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LEGISLATION, REGULATIONS AND STANDARDS

Senator Boxer Joins Groups Urging Labeling Changes for Poultry

U.S. Senator Barbara Boxer (D-Calif.) has reportedly joined the California Poultry Federation (CPF) and the Center for Science in the Public Interest (CSPI) in urging the U.S. Department of Agriculture (USDA) to reform labeling requirements for sodiumenhanced chicken. "Unfortunately, since 2003, chicken injected with sodium additives has been allowed to be misleadingly labeled as '100 percent all-natural," Boxer apparently stated at a February 24, 2010, press conference. "In these difficult times, our families should not have to pay \$2 billion for saltwater that they don't know about, they don't want and they certainly don't need."

Known as "plumping," this practice purportedly involves injecting "saltwater, chicken stock, seaweed extract or some combination thereof into chicken to increase its weight and price, while simultaneously increasing sodium content by up to 700 [percent]," according to one CPF member's Internet <u>campaign</u>. Although USDA already requires poultry containing these ingredients to carry warning labels at least one-fourth the size of the product name, CPF and its allies have asked the department to prohibit the use of "all-natural" marketing claims on enhanced chicken. Adding saltwater to poultry "is basically a hidden tax of up to 15 percent," CSPI has alleged, further asserting that salt "is probably the most harmful ingredient in the food supply" and "a major promoter of high blood pressure, stroke, heart disease, and other ailments." *See Congress Daily, CPF Press Release, CSPI Press Release, Meatingplace.com*, and *The Associated Press, February* 24, 2010.

In making these claims, CSPI cites a February 22, 2010, <u>report</u> issued by the Institute of Medicine (IOM) that blames increasing rates of high blood pressure for "more than one-third of heart attacks and almost half of heart failures in the United States each year." Titled "A Population-Based Policy and Systems Change Approach to Prevent and Control Hypertension," the report urges public health officials to adopt policies aimed at reducing sodium consumption and increasing physical activity. As a concurrent IOM press release states, "The committee's review of the science points to heavy weight, inactivity, and unhealthy diets containing too much salt and too little potassium as the major risk factors for high blood pressure." In particular, IOM has noted that "hypertension prevalence might be reduced by as much as 22 percent if Americans consumed less salt in their diet and ate more vegetables, fruit, and lean protein." The institute has advised the U.S. Centers for Disease Control and



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For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

> Mark Anstoetter 816-474-6550 manstoetter@shb.com

> > or

Madeleine McDonough 816-474-6550 202-783-8400 mmcdonough@shb.com

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com); or Dale Walker (dwalker@shb.com); 816-474-6550. Prevention "to work with partners in the public and private sectors to promote policies that make it easier for people to engage in regular physical activity, cut calories, and reduce their intake of foods containing high levels of sodium while increasing their exposure and access to produce and other foods containing potassium."

Meanwhile, *New York Times* columnist John Tierney has questioned the research and statistics often cited by public health experts and policy makers to support reducing salt consumption. Titled "When It Comes to Salt, No Right or Wrongs. Yet.," his February 23, 2010, article registers a dearth of reliable evidence in the salt debate. "For all the talk about the growing menace of sodium in packaged foods, experts aren't even sure that Americans today are eating more salt than they used to," writes Tierney.

He also argues that previous public health campaigns have sometimes resulted in unintended consequences, causing experts to concede, for example, that "their anti-fat advice may have contributed to diabetes and obesity by unintentionally encouraging Americans to eat more calories." Tierney points to recent research conducted by the University of California, Davis, and Washington University in St. Louis that "analyzed 33 countries around the world and reported that, despite wide differences in diet and culture, people generally consumed the same amount of salt," with the vast majority eating "more salt than recommended in the current American dietary guidelines." According to Tierney, the study authors have hypothesized "that networks in the brain regulate sodium appetite so that people consume a set daily level of salt." They fear that "if future policies reduce the average amount of salt in food, people might compensate by seeking out saltier foods—or by simply eating still more of everything."

