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LEGISLATION, REGULATIONS AND STANDARDS

Lawmaker Proposes Trans Fat Labeling Revisions, "Poison-Free" Poultry Law

U.S. Representative Steve Israel (D-N.Y.) has introduced a <u>bill</u> (H.R. 1486) that would amend federal labeling laws concerning *trans* fat content in food. The Trans Fat Truth in Labeling Act of 2011 would "direct the Commissioner of Food and Drugs to revise the federal regulations applicable to the declaration of the *trans* fat content of a food on the label and in the labeling of the food when such content is less than 0.5 gram."

Effective 18 months after the date of enactment, the law would (i) "require that the nutrition information on the label or labeling on an applicable food contain an asterisk or another similar notation and a note to indicate that the food has a low *trans* fat content per serving" and (ii) "prohibit the label or labeling on an applicable food from indicating that *trans* fat content per serving is zero." Applicable foods would be defined as foods for which (i) "the *trans* fat content of a serving of the food is less than 0.5 gram and greater than 0.0 gram" and (ii) "the *trans* fat content of a serving of the food is declared in the nutrition information on the label or in the labeling of the food."

Meanwhile, Israel has also introduced a **bill** (H.R. 1487) that would prohibit the use of the arsenic compound roxarsone as a food additive. The Poison-Free Poultry Act of 2011 would amend the Federal Food, Drug, and Cosmetic Act and take effect one year after enacted into law.

According to Israel's blog, EPA estimates that the average American adult eats more than 60 pounds of poultry yearly, and that much of it contains roxarsone, "a harmful form of arsenic that is added to make the birds grow faster and to make their meat appear artificially more pink." Israel wrote that roxarsone is an "arsenic-containing antimicrobial drug" that remains in the edible portions of chickens and has been found in poultry waste, "where it poses environmental and human health risks when the waste is managed."



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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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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);

McCain, Kerry Introduce Digital Privacy Bill

Senators John McCain (R-Ariz.) and John Kerry (D-Mass.) have introduced a bill that would "establish a regulatory framework... under the aegis of the Federal Trade Commission [FTC]" to protect personal data online. According to an April 12, 2011, press release, the Commercial Privacy Bill of Rights aims to protect consumers from "unscrupulous actors in the market" by creating "a baseline code of conduct for how personally identifiable information and information that can uniquely identify an individual or networked device are used, stored, and distributed."

To this end, the legislation would require collectors of information, such as online advertisers and vendors, to (i) "implement security measures to protect the information they collect and maintain"; (ii) "provide clear notice to individuals on the collection practices and the purpose for such collection"; and (iii) "collect only as much information as necessary to process or enforce a transaction or deliver a service, but allow for the collection and use of information for research and development to improve the transaction or service and retain it for only a reasonable period of time." In addition, the bill stipulates that information collectors "must provide the ability for an individual to opt-out of any information collection that is unauthorized by the Act and provide affirmative consent (opt-in) for the collection of sensitive personally identifiable information."

If adopted, the legislation would direct the FTC and state attorneys general "to enforce the bill's provisions," while allowing regulators to approve voluntary safe harbor programs that meet the protections specified in the bill. "All of this information sharing can be good to consumers," Kerry was quoted as saying. "The data deluge is worrying at the same time." See Advertising Age, April 12, 2011.

USDA to Sponsor Codex Alimentarius Commission Preparation Meeting

In preparation for the 34th Session of the Codex Alimentarius Commission, the U.S. Department of Agriculture's (USDA's) Office of the Under Secretary of Food Safety has scheduled a June 16, 2011, **meeting** to provide information and receive public comments on draft U.S. positions that will be discussed at the Codex meeting. Written comments may be submitted to U.S. Codex Manager Karen Stuck at uscodex@fsis.usda.gov.

