Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Confirms *Listeria* at Texas Fresh Produce Plant

The Food and Drug Administration (FDA) has reportedly **confirmed** the presence of *Listeria monocytogenes* at a San Antonio, Texas, processing plant implicated in four deaths. According to a November 3, 2010, FDA press release, the agency's inspection of SanGar Fresh Cut Produce identified the bacteria "in processed celery and in multiple locations in the plant environment, including on food contact surfaces."

FDA also noted that its samples matched "the DNA fingerprint of the clinical cases of *listeriosis* reported by the Texas Department of State Health Services [DSHS]," which last month closed the plant and ordered a recall of all products shipped since January 2010. "It comes as no surprise to us," one DSHS spokesperson was quoted as saying. "If there was any doubt out there, this erases it. It's another layer of confirmation that this plant had serious issues." Additional details about the outbreak and recall appear in **Issue 369** of this *Update*. *See The Associated Press,* November 3, 2010.

FDA Proposes Two Information Collections Related to Menu Labeling Law

The Food and Drug Administration (FDA) has proposed two new information collections related to voluntary registration, recordkeeping and mandatory third-party disclosure under section 4205 of the Patient Protection and Affordable Care Act of 2010. Section 4205 requires chain restaurants with 20 or more locations, as well as operators of 20 or more vending machines, to disclose "certain nutritional information on certain food items offered for sale so that consumers can make more informed choices about the food they purchase." In addition, it provides for restaurants or operators with fewer than 20 locations to biannually opt in to the federal requirements.

The first **proposed information collection** pertains to FDA's program for voluntary registration under section 4205. FDA anticipates that chains with 10 to 19 outlets "may choose to register, either because they are growing quickly, or because they are concerned about possible regulation." According to FDA,

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"[t]he primary source of potential registrants will be restaurant and specialty food chains," but also convenience and grocery stores with take-away services and food establishments in retail, hotel, corporate, education, military or entertainment settings.

The proposed information collection would apply to these businesses, which must register using Form FDA 3757 and provide details that include (i) contact information for the authorized official or vending machine operator, as well as for each restaurant location and each vending machine being registered, and (ii) "[c]ertification that the information submitted is true and accurate, that the person or firm submitting it is authorized to do so, and that each registered" restaurant or vending machine will be subject to the menu labeling provisions of the Act. After the initial registration, these businesses must register "every other year with FDA, and the registration will expire if not renewed."

The second **proposed information collection** involves section 4205's record-keeping and mandatory third-party disclosure requirements. According to FDA, section 4205 requires, in part, that chain retail food establishments disclose calorie counts for each standard menu item on menus and menu boards, and that vending machine operators make this information available on "a sign in close proximity to each article of food (or the selection button)." In addition to this mandatory third-party disclosure on menus and vending machines, these businesses must demonstrate recordkeeping compliance for the calorie analysis.

The agency has estimated that the reporting burden for the voluntary registration program will be 724 hours in the first year and 96 hours each year thereafter. FDA has also provided detailed reporting estimates "associated with discovering and recording the calorie count for each menu/vending item; and the third party disclosure burden associated with communicating that information to the consumer"; that is, the time needed "to change out redesigned menu boards." Among other things, FDA requests feedback on whether each proposed information collection is necessary and whether the estimated reporting burdens are accurate. FDA will accept comments on the first proposed collection until January 3, 2011, and on the second until January 4, 2011. *See Federal Register,* November 4, 2010.

FDA Extends Comment Period for Draft Guidance Regarding *Salmonella* in Animal Feed

The Food and Drug Administration (FDA) has **announced** an extension of the comment period for a draft compliance policy guide that proposes "certain criteria should be considered in recommending enforcement action against animal feed or feed ingredients that are adulterated due to the presence of *Salmonella*."

FDA will now accept comments until December 31, 2010. Additional information about the draft guidance appears in **Issue 359** of this *Update*. *See Federal Register*, October 29, 2010.

USDA Completes Draft Assessment of GE Sugar Beets

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) has published a **notice** inviting public comment on its draft environmental assessment for genetically engineered (GE) sugar beets. Comments must be submitted by December 6, 2010.

