Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Proposes Rule to Prevent Contamination During Food Transport

The U.S. Food and Drug Administration (FDA) has **proposed** a rule that would require certain shippers, receivers and carriers that transport food by motor or rail vehicles to take steps to prevent the contamination of human and animal food during transportation. Noting that the proposed rule will "help reduce the likelihood of conditions during transportation that can lead to human or animal illness or injury," FDA Deputy Commissioner for Foods and Veterinary Medicine Michael Taylor said, "We are now one step closer to fully implementing the comprehensive regulatory framework for prevention that will strengthen the FDA's inspection and compliance tools, modernize oversight of the nation's food safety system, and prevent foodborne illnesses before they happen." The proposed regulation aims to establish criteria for sanitary transportation practices, such as properly refrigerating food, adequately cleaning vehicles between loads and properly protecting food during transportation. The agency will accept comments until May 31, 2014. *See Federal Register*, February 5, 2014.

FDA Seeks Comments on Draft Approach for Designating High-Risk Foods

The U.S. Food and Drug Administration (FDA) has **issued** a request for comments, scientific data and other information to help the agency develop its process for designating high-risk foods. Required under the Food Safety Modernization Act to designate high-risk foods for which additional record-keeping requirements are appropriate and necessary in order to "rapidly and effectively track and trace such foods during a foodborne illness outbreak or other event," FDA specifically seeks information on (i) alternative approaches for identifying high-risk foods; (ii) whether the criteria should be weighted equally; (iii) changes in the scoring system; and (iv) how foods should be categorized. Comments will be accepted until April 7, 2014. *See Federal Register*, February 4, 2014.

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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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If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

FAA Grounds Beer Delivery Drones

The Federal Aviation Authority (FAA) has reportedly nixed a brewery's plan to use an unmanned aerial system (UAS) to deliver six-packs of its winter lager to ice-fishing shacks in Stevens Point, Wisconsin. According to media sources, Lakemaid Beer posted an online video advertising its drone delivery service, prompting FAA to notify the company that the scheme allegedly violates as many as five different regulations, "ranging from the operator's rating to the use of airspace." The agency apparently **intends** to issue regulations concerning the commercial use of drones in 2015, as larger companies like Amazon investigate the feasibility of UAS local delivery services.

Although Lakemaid has started a petition on WhiteHouse.gov asking FAA to issue an airworthiness certificate for its beer drones, the agency has since reiterated its decision to ground the program. "The FAA's prime directive is safety," an FAA spokesperson told *The Hill*. "While we are evaluating many potential uses of UAS as we move toward their safe integration into the nation's airspace, commercial operation of such aircraft is not yet allowed. When we find out about an apparent commercial UAS operation, we have several different enforcement tools available, including a warning phone call, a warning letter and an order to cease operations." *See NPR,* January 30, 2014; *The Hill,* February 5, 2014.

Navajo Nation Council Approves "Junk" Food Tax

According to news sources, the Navajo Nation Council has approved legislation that would impose a 2-percent increase in sales taxes on so-called junk food, which, if approved by Navajo Nation President Ben Shelly, would make it the first Native American-governed territory to do so. The council also passed legislation eliminating a 5-percent sales tax on fresh produce and other healthy foods such as fruits, vegetables, nuts, and seeds.

Known as the Healthy Diné Nation Act and aimed at curbing obesity and its related diseases, the legislation would increase the sales tax from 5 to 7 percent on sugar-sweetened beverages and snacks low in essential nutrients and high in salt, fat and sugar, including chips, candy, cookies, and pastries. According to some estimates, between 55 and 85 percent of the food available in grocery or convenience stores on the Navajo reservation is deemed junk food. The additional tax revenue would reportedly be used to develop wellness centers, parks, basketball courts, trails, and swimming pools.

Opponents, including some Navajo lawmakers, predict that the tax hike would drive residents to purchase items such as soda and potato chips outside the reservation. "We're certainly going to see dollars leave the Navajo reservation," a council member said. *See The Wall Street Journal,* January 31, 2014; *IndianCountryTodayMediaNetwork.com*, February 1, 2014.

