Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Senator Urges FDA to Improve Seafood Fraud Enforcement

U.S. Senator Barbara Boxer (D-Calif.) has urged the Food and Drug Administration (FDA) to take action to address seafood fraud. In her October 15, 2012, letter, Boxer defines seafood fraud as "the mislabeling of one species of fish for another fish that is often cheaper and more readily available." Boxer cites studies purportedly showing that the practice may be "pervasive" throughout the United States and contends that it not only constitutes "deceptive marketing, but it can also pose serious health concerns, particularly for pregnant women seeking to limit exposure to heavy metals or individuals with serious allergies to certain types of fish." Among the studies cited are those finding mislabeled 20 percent of 88 samples tested in Boston, 55 percent of 119 samples tested in California and 31 percent of 96 samples tested in Florida.

The senator expresses her concern with the low number of inspections FDA conducts on both imported and domestic seafood and calls for "better traceability and enforcement throughout the entire chain of sale, from bait to plate." She asks for responses to specific questions and states, "I would like to know what steps you are taking to ensure that there are adequate inspections for seafood mislabeling to ensure consumers that their seafood is safe." Among the questions are (i) "If, upon inspection, an imported product is found to be mislabeled, can the FDA refuse the product entry into the United States? If yes, how often are mislabeled products refused entry? Are there reasons why the FDA would not refuse a mislabeled product entry?"; and (ii) "Do you share all information on inspections and inspection results with the National Marine Fisheries Service and Customs and Border Protection, even if a health risk has not been identified? If not, please explain why."

Denmark Tracks Decline in Animal Antibiotic Use

The Statens Serum Institut and National Food Institute at the Technical University of Denmark recently released a report charting a decline in overall antibiotic use in the country's food animals.

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Funded by the Ministry of Science, Innovation and Higher Education, the Ministry of Food, Agriculture and Fisheries, and the Ministry of the Health, the Danish Integrated Antimicrobial Resistance Monitoring and Research Program (DANMAP) monitors "the consumption of antimicrobial agents for food animals and humans" and "the occurrence of antimicrobial resistance in bacteria isolated from food animals, food of animal origin and humans." It also studies the association between antimicrobial consumption and antimicrobial resistance, seeking to identify "routes of transmission and areas for further research studies."

Data from DANMAP 2011 apparently showed a 15-percent decrease in total veterinary consumption of antimicrobial agents since 2010, "mainly attributed to a decreased consumption in pigs." In particular, DANMAP 2011 reported a 30-percent decrease "in the number of defined doses per pig produced" due to the "yellow card" initiative that imposes "preventative measures in the pig herds with the highest [antimicrobial] consumption per pig" as well as a voluntary ban on cephalosporin use in these animals. The report also noted that, compared to 2010, antimicrobial consumption decreased 8 percent in poultry and 11 percent in fish, but remained the same in cattle and increased in companion animals.

In terms of zoonotic bacteria resistance, DANMAP 2011 recorded a "significant increase in resistance to ampicillin, neomycin, sulfonamide and tetracycline" among *Salmonella* Typhimurium isolates taken from Danish pigs, although it observed no significant changes in resistance for *Campylobacter jejuni* in Danish broilers and cattle or for *Campylobacter coli* in Danish pigs. "However, the levels of tetracycline resistance have increased since 2005, and this trend has been particularly clear in *C. coli* isolates in pigs from 2008 to 2011," states the report, adding that fluoroquinolone resistance in *C. jejuni* "was significantly higher among isolates from imported broiler meat (57%) compared with isolates from Danish broiler meat (11%)."

With regard to general levels of resistance in healthy animals, DANMAP 2011 reportedly found "a significant increase in antimicrobial resistance to betalactams (penicillin and ampicillin)" among *Enterococcus faecium* isolated from pigs, with no significant changes in resistance observed for *E. coli* isolates from Danish broilers and cattle. "[S]ignificantly higher levels of tetracycline resistance were found in *E. facecalis* isolates from imported pork, compared to isolates from Danish pork," notes the report. "In general, the highest resistance levels were found in indicator *E. coli* isolates from pigs, except for fluoroquinolone (ciprofloxacin) resistance which was higher in isolates from broilers."