In a related development, a small study has reportedly claimed that increased salt intake could contribute to hardening of the arteries. Alwyn Todd, et al., "Dietary salt loading impairs arterial vascular reactivity," *American Journal of Clinical Nutrition*, January 2010. Australian and U.S. researchers followed 35 hypertensive participants for four weeks, assigning the volunteers to supplement their low-salt diets with sodium-free tomato juice, tomato juice containing 90 millimoles (mmol) sodium or tomato juice containing 140 mmol sodium. The results apparently showed that "dietary salt loading produced significant increases in [pulse wave velocity] and [systolic blood pressure]," indicators of artery stiffness and vascular health.

Omega-3 Trade Group Responds to FTC Action Against Supplement Makers

The Global Organization for EPA and DHA Omega-3 Fatty Acids (GOED) has apparently sought clarification from the Federal Trade Commission (FTC) about the letters sent to 11 companies that promote omega-3 fatty acid supplements as a benefit for children's visual and mental development. According to GOED, FTC was not clear about whether it was concerned with claims on products containing short-chain omega-3 fatty acid (ALA) or long-chain omega-3 fatty acids (EPA and DHA).

The organization also questioned FTC about the types of scientific studies that would be required to substantiate the claims. FTC reportedly told GOED that "claims about an effect (e.g. brain development) need to be substantiated by science on that effect (e.g. brain development)" and that the scientific evidence in support of a



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claim must be based on research conducted in the age specified in the claim. "That is, if the claim is specific to toddlers two years and above, the research substantiating the claim cannot have been conducted on one year olds."

GOED contends that it is "unable to comment at the present time on FTC's specific grievances," because "the specific claims and dosages in question have not been publicly communicated." The sample letter FTC made available to the public simply called for the companies to review their product packaging and labeling to confirm they were not violating federal law by making baseless claims about the benefits of their supplements to children's brain and visual function and development. The organization contends that a large body of scientific evidence supports claims related to EPA and DHA omega-3 fatty acids "and the positive benefits related to brain health." *See Nutrition Horizon*, February 22, 2010.

FDA Seeks Comments About Safety Standards for Fresh Produce

The Food and Drug Administration (FDA) has <u>announced</u> a plan to address preventive controls aimed at reducing the risk of microbial contamination of fresh produce at farms and packing houses. The agency seeks information and public input so that it can develop safety standards and cooperative strategies to ensure compliance.

FDA is requesting comments on topics including (i) standards for domestic and foreign growers and packers; (ii) identification and prioritization of risk factors; (iii) environmental hazard assessments and "possible pathways of contamination"; (iv) methods to tailor preventive controls to particular hazards and conditions affecting an operation and to the scale of the operation; (v) microbial testing; (vi) post-harvest operations; and (vii) records and other documentation that would be useful to industry and regulators in ensuring the safety of fresh produce. Comments must be submitted by May 24, 2010. *See Federal Register*, February 23, 2010.

FSIS to Hold Second Meeting on Improving Traceability System Regarding E. Coli

The U.S. Department of Agriculture's Food Safety Inspection Service (FSIS) will hold a second meeting to discuss current product tracing systems for food intended for humans and animals. The March 10, 2010, meeting in Washington, D.C., specifically welcomes input on procedures for suppliers of source material used to produce raw ground beef products that test positive for *E. coli*. Issue 326 of this Update announced a similar meeting by FSIS and the Food and Drug Administration held in December 2009 that was designed to stimulate ideas on improving the agencies' ability to "increase the speed and accuracy of the traceback investigations and traceforward operations." *See USDA Web site*, February 22, 2010.

APHIS Extends Comment Period on GM Alfalfa

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has <u>extended</u> until March 3, 2010, the comment period for a draft environmental impact statement (EIS) for genetically modified (GM) alfalfa. APHIS made an EIS available on January 12, 2010, after the Ninth Circuit Court of Appeals ruled that



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the agency violated the National Environmental Protection Act by failing to prepare an EIS in connection with its recommendation to deregulate the crop. *See Federal Register*, February 24, 2010.