OEHHA Schedules Children's Health Symposium

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) will **conduct** a symposium on children's health February 25-26, 2014, in Sacramento. According to OEHHA, the agency will conduct the symposium "to hear some of the latest science regarding impacts of chemical exposures during development. This is a broad topic and thus we are focusing in three areas: 1) epigenetic changes from environmental exposures; 2) impacts of toxicants on the developing lung and brain: 3) new in vitro methods for assessing potential for developmental toxicity."

OEHHA hopes that regulatory scientists in the state will begin thinking about (i) "How to incorporate complex interactions into risk assessment, particularly for early life exposures"; (ii) "How to incorporate information from new toxicity testing paradigms into risk assessments now; and" (iii) "How to incorporate impacts of non-chemical stressors that increase vulnerability, and whether current methods of risk assessment adequately account for at least some of the vulnerabilities (e.g., use of weighting factors in cancer risk assessment, use of uncertainty factors)." The University of California, San Francisco Pediatric Environmental Health Specialty Unit is a symposium co-sponsor.

OEHHA Enters Prop. 65 MOU with Department of Food and Agriculture

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **entered** a memorandum of understanding (MOU) with the state's Department of Food and Agriculture relating to "cooperation and communication in the implementation of Proposition 65 with respect to exposure to Proposition 65 listed chemicals in food or food additives." According to OEHHA, the agreement "describes the types of information that will be shared between the two agencies prior to public release and a mechanism by which the sharing can be accomplished." Proposition 65 (Prop. 65) was adopted by voter initiative in 1986; it requires businesses to provide warnings when they cause an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity. The MOU applies to those chemicals listed under Prop. 65 "that are or may be found in California's soil, food products, agricultural residues and fertilizers." *See OEHHA Press Release*, February 5, 2014.

LITIGATION

Missouri AG Sues California AG over Egg Farm Rules

Missouri Attorney General (AG) Chris Koster has sued California AG Kamala Harris, seeking to enjoin the enforcement of a voter-approved ballot initiative (Prop. 2) and law (A.B. 1437) that will increase the size of egg-laying hen enclosures and decrease flock densities both for California producers and those in

other states wishing to sell eggs in California. *Missouri ex rel. Koster v. Harris*, No. 14-0067 (U.S. Dist. Ct., E.D. Cal., Fresno Div., filed February 3, 2014).

According to the complaint, Missouri egg farmers will be forced under the law to "incur massive capital improvement costs to build larger habitats for some or all of Missouri's seven million egg-laying hens, or they can walk away from the state whose consumers bought *one third* of all eggs produced in Missouri last year. The first option will raise the cost of eggs *in Missouri* and make them too expensive to export to any state other than California. The second option will flood Missouri's own markets with a half-billion surplus eggs that would otherwise have been exported to California, causing Missouri prices to fall and potentially forcing some Missouri farmers out of business."

Alleging Commerce Clause violations, Koster contends that California has attempted to regulate agricultural practices outside the state by "conditioning the flow of goods across its state lines on the method of their production." He brings an alternative count of federal preemption, alleging that if the court upholds the law and regulations as serving "a legitimate, non-discriminatory purpose to lower the risk of salmonella contamination by imposing new cage-size and flock-density standards for housing egg-laying hens, the statute and regulations would be in conflict with the express terms of 21 U.S.C. § 1052(b). Koster seeks declaratory and injunctive relief, costs and fees.

Court Allows Most "Fat-Free" Deception Claims to Proceed

A federal court in New York has denied in part and granted in part the motion to dismiss filed by the defendants to consumer-fraud litigation claiming that their Smart Balance® Fat-Free milk products with added Omega-3s are misbranded because they contain 1 gram of fat from the Omega-3 oil blend ingredient. *Koenig v. Boulder Brands, Inc.*, No. 13-1186 (U.S. Dist. Ct., S.D.N.Y., order entered January 31, 2014). The court determined that the state law-based claims were not preempted by federal food labeling laws, whether the claims involve the application of milk regulations as argued by the plaintiffs or combination product requirements as argued by the defendants.

