Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

New Legislation Would Prohibit Use of BPA in Food Containers

Senator Dianne Feinstein (D-Calif.) and Representative Edward Markey (D-Mass.) have introduced bills (S. 136; H.R. 432) that would ban the use of the chemical bisphenol A (BPA) in food containers such as baby and water bottles, sippy cups and those used for canned foods and infant formula. Markey notes in a statement that he "led the fight to ban BPA from food and beverage containers" in the past two Congresses. Feinstein, whose bill is co-sponsored by Senators Charles Schumer (D-N.Y.), John Kerry (D-Mass.), Bernard Sanders (I-Vt.), and Al Franken (D-Minn.), said, "Scientific evidence increasingly shows that BPA poses serious health risks, especially to children, and manufacturers and retailers have already started to offer BPA-free products in their shelves…. The time has come to take action."

The Senate bill was referred to the Committee on Health, Education, Labor, and Pensions, and the House bill is pending before the House Committee on Energy and Commerce. *See Feinstein* and *Markey Press Releases*, January 25, 2011.

USDA Announces Deregulation of Roundup Ready® Alfalfa

In a decision that prompted the promise of an immediate legal challenge, the U.S. Department of Agriculture (USDA) has announced that it will grant non-regulated status to genetically engineered (GE) alfalfa. According to USDA Secretary Tom Vilsack, "After conducting a thorough and transparent examination of alfalfa through a multi-alternative environmental impact statement (EIS) and several public comment opportunities, APHIS [the Animal and Plant Health Inspection Service] has determined that Roundup Ready alfalfa is as safe as traditionally bred alfalfa." The agency's Record of Decision concludes that "alfalfa events J101 and J163 do not pose a greater plant pest risk than other conventional alfalfa varieties."

The House Agriculture Committee conducted a public forum January 20, 2011, to discuss matters relating to the USDA's anticipated action on GE alfalfa's deregulation. The agency had proposed several options, including partially

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deregulating GE alfalfa and establishing isolation distances and geographic limits on where the crop is grown. According to Vilsack, this option "mirrors a healthy and productive conversation between GE, non-GE and organic interests that is already underway in the industry and continues to evolve."

Republican House members, including committee chair Frank Lucas (Okla.), expressed their concerned about the "increasingly troublesome delays" in the regulatory approval process for GE crops. Lucas also emphasized that USDA's authority over GE crops and plants does not extend to "rhetorical concerns advanced by activist groups." Because USDA determined that GE alfalfa does not pose a quantifiable plant pest risk, Lucas contended, "This should be the end of the debate. A product that has been repeatedly found to be safe should be deregulated." Lucas argued that the partial deregulation option was developed "to prevent future lawsuits," and as such "is a political objective … outside the scope of legal authority."

The Center for Food Safety, which filed the lawsuit that led to a court order requiring USDA's reconsideration of the GE crop's regulated status in light of potential environmental impacts, has issued a statement indicating that it will file an "immediate legal challenge to USDA's flawed assessment." Its executive director said, "USDA has become a rogue agency in its regulation of biotech crops and its decision to appease the few companies who seek to benefit from this technology comes despite increasing evidence that GE alfalfa will threaten the rights of farmers and consumers, as well as damage the environment." The center contends that the decision to allow the unlimited, nationwide commercial planting of a GE crop "places the entire burden for preventing contamination on non-GE farmers, with no protections for food producers, consumers and exporters." *See House Agriculture Committee Press Release*, January 20, 2011; *USDA News Release* and *Center for Food Safety Press Release*, January 27, 2011.

APHIS Updates Avian Influenza Rules

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has issued an **interim rule** updating its highly pathogenic avian influenza (HPAI) requirements for importing birds, poultry and hatching eggs. Because APHIS's previous restrictions applied only to the H5N1 subtype of avian influenza, the new rule extends its purview to include any HPAI subtype, thus barring poultry imports from any country where these subtypes "are considered to exist."

Effective January 24, 2011, the interim rule also prohibits the importation of live poultry and birds that "have been vaccinated for any H5 or H7 subtype," as well as their hatching eggs, since these imports "may produce false positive test results … during the required 30-day quarantine." In addition, APHIS has banned live poultry, birds and hatching eggs "that have moved through regions where any HPAI subtype exists."

