ISSUE 404 | AUGUST 5, 2011

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Warns CytoSport About Muscle Milk® Product Labels

Less than two weeks after a consumer fraud class action was filed in California against the company that makes Muscle Milk® beverages and protein bars, the Food and Drug Administration (FDA) sent a **letter** to its CEO warning that the products are misbranded because their labels either prominently feature the word "milk" without containing any or state that they contain no milk while made of milk-derived ingredients. The letter also warns that health-related claims or "0 *trans* fat" assertions are unauthorized because the products contain too much fat or too much saturated fat. The June 29, 2011, letter demands a response within 15 days of receipt. Additional information about the lawsuit appears in **Issue 403** of this *Update*.

According to a news source, CytoSport has indicated that it is "proactively and openly addressing the FDA's labeling concerns" and also notes, "Concerns like this have been raised before when the dairy lobby complained that other industries or products like Soy Milk, Almond Milk, Coconut Milk and Rice Milk are using the name 'milk' in connection with a product other than fluid dairy milk, all of which appeal to lactose intolerant consumers just as Muscle Milk does." Meanwhile, a dairy industry spokesperson reportedly said, "We are gratified that the FDA has finally gotten off its duff and done something with respect to at least one product." *See* (Milwaukee) *Journal Sentinel*, July 31, 2011.

FDA Deems Lazy Larry® Brownies Adulterated Under Federal Law

The Food and Drug Administration (FDA) has **warned** the company that makes Lazy Larry® brownies containing melatonin that they are adulterated under federal law.

According to FDA, "Your 'Lazy Larry' product is represented for use as a conventional food, and accordingly is not a dietary supplement." The company apparently uses the term "dietary supplement" in the product's "statement of identity" and a "Supplement Facts" panel for its nutrition labeling. FDA

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contends that these statements do "not make your product a dietary supplement," because it is marketed alongside snack foods, its Website refers to the product as a conventional food, and the appearance and packaging make the product look like a brownie.

Noting that the agency "is not aware of data to establish the safety of melatonin for use as an ingredient in conventional foods" and that "reports in the scientific literature have raised safety concerns about the use of melatonin," FDA warns the company that failure to correct the violation could result in "seizure of the illegal products and injunctions against manufacturers and distributors of those products." According to a news source, melatonin, a naturally occurring hormone, can make people who use it sleepy. The owner of a Florida smoke shop that sells the product to consumers older than 18 only reportedly objected to a outright ban on the product, noting that its label indicates that it is not suitable for children. "They restrict certain ages to buy alcohol so they should maybe do something like that with the Lazy Cakes," he said. *See cfnews13*, August 2, 2011.

"Gluten-Free" Food Labeling Proposal Reopened for Additional Comment

The Food and Drug Administration (FDA) has **reopened** the comment period for its proposed "gluten-free" food labeling rule. Originally published in January 2007, the proposed rule would have defined the term "for voluntary use in the labeling of foods, to mean that the food does not contain an ingredient that is any species of wheat, rye, barley, or a crossbred hybrid of these grains (collectively referred to as 'prohibited grains'); an ingredient that is derived from a prohibited grain and that has not been processed to remove gluten (*e.g.*, wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food; or 20 ppm or more gluten."

FDA seeks comments on a report titled "Health Hazard Assessment for Effects of Gluten Exposure in Individuals with Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten," and whether the assessment should affect the proposed definition of "gluten-free" in the final rule. According to the agency, the less than 20 ppm tolerance level was based, in part, on available methods of detection. An agency spokesperson said, "Before finalizing our gluten-free definition, we want up-to-date input from affected consumers, the food industry, and others to help assure that the label strikes the right balance." Comments are requested by October 3, 2011. *See FDA News Release*, August 2, 2011; *Federal Register*, August 3, 2011.

FSMA Fees and Burdens on Small Business on FDA Docket

The Food and Drug Administration (FDA) has issued a notice and request for comments about fiscal year 2012 fees under the Food Safety Modernization Act (FSMA). The **fee rates**, intended to "capture 100 percent of the costs of

each activity," will be assessed for facility reinspections, recalls and importer reinspections. If no foreign travel is required, the rate will be $224 per hour, and if foreign travel is required, the fee increases to $335 per hour. While a separate schedule has not been established for small businesses, FDA indicates that it will waive the fees "in limited cases . . . based on a severe economic hardship, the nature and extent of the underlying violation, and other relevant factors."

