchasing decisions."

According to the petition, which cites scientific studies and court rulings related to Bt (*Bacillus thuringiensis*) corn and the presence of growth hormone in cow's milk, unlabeled GE foods have misled consumers by failing to "differentiate foods with known health properties from novel foods with unknown health consequences." The petition also argues that FDA has "supplemental statutory authority" under the National Environmental Policy Act (NEPA) to require GE labeling on environmental grounds, including "transgenic contamination of natural crops and the wild, and massive increases in pesticide use."

"FDA's current policy uses 19th century rationale for a 21st century issue, leaving consumers in the dark to hidden changes to their food," said CFS Executive Director Andrew Kimbrell in an October 4, 2011, press release, which claims that 90 percent of Americans desire GE food labels. "It is long overdue that FDA acknowledge the myriad reasons [GE] foods should be labeled and label these novel foods once and for all."

"Pinkwashing" on Advocacy Organization's Agenda

According to a Citizens for Health alert, certain food companies are engaging in what the advocacy organization characterizes as "pinkwashing," that is, supporting breast cancer action and initiatives while making and selling products purportedly posing cancer risks. The alert is based on an **article** recently appearing in *Marie Claire*. Titled "The Big Business of Breast Cancer," the article contends, "Breast cancer has made a

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lot of people very wealthy." While the article focuses on charities that may spend more on overhead and salaries than for breast cancer research or support for patients, it also suggests avoiding "pink-ribbon merchandise." Among the questions the article proposes asking before contributing to or purchasing a "pink" branded product is whether the product itself is "contributing to the breast cancer epidemic."

Manufacturer Recalls 400 Tons of Soy Flour over *Salmonella* Concerns

Thumb Oilseed Producers' Cooperative has reportedly recalled nearly 400 tons of soybean flour and soy meal used in human food and animal feed due to possible *Salmonella* contamination. According to a press release posted on the Food and Drug Administration's Website, "[t]he recalled soybean flour and meal was distributed to a limited group of wholesale customers" in Canada, Illinois, Minnesota, New Hampshire, Pennsylvania, Vermont, and Wisconsin between November 2010 and September 2011. While no illnesses have apparently been linked to the potentially contaminated products, "[t]he recall resulted from routine sampling conducted by the company and US Food and Drug Administration (FDA) which revealed the bacteria in finished product and the manufacturing environment." *See Thumb Oilseed Press Release*, October 4, 2011.

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