APHIS has invited comments on the interim rule before March 25, 2011. It has also published a list of countries affected with HPAI subtypes that includes Japan, where the government recently ordered a cull of 400,000 chickens exposed to the H5 strain. *See Meatingplace.com,* January 24, 2011.

FDA Issues Strategic Plan for National Antimicrobial Resistance Monitoring System

The Food and Drug Administration (FDA) has released a strategic plan that outlines the 2011-2015 goals and objectives of the National Antimicrobial Resistance Monitoring System (NARMS), which aims to protect "the health of Americans through safer food." Calling the plan "a dynamic roadmap which outlines the program's commitment to sustained food safety through monitoring and research," FDA has requested comments by March 25, 2011.

Established in 1996 by FDA, the Centers for Disease Control and Prevention and the U.S. Department of Agriculture in collaboration with state and local health departments, NARMS "monitors the susceptibility of enteric bacteria to anti-microbial agents of medical importance." Its strategic goals are to (i) "develop, implement and optimize a shared database, with advanced data acquisition, analysis, and reporting tools"; (ii) "make sampling more representative and more applicable to trend analysis"; (iii) "strengthen collaborative research projects"; and "support international activities that promote food safety, especially those that promote mitigation of the spread of antimicrobial-resistant bacteria and resistance determinants." *See FDA Press Release; Federal Register,* January 24, 2011.

FDA Issues First Annual Reportable Food Registry Report

The Food and Drug Administration (FDA) has issued the first annual report on its Reportable Food Registry (RFR) designed to prevent foodborne illness outbreaks.

Summarizing 2,240 online food safety reports from the food industry and public health officials between September 2009 and September 2010, the report "is a measure of our success in receiving early warning problems with food and feed," states FDA Deputy Commissioner for Foods Michael Taylor in the preface.

Report findings apparently show that 37.6 percent of the reported food hazards were caused by *Salmonella*, 34.9 percent by "undeclared allergens/intolerances" and 14.4 percent by *Listeria.* The report highlighted "two particularly significant issues in multiple commodity groups that require attention": (i) *Salmonella* found in such products as spices and seasonings, produce, animal feed and pet food, nuts and seeds; and (ii) allergens and intolerances in fare including baked goods, fruit and vegetable products, prepared foods, dairy, and candy.

"Several key U.S. industries are already reevaluating their hazards and preventive controls, core principles of the Food Safety Modernization Act recently passed by Congress," notes Taylor. "We anticipate improved reporting as we continue our vigorous outreach to food facilities through federal, state, local, and foreign agencies, to help us expand the positive effect of the RFR on the safety of the U.S. food supply."

OSHA Adds Diacetyl Substitutes to National Emphasis Program Document

The Occupational Safety and Health Administration (OSHA) has revised its "National Emphasis Program (NEP) on Microwave Popcorn Processing Plants," to add several diacetyl substitutes to its policies and procedures for minimizing or eliminating worker exposures "to the hazards associated with microwave popcorn manufacturing."

Effective January 18, 2011, the NEP now includes 2,3-pentanedione, 2,3-hexanedione, 2,3-heptanedione, and "all other related diacetyl substances that share the same alpha-diketone structure, as well as substitute diacetyl trimer and acetoin." According to OSHA's David Michaels, "Illnesses and deaths from these chemicals are preventable and this revised directive will help ensure that employers use necessary measures to protect workers from this hazard." *See OSHA Press Release*, January 24, 2011.

WHO to Consider Restrictions on Marketing Food to Youth in 2011

According to a press report, the World Health Organization (WHO) has announced that heads of state convening at the United Nations (U.N.), September 19-20, 2011, will use the U.N. General Assembly meeting to discuss restrictions on advertising foods of poor nutritional quality to children. WHO estimates that 43 million preschool children worldwide are overweight or obese, and some refer to the problem as a "fat tsunami," responsible for millions of premature deaths annually. Norewegian Directorate of Health representative Bjorn-Inge Larsen reportedly indicated that he expects voluntary restrictions on junk food advertising to be adopted as laws that will ultimately ban the practice, similar to the way tobacco was addressed. *See The Associated Press*, January 21, 2011.