FDA has also **established** a docket "to obtain information that will be used to formulate a proposed set of guidelines in consideration of the burden of fee amounts on small business, as set forth in the FDA Food Safety Modernization Act (FSMA)." The agency is requesting public comment on the burdens "these fees impose on small business, and whether and how the Agency should alleviate such burdens." Specifically requested are comments on whether the fees should be reduced for small business and how to define small business. Comments must be submitted by October 17, 2011. *See Federal Register*, August 1, 2011.

FSIS Issues Health Alert for Ongoing *Salmonella* Outbreak

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has issued a **public health alert** "due to concerns about illnesses caused by *Salmonella* Heidelberg that may be associated with the use and consumption of ground turkey." According to FSIS, an epidemiological investigation led by the Centers for Disease Control and Prevention (CDC) and state health departments has linked an estimated 77 illnesses in 26 states to a Springdale, Arkansas, plant operated by Cargill Meat Solutions Corp., which voluntarily recalled 36 million pounds of ground turkey produced between February 20 and August 2.

"The outbreak strain of *Salmonella* Heidelberg is resistant to several commonly prescribed antibiotics; this antibiotic resistance may increase the risk of hospitalization or possible treatment failure in infected individuals," stated an August 4, 2011, CDC **investigation update**. "Consumers should check their homes for recalled ground turkey products and not eat them; restaurant and food service operators should not serve it."

NOP Allows Continued Use of 12 Substances in Organic Production

The U.S. Department of Agriculture's National Organic Program (NOP) has issued a **final rule** renewing exemptions for 12 substances on the National List of Allowed and Prohibited Substances, which governs the use of synthetic and nonsynthetic ingredients in organic production and handling. After reviewing public input, the National Organic Standards Board recommended renewals for the follow substances set to expire in September 2011: (i) ferric phosphate and hydrogen chloride (synthetic substances used in organic farming); (ii) egg

white lysozyme, L-Malic acid and microorganisms (nonsynthetic, nonorganic substances used as ingredients and in processed organic products); and (iii) activated charcoal, cyclohexylamine, diethylaminoethanol, octadecylamine, peracetic acid/peroxyacetic acid, sodium acid pyrophosphate, and tetrasodium pyrophosphate (synthetic, nonorganic substances used as ingredients and in processed organic produces). The final rule becomes effective September 12, 2011.

California Governor Signs Caffeinated Beer Beverage Ban

California Governor Jerry Brown (D) has signed a bill (**S.B. 39**) prohibiting the importation, production and sale of caffeinated beer beverages in retail establishments throughout the state. Effective January 1, 2012, the legislation provides, in part, "Beer to which caffeine has been directly added as a separate ingredient shall not be imported into this state, produced, manufactured, or distributed within this state, or sold by a licensed retailer within this state." The prohibition does not apply to beer brewed with coffee or other naturally caffeinated ingredients.

Calling caffeinated beer beverages "a threat to public health," bill sponsor Senator Alex Padilla (D-Pacoima) said the measure was adopted in response to several incidents involving underage drinkers hospitalized for alcohol overdoses after consuming caffeinated beer, which is typically packaged in large containers and has sweet, fruity flavors. "The added caffeine masks the effects of the high alcohol content, which can lead to binge drinking and dangerous behavior," Padilla said, noting that a single caffeinated beer beverage has been compared to drinking five cans of beer and one cup of coffee. California apparently joins Kansas, Massachusetts, Michigan, New York, Utah, and Washington in banning such drinks. *See Sen. Alex Padilla News Release*, August 1, 2011.

LITIGATION

Litigation Schedule Filed in Challenge to RoC Styrene Listing

If a D.C. federal court agrees to the unopposed litigation schedule filed in late July by the Styrene Information and Research Center, a decision about whether the Department of Health and Human Services (HHS) properly added styrene to its list of possible carcinogens could be reached early in 2012. *Styrene Info. & Research Ctr., Inc. v. Sebelius*, No. n/a (U.S. Dist. Ct., D.D.C., filed June 10, 2011). The industry trade group contends that the HHS National Toxicology Program (NTP) process that concluded with a determination to add the substance, which is used in plastic and foam food service packaging, to the 12th Annual Report on Carcinogens (RoC) was flawed, arbitrary and capricious, an abuse of discretion, and not in accordance with the law.

The center seeks the removal of styrene from the RoC. In its complaint for declaratory and injunctive relief, the center alleges that NTP's scientific advisory panel members ignored studies showing no causal connection between styrene exposure and cancer, substituted their own data and analyses instead of conducting a required peer review and finalized the panel's expert report before the public comment period closed. The center cites a number of other governmental findings, both domestic and international, indicating that styrene is either a "weak human carcinogen" or "possibly carcinogenic to humans." Such findings, according to the center, do not warrant styrene's RoC listing as "reasonably anticipated to be a human carcinogen." The court reportedly denied the center's request for a preliminary injunction on July 5. *See Greenwire*, August 4, 2011.