The Codex session will be held July 4-9 in Geneva, and topics on the <u>agenda</u> include the consideration of draft standards at varying stages of development. Among other matters, Codex participants will consider standards and guidelines relating to risk analysis of foodborne antimicrobial resistance, nutrition labeling, the control of *Campylobacter* and *Salmonella* in chicken meat, food additives, maximum levels for melamine in food and for arsenic in rice, fish oils, and hygienic practice for mineral waters, fresh fruits and vegetables.



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The World Health Organization and the Food and Agriculture Organization formed the Codex Alimentarius Commission in 1963 to establish food safety standards, codes of practice and guidelines and to promote the coordination of food standards activity undertaken by international governmental and non-governmental organizations. While the standards are not binding, they serve as a reference point for consumers, food producers and governments.

FDA Meeting to Discuss FSMA Preventive Controls for Facilities

The Food and Drug Administration (FDA) has <u>announced</u> an April 20, 2011, public meeting to discuss a Food Safety Modernization Act (FSMA) mandate to implement "comprehensive, science-based preventive controls across the food supply." FSMA requires human, pet and animal food and feed facilities registered under section 415 of the Food, Drug, and Cosmetic Act (21 U.S.C. 350d) "to take certain preventive actions, including to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, and to identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards."

The meeting will help FDA establish these controls as well as industry guidance "for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting their implementation." In particular, the agency has requested information on "preventive controls used by facilities to identify and address hazards associated with specific types of food and specific processes." FDA will accept registrations and presentation proposals until April 15, and comments on the event until May 20. See Federal Register, April 13, 2011.

FDA Denies Hearing for Shell Egg Irradiation Rule

The Food and Drug Administration (FDA) has <u>answered</u> criticism of a July 21, 2000, final rule allowing "the safe use of ionizing radiation for the reduction of *Salmonella* in fresh shell eggs," and denied requests for a hearing on the ground that the objections "do not raise issues of material fact or otherwise provide a basis for revoking or modifying...the regulation." FDA evidently received 26 submissions contesting the final rule, which permits the irradiation of fresh shell eggs at doses not to exceed 3.0 kiloGray (kGy), but only one letter from Public Citizen raised specific issues within the rule's scope.

The April 13, 2011, Federal Register notice responds to Public Citizen's claims that FDA misrepresented irradiation's efficacy and its effect on vitamin A loss and egg yolk carotenoids; that FDA raised the dose allowance to 3.0 kGY without properly updating its analyses; and that FDA failed to follow all of the 1980 recommendations put forth by the Bureau of Foods Irradiation Food Committee. "Despite these allegations, Public Citizen has not established that FDA overlooked significant information in the record while reaching



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its conclusion that the use of irradiation for the reduction of *Salmonella* in shell eggs is safe," states FDA, which has declined to make any changes in its rulemaking.

Illinois House Approves Bill Prohibiting Trans Fats

The Illinois House of Representatives has approved a <u>bill</u> (H.B. 1600) that would prohibit "food facilities" from selling food containing artificial *trans* fats. Effective January 1, 2013, the law would apply to any "entity that prepares, packages, serves, vends, or otherwise provides food for human consumption at the retail level," including public and private school vending machines. Starting January 1, 2016, the bill would broaden to eliminate the use of artificial *trans* fats from cafeterias operated by state or local governments or by public or private schools. Most prepackaged foods would be exempt.

If approved by the Illinois Senate and signed by the governor, the law would make Illinois and California the only states to enact *trans* fat bans. According to the bill's sponsor, Representative La Shawn Ford (D-Chicago), Illinois has the 10th highest percent of obese and overweight children in the country. "Health problems cost our state so much money, and if we can use prevention to keep people out of emergency rooms and keep them healthy, this is a step in that direction," Ford told a news source. Illinois Senator Donne Trotter (D-Chicago) reportedly plans to introduce similar legislation in the Senate. *See Press Release of Representative La Shawn Ford* and *Chicago Tribune*, April 13, 2011.