Meanwhile, the Pew Health Group has released a statement lauding Denmark's efforts, pointing to several measures that have successfully curbed the use of livestock antibiotics in the country. "Denmark stopped the administration of antibiotics used for growth promotion (i.e., non-medical uses) in broiler chickens and young pigs (finishers) in 1998, and in baby pigs (weaners)

in 1999," opines Pew's October 15, 2012, press release. "In Denmark today, all uses of antibiotics in food animals must be prescribed by a veterinarian. Additionally, farmers, veterinarians, and pharmacies must report the use and sale of antibiotics, and farm inspections are conducted regularly to ensure antibiotics are not being misused on the farm."

U.S. Representative Henry Waxman (D-Calif.) has also called for more transparency in the animal drug industry, pledging to introduce legislation intended "to increase information on the amount and use of antibiotics in animals raised for human consumption." Titled Delivering Antibiotic Transparency in Animals (DATA) Act, the bill will require (i) drug manufacturers to inform the Food and Drug Administration (FDA) about the use of their products on farms; and (ii) feed mills "to submit data to FDA on the types, purposes, and quantities of antibiotics being given to animals through feed."

"We need reliable information about the use of antibiotics in agricultural operations," said Waxman in an October 16, 2012, press release. "The more we learn, the graver the threat becomes from overuse of antibiotics by industrial-scale farms. We need this information so scientists and Congress can stop the spread of drug-resistant infections from farm animals to humans."

French MEP Feeds Foie Gras Furor

French MEP Francoise Castex has reportedly condemned California's statewide ban on the production and sale of any product that is "the result of force-feeding a bird for the purpose of enlarging its liver beyond normal size," calling the prohibition on foie gras "a battle for Europe." After a recent attempt by producers to enjoin the 2004 law failed in federal court, Castex convened a news conference in European Parliament where she eviscerated the legislation as "very negative" and a violation of international trade rules. "There are five member states where foie gras is produced, not just France," she said, referring to Belgium, Bulgaria, Hungary, and Spain.

According to Castex, the foie gras sector comprises 30 percent of the local economy in her own region of France, which has already hired an attorney to represent the country in a legal challenge to the United States. Her remarks also drew support from French Junior Minister for the Food Industry Guillaume Garot, who described the delicacy as "a cornerstone" of French cuisine and the generator of 35,000 jobs. "It's a bad idea that is not going to do anything," he was quoted as saying. "We are talking about a whole food system that is really in trouble… I am here today to defend this industry and the jobs it supports. We badly need these jobs, particularly at the current time." *See The Parliament,* October 16, 2012.

Meanwhile, eight additional MEPs have reportedly joined with Animal Equality, an international animal rights organization, in urging the European Union to institute its own ban on foie gras production, which is currently

outlawed in 22 of the 27 member states. Led by MEP Andrea Zanoni, the group called an October 17, 2012, conference to advocate barring both the manufacture and importation of foie gras made from force-fed geese and ducks. "With this conference in the European Parliament we want to help European consumers to open their eyes and ask the European Commission [for] a law that prohibits this," Zanoni told reporters. "I invite everyone to sign Animal Equality's petition and share their investigation and videos." *See Animal Equality News Release,* October 16, 2012; *France24,* October 18, 2012.

LITIGATION

JPML Denies Transfer in Cases Challenging Marketing Claims for Infant Formulas and Cereals

The Judicial Panel on Multidistrict Litigation (JPML) has denied a motion to centralize, for pre-trial purposes, 10 lawsuits pending in five districts against Gerber Products Co. and Nestlé USA, Inc. alleging that the companies "misleadingly advertise and market infant formulas and cereals as promoting immunity, digestive health, and visual and cognitive function because they contain probiotic cultures" and other ingredients. *In re Gerber Probiotic Prods. Mktg. & Sales Practices Litig.*, MDL No. 2397 (JPML, decided October 16, 2012).