APHIS conducted the assessment in response to a request that it partially deregulate GE sugar beets "to authorize the continued cultivation of the GE sugar beets subject to carefully tailored interim measures proposed by APHIS." A federal court in California determined in August that APHIS had violated federal environmental laws by approving the crop's deregulation without the preparation of an appropriate environmental assessment. More information about the court's decision appears in **Issue 361** of this *Update*. When USDA then began issuing permits to sugar beet seed producers to allow GE sugar beets to be planted in fall 2010, environmental groups and farmers challenged the action, and the court found that they were likely to succeed on the merits of their challenge. Further briefing was ordered to determine what remedy would be appropriate in light of the agency's apparent continuing violation of environmental laws.

According to a news source, the agency's latest action will essentially "nullify" the court's August ruling that invalidated the original approval issued five years ago. APHIS has outlined three alternative approaches but favors authorizing production of the GE sugar beets in 2011 subject to conditions designed to "prevent any potential plant pest risks." APHIS contends that these conditions address the court's concerns. Counsel for the Center for Food Safety, which brought the action challenging the crop's deregulation, has reportedly indicated that if USDA issues any new permits for GE sugar beet planting in 2011, the group is prepared to take the agency back to court. *See APHIS News Release* and *The Wall Street Journal,* November 2, 2010; *Federal Register*, November 4, 2010.

TTB Proposes Action on Wine Ingredient Disclosures and Labeling

The Alcohol and Tobacco Tax and Trade Bureau (TTB) has published several notices pertaining to the regulation of wine and spirits. Comments on all are requested by January 3, 2011. Responding to recent action taken by the Food and Drug Administration with respect to cochineal extract and carmine, which will have to be declared on food labels because of their potential for severe allergic reactions, TTB has **proposed** requiring the disclosure of these ingredients on wines, distilled spirits and malt beverages. Cochineal extract

and carmine are derived from an insect native to subtropical South America and Mexico. According to TTB, its proposal "would allow consumers who are allergic to cochineal extract or carmine to identify and thus avoid alcohol beverage products that contain these color additives."

TTB has also **proposed** amending wine labeling regulations "to allow the labeling of imported wines with multistate appellations of origin." According to the agency, this "would provide treatment for imported wines similar to that currently available to domestic wines bearing multistate appellations. It would also provide consumers with additional information regarding the origin of these wines." The proposed rulemaking responds to a petition filed by the Australian Wine and Brandy Corp., which requested that its exported wines be allowed to include multiple state designations where the grapes in the product are from the listed regions.

In a related matter, TTB has **announced** that it is considering amending regulations addressing various winemaking terms "commonly used in labels and in advertisements to provide consumers with information about the growing or bottling conditions of wine." The agency seeks public input on the use and definition of terms such as "estate," "estates" or "estate bottled," as well as "proprietor grown," "vintner grown," "vineyard," "orchard," "farm," "ranch," "proprietors blend," "old vine," "barrel fermented," "old clone," "reserve," "select harvest," "bottle aged," and "barrel select." *See Federal Register*, November 3, 2010.

Anti-Pesticide Group Calls for Anti-Nanotech Comments to National Organic Program

Beyond Pesticides, a Washington, D.C.-based organization opposed to the use of pesticides, has **issued** a call for comments to the U.S. Department of Agriculture's National Organic Program (NOP) supporting recommendations by the National Organic Standards Board that would prohibit the use of engineered nanomaterials from certified organic products. According to the organization's blog, the board passed the recommendations during its October 25-26, 2010, meeting.

Among other matters, the **recommendations** include a working definition for engineered nanomaterials and propose that engineered nanomaterials be prohibited in both organic production processing and packaging. The board also called for NOP to schedule a symposium on the topic to consider whether the definition is adequate and enforceable and the best regulatory approach to address the matter. Beyond Pesticides is concerned about the unknown "long-term impacts of nanomaterials on human health and the environment."

Michigan Bans Alcoholic Energy Drinks, Pennsylvania Requests Removal

The Michigan Liquor Control Commission (MLCC) has **rescinded** "the approval of all alcohol energy drinks [AEDs]," citing "widespread community concerns aired by substance abuse prevention groups, parent groups and various members of the public, as well as the Food and Drug Administration's (FDA's) decision to further investigate these products." According to a November 4, 2010, press release, the commission also believes that AED packaging "is often misleading, and the products themselves can pose problems by directly appealing to a younger customer, encouraging excessive consumption, while mixing alcohol with various other chemical and herbal stimulants."