Boston Mayor Gets Tough on Sweetened Beverages

Boston Mayor Thomas Menino (D) has issued an <u>order</u> that will require all city departments to take steps to stop "the sale, advertising, and promotion of sugary beverages on City-owned property." The mayor is apparently concerned about setting an example in a community with high obesity rates that he attributes in part to the consumption of sweetened beverages. Under the executive order, only certain types of beverages will be sold in city cafeterias and vending machines and at city concession stands, or served during meetings, city-run programs and events catered with city funds.

After a six-month grace period, city buildings and departments must phase out the sale of "red" beverages, that is, "those loaded with sugar, such as non-diet sodas, pre-sweetened ice teas, refrigerated coffee drinks, energy drinks, juice drinks with added sugar and sports drinks." The promotion of such beverages will be prohibited. "Green" beverages can continue to be sold; they consist of bottled water, flavored and unflavored seltzer water, low-fat and skim milk, and unsweetened soy milk. No more than one-third of city beverage offerings will include "yellow" beverages, or "diet sodas, diet iced teas, 100 percent juices, low-calorie sports drinks, low-sugar sweetened beverages, sweetened soymilk and flavored, sweetened milk."



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"This is the right step to be taking," said Walter Willett, chair of the Harvard School of Public Health's Department of Nutrition, who joined the mayor at the press conference announcing the ban. "We're not punishing those individuals [who consume sugary beverages]. They're going to be punished enough directly from the health consequences down the road." See msnbc. com, April 7, 2011.

LITIGATION

Federal Court Trims False Advertising and Labeling Claims Against Guacamole Maker

A federal court in California has determined that some putative class claims can proceed against a company that allegedly makes false and misleading statements about its guacamole and spicy bean dip products. *Henderson v. Gruma Corp.*, No. 10-04173 (U.S. Dist. Ct., C.D. Cal., decided April 11, 2011). The plaintiffs' first amended complaint alleged five causes of action for violations of the state's unfair competition and false advertising laws and the Consumer Legal Remedies Act. They claimed that the statements "0 g transfat," with garden vegetables," made in "the authentic tradition," "0 g cholesterol," and "all natural," as to either or both products were false and misleading.

The court first determined that the named plaintiffs, including a woman who recently brought and voluntarily dismissed similar claims against Hostess Brands, Inc., adequately alleged injury-in-fact to establish standing under Proposition 64. They alleged that they (i) "paid more for Mission Guacamole and Mission Bean Dip, and would have paid less for the products, if they had not been misled by the allegedly false and misleading labeling"; (ii) "would not have purchased the two products at the price they paid absent the advertisements with the alleged misstatements"; (iii) "instead of receiving products that were free of artificial trans fat, or receiving authentic guacamole, they purchased artificial substances containing artificial trans fats that could 'raise[] their cholesterol and damage[] the cells in their heart and arteries"; and (iv) "lost money as a result of Gruma's deception in that Plaintiffs did not receive what they paid for."

The court also found that the plaintiffs had sufficiently alleged actual reliance because they allegedly read and relied on the purportedly misleading labels in making their purchases, believing they had the qualities the plaintiffs sought and for which they were willing to pay more. Thus, the court determined that the plaintiffs had met the causation requirement for Article III standing. The court rejected the defendant's claims that the plaintiffs could not seek injunctive relief given that they are now aware of the FDA requirements for label disclosures and the products' ingredients and have said that they will not purchase the products in the future. According to the court, if it



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were to construe standing so narrowly, "federal courts would be precluded from enjoining false advertising under California consumer protection laws because a plaintiff who had been injured would always be deemed to avoid the cause of injury thereafter ('once bitten, twice shy') and would never have Article III standing."

The court struck the plaintiffs' prayer for disgorgement under the false advertising law because this would include non-restitutionary sums that are unavailable under the law. And the court granted the defendant's motion to dismiss claims based on its use of "Authentic Tradition" (found to be non-actionable puffery) and "With Garden Vegetables" (found to be a truthful statement) on its labels. According to the court, the guacamole contains avocado powder, dehydrated onion, garlic powder, and bell pepper, ingredients that "can be grown in a garden."

