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#### LEGISLATION, REGULATIONS AND STANDARDS

### Dozens of Food Groups and Activists Call on President Obama to Label GE Foods

More than 200 organizations, farms, grocers, individuals, and consumer and environmental rights organizations have <u>submitted</u> a letter to President Barack Obama (D) reminding him of his 2007 pledge "to give consumers the right to know if their food is genetically engineered (GE)." Claiming that 93 percent of Americans share his view, they call on the president to fulfill his commitment and establish a mandatory national labeling system. Among those signing the letter are the Center for Food Safety, As You Sow, Consumers Union, Greenpeace, the Sierra Club, and food companies including Eden Foods, Rudi's, Amy's Kitchen, Ben & Jerry's, and Stonyfield Farm. See Center for Food Safety Press Release, January 16, 2014.

#### FDA Guidance Differentiates Liquid Dietary Supplements from Beverages

The U.S. Food and Drug Administration (FDA) has issued two final guidance documents for industry on distinguishing liquid dietary supplements from beverages. Titled "Distinguishing Liquid Dietary Supplements From Beverages" and "Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements," the documents update 2009 draft guidance intended "to help dietary supplement and beverage manufacturers determine whether a liquid food product is properly classified as a dietary supplement or as a beverage, and to remind the industry of legal requirements regarding the substances that may be added to either type of product."

In "Distinguishing Liquid Dietary Supplements from Beverages," FDA describes the factors characterizing liquid products deemed dietary supplements and those characterizing beverages deemed conventional foods. These include product claims, names, packaging, serving size, recommended daily intake, conditions of use, and product composition, as well as statements or graphic representations in labeling, advertising and other marketing practices, including promotional Websites, and social media. For example, use of the terms "beverage," "drink," "water," or "soda" in the marketing or the product name would render the product a conventional food. Representation as a conventional beverage can also be implied by the size, shape, color, and design of the container or other packaging.



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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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"Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements," reminds industry about the different regulatory requirements under the Federal Food, Drug, and Cosmetic Act for ingredients used in these two types of products. For beverages, ingredients must be either GRAS (generally recognized as safe) or approved as food additives. For dietary supplements, any substance considered a new dietary ingredient (NDI) must have a pre-market NDI notification to FDA; non-dietary ingredients such as binders would need either food additive approval or GRAS status for their intended use. The agency noted that some of the novel substances added to conventional foods, including beverages, "may cause the food to be adulterated because these added substances may not be GRAS for their intended use and are not being used in accordance with a food additive regulation."

#### **EFSA Opens Public Consultation on Iodine Dietary Reference Values**

The European Food Safety Authority's (EFSA's) Panel on Dietetic Products, Nutrition and Allergies (NDA) has <u>launched</u> a public consultation for its <u>draft scientific opinion</u> on dietary reference values for iodine. Using data from "a large epidemiological study in European school-aged children showing that goiter prevalence is lowest for a urinary iodine concentration  $\geq 100~\mu g/L$ ," NDA has proposed setting adequate intake (AI) levels for iodine at 150  $\mu g/day$  for adults and between 70  $\mu g/day$  and 130  $\mu g/day$  for infants aged 7-11 months and all children. The panel has also recommended an AI of 200  $\mu g/day$  for pregnant and lactating women, which takes into account "the additional needs due to increased maternal thyroid hormone production and the iodine uptake by the fetus, placenta and amniotic fluid" as well as "the existence of large iodine stores in conditions of adequate iodine status before pregnancy." EFSA will accept comments on the draft scientific opinion until February 26, 2014.

#### **OEHHA to Reconsider Reproductive Toxicity of Some Substances**

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has <u>issued</u> a hazard identification document for six chemicals that will be reconsidered for listing as reproductive toxicants under Proposition 65. Used in epoxy resins or as plasticizers, the chemicals—n-butyl glycidyl ether, diglycidyl ether, phenyl glycidyl ether, methyl n-butyl ketone, methyl isopropyl ketone, and α-methyl styrene—were added to the list via the Labor Code mechanism. Changes to federal regulations affecting this listing mechanism have required that the chemicals be reconsidered. Public comments are requested by February 25, 2014, and the Developmental and Reproductive Toxicant Identification Committee will discuss them during its March 19 meeting.