EFSA Creates Task Force to Evaluate Non-Plastic Food Contact Materials

The European Food Safety Authority (EFSA) has <u>created</u> a scientific cooperation (ESCO) working group "to collect and analyze information on the safety of substances" used in non-plastic food contact materials. Citing concern that certain substances, such as inks and adhesives, are migrating into foods, EFSA initiated the working group to "identify strengths and weaknesses in different approaches used for risk assessment, propose criteria for future safety evaluations and suggest further actions to be taken." ESCO will present its findings to EFSA's executive director by the end of March 2011.

"Whilst EU rules specify that all materials coming into contact with foods must be safe, many non-plastic components of food contact materials—unlike plastic materials are not subject to specific provisions at the European level," states a February 22, 2010, EFSA press release.

EC Proposes Ban on Trade in Bluefin Tuna

The European Commission (EC) has proposed that the European Union prohibit international trade in Atlantic bluefin tuna, favored by sushi eaters in Japan and elsewhere. According to the announcement, member states will discuss the proposal to reach a common EU position before the March 2010 meeting in Doha of the Convention on International Trade in Endangered Species. While the EC is apparently concerned about the species' "poor conservation status," the trade ban would not take effect until 2011. According to a news source, environmental groups criticized the announcement, warning that a delay could encourage more fishing in the interim. *See Financial Times*, February 22, 2010.

UK Introduces Voluntary Country-of-Origin Labeling on Pork Products

The United Kingdom (UK) has introduced a new country-of-origin-labeling (COOL) code of practice for pork and pork products. Launched at a recent National Farmers Union conference, the voluntary code was drawn up by the Pig Meat Supply Chain Task Force representing processors, pig producers, retailers, and the food-service sector.

"A year ago I said that I wanted to end the nonsense of unclear country-of-origin labeling on pig meat products," Environment Secretary Hilary Benn was quoted as saying. "I expect all major retailers to sign up and join those who have already decided to end the confusion for shoppers. If they don't, their customers should ask them why they're not in favor of clear, honest labeling."

The code reportedly aims to ensure that processed products will clearly identify country of origin for pork ingredients. Companies adhering to the new code have committed to providing clearer information such as "Produced in the UK using pork from country X." Terms such as "Produced in the UK" will not be used without qualification of the pork's origin.



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Other key elements of the code: (i) a single country-of-origin label signifies the pig was born, reared and slaughtered in that country; (ii) the use of national terms and symbols, such as flags, signifies the pork comes from that country; (iii) food service outlets will make origin information readily available to customers on menus, in literature or on company Web sites; and (iv) the term "local" will be clearly defined. *See Meat International*, February 25, 2010.

OEHHA Issues Notice of Intent to Add Acrylamide to Prop. 65 List

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has issued a <u>notice</u> of its intent to list acrylamide, a chemical formed when certain foods have been cooked at high temperatures, as a reproductive toxicant under Proposition 65 (Prop. 65). According to OEHHA, the National Institute for Occupational Safety and Health and the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction have both determined that acrylamide is a developmental, male reproductive toxin. Under Prop. 65, a chemical must be listed when an authoritative body formally identifies the chemical as causing reproductive toxicity and the evidence it considered meets certain sufficiency criteria. Public comments must be submitted by April 27, 2010.

Noting the significant public interest in the chemical, which has been found in baked goods and cooked starchy foods such as potato chips and French fries, OEHHA has also published a <u>notice</u> of proposed rulemaking that would establish "a specific regulatory level having no observable effect for acrylamide." The proposed maximum allowable dose level would be 140 micrograms per day, a level "700 times greater than 0.2 micrograms per day, which is the cancer No Significant Risk Level for acrylamide" under California law. The comment deadline for this proposal is also April 27. Any request for a public hearing must be made no later than April 12.

LITIGATION

Class Notification Underway in \$35 Million Dannon Yogurt Settlement

After a federal court in Ohio preliminarily approved the settlement of claims that The Dannon Co. deceived consumers by advertising the purported digestive health benefits of its Activia[®] and DanActive[®] products, class notification was <u>initiated</u>. *Gemelas v. The Dannon Co., Inc.*, No. 1:08-cv-00236 (U.S. Dist. Ct., N.D. Ohio, E. Div., order filed January 27, 2010). Without admitting liability, Dannon has agreed to create a \$35 million fund for the settlement, which was discussed in detail in issue 320 of this Update. Claims must be submitted by October 1, 2010, and objections to the proposed settlement must be filed by May 24. The court has scheduled a June 23 hearing to consider any objections; to decide whether the settlement is fair, reasonable and adequate; and to determine what the plaintiffs' lawyers will be paid.