Federal Court Upholds Some Claims in BOOST Kid Essentials® Putative Class Actions

A federal court in New Jersey has determined that Pennsylvania and California residents may pursue claims against New Jersey-based Nestlé Healthcare Nutrition, Inc. in consolidated putative class actions alleging that the company's BOOST Kid Essentials® beverage did not provide its advertised health benefits for children. *Scheuerman v. Nestlé Healthcare Nutrition, Inc.*, No. 10-3684; *Johnson v. Nestlé Healthcare Nutrition, Inc.*, No. 10-5628 (U.S. Dist. Ct., D.N.J., decided August 1, 2011) (unpublished). So ruling, the court granted in part and denied in part Nestlé's motion to dismiss.

While the court ruled that the California plaintiff may not bring a cause of action under the New Jersey Consumer Fraud Act (NJCFA), because the defendant's presence in the jurisdiction alone is insufficient under conflict-of-law rules to apply the state's law, the court did give the California plaintiff the opportunity to amend her complaint to allege consumer fraud under California law. Because the Pennsylvania plaintiff alleged that he sometimes purchased the product in New Jersey and because he sufficiently pleaded the elements of his NJCFA claims, the court allowed him to pursue those claims. The court also determined that the plaintiffs sufficiently pleaded breach of warranty to proceed with that claim. Nestlé apparently failed to adequately address the negligent misrepresentation claims in its motion, so the court allowed that claim to proceed as well, subject to "an appropriately timed summary judgment motion."

Fruit Juice Makers Seek Dismissal of MDL Lead-Content Suits

A number of fruit juice manufacturers have filed a motion to dismiss the multidistrict litigation (MDL) consumer fraud lawsuits pending in a Massachusetts federal court. *In re: Fruit Juice Prods. Mktg. & Sales Practices Litig.*, MDL No. 2231 (U.S. Dist. Ct., D. Mass, W. Div., motion filed July 29, 2011). The lawsuits, involving plaintiffs from California, Colorado, Florida, and Massachusetts,

allege violations of state consumer protection laws, breach of warranty and unjust enrichment in the sale and promotion of fruit juices purportedly containing lead. The motion asserts that the plaintiffs lack standing because they "have suffered no economic injury," their pleadings do not allege facts showing a plausible injury, the Nutrition Labeling and Education Act preempts the claims, the suits were brought "under the laws of states in which Plaintiffs do not live and did not purchase any of Defendants' products," and the plaintiffs have failed to state any claim under the laws of their home states.

Pesticide Drift over Organic Fields May Constitute Actionable Trespass

A Minnesota appellate court has ruled, as a matter of first impression, that "a trespass action can arise from a chemical pesticide being deposited in discernable and consequential amounts onto one agricultural property as the result of errant overspray during application directed at another." ***Johnson v. Paynesville Farmers Union Coop. Oil Co.*, Nos. A10-1596 and -2135 (Minn. Ct. App., decided July 25, 2011)**.

The plaintiffs were organic farmers who alleged that the defendant, a commercial pesticide applicator, repeatedly sprayed adjacent farms on windy days, in violation of the law, resulting in contamination of their crops from drifting chemicals. Despite the plaintiffs' specific requests that the defendant avoid overspraying pesticide onto their fields when treating adjacent fields, the defendant contaminated their crops in 1998, 2002, 2005, 2007, and 2008, causing them to sell their products at lower prices or destroy some crops, and forcing them to take acreage out of production for three years following each incident to comply with National Organic Program (NOP) regulations. Alleging trespass, nuisance and negligence per se, the plaintiffs sought damages and injunctive relief.

The trial court initially granted a request for temporary injunction, but then dismissed the claims on the merits, vacated the temporary injunction and denied requests for permanent injunction and to amend the complaint. The appellate court reversed and remanded.

According to the court, the lower court misread an opinion that did not allow odor claims to be pursued under a trespass theory. The plaintiffs here "do not claim trespass based on transient odors. Instead, they primarily complain that the liquid chemicals that the cooperative sprayed into the air from neighboring fields drifted, landed, and remained on the Johnson's organic crops in detectable form, contaminating them. And while wafting odors will not affect the composition of the land, a liquid chemical pesticide or herbicide being sprayed for agricultural purposes will; by design, it descends and clings to soil or plants, killing organisms."