Manufacturers of products containing chemicals determined to be known to the state to cause cancer or reproductive toxicity are required to provide warnings to consumers under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). See OEHHA News Release, January 10, 2014.



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#### LITIGATION

#### Sixth Circuit Upholds Restrictions on Liquor Sales in Kentucky

The Sixth Circuit Court of Appeals has determined that Kentucky has a rational basis for restricting the types of retailers that may be issued licenses to sell liquor and wine, thus ruling that the law does not violate grocers' equal-protection rights. *Maxwell's Pic-Pac, Inc. v. Dehner*, Nos. 12-6056, -6057, -6182 (6th Cir., decided January 15, 2014).

A state law adopted in 1939 that today prohibits the issuance of a retail drink license to "any business in which a substantial part of the commercial transaction consists of selling at retail staple groceries or gasoline and lubricating oil," was interpreted in 1982 by the Alcohol Beverage Control Board in a regulation that defines "substantial part" (10% or greater of the monthly gross sales) and "staple groceries" (foods intended for human consumption other than soft drinks, candy, hot foods, and foods prepared for immediate consumption). Grocers challenged the restrictions on equal-protection, separation-of-powers and due-process grounds. The district court agreed with their equal-protection claim but rejected the others in granting them summary judgment.

Citing the state's interest in reducing access to products with high alcohol content, the Sixth Circuit concluded that "reasonably conceivable facts support the contention that grocery stores and gas stations pose a greater risk of exposing citizens to alcohol than do other retailers." The court was especially concerned about drunk driving, minors and people who "object to confronting wine and liquor." Accordingly, the court reversed the equal-protection ruling.

As to the grocer's claim that allowing an agency to define statutory terms violated the state constitution's separation-of-powers principle, the court ruled that the statutory language "limits the board's authority to define the terms of the statute" and thus appropriately limits the administrative board's discretion. The grocers relied on cases involving criminal statutes to support their void-for-vagueness challenge, and the court rejected the argument because, unlike in the criminal context, the statute here "affects no liberty interest." Therefore, the court affirmed the lower court's rulings as to these two issues.

#### **Prosecutor Agreement Revealed in Monster Energy Probes**

According to news sources, San Francisco City Attorney Dennis Herrera and New York Attorney General Eric Schneiderman have entered an agreement to share documents and otherwise coordinate efforts in their ongoing investigations of Monster Beverage Corp., which, they allege, illegally markets highly caffeinated beverages to children. Herrera reportedly said, "Up until now, we



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have been working in parallel fashion, but now you will see greater cooperation. I have enormous respect for Attorney General Schneiderman and am glad to be working with his office in this major consumer protection issue." Herrera further claimed that the company continues "to market its potentially dangerous products to children, despite the known risks it poses to young people. Hopefully, our efforts can lead to a reform of those practices."

The agreement was apparently struck about the same time that a court dismissed Monster Beverage's attempt to stop Herrera's investigation. Details about the ruling appear in Issue 508 of this *Update*. Meanwhile, the company has issued a statement saying, "the sale and consumption of more than 10 billion Monster energy drinks worldwide over more than 11 years has shown that our products are safe. Contrary to allegations, they are not 'highly caffeinated' and they are not marketed to children." *See Associated Press*, January 14, 2014; *Law360*, January 15, 2014.

#### **Employees Seek Approval of Wage Dispute Settlement with Benihana**

A putative class of workers employed by Benihana Inc. in its New York City-based Haru Restaurants has filed an unopposed motion for preliminary approval of an agreement that would resolve claims that the company did not pay employees all the pay to which they were entitled and did not provide certain employees with valid tip credits. *Lin v. Benihana Nat'l Corp.*, No. 10-1335 (U.S. Dist. Ct., S.D.N.Y., motion filed January 14, 2014). Under the agreement, the company would create a \$600,000 settlement fund that would reimburse certain class members the full amount of their spread-of-hours premium and other members 80 percent of purported back pay due to an invalid tip credit. Under New York law, employees who work more than 10 hours during a work day are entitled to an extra hour of pay, referred to as spread-of-hours wages. Attorney's fees and expenses would also be paid from the fund.

