Shook, Hardy & Bacon L.L.P.

ISSUE 351 | MAY 28, 2010

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

New York Lawmaker Introduces Legislation to Address Additional *E. Coli* Strains

Senator Kirsten Gillibrand (D-N.Y.) has introduced a bill that would regulate six confirmed strains of *E. coli* that have largely been ignored given the notoriety of recalls involving meat and produce contaminated with *E. coli* O157:H7. Referred to by the Centers for Disease Control and Prevention as non-0157 STECs, the six strains are apparently estimated to cause 36,700 illnesses, 1,100 hospitalizations and 30 deaths in the United States annually. In a May 27, 2010, statement, Gillibrand indicated that these strains are increasingly found in imported beef, which is not checked for the unregulated non-0157 STECs. One of the six strains was implicated in the recent outbreak linked to tainted romaine lettuce; that outbreak reportedly sent three teenagers to the hospital with kidney failure.

According to a news source, the U.S. Department of Agriculture regulated the lesser-known *E. coli* strains for three years, but industry has resisted regulation contending that the rarer strains have not been conclusively linked to beef. *The New York Times* reports that plaintiffs' lawyer Bill Marler has found the six strains in less than 1 percent of ground beef samples purchased at grocery stores, albeit at a slightly higher rate than the O157 strain. Few labs reportedly test for non-0157 STECs, but some companies, such as Earthbound Farm, the largest U.S. producer of organic salad greens, screens for all toxic *E. coli* strains. Gillibrand's legislation would amend the Federal Meat Inspection Act to define "adulterated" to include contamination with *E. coli* and would include all seven strains within the definition of *E. coli*, thus requiring USDA to spot test for the strains and "force companies (through legal pressure) to test and eliminate the pathogen." *See The New York Times*, May 26, 2010; *Senator Gillibrand Press Release*, May 27, 2010.

FTC Announces Plan to Study Food, Beverage Marketing Targeted to Kids

The Federal Trade Commission (FTC) has **announced** its intention to issue compulsory process orders to 48 food and beverage manufacturers, distributors, marketers, and quick service restaurant companies for information on their marketing activities and expenditures targeted toward children and adolescents. FTC also seeks nutritional information about the companies' food and beverage products marketed to children and adolescents in calendar years 2006 and 2009 "to evaluate possible changes in the nutritional content and variety of youth-marketed foods."

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.

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.

The plan follows FTC's July 2008 report that analyzed expenditures and promotional activities related to food and food products targeted toward children and adolescents in 2006. FTC wants to use the new data to study how industry allocates promotional activities and expenditures among various media and for different food products and to evaluate the impact of self-regulatory efforts on the nutritional profiles of foods marketed to children and adolescents.

Based on the calendar year 2009, FTC requests marketing information on (i) "the categories of foods marketed to children (ages 2-11 years) and adolescents (ages 12-17 years)"; (ii) "the types of measured and unmeasured media techniques used to market food products to children and adolescents"; (iii) "the amount spent to communicate marketing messages about food products to youth"; (iv) "the nature of the marketing activities used to market food products to youth"; (v) "marketing to youth of a specific gender, race, ethnicity, or income level"; and (vi) "marketing policies, initiatives, or research in effect or undertaken by the companies relating to the marketing of food and beverage products to children and adolescents." Comments are requested by June 24, 2010. *See Federal Register*, May 25, 2010.

FDA Issues Draft Industry Guidance on Reportable Food Registry

The Food and Drug Administration (FDA) has issued draft industry **guidance** in a question-and-answer format that provides information about complying with the reportable food registry requirements of a 2007 law. The purpose of the registry is to provide a "reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health." The draft guidance is a second edition, updated to provide information about a new federal safety reporting portal. FDA requests public comments by July 26, 2010.

The agency is particularly interested in comments addressing the meaning of the word "transfer" which is used in the context of an exemption from the requirement that "a responsible party submit a reportable food report." For the exemption to apply, "the adulteration must have originated with the responsible party, the responsible party must have detected the adulteration 'prior to any transfer to another person' of the article of food, and the responsible party must have corrected the adulteration or destroyed the food." FDA proposes that "transfer" be interpreted as "when the responsible person releases the food to another person." Commenters are invited to address whether the interpretation is appropriate and whether it "should be dependent on ownership of the food, or whether there are other interpretations we should consider, such as a combination of possession and/or ownership." *See Federal Register*, May 25, 2010.