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Double-Meat Sandwich Ads Target of Illinois Class Action Against Blimpie

A putative class action has been filed in a Madison County, Illinois, court, alleging that a fast food chain has fraudulently advertised its Super Stacked[™] sub sandwiches "as containing 'double portions of meat" compared with its standard sandwiches, when they do not have double the meat. *Williams v. Kahala Corp.*, No. 10-L-166 (Cir. Ct., 3d Jud. Cir., Madison County, Ill., filed February 12, 2010). According to the complaint, while defendant charges a premium for its Super Stacked[™] sandwiches, they "do not have double the protein" because "they do not have double the meat." The plaintiffs allege that a 12-inch BLIMPIE Best[™] sandwich has 50 grams of protein, while its Super Stacked[™] counterpart "contains only 73 grams of protein." They also allege that some Super Stacked[™] sandwiches have no "regular" counterpart with which consumers can compare.

Seeking to certify a class of all persons who purchased a Super Stacked[™] sandwich from Blimpie restaurants in Illinois, the plaintiffs allege violations of the state's Consumer Fraud and Deceptive Business Practices Act. To remain in state court, the plaintiffs seek less than \$75,000 in damages for each plaintiff and also seek a permanent injunction to stop defendant "from advertising that its Super Stacked sandwiches contain double portions of meat without, in fact, including double portions of meat in such sandwiches."

E&J Gallo Winery Faces Action in French Pinot Noir Incident

According to a news source, a putative class action has been filed against E&J Gallo Winery alleging that it falsely labeled and sold its Red Bicyclette[®] wine as Pinot Noir when the wine was "illegally cut with cheaper Syrah and Merlot grapes." The action, reportedly filed in Los Angeles Superior Court, follows news that wine makers in France were sentenced for selling the cheaper wine to the company as pinot noir. Additional details about the French scam appear in issue 338 of this Update.

Meanwhile, the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) has reportedly been investigating the matter with French authorities and may also take action against U.S. wine importers. The bureau was quoted as saying, "TTB is waiting for an official translation of the court documents and has begun investigations to determine the appropriate course of action to take regarding the American importers of these mislabeled wines. Additional actions may be indicated and appropriate once the necessary investigations have been completed and information is verified." *See Courthouse News Service* and *decanter.com*, February 26, 2010.

Cargill Admits Its Ground Beef Caused E. Coli Infection in Minnesota Dance Instructor

Cargill, Inc. has reportedly responded to a \$100 million lawsuit by admitting that a beef patty it manufactured contained *E. coli* and caused plaintiff Stephanie Smith's debilitating injuries. While not contesting strict liability, the company is denying that it was negligent. Its suppliers apparently certified that the product had been tested for *E. coli* and that all the tests were negative. The company also reportedly included in its response that its products are inspected by the U.S. Department of Agriculture and that federal law requires meat products to be labeled with warnings that meat may contain bacteria that will cause illness if not properly cooked.



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Smith, who is confined to a wheelchair and was profiled in a *New York Times* article, is represented by food lawyer William Marler. He was quoted as saying, "Never in my 23 years have I seen a food company admit liability out of the box in their answer to a complaint." He reportedly noted that the admission may not indicate possible settlement of the case, which is pending in a Minnesota federal district court. Cargill evidently hopes the case will settle and, according to a news source, said in a statement that it has acknowledged its responsibility for Smith's injuries and has provided financial assistance for her expenses and rehabilitation. Still, the company asserts that Smith's "injuries or damages were caused, in whole or in part, by the acts or omissions of others over whom [Cargill] had no control or right of control." *See St. Cloud Times*, February 20, 2010; *Minneapolis St. Paul Business Journal* and *Meatingplace.com*, February 22, 2010.

