Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Bipartisan Senate Bill Takes Aim at Food Safety

U.S. Senators Dick Durbin (D-Ill.), Judd Gregg (R-N.H.), Ted Kennedy (D-Mass.), and Richard Burr (R-N.C.) have introduced the FDA Food Safety Modernization Act (S. 510), which would expand and strengthen the Food and Drug Administration's (FDA's) authority to address the safety of the nation's food supply. The proposal, which has reportedly attracted the support of industry and consumer groups alike, would increase the frequency of food plant inspections, expand FDA's access to records, give the agency the authority to recall tainted food products, and require the creation of a national strategy to protect the food supply from terrorist threats and intentional contamination.

Originally introduced in July 2008 with many of the same sponsors, the bill would require all food facilities to have HACCP plans in effect and allow the FDA to suspend the registration of any food facility that "has a reasonable probability of causing serious adverse health consequences or death to humans or animals." It would also give the agency access to records in a food emergency and require the Secretary of Health and Human Services to establish a pilot project "to test and evaluate new methods for rapidly and effectively tracking/tracing fruits and vegetables in the event of a food-borne illness outbreak."

From the Senate floor, Senator Durbin reportedly commented, "When I introduced this bill in the last Congress, we were in the middle of one of the largest food-borne illness outbreaks in the history of our country. Nearly 1,500 people fell sick last spring and summer because of *Salmonella Saintpaul*…. Less than a year later, we find ourselves in the middle of yet another nationwide outbreak; peanut butter tainted with *Salmonella*, the second case of its kind in two years…. It is clear that the Food and Drug Administration, who regulates these foods and 80 percent of our food supply, including virtually all food imports, cannot keep up. The agency is underfunded and overwhelmed."

Unlike proposed legislation introduced earlier in the year by Representative Rosa DeLauro (D-Conn.), this bill focuses on revamping the 1938 law that created the FDA rather than establishing a stand-alone food safety agency within the Department of Health and Human Services. *See U.S. Food Law Report* and *meatingplace.com*, March 4, 2009.

In other legislative developments, Representative Pete Sessions (R-Texas) has introduced a resolution (H. Res. 202) to express the sense of the House that FDA's commissioner should evaluate the scientific evidence as to whether to add more folic acid to enriched grain products and expand folic acid fortification requirements to cornmeal and corn-based food products. *See CQ Bill Track,* March 3, 2009.

USDA Announces Referendum Opportunity for the Soybean Checkoff Program

The U.S. Department of Agriculture's Agriculture Marketing Service (AMS) has announced an opportunity for soybean producers to request a referendum on the Soybean Promotion and Research Order (the Order), as authorized by the Soybean Promotion, Research, and Consumer Information Act. The referendum would require participation by 10 percent of 589,182 eligible producers, provided that one-fifth of the requests do not come from any one state. If these conditions are met, AMS will hold a referendum within 1 year of the request and publish the results in the *Federal Register.* The agency will accept referendum requests between May 4 and 29, 2009. *See Federal Register,* March 4, 2009.

AMS earlier this week issued a final rule amending the Soybean Promotion, Research and Consumer Information program, also known as the soybean checkoff program, to update the number of eligible soybean producers. The USDA Farm Service Agency (FSA) based its data on information obtained from 2006 and 2007 acreage reports, revising the number of eligible producers to 589,182 from the previous count of 663,880. FSA included "all producers that were engaged in the production of soybeans in at least one of the 2 years," but excluded "counting a producer more than once if that producer engaged in production in both years." The agency noted that most producers subject to the Order are small businesses defined by the Small Business Administration as those farms having annual receipts of less than $750,000. *See Federal Register,* March 2, 2009.