Among other things, the court refused to find the defendants' "combination products" preemption theory tenable because (i) it was based on FDA compliance policy guides, "which constitute advisory opinions"; (ii) the defendants failed to cite any FDA policy or regulations directly addressing the milk products at issue or any guidance involving fat-free claims for a "combination product"; (iii) the guidance that the defendants cited—bottled water, peas and carrots, and jellies—have no bearing on Smart Balance; and (iv) reliance on the Filled Milk Act of 1923, which established the standard of identity for milk, is unconvincing given that it may no longer be good law and it focused on issues unrelated to the claims in this case.

The court also found most of the claims sufficiently pleaded. It ruled, however that breach of express warranty was not sufficiently pleaded because the plaintiffs must establish privity, but failed to specify where or from whom they purchased the defendants' products. The plaintiffs will be allowed to amend this claim. Dismissed as duplicative of the other causes of action was the plaintiffs' claim for unjust enrichment, and the court shortened the time of the putative class period under relevant statutes of limitation. The court ordered the parties to appear for a February 20, 2014, status conference.

Florida Class Action Filed over ECJ Designation on Food Ingredient Lists

A putative statewide consumer-fraud class action has been filed in a Florida state court against Living Harvest Foods, Inc. over use of the term "evaporated cane juice" (ECJ) on food product labels rather than sugar. *Miller v. Living Harvest Foods Inc.*, No. n/a (Fla. Cir. Ct., Miami-Dade Cnty., filed January 30, 2014). While the specific products at issue are not named, the plaintiff contends that the defendant "conceals the fact that its Products have added sugar by referring to the sugar as ECJ, a 'healthy' sounding name made up by the sugar industry years ago to sell sugar to 'healthy' food manufacturers to use in their consumer products. ECJ is not the common or usual name of any type of sweetener, or even any type of juice, and the use of such a name is false and misleading. Defendant[] uniformly lists ECJ as an ingredient on its Products, as well as on its website and other promotional material."

The complaint cites U.S. Food and Drug Administration (FDA) guidance materials on the subject and warning letters to other food companies, noting that the defendant continued to use the "unlawful and misleading reference to 'evaporated cane juice'" on its ingredient labels despite FDA's actions. Alleging that this labeling misleads consumers into "paying a premium price for products that do not satisfy the minimum standards established by law for those products and for inferior or undesirable ingredients or for products that contain ingredients not accurately listed on the label by its common name," the plaintiff seeks both injunctive and compensatory relief. The complaint includes counts for violations of Florida's Deceptive and Unfair Trade Practices Act and unjust enrichment.

Texas Appeals Court Dismisses Mushroom Distributor's Malpractice Action

A Texas Court of Appeals has affirmed a lower court's grant of the defendants' summary judgment motion in a legal malpractice action brought by a mushroom distributor, finding that he failed to prove lost profits as to his negligence claim and filed his breach of fiduciary duty claim too late under the applicable statute of limitations. *Thomas v. Carnahan Thomas, LLP*, No. 05-11-01615-CV (Tex. Ct. App., 5th Dist., decided February 5, 2014). The defendants represented mushroom distributor Stuart Thomas and provided legal advice as to one of the ongoing disputes he had with the company that

produced the mushrooms he distributed. Among other matters, the attorneys told Thomas he could violate non-compete agreements in his distribution and employment contracts and also unsuccessfully represented him in handling his declaratory judgment action as to the non-compete agreements.

The court agreed with the attorneys that Thomas had no evidence of lost profits because his claims were based in part on gross revenues and periods of net losses in his operations, and were further unsupported by evidence such as tax returns or balance sheets. Thomas also failed to provide "reasonably certain evidence" that he could have operated in other markets and what his profits would have been had he done so. As to the breach of fiduciary duty claim first asserted in the third amended petition, the court refused to find that it related back to the originally filed complaint because Thomas (i) made it clear that the claim was unrelated to the malpractice allegations in the original complaint, (ii) failed to raise "a genuine issue of material fact regarding whether the statute of limitations was deferred by the continuing tort doctrine," and (iii) "failed to raise a fact issue that the Attorneys concealed his cause of action."