#### Jensen Brothers Ask Court Not to Impose Jail Time

Eric and Ryan Jensen, who owned the cantaloupe farm linked to a deadly 2011 *Listeria* outbreak, have reportedly urged a court, following their pleas to charges related to the incident, not to sentence them to prison. Additional details about the plea and charges appear in Issue 500 of this *Update*. They apparently claim that they do not need correctional treatment and have done everything possible to make the victims whole, including declaring bankruptcy to make a pool of money available to compensate them. The brothers pleaded guilty to six misdemeanor charges that each carry potential sanctions of one year in prison, a \$250,000 fine, or both, as well as one year of supervised release. A sentencing hearing will be held in late January 2014.

According to Eric Jensen's brief, "this case has already prompted a new awareness of food safety law and the strict liability imposed on producers and food



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processors. Any desired respect for the law has been accomplished. We have reached a point of diminishing returns on this issue." Representing 47 of 147 individuals affected by the outbreak, plaintiffs' lawyer William Marler opined that a sentence of probation would be appropriate given the "nonintent" nature of the alleged crime. *See Law360*, January 16, 2014.

#### Putative Class Claims Diamond Foods' Tortilla Chips Are Not Natural

A California resident has filed a putative statewide class action in a California federal court against Diamond Foods, Inc., alleging that the company misleads consumers by prominently labeling its line of TIAS Tortilla Chips® as "All Natural" when they contain artificial ingredients such as maltodextrin and/or dextrose. *Surzyn v. Diamond Foods, Inc.* No. 14-136 (U.S. Dist. Ct., N.D. Cal., filed January 9, 2014). The complaint has been crafted to avoid some of the pitfalls that other plaintiffs have encountered bringing similar claims, including express references to the defendant making "the exact same 'All Natural' claim in the exact same prominently displayed location on the front packaging," to forestall a court finding that the plaintiff lacks standing to pursue claims for products she did not actually purchase.

Alleging economic injury, that is, not receiving the benefit of the bargain, and expressly not seeking "to contest or enforce any state law that has requirements beyond those required by Federal laws or regulations," the plaintiff claims that the "All Natural" food product representation "is material to a reasonable consumer" and that Consumers Union has found that 86 percent of consumers "expect a 'natural' label to mean processed foods to not contain any artificial ingredients." She also focuses on the package labeling for the products and avoids any reference to Website product representations.

The plaintiff alleges 14 specific injuries as a direct result of deceptive labeling, including consumers receiving products that did not measure up to their expectations; ingesting a substance other than what was represented; being denied "the benefit of knowing what they ingested" and "of truthful food labels"; unwittingly supporting "an industry that contributes to environmental, ecological, and/or health damage"; and being "denied the benefit of the beneficial properties of the natural foods promised."

Claiming negligent representation and violations of the state's Unfair Competition Law, False Advertising Law and Consumers Legal Remedies Act, the plaintiff seeks to enjoin the defendant from making "natural" claims for the products, restitution, disgorgement, actual damages, attorney's fees, and costs.

#### Food Activist Targets Gatorade Ad in New York AG Complaint

Food activist and blogger Nancy Huehnergarth has reportedly filed a complaint with the New York attorney general (AG) over a purportedly deceptive "viral advertising campaign" from 2013 featuring a mobile game that promoted



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Gatorade® as a performance enhancer while denigrating water as "the enemy of performance." According to a news source, gamers using the app navigated an avatar through an obstacle course and picked up bottles of Gatorade® to increase his speed while avoiding drops of water that slowed him down.