The court also determined that the lower court misconstrued the organic-certification regulation when it ruled that the plaintiffs failed to present sufficient evidence of damages caused by the drift. According to the court, even if pesticide residues show less than 5-percent contamination (EPA's tolerance standard), a certifying agent could decide not to certify a field as organic because any noncompliance with NOP requirements can lead to a revocation or suspension of certification. The operative regulation requires that crops labeled and sold as "organic" be produced from fields that have had "no prohibited substances . . . applied to [them] for a period of 3 years immediately preceding harvest of the crop."

Challenge to Humane Livestock Slaughter Law Dismissed

An intermediate appellate court in Washington has affirmed the dismissal of a lawsuit challenging part of a state law requiring the humane slaughter of livestock. *Pasado's Safe Haven v. Washington*, No. 64452-1-I (Wash. Ct. App., decided July 25, 2011). The plaintiff, an animal rights advocacy organization, challenged that part of the statute which included within the "humane method" definition "a method in accordance with the ritual requirements of any religious faith whereby the animal suffers loss of consciousness by anemia of the brain…" Also challenged was a provision stating that "Nothing in this chapter shall be construed to prohibit, abridge, or in any way hinder the religious freedom of any person or group."

The court ruled that the plaintiff had not presented a justiciable claim because the court could not strike just part of the statute without bringing "about a result that our legislature 'never contemplated nor intended to accomplish.'" According to the court, striking one of just two methods allowed for the slaughter of livestock "would fundamentally alter the statute's meaning." The plaintiff did not ask for the entire statute to be stricken, thus, the court determined that "regardless of our resolution of the merits of the various challenges made, at the end of this case the status quo would necessarily prevail. Our opinion would be nothing more than an advisory one."

OTHER DEVELOPMENTS

Industry Groups Concerned About Efforts to Stop FDA's Review of GE Salmon

A coalition of 38 industry organizations has sent a **letter** to U.S. House and Senate leaders urging Congress to allow the Food and Drug Administration (FDA) to complete its review of an application for genetically engineered (GE) salmon.

The coalition's letter comes on the heels of a recent House-approved appropriations amendment that prohibits FDA from using money in fiscal year 2012

to finalize its review of AquaBounty Technologies' application to produce fast-growing GE Atlantic salmon and the efforts of a bipartisan group of congressional lawmakers to halt the application's approval process.

According to the "Animal Agriculture Coalition," if it the amendment becomes law, FDA's ability to process such applications using best-available science would be diminished, damaging the agency's credibility "at home and overseas." Coalition members include the Biotechnology Industry Organization (BIO), whose president and CEO was quoted as saying that "disrupting FDA's science-based assessment process based on non-scientific political concerns would set a dangerous precedent in our country." *See BIO Press Release*, August 3, 2011.

CSPI Targets Serving Sizes in Letter to FDA

The Center for Science in the Public Interest (CSPI) recently sent a letter to Food and Drug Administration (FDA) Commissioner Margaret Hamburg urging the agency to act on an April 2005 advance notice of proposed rulemaking (ANPR) related to serving-size regulations. According to the letter, CSPI first responded to the ANPR by asking FDA to (i) "take enforcement action against manufacturers that mislabel products as multiple servings when they are typically consumed in one eating occasion," and (ii) "initiate a rulemaking proceeding to revise the Reference Amounts Currently Consumed ('RACC') regulations to reflect consumption patterns that have developed since the data were collected" in the 1970s. In particular, the consumer watchdog has singled out canned soup, ice cream, coffee creamer, and aerosol non-stick cooking sprays as bearing "unrealistic" serving-size labels that "understate the calories, sodium and saturated fat consumers are likely to get from those products."

"Given the prevalence of hypertension, heart disease, and stroke in America, we need accurate food labels that would ensure that consumers would really know what they're likely to consume," said CSPI Executive Director Michael Jacobson in an August 2, 2011, press release, which noted that FDA is currently reviewing serving sizes as part of broader food label revisions. "The FDA should define serving sizes to reflect what consumers actually eat, as the law requires, not what the soup industry pretends that they eat."

China Cracks Down on Food Producers in Major Food Safety Campaign

According to a news source, Chinese officials have arrested about 2,000 people and shut down almost 5,000 food production facilities since April 2011, in an effort to stop the industry's use of illegal food additives. The initiative apparently followed scandals involving pork so full of bacteria that it allegedly glowed in the dark and milk laced with melamine that led to the deaths of least six infants and sickened more than 300,000 in 2008. The

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Chinese government claims that nearly 6 million food businesses have been inspected and "underground" food production and storage sites destroyed. *See Agence France Presse*, August 4, 2011.

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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.