OTHER DEVELOPMENTS

Organic Industry Watchdog Challenges Ethics and Accuracy of Bread Marketing Claims

The Cornucopia Institute has <u>written</u> to the CEOs of Sara Lee and National Public Radio to express its concerns with the marketing campaign for Sara Lee's Earth-Grains[®] products. In its February 22, 2010, letter, the institute refers to a study it made of the claims and calls for Sara Lee to "immediately suspend promotional activities until your organization can complete its own analysis of our findings." Institute co-director Mark Kastel stated, "Even though they've done a countrywide media rollout, including underwriting spots on National Public Radio, Sara Lee is, in essence, playing a shell game.... If advertising executives could be charged with malpractice, this would be a major felony."

According to the institute, Sara Lee claims that its EarthGrains® bread contains, "Eco-Grain™," an ingredient that "is more sustainable than organic grain." The institute calls this a "crass and exploitive marketing ploy" that has angered the organic community because the grain represents 20 percent of all the ingredients in one EarthGrains® product only, Sara Lee's "100% Natural" EarthGrains® 24-ounce bread loaves. With 80 percent conventional wheat, the bread purportedly reduces synthetic fertilizer use 3 percent only, when compared to a 100 percent reduction for a loaf of certified organic bread. The company's other breads allegedly contain no Eco Grain™. The institute also faults Sara Lee for using genetically engineered ingredients and chemical solvents in its products.

Sara Lee has issued a response, noting that it never claimed the grain was organic. In a statement, the company reportedly said, "We've been completely transparent about the environmental benefits ... At the moment, there is 20 percent Eco-Grain in our bread. We are looking to increase that percentage as more farmers are identified to grow the crop. We feel that by commercializing innovative farming practices like precision farming, which has a number of benefits for both the consumer and environment, EarthGrains can help to lead the bread industry in the right direction." The "precision agriculture" to which it refers apparently relies on satellite imaging to



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pinpoint fertilizer requirements in different parts of the field, thus reducing fertilizer usage and emissions while increasing yields. *See Cornucopia News*, February 22, 2010; *Bakerandsnacks.com*, February 26, 2010.

Pediatric Association Recommends Choking Hazard Label for Foods

The American Academy of Pediatrics (AAP) has issued a policy <u>statement</u> calling for warning labels on foods that pose a high risk of choking. The medical organization has identified hot dogs as "the food most commonly associated with fatal choking among children," as well as other high-risk foods that include "hard candy, peanuts/ nuts, seeds, whole grapes, raw carrots, apples, popcorn, chunks of peanut butter, marshmallows, chewing gum, and sausages."

According to a February 22, 2010, press release, the policy contains "recommendations for government agencies, manufacturers, parents, teachers, child care workers and health care professionals to help prevent choking among children." In addition to the warning labels, AAP has urged these groups to consider strategies for (i) recalling food products that pose a significant choking hazard, (ii) establishing "a nationwide food-related choking-incident surveillance and reporting system," (iii) designing new food and redesigning existing food to minimize choking first aid. AAP has also suggested granting the Food and Drug Administration the authority "to address choking-related risks of all food products, including meat products that fall under the jurisdiction of the U.S. Department of Agriculture." *See The Associated Press*, February 22, 2010.

Public Health Advocates Call for End to FOP Labeling

Two public health advocates have penned an <u>article</u> in the February 23, 2010, edition of the *Journal of the American Medical Association* (JAMA) that calls for an end to all front-of-package (FOP) food labels. According to New York University Professor Marion Nestle and Children's Hospital Boston Obesity Program Director David Ludwig, the food industry has historically used loopholes in labeling laws to make tenuous health claims and develop "self endorsement labeling systems" in an effort to sell more products. The authors note that although the Food and Drug Administration (FDA) "intends to examine the entire issue of front-of-package labeling," the agency continues to maintain that "point of purchase labeling ... can be an effective way of promoting informed food choices and helping consumers construct healthier diets."