The court denied the defendant's motion to dismiss as to the plaintiffs' claims based on the company's use of the phrase "All Natural," because the products allegedly contain artificial *trans* fats. The court also said that the plaintiffs can pursue claims that use of the word "Guacamole" on the product label could be misleading because the word appears in a font two sizes larger than the smaller "flavored dip," and the reasonable consumer "could interpret Defendant's statements and label to imply that the product is indeed guacamole, which it is not, as it allegedly contains less than 2% avocado powder." The court dismissed as preempted those parts of the complaint based on the company's use of "0 g transfat" or "0 g cholesterol" because these phrases are regulated and permitted under federal law.

Ninth Circuit Issues Ruling on Seasonal Farm-Worker Wages

The Ninth Circuit Court of Appeals has determined that the owner of peach and pear orchards in Oregon violated the law by crediting its seasonal workers' housing costs toward their minimum wage and by paying them the day after their last workday. <u>Bobadilla-German v. Bear Creek Orchards, Inc.</u>, Nos. 10-35205, 10-35268 (9th Cir., decided April 12, 2011).

The owner recruited several hundred seasonal farm workers in Arizona for the month-long harvest in 2004-2006 and offered them optional on-site housing and meals. The company charged \$5-\$7 a day for housing and deducted that amount from workers' paychecks, crediting it toward their minimum wage. "In many instances, if housing costs were not credited toward the workers' minimum wage, their wage would have been below the lawful minimum wage." The workers generally received their final paychecks on the day following their last day of work.

A class of workers sued the company, alleging violations of federal and state minimum wage laws and violation of a state wage-and-hour law. Oregon law allows employers to deduct the "fair market value of lodging" provided



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by employers for the private benefit of employees. According to the Ninth Circuit, while the on-site housing was "optional," no other housing was available close enough to the fields for the numbers of seasonal workers required, and housing the workers on site was a benefit to the employer in terms of ensuring that workers would start promptly in the morning and not face transportation issues. Under these circumstances, the court determined that the on-site housing was required by the employer and not a private benefit to the employees since it was "necessary in order for the employer to maintain an adequate work force at the times and locations the employer needs them."

Because Oregon wage-and-hour laws require that seasonal workers receive compensation on the last day worked, the court also determined that the company violated the law by failing to pay some of the workers until the day after their last workday.

No MDL for Quaker Oats Trans Fat Lawsuits

The Judicial Panel on Multidistrict Litigation (JPML) has denied a request that five false-advertising lawsuits pending in two federal district courts against The Quaker Oats Co. be consolidated for pretrial proceedings in Illinois. *In* re: Quaker Oats Trans-Fat Mktg. & Sales Practices Litig., MDL No. 2230 (J.P.M.L., decided April 8, 2011). The putative class actions involve claims that the company advertises its Chewy Bars® as containing "0 grams trans fat" when they purportedly contain "dangerous amounts of artificial trans fat, a toxic product that causes cancer, diabetes, and heart disease, and is banned in an increasing number of United States and foreign jurisdictions."

The JPML apparently determined that centralization would not "serve the convenience of the parties and witnesses or further the just and efficient conduct of this litigation." The panel noted that four of the pending actions were filed in one district court in California and were already underway. Given that one company is the sole defendant "and one law firm represents at least one plaintiff in three of the four Northern District of California actions," the JPML opined that the parties would be able "to cooperate and minimize the possibilities of duplicative discovery and inconsistent pretrial rulings between the four Northern District of California actions and the sole outlying Northern District of Illinois action."

Fishy Seafood Labels Result in Felony and Misdemeanor Convictions

According to the Department of Justice, a Massachusetts-based fish packer has been convicted of several criminal charges for falsely labeling packages of frozen fish fillets. A federal jury in Boston found Stephen Delaney guilty of a felony violation of the Lacey Act for falsely labeling \$8,000 worth of frozen pollock, a product of China, as more expensive cod loins, a product of Canada. The jury also convicted Delaney of one misdemeanor violation



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for misbranding food under the Food, Drug, and Cosmetic Act; he allegedly placed into interstate commerce \$203,000 worth of Chinese frozen fish fillets falsely labeled as products of Canada, Holland, Namibia, and the United States. Evidence at trial apparently indicated that he also changed 4 oz. labels on some packages to 5 oz. labels. Delaney will be sentenced on June 8, 2011; he faces up to six years in jail and up to \$350,000 in fines. See Department of Justice Press Release, April 11, 2011.

