Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

FDA Rule Requires Color Additive Information on Animal Food Labels

The Food and Drug Administration (FDA) has issued a **final rule** requiring animal and pet food labels to list "the common or usual names" of any certified color additives used in the products. Issued in response to the Nutrition Labeling and Education Act of 1990, the final rule brings animal food labeling in line with current human food regulations by adding "paragraph (k) to the animal food labeling regulations at § 501.22 (21 CFR 501.22)."

The first part of paragraph (k) explains that any FDA-certified color additive used in animal foods "must be declared in the ingredient list" under the name listed in 21 CFR part 74 or 21 CFR part 82, although manufacturers are permitted to "parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name." In addition, the new rules require that the term "Lake" be included "in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake)."

The second part of paragraph (k) details the language permitted for color additives exempt from FDA certification. These additives may be declared on animal food labels as (i) "'Artificial Color,' 'Artificial Color Added,' or 'Color Added' (or by an equally informative term that makes clear that a color additive has been used in the food)"; or (ii) "'Colored with _____' or '_____ color,' the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter." The final rule takes effect November 18, 2013.

FSIS Schedules Codex Meeting on Animal Feed Contaminants

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **announced** a January 18, 2012, public meeting in Washington, D.C., to consider draft U.S. positions to be presented during the 6th session of the Ad Hoc Intergovernmental Task Force on Animal Feeding of the Codex Alimentarius Commission on February 20-24 in Berne, Switzerland. The January agenda includes discussion of draft risk assessment guidelines for feed and a proposed list of feed hazards. *See Federal Register,* November 17, 2011.

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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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State AGs Provide Comments on FTC/Phusion Projects Settlement

The attorneys general of a number of states have submitted a **comment** to the Federal Trade Commission (FTC) taking issue with several aspects of a proposed settlement agreement with the company that makes the caffeinated alcoholic beverage Four Loko®. Additional information about the proposed settlement appears in Issue **412** of this *Update*.

Attached to the November 16, 2011, letter are numerous Facebook comments by individuals who apparently "like" various Four Loko® photos, press announcements and news items. The AGs express their concern that FTC will allow Phusion "to market as much as 2.5 servings of alcohol (1.5 oz of ethanol) as if it were one serving and avoid the Order's requirements for label disclosure and resealability, and its prohibition against depicting consumption directly from the can. By condoning the marketing of 'single serving' FMBs [flavored malt beverages] with 2.5 servings of alcohol, the Order would undermine federal guidelines for moderate drinking." They also request that FTC define "resealable" and undertake a study after the order is finalized on "the impact of the label disclosure."

According to the AGs, if an alcohol product is labeled with a disclosure that it contains "as much alcohol as [x] regular (12 oz, 5% alc/vol) beers," given the current lack of data, it is unknown how such disclosures will "influence the purchasing and consumption decisions of [Four Loko] consumers." Quoting some of the Facebook statements attached to the letter, the AGs note that these consumers self-report excessive alcohol consumption and "an intent to consume the product to become intoxicated." Thirty-four state AGs, the AGs of Guam and the Northern Mariana Islands, as well as the city attorney of San Francisco signed the letter.

Congress Blocks USDA's Proposed School Lunch Rules, Boosts FDA Food Safety Budget

Congress has approved and President Barack Obama (D) has signed a bipartisan agricultural spending bill (**H.R. 2112**) that will block or delay regulations aimed at making school lunches healthier.

Signed into law on November 18, 2011, the bill will, among other things, prohibit the U.S. Department of Agriculture (USDA) from limiting starchy vegetables, such as potatoes, to two servings a week and will continue to allow two tablespoons of tomato paste to count as a vegetable. It will also require further study of USDA's long-term sodium reduction requirements that would reduce by half the amount of sodium in school meals over the next 10 years.

Although some lawmakers claim that the bill will prevent costly regulations and provide school districts greater flexibility in improving the quality of school meals, critics assert that it will keep schools from serving an array

of vegetables while allowing foods such as french fries to remain regular menu items. "It's a shame that Congress seems more interested in protecting industry than protecting children's health," said Center for Science in the Public Interest Policy Director Margo Wootan in a November 15, 2011, statement. "At a time when child nutrition and childhood obesity are national health concerns, Congress should be supporting USDA and school efforts to serve healthier school meals, not undermining them."

In a related development, Congress increased the Food and Drug Administration's budget by an extra $50 million to help implement the Food Safety Modernization Act and bioterrorism countermeasures. The bill appropriates $334 million more than the House approved in June. *See Associated Press,* November 15, 2011; *Food Safety News,* November 16, 2011.

California Food Safety Officials Recall Raw Milk for *E. Coli*

The California Department of Food and Agriculture (CDFA) has **issued** a statewide recall and quarantine order for raw or unpasteurized milk products implicated in five cases of *E. coli* O157:H7. According to CDFA, the recall includes raw milk, raw butter, raw cream, raw colostrum, and a raw product called "Qephor" produced by Fresno-based Organic Pastures dairy, which is barred from selling these items "until further notice."