OTHER DEVELOPMENTS

Subway Responds to Petition Seeking Removal of Chemical from Bread

Subway has reportedly announced plans to remove azodicarbonamide from its breads after a food blogger's petition criticized the restaurant chain for including "the same chemical used to make yoga mats, shoe soles, and other rubbery objects" in its U.S. products. Owned by Doctor's Associates Inc., Subway apparently released a media statement confirming that it had started phasing out the ingredient before FoodBabe.com's Vani Hari launched her campaign, which garnered 60,000 signatures and sent readers to the company's Facebook page to complain. "We are already in the process of removing azodicarbonamide as part of our bread improvement efforts despite the fact that it is a USDA [U.S. Department of Agriculture] and FDA [Food and Drug Administration] approved ingredient. The complete conversion to have this product out of the bread will be done soon," a Subway spokesperson was quoted as saying. *See Associated Press* and *CNN,* February 6, 2014; *The Independent,* February 7, 2014.

Meanwhile, the Center for Science in the Public Interest (CSPI) has harnessed the media attention to insist that FDA bar the use of azodicarbonamide in all food products, claiming that at least one byproduct of the chemical is a recognizable carcinogen. "Azodicarbonamide has long been used by commercial bakers to strengthen dough, but has been poorly tested," said CSPI Senior Scientist Lisa Lefferts in a February 4, 2014, press release. "Considering

that many breads don't contain azodicarbonamide and that its use slightly increases exposure to a carcinogen, this is hardly a chemical that we need in our food supply."

PHAI Staff Attorney Calls for States to Curtail Digital Food Marketing to Kids

In a Food and Drug Law Institute (FDLI) *Update* article titled "State Law Approaches to Curtail Digital Food Marketing Tactics Targeting Young Children," Public Health Advocacy Institute (PHAI) staff attorney Cara Wilking describes the types of digital marketing to children younger than age 8 that should be proscribed because they are unable to identify it as marketing. These include "advergames" and "digital sweepstakes," which Wilking contends constitute deceptive trade practices and illegal lotteries.

She calls for food and beverage companies to cease using "harmful digital marketing tactics" and for state attorneys general to take action against this marketing under consumer-protection statutes. Among other matters, Wilking argues that a number of state consumer-protection laws "explicitly address indirect advertising akin to pester power marketing in order to cover unfair and deceptive marketing that is designed to influence others" as she explains how the parental responsibility concept should not preclude legal interventions to protect child consumers.

PHAI President Richard Daynard was long active in campaigns against cigarette manufacturers, and Wilking compares the "limited progress made to reduce children's exposure to potentially harmful food marketing via the federal government and self-regulatory bodies, and the magnitude of the health threats posed by diet-related chronic disease and its impact on state healthcare systems" to "the nation's history with tobacco control." She notes, "As occurred with tobacco marketing, intervention by [state attorneys general] may just be the game-changer that accelerates progress on harmful food marketing to children." *See FDLI Update*, January/February 2014.

"Fiery Poet-Priest" Accidentally Used to Hawk Potato Crisps

A recent marketing promotion has drawn the attention of keen-eyed literary buffs after a University of Anglia lecturer tweeted that the stock photo of a stern-looking man used to sell Tyrrells Potato Crisps is actually a portrait of R.S. Thomas, a famous Welsh poet who died in 2000 and was known as "the fiery poet-priest." Jeremy Noel-Tod, who teaches literature and creative writing, told *The Church Times* that he imagined Thomas would have been "deeply contemptuous of the whole business, though he is also reported to have a wickedly dry sense of humor in person, so he might privately have relished the way in which this facetious piece of marketing has backfired."

"When we see an eccentric old photograph—like the one on the front of this bag—we can't help but dream up a silly caption," states the packet of sweet-chilli and red-pepper crisps adorned with Thomas's visage that offers winners "a fleeting look of contempt, or £25,000 in cash—whichever they'd prefer." Tyrells has since issued a statement clarifying that it purchased the photo from a stock library and did not know of its connection to Thomas at the time.

"My reaction was a mixture of real amusement at the absurdity of it and real anger that a respected poet should suffer such an undignified posthumous fate for the sake of selling overpriced fried potatoes," said Noel-Tod. "It does seem to me to raise a real ethical question about the casual appropriation of images of the supposedly anonymous dead for jocular commercial purposes." *See The Church Times,* January 10, 2014; *The Guardian,* January 28, 2014.