ISO Nanotech Standard Addresses Inhalation Toxicity Testing

The International Organization for Standardization (ISO) has finalized a new standard that apparently establishes parameters for monitoring the concentration, size and size-distribution of nanoscale particles in an inhalation chamber as part of an effort to assess their potential toxicity. ISO 10808-2010, titled "Nanotechnologies—Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing," reportedly establishes a battery of tests that will help researchers learn about potential effects of nanoparticles on human health and the environment. ISO Technical

Committee ISO/TC 229, Nanotechnologies, developed the standard, and its Chair Peter Hatto was quoted as saying, "Traditional methods used in other areas are considered insufficient for testing nanoparticles since parameters specific to them like particle surface area or number, might be crucial determinants of toxicity." He called the test an "important asset to the industry." *See Nanowerk*, January 26, 2011.

UK Issues Foresight Report on Global Farming Future

The U.K. Department for Business Innovation and Skills has **released** the results of a Foresight project titled "The Future of Food and Farming: Challenges and choices for global sustainability," which examines "the increasing pressures on the global food system between now and 2050." Sponsored by the Department for Environment, Food and Rural Affairs and the Department for International Development, the report apparently relied on 400 experts from 35 countries to analyze five key challenges: (i) "Balancing future demand and supply sustainably"; (ii) "Ensuring that there is adequate stability in food prices"; (iii) "Achieving global access to food and ending hunger"; (iv) "Managing the contribution of the food system to the mitigation of climate change"; and (v) "Maintaining biodiversity and ecosystem services while feeding the world."

The report urges policy-makers "to consider the *global food system* from production to plate" and adopt "a broad view of food that goes beyond narrow perspectives of nutrition, economics and food security." In particular, the project's high-level conclusions focus on sustainable agriculture that conserves water, minimizes waste and curbs the consumption of resource-intensive foods; adaptation to climate change; prioritization of rural development to end hunger; and curbs on the loss of biodiversity. The findings also warn against excluding new technologies such as genetic modification "*a priori* on ethical or moral grounds," calling instead for increased research investment in modern agricultural technologies as well as "open and transparent decision-making."

"The solution is not *just* to produce more food, or change diets, or eliminate waste," opines the report. "The potential threats are so great that they cannot be met by making changes piecemeal to parts of the food system. It is essential that policy-makers address all areas at the same time." *See BBC News,* January 24, 2011.

LITIGATION

Court Dismisses Claims That HFCS Beverage Is Not "All Natural"

A federal district court in New York has granted the motion for summary judgment filed by Snapple Beverage Corp. in a case alleging that the company misled consumers by labeling its teas and juice drinks as "All Natural" because

the company's beverages contain high-fructose corn syrup (HFCS). *Weiner v. Snapple Beverage Corp.*, No. 07-8742 (U.S. Dist. Ct., S.D.N.Y., decided January 21, 2011). The court had previously denied plaintiffs' motion for class certification but determined, despite that denial, that it could decide the merits of the summary judgment motion even though the lawsuit now failed to satisfy the requirements of original diversity jurisdiction.

The defendant argued that the plaintiffs did not offer any evidence showing injury from Snapple's "All Natural" labeling, and the court agreed. Analyzing each claim—violation of a state deceptive practices law, unjust enrichment, and breach of express and implied warranty—the court found that the plaintiffs failed to present reliable evidence that they paid a premium for the company's products.

According to the court, "Plaintiffs have provided nothing but conjecture as to the prices they paid for Snapple and the prices of comparable beverages available for sale at the time of their Snapple purchases. Thus, they have not provided a sufficient 'basis in fact' upon which a damages award could be based." Similarly, the court found that they could not show "that Snapple benefited unjustly at their expense," or that they purchased the beverages "in reliance on the 'All Natural' label."

Taco Bell Customer Questions the Beef Content of Tacos, Burritos

A California resident has filed a putative class action against Taco Bell Corp., alleging that the company violates consumer protection laws by mislabeling some of its beef products as containing seasoned beef "when in fact a substantial amount of the filling contains substances other than beef." *Obney v. Taco Bell Corp.*, No. 11-00101 (U.S. Dist. Ct., C.D. Cal., S. Div., filed January 19, 2011). Seeking to certify a nationwide class of consumers and claiming that damages exceed $5 million, the plaintiff alleges violations of California's Consumer Legal Remedies Act and unlawful business acts and practices, including misbranded food in violation of federal law. She also asks for declaratory and injunctive relief, a corrective advertising campaign, attorney's fees, and costs.