According to the court, five of the 10 lawsuits are already consolidated in the District of New Jersey where Gerber is headquartered. One of these cases was filed in California, "thus one transferor court already has concluded that under Section 1404 the District of New Jersey is the proper venue for this litigation." Because the defendants filed section 1404 change of venue motions in the remainder of the cases, and if all of the actions are ultimately transferred to New Jersey, the panel notes that this move "produces significant advantages" over multidistrict litigation proceedings. "It allows for the possibility of consolidation of actions for trial, which potentially avoids the increased costs associated with multiple trials after the Panel remands actions to the various transferor courts once pretrial proceedings are concluded."

Stating that "where a reasonable prospect exists that resolution of Section 1404 motions could eliminate the multidistrict character of a litigation, transfer under Section 1404 is preferable to centralization," the JPML denied the request to centralize the 10 actions before a multidistrict litigation court.

Federal Court Approves Diamond Walnuts Settlement

A federal court in California has given final approval to the $2.6-million settlement of a class action alleging that Diamond Foods falsely represented that the omega-3 in its walnuts provides health benefits. *Zeisel v. Diamond Foods, Inc.*, No. 10-01192 (U.S. Dist. Ct., N.D. Cal., decided October 16, 2012). Additional information about the case appears in Issue **436** of this *Update*.

While additional claims may be filed by class members until October 26, as of September 7, more than 23,000 class members had submitted claims, and they have been submitted at a rate of about 1,000 each week. The court issued its ruling after the parties provided supplemental briefing on the *cy pres* issue. Under the unpublished final disposition, the court indicated that any residual funds will be provided to the American Heart Association, which "provides education on issues relating to heart healthy food, including education about how to read food labels."

The court approved the request for attorney's fees and costs representing about 30 percent of the settlement amount and a $5,000 incentive payment to the named plaintiff. Diamond will be required to change its product labels and Website. According to the court, only one person opted out of the proposed settlement, and no objections were filed. It concluded that the agreement was "fair, reasonable, and adequate."

Coalition Challenges NYC Size Limits on Sugar-Sweetened Beverages

A coalition of industry and union interests has filed a petition seeking to enjoin or invalidate the New York City (NYC) Department of Health prohibition on the sale of certain sugar-sweetened beverages in servings exceeding 16 ounces from certain types of business establishments. *N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. NYC Dept. of Health & Mental Hygiene*, No. 653584/2012 (N.Y. Sup. Ct., N.Y. Cnty., filed October 12, 2012). The coalition contends that the Board of Health acted beyond its powers in adopting the prohibition and that it is arbitrary and capricious in its design and application.

Members of the coalition include trade associations for Korean-American grocers, restaurants, beverage makers, and theater owners, as well as the Hispanic Chamber of Commerce and a soft drink and brewery workers union local. According to the petition, the rule does not apply to beverages higher in calories than soft drinks, including alcohol-based drinks, wines, high-calorie coffee drinks, milkshakes, fruit smoothies, and 100-percent fruit juices. Nor does it apply to every type of vendor; it apparently "applies to restaurants, delis, fast-food franchises, movie theaters, stadiums and street carts, but not to grocery stores, convenience stores, 7-Elevens, corner markets, gas stations and other similar businesses—literally thousands of stores—that sell the same beverage products."

The prohibition also apparently allows "unlimited free refills, and allows customers to add as much sugar as they want to any beverage after it is purchased." As to such "loopholes," the petition states, "When these loopholes are contrasted with the provision in the Ban that forbids establishments with self-serve fountains from offering cups larger than 16 ounces even when used for diet sodas, zero-calorie beverages, and water, it is not possible to say DOH is doing anything but making political, economic, and pure policy judgments unrelated to any technical or scientific expertise."

Contending that the rule exceeds the health department's authority, the petitioners note that legislative bodies, such as City Council and the state legislature, have refused on multiple occasions to adopt similar laws that would target sweetened beverages. They claim that the prohibition is "fundamentally beyond the role of the executive branch of City government to unilaterally devise and implement social policy." The petition cites an appellate court ruling striking down a public smoking ban adopted by the State Public Health Council for the same reason and argues that the soda prohibition is indistinguishable from the smoking ban.