Huehnergarth, who co-founded the New York State Healthy Eating and Physical Activity Alliance and was instrumental in getting "junk" food removed from school vending machines in her community, apparently filed the complaint because she believed the campaign provided an inaccurate message to children. "It's preying on youth while slipping past parents who don't necessarily police a mobile device quite as carefully as they do a computer. I think it's chutzpah to the highest degree," she said. Parent company PepsiCo responded in a statement, "The mobile game, Bolt! from Gatorade was designed to educate athletes about the scientifically proven concept that sport drinks can have advantages when it comes to athletic performance because they contain carbohydrates that provide fuel and electrolytes that aid in hydration."

Center for Science in the Public Interest Executive Director Michael Jacobson was quoted as saying, "I think the basic strategy is to make people think they will become better athletes if they drink Gatorade, but the average consumer's health and wallet would be better off if they stuck with water." The game evidently won an Interactive Advertising Bureau Mixx award for mobile marketing and has been nominated for several others. It attracted some 4 million Facebook likes and was downloaded 2.3 million times. While the game is no longer available, it was reportedly played more than 83 million times; nearly three-fourths of the players were between the ages of 13 and 24. See ABCNews.com, January 9, 2014.

#### OTHER DEVELOPMENTS

#### **IOM Issues Caffeine Workshop Summary**

The National Academies' Institute of Medicine (IOM) has **issued** the summary from an August 5-6, 2013, workshop titled "Caffeine in Food and Dietary Supplements." Convened at the request of the U.S. Food and Drug Administration, workshop participants included "scientists with expertise in food safety, nutrition, pharmacology, psychology, toxicology, and related disciplines; medical professionals with pediatric and adult patient experience in cardiology, neurology, and psychiatry; public health professionals; food industry representatives; regulatory experts; and consumer advocates." They addressed the "changing caffeine landscape" in which new food and dietary supplement products including the substance are entering the marketplace at a rapid pace and may be "targeting populations not normally associated with caffeine consumption."



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Among the workshop objectives were (i) "[e] valuate the epidemiological, toxicological, clinical, and other relevant literature to describe important health hazards associated with caffeine consumption"; (ii) "[d]elineate vulnerable populations who may be at risk from caffeine exposure"; (iii) "[d]escribe caffeine exposure and risk of cardiovascular and other health effects on vulnerable populations, including additive effects with other ingredients and effects related to pre-existing conditions"; (iv) "[e]xplore safe caffeine exposure levels for general and vulnerable populations"; and (v) "[i]dentify data gaps on caffeine stimulant effects, including but not limited to cardiovascular, central nervous system, or other health outcomes."

Monster Beverage, Inc. medical advisor Bob Arnot provided public comments during the workshop and reportedly noted that the evidence on how little caffeine adolescents and children actually consume was striking. He also observed that the alleged adverse effects experienced by adolescents who consumed caffeinated energy drinks were not necessarily causally associated with that consumption.

#### Harvard Law School Adopts New Focus on Food Law

According to an article appearing in the January 2014 issue of the Harvard Law Bulletin, Harvard Law School has established a food law and policy clinic in light of "more and more people deeply concerned about what they're eating and what it means for our health, the economy, the environment, social justice, and even national security." The school has also launched the Food Law Lab that "will be a locus for research, scholarship and teaching on the legal regulation of food." Lab director Professor Jacob Gersten has predicted that "in the next decade, food law will become as big as environmental law. In terms of sheer volume and variety of legal happenings, the field is quite vibrant right now."

Among other issues of interest are changes to food safety regulations under the Food Safety Modernization Act, U.S. Supreme Court jurisprudence on genetically modified seeds, state and local government regulations such as New York City's effort to regulate soft-drink sizes, food insecurity, obesity, sustainability, bio- and agro-terrorism concerns, and food labeling issues. The Harvard clinic was behind a report released in September 2013 that discussed how "confusing food date labels lead to food waste." Food law at Harvard is apparently "a hot topic," with some courses oversubscribed.