Meanwhile, the safety reporting portal, recently launched by the National Institutes of Health and FDA, will, when fully developed, provide "a mechanism for the reporting of pre- and post-market safety data to the federal government." The new site apparently provides "greater and easier access to online reporting" of safety problems. Industry can currently use the site to report safety problems involving foods, including animal feed and animal drugs, "as well as adverse events occurring on human gene transfer trials." Consumers are also able to use the portal "to report problems with pet foods and pet treats." *See FDA Press Release*, May 24, 2010.

GAO Report Targets FDA's Food Safety Research

The Government Accountability Office (GAO) this week released a **report** assessing Food and Drug Administration (FDA) efforts to address "serious deficiencies" in its food safety research. After a recent survey indicated that only 36 percent of FDA managers felt the agency "was making great progress in keeping pace with scientific advances," GAO began investigating the ways in which "FDA may use science to more effectively support its regulatory work and to inform the public about food content and safety."

To this end, the report examines FDA's "(1) progress in addressing selected recommendations identified by the Science Board; (2) incorporation of scientific and risk analysis into its oversight of the accuracy of food labeling, fresh produce, and the safety of dietary supplements; and (3) a new computer screening tool that may improve its efforts to screen imports using a risk-based approach." It specifically notes the creation of the Office of the Chief Scientist, which aims to "identify major scientific cross-cutting opportunities across FDA," as well as a new computer tool, PREDICT, that seeks to improve "risk-based import screening efforts."

The GAO findings, however, also suggest that "gaps in scientific information have hampered FDA's oversight of food labeling, fresh produce, and dietary supplements." In particular, the report claims that insufficient oversight has contributed to "inadequate labeling," including outdated Nutrition Facts panels and a failure to implement "a simplified, empirically valid system" for front-of-package labeling. According to GAO, "FDA does not have empirical research on consumer perceptions to support enforcement against misleading food labels." *See GAO Report Summary,* April 23, 2010.

GAO Testimony Takes Aim at Herbal Dietary Supplements' Marketing Practices, Contaminants

The Government Accountability Office (GAO) has delivered **testimony** before the U.S. Senate's Special Committee on Aging that highlights examples of deceptive or questionable marketing practices involving certain dietary supplements. GAO also reported that some herbal dietary supplements contained contaminants, including trace amounts of lead.

According to GAO Managing Director of Forensic Audits and Special Investigations Gregory Kutz, investigators posing as elderly customers asked sales staff at 22 retail establishments a series of questions regarding herbal dietary supplements in addition to reviewing 30 retail Websites' "written marketing language" about the supplements. In several cases that both the Food and Drug Administration (FDA) and the Federal Trade Commission deemed "improper and likely in violation of statutes and regulations," "written sales materials for products sold through online retailers claimed that herbal dietary supplements could treat, prevent or cure conditions such as diabetes, cancer, or cardiovascular disease." Improper medical advice was also dispensed by sales staffs in claiming that certain supplements would prevent or cure conditions such as high cholesterol or Alzheimer's disease.

GAO also found trace amounts of at least one potentially hazardous contaminant in 37 of the 40 herbal dietary supplement products tested, "though none in amounts considered to pose an acute toxicity hazard." All 37 supplements tested positive for trace amounts of lead and, of those, 32 also contained mercury, 28 cadmium, 21 arsenic, and 18 residues from at least one pesticide. Noting that the levels of contaminants did not exceed any FDA or Environmental Protection Agency regulations governing dietary supplements or their raw ingredients, the report acknowledged that "FDA agreed that 16 of the 40 supplements tested would be considered in violation of U.S. pesticide tolerances." Manufacturers told GAO that contaminant levels identified "were too low to raise any issues during their own internal product testing processes."

Commerce Secretary Declares Fishery Disaster for Gulf of Mexico

U.S. Department of Commerce Secretary Gary Locke (D) has reportedly declared a fishery disaster in the Gulf of Mexico as a result of the ongoing Deepwater Horizon oil spill's effect on commercial and recreational fisheries in Louisiana, Mississippi and Alabama. Made in response to requests from Louisiana Governor Bobby Jindal (R) and Mississippi Governor Haley Barbour (R), the determination will help ensure that the federal government "is in a position to mobilize the full range of assistance that fishermen and fishing communities may need," Locke said.

The Commerce Department has asked for $15 million in supplemental funding "as a backstop to address this disaster," $5 million in economic development assistance through the Economic Development Administration and unemployment coverage. In addition, the Small Business Administration has offered economic injury disaster loans to help fishermen and other affected businesses. *See U.S. Commerce Department Press Release*, May 24, 2010.