The harms cited in the petition include lost business, wasteful costs to repackage beverages sold in bottles exceeding the limit, lost jobs, and higher theater ticket prices to make up for lost concession sales. The petitioners report that thousands of concerned individuals and business owners opposed the proposal, which was adopted "essentially just as the Mayor proposed, without making a single substantive change to address the comments submitted in response to the proposal." They refer to Brian Wansink's study concluding that the prohibition will not succeed.

The petitioners ask the court to enjoin the rule's implementation or declare that the New York City Charter provisions on which the department based its authority to adopt the prohibition violate the separation-of-powers doctrine by the breadth of their delegation of authority. They also support their request for injunction on the ground of substantive invalidity, claiming that the prohibition is "riddled with arbitrary exclusions, exemptions, and classifications that are unrelated to the stated purpose of the rue." They allege that the board had no coherent justification for selecting 16-ounce containers as the standard for regulation.

They request that the court act on their petition by December 15, 2012, "so that affected businesses can avoid expending funds to comply with a law that Plaintiffs believe should be struck down." Set to take effect March 12, 2013, the rule, if upheld, would purportedly require three months for beverage makers to retool their facilities and equipment.

Class Claims Bottled Water Is Not Natural Spring Water

Nestlé Waters North America (NWNA) has removed to federal court a putative class action alleging that the company failed to disclose that its Ice Mountain® 5-gallon bottles are not 100 percent natural spring water, "but are actually resold water sourced from municipal water systems." *The Chicago Faucet Shoppe, Inc. v. NWNA, Inc.*, No. 1:2012cv08119 (U.S. Dist. Ct., N.D. Ill., filed October 10, 2012). The named plaintiff, a company that contracted with NWNA in 2008 to deliver the water bottles to its Chicago office, filed the action on behalf of all purchasers in Illinois, Michigan, Minnesota, and Missouri under Illinois consumer fraud laws.

The removal notice claims that under the Class Action Fairness Act, diversity of citizenship exists between putative class members and the defendant and that the amount in controversy exceeds the $5-million jurisdictional threshold. "According to NWNA's records, since October 2009, more than $5,000,000 of Ice Mountain® brand 5-ballon bottled water has been sold in Illinois alone. Consequently, the total aggregated amount of the putative class members' claims for actual damages, punitive damages, and attorneys fees exceeds $5,000,000."

Farm Workers Sue California over Heat-Related Death and Illness

The United Farm Workers has reportedly filed a lawsuit against the California Division of Occupational Safety and Health (Cal/OSHA) over its alleged "systemic failure" to enforce a 7-year-old regulation requiring farmers to provide water, shade and rest to employees to prevent heat illness or death. *Bautista v. Cal/OSHA*, No. n/a (Cal. Super. Ct., Los Angeles Cnty., filed October 18, 2012). The union contends that "[a]t least 28 farm workers have died of potentially heat-related causes since the regulation was first approved in 2005. This year alone, Cal/OSHA is investigating heat as a factor in the deaths of four people."

The complaint, filed on behalf of individual farm workers, the United Farm Workers (UFW) and UFW Foundation, alleges, among other matters, that Cal/OSHA has failed to (i) "conduct on-site inspections for complaints"; (ii) "evaluate the conditions alleged in a complaint when it does conduct inspections"; (iii) "issue citations for serious, repeat, or willful violations of the Heat Illness Prevention regulation that it has found to exist"; (iv) "investigate the causes of potentially heat-related injuries and fatalities and to evaluate the conditions involved in such incidents"; (v) "conduct re-inspections or penalize an employer's failure to accomplish and certify abatement of violations of the Heat Illness Prevention regulation, effectively providing free passes to employers that choose not to comply with the law"; (vi) initiate investigations into serious heat complaints against agricultural employers within three days, which is especially critical in this highly mobile industry where work sites and workers may migrate miles each day"; and (vii) "impose and collect meaningful penalties for violation of the Heat Illness Prevention regulation." *See United Farm Workers Press Release*, October 18, 2012.