Insurers Dispute Coverage for Food-Related Injury

Seeking a declaration about respective indemnity obligations, National Union Fire Insurance Co. of Pittsburgh, Pa. has filed a complaint in a California federal court against several other insurance companies in a dispute stemming from a neurological injury allegedly caused by the mahi-mahi fish served in a fish burrito at a Rubio's Restaurant. *Nat'l Union Fire Ins. Co. of Pittsburgh, Pa. v. Nationwide Mut. Fire Ins. Co.*, No. 11-00755 (U.S. Dist. Ct., S.D. Cal., filed April 11, 2011). The injured consumer apparently seeks damages in excess of \$7 million. The insurance defendants are allegedly defending the fish supplier and restaurant in the personal-injury action, and National Union claims that its policy provides excess insurance only and that the other carriers have a duty to indemnify the insureds first.

OTHER DEVELOPMENTS

CSPI Launches "Chemical Cuisine" Mobile App Database

The Center for Science in the Public Interest (CSPI) has launched a mobile application of its "Chemical Cuisine" glossary of food additives to bring safety ratings directly to consumers' smart phones. The CSPI app provides a list of safe additives and flags those "that everybody should avoid, as well as a number of additives most people would do well to cut back on," according to CSPI.

"Shopping for groceries was a lot easier when more food came from farms, and not factories," said CSPI Executive Director Michael Jacobson. "And the tens of thousands of packaged foods on supermarket shelves have a bewildering array of chemical food additives, designed to variously enhance the taste, texture, color, or shelf life of the product." See CSPI Press Release, April 22, 2011.

SDA-Enriched Soy Makes Splash at 2011 Experimental Biology Meeting

Researchers presenting at the 2011 Experimental Biology conference in Washington, D.C., have reportedly claimed that stearidonic acid-enriched (SDA) soybean oil is "an effective source of long-chain polyunsaturated fat in



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foods," and that soy genetically engineered to produce these omega-3 fats, commonly found in fish, could be on tables as early as 2012. The panel on SDA-enriched soy was evidently part of the meeting's omega-3 symposium led by Tufts University Friedman School of Nutrition and Public Health Dean Eileen Kennedy, who noted that the American diet is typically lacking two long-chain omega-3s, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), in part because consumers are wary of methyl mercury warnings for seafood.

"Against this backdrop, SDA-enriched soybean oil is very attractive," Kennedy apparently told *Science News*. "Moreover, if and when SDA-enriched oil becomes available, it should cost less than fish-oil capsules (some of which have allegedly been found contaminated with pesticides, dioxins and other toxic pollutants), and run just a small fraction of the price of getting an equivalent amount of omega-3s from eating fish."

Meanwhile, St. Louis-based Solae LLC has apparently confirmed plans to market SDA-enriched foods once the Food and Drug Administration (FDA) approves the crops for planting. Under development by Monsanto, SDA-enriched soybeans convert a botanical omega-3 known as alpha linolenic acid into EPA and have already received "generally recognized as safe" status from FDA. As one panelist with the University of South Dakota's Sanford School of Medicine described it, this product could become part of a successful fortification program, "like adding iodine to salt." See Science News, April 9, 2011.

Chicago School Draws Fire for Ban on Homemade Lunches

A Chicago public school that six years ago prohibited most homemade lunches has recently found itself in the media spotlight, with some parents publicly questioning the policy that Little Village Academy Principal Elsa Carmona has defended as more nutritious for children. *The Chicago Tribune* has reported that Carmona instituted the ban after watching students bring "bottles of soda and flaming hot chips" on field trips. "While there is no formal policy, principals use common sense judgment based on their individual school environments," confirmed a Chicago Public Schools spokesperson. "In this case, this principal is encouraging the healthier choices and attempting to make an impact that extends beyond the classroom."