European Union Upholds the Right of Member States to Refuse GM Crops

EU environment ministers have reportedly upheld the sovereign right of nations to outlaw genetically modified (GM) crops even when approved by the European Food Safety Authority (EFSA). The European Commission (EC) had asked the ministers to overturn Austria's and Hungary's ban on a GM maize produced by Monsanto, but 22 states backed the countries' measures over the opposition of the United Kingdom, The Netherlands, Finland, and Sweden. Green MEP Caroline Lucas then accused the commission of trying to "bulldoze through their pro-GM agenda in spite of public opposition." "I just hope that [EC President José Manuel Barroso] will realize the commission needs to change its position of GMOs," Lucas was quoted as saying.

The ministers will next week consider a similar GM maize ban pending in France and Greece. Although the European Union currently imports animal feed made with GM crops, member states have balked at allowing farmers to cultivate GM foods on domestic soil. The debate has also raised questions about the role of EFSA in reviewing and approving agricultural products for EU use. *See The Parliament.com* and *Financial Times*, March 3, 2009.

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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China Passes New Food Safety Law to Raise Consumer Confidence

Chinese legislators this week passed a new food safety law that consolidates hundreds of regulations, imposes stricter penalties for safety violations and establishes a national commission based in the Ministry of Health to monitor the food and beverage industry, improve standards and authorize product recalls. Effective June 1, 2009, the law will also hold celebrities liable for endorsing faulty products; require farmers to abide by stricter rules pertaining to pesticides, fertilizers, veterinary drugs, and feed additives; and implement record-keeping requirements for farmers raising crops and livestock for human consumption. Loopholes in the Chinese food safety system attracted international attention last year when melamine-tainted infant formula produced by the state-owned Sanlu Group dairy sickened thousands of children. "At present, China's food security situation remains grim, with high risks and contradictions popping out," the ministry stated in a press release. *See Marler Blog,* March 1, 2009.

The new law has already drawn criticism by some Chinese officials, foreign manufacturers and domestic consumers, the latter of whom registered skepticism about the government's ability to police the system at the local level. The deputy director of China's National Institute of Nutrition and Food Safety said the effort was a "lost opportunity" to create a single agency like the U.S. Food and Drug Administration. "There has been no fundamental reform of the system that many people in the industry hoped for," the deputy director said. "There will be better coordination, but problems like Sanlu will still happen." *See USA Today,* March 1, 2009; *Associated Press,* March 2, 2009.

California Proposes Listing Aspartame as Prop. 65 Carcinogen

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has published a **notice** seeking public comment on its latest proposal to add candidate chemicals to the state's Proposition 65 (Prop. 65) list of chemicals known to the state to pose a cancer or reproductive health risk. Aspartame is among the 38 chemicals OEHHA is considering adding to the list. Comments on the proposal must be submitted by May 5, 2009, and the agency's Carcinogen Identification Committee will meet May 29 to "provide OEHHA with advice on the prioritization of these chemicals for possible preparation of hazard identification materials." According to OEHHA, "[n]o listing decisions will be made concerning these chemicals at the May 29 meeting."

Suffolk County Legislature May Ban BPA in Baby Bottles

A Suffolk County, New York, legislative committee on March 3, 2009, voted unanimously to prohibit the packaging chemical bisphenol A (BPA) from polycarbonate baby bottles. According to published reports, the bill goes before the full Suffolk County Legislature next week. The vote would reportedly ban BPA from baby bottles and cups sold in the county that are intended for children ages 3 or younger. Similar bills are under consideration in Washington state, Minnesota and Connecticut. *See Foodproductiondaily.com,* March 4, 2009.

LITIGATION

California Plaintiffs Allege False Advertising and Labeling of Frozen Waffles

California consumers have filed a putative class action against Van's International Foods and retailers Whole Foods Market California, Inc., Trader Joe's Co., and Costco Wholesale Co., alleging that Van's frozen waffles did not accurately state the calorie and nutrient content throughout 2007 and into 2008. *Hodes v. Van's Int'l Foods*, No. 09-01530 (U.S. Dist. Ct., C.D. Cal., filed March 4, 2009). According to the complaint, which seeks certification of a nationwide class, the sale in late 2006 of the company that made Van's frozen waffles involved a change in personnel that required "reverse engineering the recipes for Van's existing product lines." That process allegedly resulted in findings that the nutritional information on the product packaging "contained numerous substantial inaccuracies." The calorie, fat, sodium, carbohydrates, calcium, iron, and fiber content listed purportedly varied by 20 to 100 percent or more from the actual nutritional values.