"While laboratory samples of Organic Pastures raw milk have not detected *E. coli* O157:H7 contamination, epidemiologic data… links [sic] the illnesses with Organic Pastures raw milk," states a November 15, 2011, CDFA press release explaining that the five known cases apparently involved children whose only common food exposure was unpasteurized milk. The agency has also started "a complete inspection at Organic Pastures dairy—of all facets of operations, from the cows to the bottling plant," where the quarantine will only be lifted once the facility meets "all sanitation requirements under the state law."

LITIGATION

Nutella® False Ad Suits to Proceed as Statewide Class Action

A federal court in California has entered an order certifying a class in consolidated lawsuits alleging that the company which produces Nutella® falsely advertises its product as healthy and beneficial to children despite making the hazelnut spread with "dangerous levels of fat and sugar." *In re Ferrero Litig.*, No. 11-205 (U.S. Dist. Ct., S.D. Cal., decided November 15, 2011). The court limited the class to California consumers, agreeing with the defendant that California law could not be applied to the claims of non-California class members who neither saw the advertisements nor purchased the product in the state. Because the defendant is a Delaware corporation that does business

from its New Jersey headquarters and the product is made in Canada, the non-California class members would also have been unable to show that their claims arose out of conduct that occurred in California.

The court refused to certify an 11-year class, noting that nationwide TV ads for Nutella® began airing in August 2009, and that the statute of limitations for several of the class claims is three years. Accordingly, the court concluded that "the appropriate class period start date is August 2009." Considering whether common issues predominate over individual ones, the court rejected the defendant's contention that the case "involves class members' individual expectations, dietary preferences, nutritional knowledge, and imperfect substitutes in the market," but indicated that these issues may prove relevant to the merits of the case. In this regard, the court stated, "Plaintiffs present sufficient facts to show that all of the class members' claims share a common contention: namely, that Defendant made a material misrepresentation regarding the nutritious benefits of Nutella®" that violated state consumer fraud laws.

First Wave of Settlement Checks Distributed in *Salmonella*-Tainted Egg Outbreak

Attorneys involved in the settlement of injury claims linked to *Salmonella*-contaminated eggs traced to Wright County Egg in Iowa have reportedly told *The Associated Press* that the first checks, issued by the egg producer's insurer, are on their way to the first of dozens of individuals sickened during the 2010 outbreak. Among the first wave of legal settlements are six-figure checks issued on behalf of several children. Although most of the settlement's terms are confidential, a federal judge in Iowa apparently approved deals in open court on November 10, 2011, totaling $366,000 for three children residing in California, Iowa and Texas. Because they were hospitalized, they are receiving higher amounts than those not as seriously stricken. *See MSNBC.com,* November 16, 2011.

Putative Class Disputes King Arthur's "All Natural" Product Claims

Seeking to certify a nationwide class of consumers, a California resident has filed consumer fraud claims against a company that makes numerous breakfast-, dessert- and bread-mix products promoted as "All Natural," while containing purported synthetic ingredients, such as ascorbic acid, disodium phosphate, potassium carbonate, and sodium acid pyrophosphate. *Larsen v. King Arthur Flour Co., Inc.*, No. 11-5495 (U.S. Dist. Ct., N.D. Cal., filed November 14, 2011). The complaint focuses on 64 specific products carrying "All Natural" labels and identifies which alleged synthetic ingredient is contained in each. The plaintiff alleges that she "did not receive the 'All Natural' baking mixes she bargained for . . . and has lost money as a result in the form of paying a premium for King Arthur's Mixes because they were purportedly all natural rather than paying the lesser amount for non-natural alternatives."

The complaint, which also seeks to certify a sub-class of California consumers, alleges common law fraud; unlawful, unfair and fraudulent business practices under California's unfair competition law; statutory false advertising; violation of California's Consumers Legal Remedies Act; and restitution based on quasi-contract/unjust enrichment. The plaintiff requests restitution; compensatory, statutory and punitive damages; injunctive relief; attorney's fees; costs; interest; and "an order requiring an accounting for, and imposition of, a constructive trust upon all monies received by King Arthur as a result of the unfair, misleading, fraudulent and unlawful conduct alleged herein."

Court Dismisses Insurer's Suit Against Four Loko® Company

A federal court in Illinois has granted the motion to dismiss filed by Phusion Projects, Inc., which sells Four Loko®, a caffeinated alcoholic beverage, in a case brought by one of the company's insurers seeking a declaration that it owed no duty to defend or indemnify the beverage maker in third-party lawsuits claiming injury, death or economic harm. *Selective Ins. Co. of S.C. v. Phusion Projects, Inc.*, No. 11-3378 (U.S. Dist. Ct., N.D. Ill., E. Div., decided November 15, 2011). According to the court, the case presented no case or controversy because Phusion has withdrawn its tender of defense and request for indemnification from this insurer.