According to plaintiff's counsel, testing has shown that "the taco meat filling is about 35 percent meat." The complaint asserts that the company's use of the term "seasoned beef" in the labeling and advertising of its beef tacos and burritos is inconsistent with the U.S. Department of Agriculture's (USDA's) definition of ground beef. USDA apparently defines ground beef as consisting of "chopped fresh and/or frozen beef" and not containing "added water, phosphates, binders, or extenders." The complaint also asserts that USDA's industry guidance "requires food labeled as 'Taco filling' to contain 'at least 40 percent fresh meat.'"

Taco Bell President Greg Creed has reportedly indicated that the company intends to take legal action against those who filed the lawsuit and says that their allegations are "false claims." The fast-food chain apparently issued a statement saying that the company "is proud of the quality of our beef and identif[ies] all the seasoning and spice ingredients on our website." Creed also reportedly said, "At Taco Bell, we buy our beef from the same trusted brands you find in the supermarket. We start with 100 percent USDA-inspected beef. Then we simmer it in our proprietary blend of seasonings and spices to give our seasoned beef its signature Taco Bell taste and texture." *See Associated Press* and *CBS,* January 26, 2011

E. Coli-Tainted Spinach Suit Settled

A Utah woman who claims that *E. coli*-tainted spinach caused her irritable bowel syndrome and subsequent chronic incapacitation has reportedly settled her lawsuit against three California-based companies. Chelsey Macey, 26, and her husband were seeking damages in excess of $5 million. A jury awarded the couple that amount in compensatory damages, but before it could consider an award for pain and suffering, the parties apparently settled. The defendants were Dole Food Co., Natural Selection Foods and Mission Organics. *See KSBW.com*, January 20, 2011.

No Visas Issued for Costa Rican Banana Plantation Workers

According to a news source, Costa Rican farmers who allege they were injured by exposure to a pesticide used on Dole Food Co.'s banana plantations have been unable to obtain visas to enter the United States for medical testing. A state court ordered that the plaintiffs be tested in U.S. laboratories, apparently to avoid evidence tampering. Embassy officials have reportedly denied the visas finding that the applicants lack "sufficient ties to Costa Rica." Plaintiffs' counsel Mark Sparks contends that his clients are "extremely poor" and lack the indicia of residency, such as bank accounts, business records and car titles, that embassy officials have requested.

Plaintiffs' and defendants' counsel have reportedly drafted a letter for the presiding judge to send to U.S. embassy officials to allow the Costa Rican plaintiffs to travel to Los Angeles for the limited purpose of medical testing and responding to interrogatories. At least one legal commentator has suggested that the letter may not be persuasive, saying "State courts obviously don't have any way of compelling the federal government to allow a non-citizen to come to the United States." *See* (California) *Daily Journal*, January 21, 2011.

OTHER DEVELOPMENTS

GMA and FMI Announce New FOP Labeling System

The Grocery Manufacturers Association (GMA) and the Food Marketing Institute (FMI) have **introduced** a new front-of-pack (FOP) labeling system in response to first lady Michelle Obama's campaign for clearer consumer information. According to a January 24, 2011, press release, the Nutrition Keys initiative summarizes important information "from the Nutrition Facts panel in a clear, simple and easy-to-use format" that adheres "to current U.S. Food and Drug Administration [FDA] guidelines and regulations." The FOP label features four basic icons for calories, saturated fat, sodium, and sugars, as well as optional "nutrients to encourage" icons indicating that the product meets FDA "good source" requirements and contains more than 10 percent of the daily value per serving for protein and the following under-consumed nutrients: potassium, fiber, vitamin A, vitamin C, vitamin D, calcium, and iron. *See GMA Press Release,* January 24, 2011.

Food companies can begin using the new icons this year, but the system has already drawn criticism from consumer advocates and health officials who support FOP labels that also teach consumers what nutrients to avoid. "The industry's unveiling today of its front-of-package labeling system is troubling and confirms that this effort should not circumvent or influence FDA's effort to develop strong guidelines for FOP labels," said U.S. Representative Rosa DeLauro (D-Conn.). "Given that negative and positive nutrients will not be differentiated on the package, there is significant risk that these labels will be ignored. An adequate labeling system must clearly alert consumers about potentially unhealthy foods, and should not mislead them into believing that some foods are healthy when they clearly are not." *See The Center for Science in the Public Interest Press Release, DeLauro Press Release* and *The New York Times,* January 24, 2011.

CSPI Report Calls Antibiotic-Resistant Bacteria "Foodborne Hazard"

The Center for Science in the Public Interest (CSPI) has released a **report** claiming that antibiotics used on farms "may be causing more serious pathogens in the nation's food supply."