The plaintiffs allege that the company continued to "distribute its frozen waffles in packaging containing false and misleading nutritional information long after learning that the information was incorrect." Efforts were allegedly made in late 2008 to provide more accurate information, but the company purportedly "attempted to reduce the serving size and altered the recipes of many of its products to help mask the changes or cover up the misrepresentations contained on the labels of other products." The complaint alleges fraud, breaches of express and implied warranties, false advertising, and unfair business practices. Remedies sought include injunctive relief, compensatory and punitive damages, restitution, prejudgment interest, attorney's fees and costs.

California Consumer Alleges "All Natural" HFCS Beverage Claims Are Misleading

A putative class action filed in a California federal court against Snapple Beverage Corp. alleges that the company misleads consumers by labeling as "All Natural" products containing high fructose corn syrup (HFCS) and using the names of fruits for some products that "do not contain any significant amount of the fruit listed in the product's name." *Von Koenig v. Snapple Beverage Corp.*, No. 09-00337 (U.S. Dist. Ct., E.D. Cal., Sacramento Div., filed March 4, 2009).

The named plaintiff seeks to certify two subclasses of California consumers "to redress Defendant's deceptive, misleading and untrue advertising and unlawful, unfair and fraudulent business acts and practices." One subclass would involve those who purchased the company's "All Natural Products" that contained HFCS; the other would include those who purchased "Fruit Products … which included the name or picture of a fruit in the product name or label but which did not contain a substantial amount of that fruit." As an example, the named plaintiff claims that the company's "Acai Blackberry Juice Drink®" contains neither blackberry juice nor acai berry juice.

The complaint, which details how HFCS is created, alleges misleading and deceptive advertising; untrue advertising; unlawful, unfair and fraudulent business acts and practices; and violations of the Consumers Legal Remedies Act. Plaintiffs seek actual and punitive damages, restitution, injunctive relief, corrective advertising, attorney's fees, and costs.

Wild Bird Food Company Sues Supplier for Selling Tainted PCA Peanut By-Products

Seeking "substantial damages," a company that makes wild bird food has filed a lawsuit against a supplier that allegedly sold it peanut by-products originating from the Georgia facility linked to the *Salmonella* contamination outbreak. *The Scotts Co., LLC v. Cereal Byproducts Co.*, No. 09-108 (U.S. Dist. Ct., S.D. Ohio, E. Div., filed February 17, 2009). According to the complaint, the defendant sold and shipped peanut by-products to the plaintiff in December 2008 and January 2009, after it was known that the outbreak originated in the Blakely, Georgia, facility owned and operated by the Peanut Corp. of America (PCA), and repeatedly "made false representations" that the by-products did not come from a potentially contaminated PCA facility. The plaintiff was allegedly forced to recall its suet wild bird food products and incurred unspecified costs and injury to goodwill. The complaint alleges breach of contract, negligent misrepresentation and violations of Ohio's deceptive trade practices law.

Settlement Approved in Omega-3 Egg Litigation

A federal court in Washington recently approved a class action settlement in a case filed against egg farmers who allegedly engaged in unfair, deceptive and improper conduct in the marketing and sale of omega-3 fortified eggs. *Schneider v. Wilcox Farms, Inc.*, No. 07-01160 (U.S. Dist. Ct., W.D. Washington at Seattle, filed January 12, 2009). As we reported in issue 226 of this Update, the complaint alleged that the eggs the defendant marketed and sold contained omega-3 fatty acids "without proven cardiovascular benefits" and charged a premium for them, while taking advantage of consumers' limited knowledge about different kinds of omega-3 and "artificially inflating the perceived amount of beneficial omega-3 fatty acids" in their product.