Nestle and Ludwig, however, remain skeptical that these systems will not be co-opted by food and beverage manufacturers seeking to promote sales. They opine that "consumers believe front-of-package claims, perceive them to be government-endorsed, and use them to ignore the Nutrition Facts Panel." In particular, Nestle and Ludwig argue that FOP labeling practices are problematic because: (i) "Few, if any, claims can be verified"; (ii) "Claims based on individual nutritional factors are misleading"; (iii) "Even [FOP] labels restricted to nutrient content can be deceptive by presenting information out of context"; (iv) "'Healthier' processed foods are not necessarily healthy"; and (v) "[FOP] claims produce conflicts of interest" between FDA's educational goals and reasonable business objectives.





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The authors thus urge FDA to consider "an outright ban on all front-of-packaging claims" while revising the Nutrition Facts Panel "to facilitate informed dietary choice and minimize the possibility of market manipulation."

MEDIA COVERAGE

Nicholas Kristof, "Do Toxins Cause Autism?," The New York Times, February 25, 2010

"Concern about toxins in the environment used to be a fringe view. But alarm has moved into the medical mainstream," writes *New York Times* op-ed contributor Nicholas Kristof in this February 25, 2010, piece examining a purported shift in how the scientific community perceives the likelihood that ubiquitous chemicals affect the developing brain. Kristof references a forthcoming opinion piece in *Pediatrics* that reportedly cites "historically important, proof-of-concept studies that specifically link autism to environmental exposures experienced prenatally." Although the *Pediatrics* editorial apparently focuses on the impact of medications such as thalidomide, misoprostol and valproic acid, Kristof extends his concern to other chemicals such as phthalates and bisphenol A. "At a time when many Americans still use plastic containers to microwave food, in ways that make toxicologists blanch, we need accelerated research, regulations and consumer protection," he opines.

While Kristof warns against "sensationalizing risks," he nevertheless urges consumers "to be wary of personal products ... unless they are marked phthalate-free" and advises children and pregnant women "to avoid most plastics marked at the bottom as 3, 6 and 7." Expounding these precautions, Kristof maintains that "in the case of great health dangers of modern times—mercury, lead, tobacco, asbestos—journalists have been too slow to blow the whistle. In public health, we in the press have more often been lap dogs than watchdogs."

Lyndsey Layton, "Alternatives to BPA Containers Not Easy for U.S. Foodmakers to Find," *The Washington Post*, February 23, 2010

According to this article, companies trying to find ways to can their food products in metal containers without bisphenol A (BPA) have found that the search is costing millions and may not ultimately result in BPA-free foods. Companies no longer using cans with linings containing BPA have apparently found traces of the ubiquitous chemical in their foods and are trying to determine whether the source is cutting boards, latex gloves or even the food items themselves.

Food manufacturers are not waiting for the government to act on proposals to ban the substance; they reportedly began searching for alternatives in 2008 after consumer pressure motivated manufacturers to remove BPA from plastic baby bottles. While it has been relatively easy for plastic-bottle makers to find a simple BPA substitute, canned-food manufacturers face problems such as alternative lining disintegration, taste issues and the inability of the other linings to withstand the high temperatures needed to kill bacteria.



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Referring to the Food and Drug Administration's recent decision to reconsider its finding that BPA is safe to use, the article quotes the North American Metal Packaging Alliance's chair who said that the chemical has been "used safely in metal food packaging for decades. They have been deemed safe by regulatory agencies around the world." He also noted that no case of food-borne illness from a metal packaging failure has occurred since the industry started using BPA in can linings more than three decades ago. Japanese manufacturers apparently began reducing their use of BPA between 1998 and 2003 and also stopped producing tableware containing BPA for school lunches. Researchers reportedly documented a significant reduction of BPA levels in the blood of test subjects after the change.

OFFICE LOCATIONS

Geneva, Switzerland +41-22-787-2000 Houston, Texas +1-713-227-8008 Irvine, California +1-949-475-1500 Kansas City, Missouri +1-816-474-6550 London, England +44-207-332-4500 Miami, Florida +1-305-358-5171 San Francisco, California +1-415-544-1900 Tampa, Florida +1-813-202-7100 Washington, D.C. +1-202-783-8400

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FOOD & BEVERAGE LITIGATION UPDATE

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.