SCIENTIFIC/TECHNICAL ITEMS

Researchers Examine Influence of Deregulation on Fast Food Consumption

A study **published** in the *Bulletin of the World Health Organization* has reported "a strong and positive association between fast food consumption and age-standardized mean BMI [body mass index]" in high-income countries, citing market deregulation as a possible factor in increased fast food consumption. Roberto De Vogli, et al., "The influence of market deregulation on fast food consumption and body mass index: a cross-national time series analysis, *Bulletin of the World Health Organization,* February 2014. In addition to analyzing data on fast food consumption and age-standardized BMI from 25 high-income countries, researchers apparently used the index of economic freedom (IEF) created by the Heritage Foundation and the *Wall Street Journal* to gauge the extent of market deregulation policies adopted by each country.

According to the results, the average number of annual fast food transactions per capita increased from 26.61 to 32.76 between 1999 and 2008, while age-standardized mean BMI increased from 25.8 to 26.4 kg/m^2. The study also noted that "market deregulation is a strong predictor of higher fast food consumption," with each 1-unit increase in the IEF associated with (i) an increase of 0.2715 in the average number of per capita annual transactions at fast food outlets and (ii) an increase of 0.0232 kg/m^2 in BMI. At the same time, however, researchers recommended further study to determine why the intake of animal fats and total caloric intake did not appear "to be significant mediators of the association" between fast food consumption and BMI, suggesting that subsequent studies focus on "the metabolic effects of long-term exposure to fast foods produced from the meat of animals fed on corn, kept in confinement and exposed to excessive fertilization," among other things.

"Our study provides novel findings on the association between fast food consumption and mean population BMI and on the influence of market deregulation as a contributor to higher fast food consumption and BMI," conclude the study's authors. "In particular, they suggest that government regulations hindering the spread of fast food consumption might help to mitigate the obesity epidemic. Indeed, although all countries included in our sample have experienced increases in fast food consumption and mean BMI over the period studied (1999–2008), nations that have adopted more stringent market regulations have experienced slower increases in both. More research is needed to confirm whether deregulation is a significant contributor to body weight and to determine what types of government interventions could mitigate the obesity epidemic and curb the spread of transnational fast food companies."

Study Allegedly Links Added Sugar Consumption to Increased CVD Mortality

A recent study has purportedly concluded that adults who consumed more than 21 percent of their daily calories from added sugars (those found in sweetened beverages, grain-based desserts, fruit drinks, dairy desserts, candy, and other processed foods) doubled their risk of cardiovascular disease (CVD) mortality. Quanhe Ye et al., "Added Sugar Intake and Cardiovascular Diseases Mortality Among US Adults," *JAMA Internal Medicine,* February 2014. Led by researchers from the Centers for Disease Control and Prevention, the study relied on data from the National Health and Nutrition Examination Surveys 1998-1994, 1999-2004 and 2005-2010, which showed that more than 70 percent of adults receive at least 10 percent of their caloric intake from added sugars. The results also allegedly found that, compared to participants who consumed less than 8 percent of calories from added sugar, those who consumed approximately 17-21 percent of calories from added sugar had a 38 percent higher risk of CVD mortality, raising questions about recommended sugar consumption guidelines issued by the World Health Organization, Institute of Medicine and American Heart Association.

As University of California, San Francisco, School of Medicine Professor Laura Schmidt explains in a concurrent commentary on the study, "Yang et al. inform this debate by showing that the risk of CVD mortality becomes elevated once added sugar intake surpasses 15% of daily calories—equivalent to drinking one 20-ounce Mountain Dew soda in a 2,000-calorie daily diet. From there, the risk rises exponentially as a function of increased sugar intake, peaking with a 4-fold increase risk of CVD death for individuals who consume one-third or more of daily calories in added sugar." Schmidt argues that these findings not only provide physicians and consumers "with actionable guidance," but lend support to sugar-sweetened beverage (SSB) taxation efforts.

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"[SSBs] are by far the single largest source of added sugar in the American diet, accounting for 37.1 percent of all that is consumed nationally," she writes. "[Yang et al.'s] prospective analysis further documents that even relatively modest but regular consumption of SSBs—drinking one 12-ounce soda a day—increases the risk of CVD mortality by almost one-third, independent of total calories and other cofactors. This study thus underscores the appropriateness of evidence-based sugar regulations, specifically, SSB taxation."

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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.