The MLCC's order gives retailers 30 days to remove AEDs from commerce and includes a list of affected products. "The Commission's concern for the health, safety and welfare of Michigan citizens and the fact that there is not enough research to validate that these products are safe for consumption has made me believe that until further research is done by the FDA, they should no longer be on Michigan shelves," stated MLCC Chair Nida Samona. "Alcohol has been recognized as the number one drug problem among youth, and the popularity of alcohol energy drinks is increasing at an alarming rate among college students and underage drinkers."

Meanwhile, the Pennsylvania Liquor Control Board (PLCB) has reportedly sent 17,000 letters to retailers statewide, asking them to voluntarily stop distribution and sale of all AEDs. Although it lacks the standing to prohibit beverages deemed safe by federal regulators, PLCB issued the request after authorities allegedly linked multiple alcohol poisoning incidents to popular products such as "Four Loko," an AED manufactured by Phusion Projects, LLC, that contains 12 percent alcohol and "high doses of caffeine and sugar." The board also pointed to an ongoing FDA investigation into the safety of AEDs. "It's the multipronged danger these drinks present," one PLCB spokesperson said. "They're inexpensive, in large cans, with high alcohol content. When you add in all the stimulants, it's a recipe for disaster." *See Lancaster Online.com* and *Law360,* November 2, 2010.

Meanwhile, New York University Professor Marion Nestle has "been following the current furor" on her *Food Politics* blog, which chastises AED labels for "*voluntarily*… marketing the higher alcohol content." She also highlights one recent article that accuses Four Loko of retroactively sanitizing its social media "to remove all traces of evidence that the company… was promoting it as a party drink." Nestle concludes, "None of this is news, really. The Marin Institute, which calls itself the 'Alcohol Industry Watchdog,' has been writing about the dangers of caffeinated alcohol beverages to young drinkers since the products were first released." Additional information about the FDA's AED investigation appears in **Issue 370** of this *Update*. *See Fast Company,* November 1, 2010; *Food Politics,* November 4, 2010.

Restaurant Toy Giveaways Face Uncertain Future in San Francisco

The San Francisco Board of Supervisors has given preliminary approval to an **ordinance** (No. 101096) that would prohibit restaurants from offering toy giveaways in children's meals deemed too high in calories, salt or fat.

Approved by an 8-to-3 vote on November 2, 2010, the legislation reportedly has enough votes to override Mayor Gavin Newsom's expected veto when the bill comes before the board for a final vote. If approved, the law would take effect in December 2011.

Under the ordinance, restaurants would be prohibited from offering "incentive items" such as toys, trading cards or admission tickets in meals containing more than 600 calories and 640 milligrams of sodium, and if fat makes up more than 35 percent of the calories, except for fats contained in nuts, seeds, eggs, or low-fat cheese. It would also require meals to include a certain amount of fruits and vegetables.

District 8 Supervisor Bevan Dufty (D) reportedly said the legislation is a way for the fast-food industry to rethink its marketing to children. "If you have to put a Shrek doll with a package of carrots, maybe that's what you have to do, but there hasn't been a real incentive for this industry to do that," he said. *See The San Francisco Chronicle,* November 3, 2010.

LITIGATION

Second Circuit Dismisses Burn Claims Against Starbucks

The Second Circuit Court of Appeals has affirmed a district court's dismissal of claims filed by a 76-year-old woman who alleged that she was seriously burned when trying to remove the lid from a cup of tea she purchased at Starbucks. *Moltner v. Starbucks Coffee Co.*, No. 09-4943 (2d Cir., decided November 3, 2010).

The court issued a non-precedential **summary order** to affirm the grant of defendant's summary judgment motion. According to the court, the district court correctly excluded the testimony of plaintiff's experts because they were unreliable under Federal Rule of Evidence 702 standards. In this regard, the court stated, "[w]ithout the testimony of her expert witnesses, Moltner's claims fail because there is no way for a reasonable juror to determine, with respect to her defective design claim, whether the risks posed by the product's design outweighed its utility, or, with respect to her negligence claim, whether Starbucks failed to exercise due care." (citation omitted).