Without conceding liability, the defendants agreed to pay $2,500 to each of the two named plaintiffs and attorney's fees of $160,000. The order dismisses the plaintiffs' claims with prejudice and bars members of the settlement class, defined as "[a]ll persons who reside in Washington or Oregon and who purchased one or more cartons of Wilcox's Omega-3 Eggs in either state since January 1, 2003, from bringing "any claim arising from the marketing and sale of Omega-3 eggs within the Class Period."

Preliminary Injunction Halts Enforcement of California Slaughterhouse Law

A federal court has granted the meat industry's motion for a preliminary injunction and ordered California not to enforce a law, adopted on January 1, 2009, that would have required the immediate euthanization of nonambulatory animals in slaughter-houses regulated by the Federal Meat Inspection Act. *Nat'l Meat Ass'n v. Brown*, No. 08-1963 (U.S. Dist. Ct., E.D. Cal., decided February 19, 2009). The court found that the

plaintiffs had a strong likelihood of success on the merits of their claim that the state law is expressly and impliedly preempted by the federal statute and that they were likely to suffer irreparable harm because some proscribed conduct is punishable by criminal fines and the state is immune from paying for other potential monetary losses. Balancing the public interests involved, the court found that the safety of the public food supply and the humane treatment of animals are adequately protected by the federal law. According to a news source, the plaintiffs will seek a permanent injunction and declaratory judgment that the state law is preempted as it pertains to non-ambulatory animals that the Food Safety and Inspection Service allows to be processed. *See Meatingplace.com*, February 23, 2009.

Pelman Reassigned to Third District Court Judge

Since it was filed in 2002, the lawsuit filed by a putative class of teenagers alleging obesity-related injury purportedly caused by reliance on deceptive advertising for fast food has been appealed twice to the Second Circuit Court of Appeals and is now before its third trial court judge. *Pelman v. McDonald's Corp.*, No. 02 Civ. 7821 (S.D.N.Y., filed Sept. 30, 2002). The case was reassigned to Judge Kimba Wood on February 27, 2009. Judge Wood was one of former President Bill Clinton's picks for attorney general, but withdrew from consideration after questions were raised about the immigrants she had hired as household help. Nominated to the federal court bench in 1988 by President Ronald Reagan, the Harvard-educated jurist has apparently served as chief judge of her district since 2006.

Italian Magistrate Orders Payment of Damages for Contaminated Milk

An Italian magistrate has reportedly determined that Nestlé Italia and Tetra Pak International are liable for the "psychological prejudice" of parents who gave their daughters milk purportedly contaminated with chemicals from the carton. The milk was apparently withdrawn from sale in France, Spain, Portugal, and Italy in late 2005, over concerns about the leaching of IsopropilThioXantone, a chemical used in printing on the cartons, into the dairy product. Millions of liters of liquid baby milk were reportedly recalled, and a consumers' organization indicates that the latest ruling is the first in Italy since the product was withdrawn from the market. *See Agence France Presse*, March 2, 2009.

Chinese Courts Agree to Accept Melamine-Tainted Milk Cases

According to a news source, the executive vice president of China's highest court has indicated that the courts will begin accepting the paperwork filed by parents who decided not to participate in the government's compensation plan for injuries allegedly suffered by children who consumed melamine-tainted milk products. Court official Shen Deyong reportedly said in an online interview, "The courts have done the preparation work and will accept the compensation cases at any time." He also reportedly indicated that more than 95 percent of the 300,000 victims' families had accepted compensation. An organizer for those who held out said that hundreds are prepared to file individual claims, many of which the courts previously refused. Under China's legal system, the courts must first accept the paperwork and then decide whether to act on the claims by opening an investigation or rejecting them. *See Associated Press*, March 3, 2009.