USDA and DOJ Hold Second Workshop on Competition Issues

The U.S. Department of Agriculture (USDA) and Department of Justice (DOJ) recently held the second workshop in a series dedicated to competition and regulatory issues in agriculture. Held in Normal, Alabama, the forum reportedly focused on the poultry industry and featured the remarks of U.S. Attorney General Eric Holder and USDA Secretary Tom Vilsack, as well as roundtable discussions with farmers, academics and other stakeholders. According to a May 21, 2010, USDA press release, Holder reiterated that both agencies were committed to "protecting competition in those markets."

News sources have also noted Holder's pledge to "understand why a growing number of American producers and farmers find it increasingly difficult to survive what they've done for decades." A transcript of the proceedings will become available on the DOJ Antitrust Division **Website** at a later date. *See The Huntsville Times,* May 21, 2010.

Mexico Adopts Stringent School Food Rules to Combat Obesity

Mexican health officials have reportedly unveiled stringent guidelines that would prohibit the sale of processed or fried foods on school grounds. According to media sources, the regulations would ban soft drinks and other sugar-sweetened beverages along with more traditional fare such as meat tortas, tamarind candy and atole, unless they were reformulated to meet nutritional guidelines. The school vendors and cooperatives that often function in lieu of cafeterias would be limited to serving low-calorie food and beverages such as bottled water, low-fat milk and 100-percent fruit juices.

Meanwhile, Secretary of Public Education Alonso Lujambio has also pledged to incentivize healthier fare at the food stalls outside schools at closing time. If approved by the Federal Regulatory Improvement Commission, the rules will take effect for 220,000 public and private schools in August 2010. *See The Guardian, Secretaría de Salud Press Release* and *The Associated Press,* May 27, 2010.

GeneWatch UK Director Resigns from FSA Steering Group on GM Foods

GeneWatch UK Director Helen Wallace has apparently resigned from a Food Standards Agency (FSA) steering committee dedicated to discussing genetically modified (GM) foods, after claiming that the group "is nothing more than a PR exercise on behalf of the GM industry." Charged with managing a public dialogue on the potential risks and benefits of GM food, the external stakeholders on the committee currently include consumer advocates, trade association representatives, market and policy experts, and scientists.

In her May 26, 2010, resignation letter, Wallace pointed to several Freedom of Information requests that allegedly revealed how the Agricultural Biotechnology Council and similar organizations influenced the dialogue agenda and other FSA activities. According to Wallace, the steering committee "was set up from the outset to provide free 'reputation management' to the GM industry at taxpayers' expense." She also accuses FSA of using the discussion to focus on "on a non-existent positive future where new GM crops will 'feed the world', whilst lobbying to end the segregation of GM and non-GM food and feed entering Britain and Europe, and opposing the labelling of meat and dairy products produced using GM feed."

FSA has since responded to the resignation by reaffirming its neutrality and pledging to continue its public outreach efforts. "The issues surrounding this topic are important to the future of agriculture and food production," stated a May 27 news release. "The steering group's aim in conducting that dialogue is be to ensure that the issues, concerns and aspirations that the public have with respect to the use of genetic modification in the production of food are identified and recognized in future policy."

LITIGATION

Defamation Verdict Against Peruvian Scientist in GM Maize Research Dispute to Be Reviewed

According to a news source, the Peruvian Superior Court has agreed to hear an appeal filed by a medical sciences biotechnologist convicted of defamation by a lower court for criticizing another scientist whose research allegedly showed that genetically modified (GM) maize had been illegally planted in a valley on the Peruvian coast. The researcher, Antonietta Gutierrez, apparently chose to seek redress through the courts when her work was questioned by Ernesto Bustamante, vice president of the Peruvian Association of Biologists, an undertaking that has drawn condemnation from the nation's scientists. Claiming that "the verdict destroys the integrity of science," they have urged other scientists to sign a declaration in support of Bustamante, claiming that the law explicitly exempts scientific critiques from defamation's scope. *See Crop Bulletin Update*, May 20, 2010.

LEGAL LITERATURE

Eloisa Rodriguez-Dod, "It's Not a Small World After All: Regulating Obesity Globally," *Mississippi Law Journal*, 2010

Law Professor Eloisa Rodriguez-Dod discusses a number of ways that governments in the United States and around the world are attempting to address the growing incidence of obesity among their populations. This **article** provides information about municipal *trans* fat bans and menu-labeling ordinances, China's restrictions on the morbidly obese adopting children, Spain's voluntary food advertising regulations, and Japan's workplace penalties for employers whose workers' waist measurements do not shrink to accepted levels. The author distinguishes smoking cigarettes from overeating by referring to the former as an addiction and the latter as personal choice. She suggests that governments can and should regulate personal choice "to protect the health and welfare of its citizens." While acknowledging that no "magic bullet" has yet been found to prevent overweight and obesity and that measures already in place are too new to assess their effectiveness, the author concludes, "whatever can fairly be done should be done to lessen this health crisis."