Harvard Law School Center for Health Law and Policy Innovation Director Robert Greenwald said of the initiatives, "I really think that ultimately we're building the infrastructure for a long-term and sustainable movement to truly transform both what we produce and what we eat. Our food production system is not sustainable in terms of the environment and public health, in that we have malnutrition in the face of obesity. We want to be at



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the forefront and help guide this transformation." Students are apparently undertaking client-based projects throughout the country.

#### Report Says UK Obesity Crisis Was Underestimated

A recent <u>report</u> issued by the U.K.'s National Obesity Forum suggests that a 2007 prediction that 50 percent of the British population would be obese by 2050 significantly underestimated the scale of the country's obesity crisis. Titled "State of the Nation's Waistline," the report notes that "it is entirely reasonable to conclude that the determinations of the 2007 [report], while shocking at the time, may now underestimate the scale of the problem."

Noting that health professionals could do more, such as intervening earlier, initiating discussion with patients on obesity and weight management issues, routinely measuring children's height and weight and adults' waist circumferences, and encouraging citizens to take a more proactive approach regarding their own health, Forum Chair David Haslam says that these actions go hand in hand with government leadership and ensuring responsible food and drink manufacturing and retailing. "We need more proactive engagement by healthcare professionals on weight management, more support and better signposting to services for people who are already obese, and more importance placed on what we drink and how it affects our health," observed Haslam.

Among other things, the report recommends (i) harder-hitting campaigns, similar to those for anti-smoking; (ii) better training for primary health care professionals on obesity and weight management; (iii) government initiatives that focus on the importance of hydration—often underlooked—in weight management; (iv) government policies that reduce the amount of sugar in beverages, reduce consumption of sugar-sweetened beverages, and promote water as the best hydration source; (v) increased focus on strategies to support individuals who are already obese; and (vi) greater promotion of physical activity outside educational settings.

#### CSIRO Uses RFI Sensors to Track Flight of the Honey Bee

The Australian Commonwealth Scientific and Industrial Research Organization (CSIRO) has reportedly launched a new research initiative designed to monitor honey bee behavior using tiny radio frequency identification (RFI) sensors. According to a January 15, 2014, CSIRO news release, researchers have for the first time fitted 5,000 bees in Hobart, Tasmania, with 2.5-by-2.5 millimeter sensors as part of CSIRO's efforts to improve pollination and productivity on farms as well as understand threats to hive health such as colony collapse disorder. These sensors will transmit information about each individual bee's movements whenever it passes a data-gathering checkpoint, allowing



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scientists "to build a comprehensive three dimensional model and visualize how these insects move through the landscape."

"Bees are social insects that return to the same point and operate on a very predictable schedule. Any change in their behavior indicates a change in their environment," explained lead researcher Paulo de Souza. "If we can model their movements, we'll be able to recognize very quickly when their activity shows variation and identify the cause. This will help us understand how to maximize their productivity as well as monitor for any biosecurity risks."

#### MEDIA COVERAGE

#### Bittman Issues Call to Action on Healthful Food Policies

New York Times op-ed writer Mark Bittman has authored a commentary urging the federal government to adopt policies and incentives to benefit growers and consumers "with products that [are] less damaging to the environment and public health." Focusing on three broad food categories—"industrially produced animal products," "junk food" and "real food"—Bittman explains how certain policies can either promote their production and consumption or restrict their use, much as tobacco-control policies have changed over time and affected production, sale and use patterns. While acknowledging that such changes can be disruptive and that certain sectors can be harmed by new agricultural policy, Bittman claims that government action is more effective than efforts to change the industry and is desirable in the long run. "We can pressure corporations all we want, and what we'll get, mostly, is healthier junk food. Really, though, as long as sugar is profitable and 100 percent unrestricted (and subsidized and protected!), marketers will try to get 2-year-olds hooked on soda and Gatorade," he writes. See The New York Times, January 14, 2014.