OTHER DEVELOPMENTS

Food Safety Expert Says Canada's *Listeria*-Testing Rules Do Not Go Far Enough

As the Canadian Food Inspection Agency (CFIA) unveiled tougher *Listeria*-testing rules for ready-to-eat meat manufacturing facilities at the end of February 2009, one of the federal government's food safety advisors reportedly claimed that the rules do not go far enough for large operations. The tougher rules resulted from last summer's listeriosis outbreak that purportedly led to the deaths of 20 Canadians and was traced to ready-to-eat meats produced at a Maple Leaf plant in Toronto. The company reportedly cited the build up of *Listeria* "deep inside" two slicing machines as the most likely source.

Under the new rules, effective April 1, operators producing deli meats and hot dogs must (i) begin testing food-contact surfaces up to once a week per line; (ii) look for trends in the results to catch potential problems; (iii) report all positive tests immediately to agency inspectors, who will be required to increase the frequency of their own monitoring tests; and (iv) test meat products up to 12 times a year for possible *Listeria* contamination.

University of Manitoba food microbiologist Rick Holley, a member of the agency's academic advisory panel on food safety, reportedly said that the new testing regime for food-contact surfaces should be the minimum for any big operation. According to Holley, "In a large operation, such as we see in the companies the size of Maple Leaf, they would be well advised to increase food-contact surface sampling frequencies beyond the description and the scaffold that has been given in this document."

A meat inspectors union representative reportedly said that while the changes are "good," the CFIA needs to devote more resources to get the job done. "The problem is they're going to be asking their staff to do more than they were already doing," he was quoted as saying. "On top of having to monitor more rigorously what the plants are doing, they're also going to be stepping up their own testing. All those are good things. Everything they've put on paper is good, but there are no more additional resources." *See canada.com*, February 27, 2009.

MEDIA COVERAGE

Michael Moss and Andrew Martin, "Food Safety Problems Slip Past Private Inspections," *The New York Times,* March 6, 2009

"An examination of the largest food poisoning outbreaks in recent years – in products as varied as spinach, pet food, and a children's snack, Veggie Booty – show that auditors failed to detect problems at plants whose contaminated products later sickened consumers," claims this article exploring the role of private inspectors in the current food safety system. The authors point to the recent *Salmonella* outbreak linked to a Peanut Corp. of America (PCA) plant in southwest Georgia. According to a March 27, 2008, internal audit obtained by *The New York Times,* the

operation received a food safety rating of "superior" from a third-party inspector hired by PCA to verify plant conditions on behalf of the Kellogg Co. and other food companies supplied by the peanut processor. "Federal investigators later discovered that the dilapidated plant was ravaged by *Salmonella* and had been shipping tainted peanuts and paste for at least nine months," opines the article, highlighting a potential conflict of interest between third-party auditors and the companies that hire them to perform inspections.

The PCA inspector reportedly worked for the Kansas-based American Institute of Baking (AIB), which has clients in the meat, seafood, vegetables, spices, oils, and dairy sectors, and which also sells educational services to food and beverage companies. Some industry stakeholders, however, have apparently expressed misgivings about AIB's "dual role as an educator and inspector," noting that the company's expertise in baking processes does not necessarily extend to other products. "The contributions of third-party audits to food safety is the same as the contribution of mail-order diploma mills to education," one food safety consultant was quoted as saying.

The article notes that despite these concerns, the Food and Drug Administration has "proposed expanding the role of private auditors to inspect the more than 200,000 foreign facilities that ship food to the United States." In addition, federal efforts to toughen audit standards and reporting requirements have met "stiff resistance from the food industry." The authors nevertheless conclude that not only did the third-party auditors fail to identify significant problems at the Georgia peanut plant, but "state inspectors also found only minor problems, while a federal team last month uncovered a number of alarming signs, as well as testing records from the company itself that showed *Salmonella* in its products as far back as June 2007."