The court issued a **per curiam order** to affirm the lower court's ruling that Starbucks' motion to remove the case to federal court was timely filed.

The plaintiff did not specify her damages in her initial complaint. Thereafter, Starbucks filed a pleading requesting the amount of her total damages, and she responded by stating that they did not exceed $3 million. Eight days later, Starbucks filed its notice of removal. The plaintiff argued that the notice was untimely because it had been filed more than 30 days after she filed her complaint. Disagreeing, the court stated, "We join the Eighth Circuit, as well as all of the district courts in this Circuit to have addressed the issue, in holding that the removal clock does not start to run until the plaintiff serves the defendant with a paper that explicitly specifies the amount of monetary damages sought."

California Appellate Court Refuses to Certify Chipotle Employee Class Action

A California court of appeals has denied the request of a former Chipotle employee to certify a class of current and former non-managerial employees alleging that the company violated labor laws by denying them meal and rest breaks. *Hernandez v. Chipotle Mexican Grill, Inc.*, No. B216004 (Cal. Ct. App., 2d Dist., Div. 8, modified opinion filed October 28, 2010). The court agreed with the defendant that California law requires that employers provide, but not ensure, that employees take breaks.

The court also found no error in the trial court's denial of class certification because the court record showed that "Chipotle did not have a universal practice with regard to breaks." Apparently, while the company paid for meal and rest breaks, some employees declared that they always missed meal breaks, some missed meal breaks but not rest breaks, some were not denied meal breaks, and others declared their breaks were delayed or interrupted with varying degrees of frequency. The record also provided substantial evidence of an antagonism so substantial among class members "as to defeat the purpose of class certification."

Menu Labeling Claims Under Prop. 65 Can Proceed in California

The California Supreme Court has denied a petition for review filed by fast food restaurants seeking to overturn an intermediate appellate court ruling allowing further proceedings on claims that they violated Proposition 65 by selling grilled chicken products to consumers without appropriate warnings about carcinogens created by the cooking process. *Physicians Comm. for Responsible Med. v. McDonald's Corp.*, No. S186566 (Cal., decided October 27, 2010). The intermediate appellate court determined that federal law did not preempt the claims. Additional information about its ruling appears in **Issue 360** of this *Update*.

Nestlé Files Supply Chain Lawsuit in Lean Cuisine® Recall

Nestlé Prepared Foods Co. has filed a complaint against the suppliers of ingredients for its Lean Cuisine® frozen meals, which it was apparently forced to recall when it learned that some of the meals were contaminated with foreign, hard blue plastic pieces. *Nestlé Prepared Foods Co. v. Nat'l Food Trading Corp.*, No. 10-1077 (U.S. Dist. Ct., D. Utah, Cent. Div., filed October 29, 2010). According to the complaint, the plastic pieces were mixed into the sun-dried tomatoes that defendants sold to Nestlé. Customer complaints purportedly alerted Nestlé to the contamination, and "[a]t least one consumer reported an injury caused by the hard blue plastic materials."

Recalling some 880,000 pounds of frozen meals allegedly caused Nestlé to incur "substantial losses, including, but not limited to, refunds to customers, the value of the recalled meals, the value of the unusable sun dried tomatoes, cancelled orders, and the costs of shipping, storage, plant operations, and investigation, as well as interest." The company also claims damage to its reputation. It alleges breaches of contract, express warranty and implied warranty; strict product liability; and negligence and seeks an award of compensatory damages, interest, costs, and attorney's fees.

Florida Diner Claims Restaurant's Negligence Led to Artichoke-Induced Injury

A Florida man has sued a Houston's restaurant and its manager for failing to train servers to explain to patrons how to eat grilled artichokes, contending that their negligence led to his hospitalization and exploratory bowel surgery. *Carvajal v. Hillstone Restaurant Group, Inc.*, No. 10-57757 CA 03 (Fla. Cir. Ct., 11th Cir., Miami Dade County, filed October 27, 2010). He alleges ordering a special item offered by a server, "which Plaintiff advised he had never seen or heard of previously." According to the complaint, plaintiff Arturo Carvajal was not instructed that the outside portion of the leaf should not be eaten, although the restaurant "had a duty to use reasonable care with respect to the serving and explanation of items not described on the menu; which by their appearance as served appeared wholly consumable." He is seeking damages in excess of $15,000.