#### SCIENTIFIC/TECHNICAL ITEMS

#### Food and Beverage Marketing in Schools Target of New Study

A recent study examining national trends in school nutrition environments has reportedly concluded that "most U.S. elementary, middle and high school students attend schools where they are exposed to commercial efforts aimed at obtaining food or beverage sales or developing brand recognition and loyalty for future sales." Yvonne Terry-McElrath, et al., "Commercialism in US Elementary and Secondary School Nutrition Environments: Trends from 2007 to 2012," JAMA Pediatrics, January 2014. Relying on data from two parallel surveys of school administrators—the Food and Fitness study for elementary schools and the Youth, Education and Society study for middle and high



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schools—that were conducted by the Bridging the Gap program between 2007 and 2012, University of Michigan researchers measured student exposure to (i) "exclusive beverage contracts and associated incentives, profits and advertising"; (ii) "corporate food vending and associated incentives and profits"; (iii) "posters/advertisements for soft drinks, fast food, or candy"; (iv) "use of food coupons as incentives"; (v) "event sponsorships"; and (vi) "fast food available to students."

Their results purportedly showed that despite a significant decrease in beverage vending, students were still exposed to other forms of food and beverage commercialism at all academic levels. In particular, the researchers reported that nearly two-thirds of elementary school students attended institutions using food coupons in incentive programs, while 49.5 percent of middle school students and 69.8 percent of high school students attended institutions with exclusive beverage contracts. Moreover, they noted, "exposure to elementary school coupons, as well as middle and high school exclusive beverage contracts, was significantly more likely for students attending schools with mid or low (vs high) student body socioeconomic status." Additional details about Terry-McElrath's research appear in Issue 449 of this *Update*.

Meanwhile, a concurrent editorial authored by Rudd Center for Food Policy and Obesity Director of Marketing Initiatives Jennifer Harris and Food, Nutrition & Policy Consultants President Tracy Fox warns that "the school-based food and beverage marketing described in Terry-McElrath et al. understates the overall picture." In addition to the branded fast food sold in school cafeterias on a weekly or daily basis, Harris and Fox highlight fundraising initiatives sponsored by food companies, the use of soda and sports drinks logos on donated equipment, and the digital advertising that appears on search engines and educational Websites used in the classroom. They also criticize the industry-backed Children's Food and Beverage Advertising Initiative and similar pledges for failing to close loopholes that currently permit these activities.

"If companies choose to continue marketing unhealthy foods and beverages in schools, states and school districts have significant leeway to restrict advertising to students in public schools," concludes the editorial, which points to a 2007 Maine law that limits food marketing in all public schools. "Policy makers, school district leaders, and parents should take action to ensure that the entire food and nutrition environment in schools promotes students' health and well-being."

#### Researchers Find Some Populations More Sensitive to Fast Food Price Changes

University of North Carolina Gillings School of Public Health researchers have apparently assessed the "subgroup-specific effects of fast food price changes on fast food consumption and cardiometabolic outcomes," reporting



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greater sensitivity to fast food price changes among sociodemographic groups with a disproportionate burden of chronic disease. Katie Meyer, et al., "Sociodemographic Differences in Fast Food Price Sensitivity," JAMA Internal Medicine, January 2014. Using data from 5,115 participants enrolled in the Coronary Artery Risk Development in Young Adults study, which included food-frequency questionnaires as well as clinical measures such as body mass index (BMI) and homeostasis model assessment of insulin resistance scores, the study's authors determined that, over 20 years of follow-up, "fast food price was inversely associated with frequency of fast food consumption, with greater price sensitivity among blacks, as compared with whites, and among others with lower educational attainment." In addition, the results suggested that "fast food price was inversely associated with BMI in blacks and among those with lower education attainment or at the middle income level but was positively associated with BMI among whites and among participants with higher educational attainment or at the highest income level."

"These findings have implications for fiscal policy considerations, particularly as they relate to sociodemographic disparities in fast food consumption and subsequent health outcomes," state the researchers. "Whereas many low-income and minority populations fight price increases because they note that they unduly affect the poor, it is equally important for us to remember that these reduced unhealthy behaviors can ameliorate health disparities and to call out for strong support for the inclusion of subgroup-specific elasticity estimates in model-based evaluations of policy approaches, as proposed by others."

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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.