Canadian Victims of Contaminated Beef File Class Action Claims

Two British Columbia residents have reportedly filed individual and putative class action suits against the Canadian meat processor that was forced to recall 1,800 ground beef products in an *E. coli* contamination outbreak that involved retail chains in the United States and Canada. The class action, filed October 12, 2012, by Erin Thornton in B.C. Supreme Court, names XL Foods Inc. and its owner Nilsson Bros., Inc. as defendants. She alleges that XL Foods

was negligent and that both defendants breached disclosure obligations and mishandled the recall. According to news sources, at least 15 people in four provinces have been sickened by the *E. coli* strain linked to the defendants' Brooks, Alberta-based plant. Class actions have also apparently been filed in other provinces. U.S. officials reportedly discovered *E. coli* O157 at the plant on September 3, and the recall began September 16. *See The Canadian Press* and *The Province*, October 17, 2012.

OTHER DEVELOPMENTS

NEJM Perspective Focuses on Use of SCOTUS Health-Care Ruling to Promote Policy Objectives

A *New England Journal of Medicine (NEJM)* perspective essay titled "The Taxing Power and the Public's Health" asserts that the U.S. Supreme Court's recent ruling in a case challenging the validity of the Affordable Care Act opens the door to government using its taxing authority to achieve a range of policy objectives including "interventions to promote public health." According to the authors, assuming that federal, state and local governments can overcome adverse public sentiment or industry opposition, they could, for example, adopt taxing strategies that provide credits to those with a healthy body mass index (BMI) or proof of BMI improvement.

The October 18, 2012, essay cites the argument made by health-care law opponents who invoked the hypothetical of government taxing people who fail to buy broccoli. The authors state, "nothing in [Chief Justice John] Roberts's opinion stops the government" from imposing such a tax. They conclude, "The Court has highlighted an opportunity for passing creative new public health laws, authorized by the taxing power; this opportunity now awaits its political moment."

Battle over "Addictive" Flamin' Hot Cheetos® Heats Up

School districts in California, New Mexico and Illinois have reportedly publicized their intention to ban "Flamin' Hot" Cheetos® snacks from campus vending machines and lunches over concerns about the product's nutritional content. According to media reports, the schools in question have described the snack item as "hyperpalatable" with each bag containing 26 grams of fat and one-quarter of the recommended daily amount of sodium. As University of Michigan clinical psychologist Ashley Gearhardt further explained, "Our brain is really hardwired to find things like fat and salt really rewarding, and now we have foods that have them in such high levels that it can trigger an addictive process."

"It's something that has been engineered so that it is fattier and saltier and more novel to the point where our body, brain and pleasure centers react to it more strongly than if we were eating, say, a handful of nuts," Gearhardt said.

"Going along with that, we are seeing those classic signs of addiction, the cravings and loss of control and preoccupation with it."

Meanwhile, Frito-Lay has reiterated its children's marketing guidelines in its response to school complaints about the product, which has been on the market since the 1990s. "Frito-Lay is committed to responsible and ethical marketing practices, which includes not marketing our products to children ages 12 and under," said the company in a statement. "We also do not decide which snacks are available on school campuses and do not sell snack products directly to schools." *See The Chicago Tribune,* October 11, 2012; *ABC News,* October 16, 2012; *The Los Angeles Times,* October 17, 2012.

CSPI Celebrates Food Day with Video Contest

The Center for Science in the Public Interest (CSPI) has invited the submission of "videos of people pouring out soda on or about October 24" to celebrate the second annual Food Day. Videos will be accepted until November 7, 2012, with the winning entry receiving $1,000. According to CSPI executive director Michael Jacobson, "Food Day is about inspiring people to change diets for the better and by advocating for better food policies. Making a 'Pour One Out' video is the perfect way for a budding filmmaker—or anyone with a smartphone, frankly—to join the movement for healthy, affordable, and sustainable food." Entries will apparently be judged for creativity, originality and message effectiveness. *See CSPI News Release*, October 16, 2012.