Because Phusion refused to withdraw its request "with prejudice and for all purposes" and continued to provide the insurer with notice of new claims "in compliance with the policy notice provision," the insurer argued that the beverage company was reserving its right to reassert a demand for coverage in the future thus rendering the insurer's claims appropriate for immediate resolution. The court disagreed, stating, "neither party appears to have any significant interest in having plaintiff's hypothetical future claim resolved now. . . . Illinois law supports defendants' argument that where an insured has 'deactivated' an insurer with respect to a particular claim, that insurer is 'relieved of its obligation to the insured with regard to that claim,' and neither the insured's ongoing notification to the insurer of potential new claims, nor the insured's indication that it is placing plaintiff on 'standby' triggers a renewed duty to defend."

MEDIA COVERAGE

Farmers Struggle to Cope with Alabama Immigration Laws

NBC's *Rock Center* recently reported on how Alabama's new immigration law is affecting farmers in the region, where stricter enforcement measures for undocumented workers have apparently left agricultural communities struggling to find workers. As cucumber farmer Jerry Danford explained to correspondent Kate Snow, the new rules have drained the seasonal labor pool and made it difficult for Alabama producers to compete with neighboring states. "Since the bill was signed into law, Danford has watched many of the immigrant workers he relied on leave. He worries that none of them will return for the spring harvest, when a

provision requiring that employers check the immigration status of workers will be in effect," reports Snow.

Although Alabama Governor Robert Bentley (R) defended the law as necessary to uphold federal standards and secure jobs for Americans, the domestic workers interviewed by Snow preferred other kinds of work over field jobs, which typically pay $10 per hour. Any higher, said Danford, and the pickle company "won't buy from you then. They'd turn to suppliers in other states where labor is cheaper—states that allow undocumented immigrants to continue working under the radar."

"Americans lose sight about how we get our pickles in a pickle jar in a grocery store," opined the farmer, who is considering more row crops harvested by machine next season. "People are not informed about what it takes to do these special crops. Now a lot of people aren't interested. The lawmakers that passed this law, they didn't come out here and interview people. If they had done their homework, they would have realized." *See Rock Center,* November 14, 2011.

SCIENTIFIC/TECHNICAL ITEMS

Researchers Analyze Media Coverage of Nanotechnology Risks

Lehigh University researchers studying U.S. and U.K. nanotechnology news coverage from 2000 to 2009 have found relatively few articles about "nanotechnology health, environmental, and societal risks." Sharon Friedman & Brenda Egolf, "A Longitudinal Study of Newspaper and Wire Service Coverage of Nanotechnology Risks," *Risk Analysis*, November 2011. Their article appeared in an issue devoted to nanotechnology risks, communications and labeling. According to Friedman and Egolf, most of the coverage from 29 newspapers and two wire services "focused on news events" and any discussion of risks or scientific uncertainties "was counterbalanced by many more articles extolling nanotechnology's benefits." The authors conclude that with the general public's minimal knowledge about nanotechnology, "this type of coverage could create public distrust of nanotechnology applications should a dangerous event occur."

Research Examines Soft Drink Consumption and Heart Health

A study recently presented at the American Heart Association's (AHA's) 2011 Scientific Sessions in Orlando, Florida, has suggested a link between sugar-sweetened beverage (SSB) consumption and incident cardiovascular (CV) risk factors in women regardless of weight gain. Christina Shay, et al., "Sugar-Sweetened Beverage Consumption and Incident Cardiovascular Risks Factors: The Multi-Ethnic Study of Atherosclerosis (MESA)," AHA 2011 Scientific Sessions, November 2011. Researchers apparently used data from approximately 4,000 adult participants enrolled in the Multi-Ethnic Study of Atherosclerosis between 2000 and 2007, identifying during follow-up several incident CV risk factors that included

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(i) weight gain; (ii) increase waist circumference; (iii) low HDL, LDL and triglycerides; (iv) impaired fasting glucose; and (v) type 2 diabetes.

The results evidently indicated that, compared with consuming less than one SSB per day, intake of more than two servings per day "was significantly associated with greater risk for incident increased [waist circumference], hypertriclyceridemia and [impaired fasting glucose] among women." According to a November 13, 2011, AHA press release, the study also surmised that women "may have a greater chance for developing cardiovascular disease risk factors from sugar-sweetened drinks because they require fewer calories than men."

"Women who drank more than two sugar-sweetened drinks a day had increasing waist sizes, but weren't necessarily gaining weight," said lead author Christina Shay, an assistant professor at the University of Oklahoma Health Sciences Center in Oklahoma City. "These women also developed high triglycerides and women with normal blood glucose levels more frequently went from having a low risk to a high risk of developing diabetes over time."

Meanwhile, the American Beverage Association (ABA) issued a November 13, 2011, statement noting that the study failed to control for additional heart disease risk factors such as "increasing age and family history." As a result, explained ABA, this kind of study "cannot show that drinking [SSBs] causes increased risk for cardiovascular disease. It simply looks at associations between the two, which could be the result of numerous other confounding factors… Furthermore, participants who consumed two or more [SSBs] per day at the beginning of the study already had a number of risk factors for cardiovascular disease. And while overweight or obesity are known cardiovascular disease risk factors, the evidence that one type of food or beverage causes heart disease simply is not there."

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