KFC Advertising Disputed Before Delaware Chancery Court

KFC franchisees have reportedly made their closing arguments before a Delaware Chancery Court in a dispute over the company's advertising policies. They contend that 1997 amendments to the company's corporate documents gave them the authority to propose and approve different advertising recommendations. The lawsuit was apparently filed after KFC Corp. launched an advertising campaign for grilled chicken menu offerings, which the franchisees opposed for their potential to dilute the company's fried chicken brand. According to a news source, the franchisees argued that while they can veto funding for advertising by majority vote, this power is illusory because KFC

could institute delays, thus causing a blackout that would inflict significant damage on franchisees.

The company apparently countered that the franchisees do have the right to make recommendations or modifications to the company's advertising policy and have exercised that right on several occasions. Still, the company reportedly indicated that the franchisees cannot have "plenary authority" over advertising strategy because that would interfere with the company's investments in market research and brand development. *See Product Liability Law 360*, November 1, 2010.

OTHER DEVELOPMENTS

German Agency Holds Forum on Safety of Recycled Food Packaging

Germany's Federal Institute for Risk Assessment (BfR) recently held its **Ninth Forum on Consumer Protection** in Berlin, where 300 participants discussed the alleged health risks of recycled materials used in food packaging.

More specifically, the meeting focused on cardboard packaging made from recycled paper, which evidently contains mineral oils used in newspaper ink that can migrate "in relevant amounts into the packaged foods." While acknowledging that a final assessment "is not yet possible," BfR has cited animal tests suggesting that these mineral oil residues "are deposited in the liver and lymph nodes and could damage these organs." It has thus recommended minimizing the migration of these oils into foods. "This concerns dry foods with a large surface such as rice, semolina, corn flakes and noodles," states the BfR press release. "As a possibility, the BfR Forum discussed the use of liner bags, for example made of aluminum coated plastics, in carton packages, which could act as a barrier to the migration of mineral oils."

SCIENTIFIC/TECHNICAL ITEMS

Skin "Efficiently Absorbs and Metabolizes" BPA, Claims New Research

A recent study has reportedly concluded that viable skin can absorb bisphenol A (BPA), raising concerns about exposure from handling BPA-laden products such as receipts. Daniel Zalko, et al., "Viable skin efficiently absorbs and metabolizes bisphenol A," *Chemosphere,* October 2010. French researchers used both pig and human cultures to determine that "BPA is readily absorbed and metabolized by the skin," which converted the substance into two conjugates known as BPA mono-glucuronide and BPA mono-sulfate. "The trans-dermal route is expected to contribute substantially to BPA exposure in human [sic], when direct contact with BPA (free monomer) occurs," concluded the authors.

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The study evidently confirms earlier findings released ahead-of-print in *Environmental Health Perspectives* indicating cashiers had the highest urinary BPA concentrations among a sample of 389 pregnant women. According to a November 2, 2010, *Science News* article, University of Missouri-Columbia Professor Frederick vom Saal has described the French research as "unequivocal in showing that yes, BPA can go through human skin." He also noted that the new data reinforce worries about store receipts "because we know from many thermal papers that receipts can contain a heck of a lot of BPA." Vom Saal is currently leading a study to measure the amount of BPA transferred to human skin from thermal receipt paper.

Australian Researchers Advocate Mandatory Sodium Limits for Processed Foods

Mandatory sodium limits for processed foods could be 20 times more effective than voluntary reduction measures. Linda Cobiac, et al., "Cost-effectiveness of interventions to reduce dietary salt intake," *Heart*, November 2010. Australian researchers evaluated the public health benefits and cost-effectiveness of four possible strategies for reducing dietary salt: (i) the current Australian program that provides incentives for food manufacturers to voluntarily reduce sodium in their processed foods, (ii) a government mandate to moderate salt in processed foods, (iii) dietary advice for people at increased risk of cardiovascular disease, and (iv) dietary advice for anyone at high risk.

Writing that "dietary advice targeting individuals is not cost-effective," the study's authors concluded that programs which "encourage the food industry to reduce salt in processed foods are highly recommended for improving population health and reducing health sector spending in the long term." They suggested, however, that "regulatory action from government may be needed to achieve the potential of significant improvements in population health."

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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.

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