MEDIA COVERAGE

NBC's *Open Channel* Blog Documents Chronic Kidney Disease in Sugarcane Workers

NBC's *Open Channel* blog has reported "an inexplicable epidemic in Central America, where more than 16,000 people—mostly sugarcane workers—have died from incurable chronic kidney disease [CKD]." According to *Open Channel,* "hundreds, if not thousands" of people in the sugar-producing city of Chichigalpa, Nicaragua, have allegedly contracted CKD, which has apparently increased "five-fold in the last two decades" throughout the region and turned up in parts of India and Sri Lanka. Citing the Center for Public Integrity (CPI), NBC's Kerry Sander and Lisa Riordan summarize the unique profile of CKD in sugarcane workers who do not exhibit the obesity, diabetes and hypertension often linked to the disease in developed countries like the United States. "It affects people who don't have diabetes or hypertension, which are the usual risks factors for chronic kidney disease," one CPI reporter told the blog. "No one can figure out what it is that's making all these people sick."

Meanwhile, researchers with Boston University have evidently associated the disease in Central America with "strenuous labor, dehydration and environ-

mental conditions in which chemicals may play role." In particular, *Open Channel* notes that the World Health Organization in June 2012 announced a study identifying the chemicals "thought to be an essential cause of the disease: cadmium and arsenic. Both are heavy metals found in fertilizers and pesticides that can cause an array of health effects, including the type of kidney damage ravaging the communities in Sri Lanka and Nicaragua." In addition, scientists have purportedly expressed concern over the workers' practice of chewing raw sugarcane to produce a "sweet sugary liquid" as a "pick-me-up" during harvesting. "We believe high amounts of sugar solutions may not cause much kidney damage," said one renal disease expert at the University of Colorado, Denver. "But under certain circumstances, such as dehydration, we're concerned the sugar may actually be toxic in causing damage to the kidney."

"Whether or not sugar consumption plays a direct role in causing the Central American form of CKD, activists say it is a thread that connects the disease to its northern cousin," conclude Sander and Riordan. "And with recent steep increases in the price and demand of sugar, more people are working longer hours in the sugarcane fields of Central America. In 2011, the U.S. imported 330,000 metric tons of raw sugar from Central America, or nearly one-quarter of the total raw sugar imports that year, according to the United States Department of Agriculture."

SCIENTIFIC/TECHNICAL ITEMS

Studies Claim Food and Beverage Youth Marketing in Australia Fails Ad Regs

Researchers with the New South Wales Cancer Council and University of Adelaide have assessed food and beverage TV advertisements broadcast in five major Australian cities during children's programming from September 1 to October 31, 2010, and found a total of 951 breaches of both mandatory and voluntary regulations. Michele Roberts, et al., "Compliance with children's television food advertising regulations in Australia," *BMC Public Health*, October 5, 2012.

According to the study, "[a]lmost 83% of all food and beverages advertised during children's programming times were for foods classified as 'Extras' in the Australian Guide to Healthy Eating. There were also breaches in relation to the amount of advertising repetition and the use of promotional appeals such as premium offers, competitions, and endorsements by popular children's characters." The researchers conclude that the country's current regulatory system "is not providing comprehensive protection for children from exposure to television advertising for unhealthy foods." They also contend that the regulations have not been effectively implemented and are inadequately monitored.

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In a related study published in *Public Health Nutrition*, Australian researchers surveyed all advertisements on three TV channels over five years and found that children were exposed to as many "junk food" brands both before and after self-regulation pledges were made by leading food manufacturers in 2009. Kathy Chapman, a Cancer Council nutritionist and director of health policy, participated in both studies and reportedly said, "These studies combined show industry codes of practice are not having an impact and we are seeing such big loopholes for the food industry to get away with this." Australian Food and Grocery Council chief executive Gary Dawson said that the industry had succeeded in removing "non-core food advertising" targeting children. *See Sydney Morning Herald*, October 13, 2012.

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FOOD & BEVERAGE LITIGATION UPDATE

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.