But some parents have faulted the school for providing unappetizing fare while bringing in more money from students forced to purchase lunch. Their complaints have since received national attention from groups like the Center for Consumer Freedom (CCF), which called the policy "a fundamental infringement on parental responsibility."

"Would the school balk if the parent wanted to prepare a healthier meal?," asked one CCF researcher. "This is the perfect illustration of how the government's one-size-fits-all mandate on nutrition fails time and time again. Some



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parents may want to pack a gluten-free meal for a child, and others may have no problem with a child enjoying a soda." See Chicago Tribune, April 11, 2011.

MEDIA COVERAGE

Maximillian Potter, "The Assassin in the Vineyard," Vanity Fair, May 2011

"When Aubert de Villaine received an anonymous note, in January 2010, threatening the destruction of his priceless heritage unless he paid a one-million-euro ransom, he thought it was a sick joke," writes Maximillian Potter in this May 2011 Vanity Fair article chronicling "an unprecedented and decidedly un-French" plan to poison the world's most famous vineyard, La Romanée-Conti. Considered the Holy Grail of Burgundy, the eponymous wines produced by this 4.46-acre, centuries-old vineyard currently sell for \$6,455 per bottle, with 1945 vintages fetching upward of \$38,000 per bottle. According to Potter, it was only a few months before a record-setting auction of Romanée-Conti that "word of the attack began seeping into the world beyond Burgundy," which has since sought to keep the affair quiet.

Potter traces the remarkable crime from early 2010, when vineyard owner de Villaine began receiving anonymous ransom demands in the mail, to the arrest of a career criminal known as Jacques Soltys, who later committed suicide in prison. Soltys evidently had a background in winemaking and used his expertise to target other topflight wineries as well as the Domaine de Romanée-Conti, where he drove home his threats by poisoning several of the priceless vines. As Potter explains, "from what the police had discovered, the criminal, or criminals, used a syringe to inject the poison. This was especially significant—over the centuries, *vignerons* had used such a *pal* or syringe-like technique to inject liquid carbon disulfide into the soil and save the vineyards from devastating infestations by the phylloxera insect."

With the arrest of Soltys and an accomplice, however, the region's vineyards have apparently pledged themselves to resolving the matter without trial. In addition to fearing that further media attention "would inspire copycat crimes," they have expressed concern that rumors of poisoned vines would compromise the reputation of their wines. As one Cote winemaker told Potter, "'Wine' and 'poison,' these two words do not belong in the same sentence."

SCIENTIFIC/TECHNICAL ITEMS

Swedish Researchers Allegedly Find Arsenic in Baby Foods

A forthcoming study has allegedly identified "high levels" of arsenic in rice-based baby foods, as well as elevated levels of iron, molybdenum and manganese in infant formula. Karin Ljung, et al., "High concentrations of



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essential and toxic elements in infant formula and infant foods – A matter of concern," *Journal of Food Chemistry*, August 2011. According to media sources, researchers from the Unit of Metals and Health at Karolinska Institute in Stockholm tested leading baby food brands for toxic and essential elements, finding that the samples contained more micrograms of arsenic and other toxins than occurs in breast milk. "These elements have to be kept at an absolute minimum in food products intended for infant consumption," warned the study authors, who also noted that "[d]rinking water used to mix powdered formula may add significantly to the concentrations in the readymade products."

Meanwhile, the British Specialist Nutrition Association has publicly refuted the significance of the findings, telling reporters that its members "carefully select and control their ingredients as well as the baby food." In addition, the researchers apparently confirmed that none of the identified toxins exceeded safety thresholds, which are currently under review by both the U.K. Food Standards Agency and European Commission. *See The Daily Mail*, April 11, 2011.

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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.