Kim Severson and Andrew Martin, "It's Organic, but Does That Mean It's Safer?," *The New York Times,* March 4, 2009

"The plants in Texas and Georgia that were sending out contaminated peanut butter and ground peanut products had something else besides rodent infestation, mold and bird droppings. They also had federal organic certification," opines this article examining a marketplace perception that organic food is both healthier and safer than conventional products. The authors suggest that a convoluted organic certification program has subverted an organic ethos "built on purity and trust … between the farmer and the customer." With fees sometimes exceeding thousands of dollars, manufacturers are apparently dependent on a "web of agents" sponsored by those farmers and operations seeking certification. "A private certifier took nearly seven months to recommend that the USDA revoke the organic certification of the peanut company's Georgia plant, and then did so only after the company was in the thick of a massive recall," states the article, which notes that agents are required to report any health and safety violations to the proper authorities.

Critics of the current system have apparently emphasized this conflict of interest between organic certification agents and those paying for the inspections.

According to one organic inspector, "Certifiers have a considerable financial incentive in keeping their clients going." Organic food advocates have thus urged the National Organic Program and USDA Deputy Secretary Kathleen Merrigan to revamp the certification process with additional funding and staffing. "Meanwhile, consumers remain perplexed about which food to buy and which labels assure safer and better-tasting foods," concludes the article, adding, the organic label fails to ensure that the food "was grown locally, harvested from animals that were treated humanely or produced by workers who were paid a fair wage."

SCIENTIFIC/TECHNICAL ITEMS

Study Claims Obesity Risks Similar to Those of Smoking

A recent study has reportedly compared long-term teen obesity risks to those incurred by smokers. Martin Neovius, et al., "Combined effects of overweight and smoking in late adolescence on subsequent mortality: nationwide cohort study," *British Medical Journal,* February 24, 2009. After examining the death rates of 45,920 Swedish servicemen over 38 years, researchers found that recruits who were obese in 1969 and 1970 were twice as likely to die by age 60 than those who had a normal body mass index between 25 and 29.9. Obese men thus experienced an increase in risk the same as that of normal-weight men who smoked half a pack of cigarettes or more per day. The study results also suggested that overweight recruits were approximately one-third more likely to die prematurely, a risk profile similar to that of normal-weight men who smoked 10 cigarettes per day.

Although one expert from Emory University's Rollins School of Public Health cautioned that the data might overestimate the risk for overweight men, he nevertheless noted that smoking is "widely acknowledged" to be the single most important cause of preventable deaths and disease. "It's fairly dramatic when you say something is as lethal as smoking," he was quoted as saying. "We know of very few things from a health perspective that are as lethal as smoking." *See The New York Times,* March 4, 2009.

Health Canada Finds BPA in Canned Drink Products

Health Canada has **published** the results of a survey it conducted to detect and measure levels of bisphenol A (BPA) in canned beverages such as soft drinks, tea and energy drinks. The federal agency detected the chemical in nearly all of the samples tested, with some of the highest levels appearing in energy drinks containing caffeine. Health Canada scientists detected no BPA in two tonic water products and one energy drink product. According to the survey, "It is believed that quinine hydrochloride, which is commonly used as a bittering agent in tonic type drinks, may interfere with BPA extraction."

While the levels found in the beverages were below regulatory limits, some scientists are reportedly concerned that the large number of sources of exposure may pose cumulative risks to human health. University of Missouri biologist

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Frederick vom Saal contends that harmful effects of the chemical, which mimics the effects of estrogen in the body and has purportedly been linked to hormonally caused illnesses, occur at concentrations up to 1,000 times below Health Canada's safety limit. The level of BPA found in each of the canned beverages, at about half a part per billion, is apparently 500 times more than the level of naturally occurring estrogen circulating in most people.

Industry representatives deemed the BPA levels that Health Canada found "extremely low," noting that an adult would have to consume 900 cans daily to exceed the government's safety level. *See Globe and Mail*, March 5, 2009. ■

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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.