Calling for increased scrutiny by the federal government, the January 25, 2011, report asserts that recording outbreaks of foodborne illnesses and subsequently testing the pathogens for antibiotic resistance "is a critical step if policymakers are to document the link between antibiotic use on farm animals and human illness from antibiotic-resistant bacteria."

The consumer watchdog found that between 2000 and 2009, multi-drug resistance was found in 10 out of 14 antibiotic-resistant foodborne outbreaks. Of 35 documented outbreaks between 1973 and 2009, most involved raw

milk, raw milk cheeses and ground beef. "Outbreaks from antibiotic resistant strains of *Salmonella*, though rare, cannot be ignored by our food safety regulators," said CSPI Food Safety Director Caroline Smith DeWaal. "The problem has clearly emerged with respect to some high risk foods. Both humans and animals rely on antibiotics to stay healthy. But overuse in some sectors may squander their effectiveness and leave consumer[s] vulnerable to hard-to-treat foodborne infections." *See CSPI Press Release,* January 25, 2011.

MEDIA COVERAGE

William Neuman, "F.D.A. and Dairy Industry Spar Over Testing of Milk," *The New York Times,* January 25, 2011

"Each year, federal inspectors find illegal levels of antibiotics in hundreds of older dairy cows bound for the slaughterhouse," opens this article about the Food and Drug Administration's (FDA's) recent decision to begin testing milk from farms "that had repeatedly sold cows tainted by drug residue." Concerned that "the same poor management practices which led to the meat residues may also result in drug residues in milk," FDA evidently singled out approximately 900 dairy farms for testing that would include "two dozen antibiotics beyond the six that are typically tested for." The new protocol also covered flunixin, "a painkiller and anti-inflammatory drug popular on dairy farms … which often shows up in the slaughterhouse testing."

Although the plan reportedly drew support from consumer advocates like the Center for Science in the Public Interest, it prompted a backlash from dairy farmers and state regulators who objected to the week-long wait for test results. According to *Times* reporter William Neuman, these groups feared that the delay would force farmers to either dump large quantities of milk or risk putting contaminated milk in consumer products, which would then be subject to massive recalls.

"In a sharply worded Dec. 29 letter," notes Neuman, "the top agricultural officials of 10 Northeastern states… told the [FDA] that its plan was badly flawed," in part because massive milk dumps "could create environmental problems." FDA has since agreed to review its new policy, stressing that it "remains committed to gathering the information necessary to address its concern with respect to this important potential public health issue."

SCIENTIFIC/TECHNICAL DEVELOPMENTS

JAMA Commentary Warns of Energy Drink Risk

A January 25, 2011, commentary in the *Journal of the American Medical Association* (*JAMA*) has claimed that "regular (nonalcoholic) energy drinks

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might pose just as great a threat to individual and public health and safety" as the alcoholic versions recently barred by the Food and Drug Administration (FDA) and Federal Trade Commission (FTC). According to authors Amelia Arria and Mary Claire O'Brien, "health professionals should inform their patients of the risks associated with the use of highly caffeinated energy drinks; the public should educate themselves about the risks of energy drink use, in particular the danger associated with mixing energy drinks and alcohol; and the alcohol and energy drink industries should voluntarily and actively caution consumers against mixing energy drinks with alcohol, both on their product labels and in their advertising materials."

Calling for increased regulation, the article focuses on research suggesting that the caffeine in energy drinks could cause "adverse health events in susceptible individuals," including adolescents and pregnant women. It also alleges that mixing energy drinks with alcohol "has been linked consistently to drinking high volumes of alcohol per drinking session and subsequent serious alcohol related consequences." Moreover, the authors note, "regardless of whether energy drinks are mixed with alcohol," their use "might confer a risk for alcohol dependence and perhaps nonmedical prescription drug use."

"The National Institutes of Health must recognize the lack of systematic research on the health and safety effects of energy drink consumption, especially among adolescents," concludes the commentary, which recommends setting an upper limit on the amount of caffeine permitted in energy drinks. "To promote informed consumer choices, regulatory agencies should require specific labeling regarding caffeine content, with warnings about the risks associated with caffeine consumption in adolescents and in pregnant women as well as with explicit information about the potential risks associated with mixing energy drinks with alcohol." ■

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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.