OTHER DEVELOPMENTS

Food Makers and Chain Restaurants Improving Product Quality

According to **research** recently conducted by Harvard's Medical School and School of Public Health in collaboration with the Center for Science in the Public Interest (CSPI), food manufacturers and chain restaurants have responded to *trans* fat restrictions and bans by improving the quality of the foods rather than simply reverting to the use of saturated fats. Dariush Mozaffarian, Michael Jacobson & Julie Greenstein, "Correspondence: Food Reformulations to Reduce Trans Fatty Acids," *The*

New England Journal of Medicine, May 27, 2010. The authors state that they "identified 83 reformulated products (58 supermarket foods and 25 restaurant foods)," and studying product labels, they found that *trans* fats and saturated fats were reduced in 90 percent of the supermarket products and 96 percent of the restaurant products.

In a statement about the research, CSPI's executive director said, "This paper demonstrates that the U.S. food industry has been generally responsible in replacing partially hydrogenated oils with more healthful oils. That should pave the way for the U.S. Food and Drug Administration to eliminate partially hydrogenated oils from the food supply. The agency could do that quite easily by stating that it no longer considers partially hydrogenated oil to be 'generally recognized as safe,' and give companies a year or two to switch to healthier oils." *See CSPI Press Release*, May 26, 2010.

Perishable Pundit Concludes Series on Produce Traceability

An online publication focused on the produce industry has published the final installment of a recent series of articles about produce traceability contributed by a produce standards consultant. Titled "What is the ROI on PTI?," the article by Gary Fleming discusses the benefits of implementing the Produce Traceability Initiative (PTI), a voluntary industry-developed standard, even though it is not required by law. As *Perishable Pundit's* Jim Prevor notes, if the law does not require PTI and buyers do not require a PTI-compliant supply chain, "then we are left with attempting to justify PTI on a return-on-investment basis."

According to Fleming, PTI was intended to use existing technology and standards "to enable whole chain traceability with the minimal amount of costs." Among other matters, PTI standardizes the information used to trace produce and how that information is captured, provides quicker access to information in the event of a recall and allows companies to use their own tracking systems augmented with PTI-specific data that enable instant identification of who shipped the product; when, where and how much was shipped; where it was stored; and the purchase order/invoice on which it was received and shipped. Fleming also contends that other benefits to the produce industry, including increases in efficiency, make PTI's implementation desirable. *See Perishable Pundit*, May 25, 2010.

MEDIA COVERAGE

Jerome Groopman, "The Plastic Panic," *The New Yorker,* May 31, 2010

"Bisphenol A, commonly known as BPA, may be among the world's most vilified chemicals," opens this May 31, 2010, *New Yorker* article that positions the present-day furor in the long and often convoluted history of toxicology. According to author Jerome Groopman, scientists cannot agree whether BPA is a cautionary tale against overstating risks or understating them. He notes that in the past, regulators were sometimes quick to bar substances like cyclamates based on public fears that later proved unfounded, while overlooking the adverse health effects of contaminants such as lead—"for years thought to be safe in small doses..."

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 351 | MAY 28, 2010

Groopman ultimately blames the "inadequacy of the current regulatory system" for fomenting this "atmosphere of uncertainty." Acknowledging "the potential pitfalls of epidemiological research," he nevertheless criticizes Congress and the Environmental Protection Agency for failing thus far to overhaul the Toxic Substances Control Act of 1976 and other consumer protection laws to standardize scientific methodology and minimize conflicts of interest. "Academic researchers have found that the enormous financial stakes—the production of BPA is a six-billion-a-year industry—have prompted extra scrutiny of their results," he opines. "In 2007…a majority of non-industry-supported studies initially deemed sound by the National Toxicology Program on the safety of BPA were dismissed as unsuitable after a representative of the [American Chemistry Council] drafted a memo critiquing their methods; experimental protocols often differ from one university lab to another."

Groopman holds out hope, however, that new legislation introduced by Senator Frank Lautenberg (D-N.J.) will address some of these issues by granting EPA authority "to establish safety criteria in chemical compounds; to create a database identifying chemicals in industrial products; and to set specific deadlines for approving or banning compounds." As the article concludes, "[W]hile the evidence of these chemicals' health consequences may be far from conclusive, safer alternatives need to be sought. More important, policymakers must create a better system for making decisions about when to ban these types of substances, and must invest in research that will inform those decisions."

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

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.