Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

110th Congress

[1] House Subcommittee Issues Subpoenas to Private Food Testing Laboratories

Because private laboratories, which test foods subject to Food and Drug Administration (FDA) import alerts, have mostly failed to respond to a **request** for information relating to a House committee food safety investigation, their records are now reportedly subject to a subcommittee subpoena. Only one lab apparently responded to a May 1 request from the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations.

In that letter, Representatives John Dingell (D-Mich.) and Bart Stupak (D-Mich.) state that they learned during a February 2008 hearing "that it is routine practice for private laboratories to discard volatile test results at the direction of the importer. When this occurs, the importer will then instruct the same private laboratory to test the product repeatedly until a clean result is obtained or the importer will hire another private laboratory to test the product. This repeated testing is done without alerting FDA that potentially dangerous food has been imported into this country—a practice which we find deplorable."

A lab owner and past president of the American Council of Independent Laboratories responded to any suggestion of impropriety by stating, "If the government thinks that reporting all food test results is required to ensure the public safety, the FDA and Congress must mandate such actions, not look for a scapegoat once a problem is uncovered." He welcomed the congressional investigation, claiming that the industry (i) has "worked to educate the FDA and Congress about the significant weaknesses in the current FDA import system," and (ii) "strongly" recommends "mandatory third party sampling to assure [sic] sample integrity," laboratory accreditation and mandatory "notification to the FDA of all analysis done on food imports under the import alert." *See GMA Food Safety Daily Digest*, June 11, 2008; *Congress Daily*, June 12, 2008.

[2] House and Senate Spar over Appropriate Legislative Vehicle for Bisphenol A and Phthalate Bans

According to news sources, House and Senate lawmakers differ about whether to include measures that would prohibit the use of bisphenol A and phthalates from children's products in legislation to reform the Consumer Product Safety Commission (CPSC). CPSC reform bills (H.R. 4040; S. 2663) approved by both chambers are currently before a conference committee, and conflicting instructions have apparently been given to conferees.

California Democratic Senators Barbara Boxer and Dianne Feinstein successfully added a phthalate

ban to the Senate bill, hoping to use it as leverage against the Environmental Protection Agency and the industry to agree to stricter toxic chemical controls, while Senator Chuck Schumer (D-N.Y.) urged the conference committee to include his bill banning bisphenol A from plastic products intended for children younger than age 7. House lawmakers, who have introduced stand-alone bills to ban the chemical substances, are reportedly resisting the senators' efforts, contending that "consumers are best served by keeping this bill focused on the daunting task of reforming the CPSC." The House has apparently passed a motion instructing House conferees to reject the Senate CPSC reform bill.

Meanwhile, during a June 10, 2008, hearing before the House Committee on Energy and Commerce's Subcommittee on Commerce, Trade and Consumer Protection, an FDA panelist continued to insist that the agency has no reason to call for consumers to stop using products containing bisphenol A. According to Norris Alderson, FDA's associate commissioner for science, "the current level of exposure to adults and children is safe." A CPSC scientist reportedly testified that alternatives to the chemical may not be available and a ban could result in less effective protective gear for children, such as helmets and goggles. CPSC chemist Michael Babich referred to a 2001 study that concluded phthalates pose a minimal or even non-existent risk to children because they would have to mouth toys containing the chemical for 75 minutes or more a day to put themselves at risk. Countering these safety assurances, a spokesperson from the National Toxicology Program was quoted as saying, "The possibility that bisphenol A may alter human development cannot be dismissed."

In a related development, the FDA's chief scientist has reportedly announced that a subcommittee of the agency's Science Board would be set up to review research on the safety of bisphenol A. According to Frank Torti, the subcommittee will conduct a public meeting, review a forthcoming FDA task force report and announce its findings at the board's annual meeting in fall 2008. FDA will also apparently review reports on the chemical from scientific and regulatory agencies in other countries. *See Product Liability Law 360* and *Inside EPA*, June 9, 2008; *Congress Daily* and *Associated Press*, June 10, 2008; and *The Wall Street Journal*, June 11, 2008.

Government Accountability Office (GAO)

[3] GAO Report Faults FDA for Delay in Food Protection Plan

The Government Accountability Office (GAO) this week issued a **report** criticizing the Food and Drug Administration (FDA) for failing to execute its Food Protection Plan, which the agency developed in November 2007 to improve inspection programs and allay consumer fears over tainted imports. GAO investigators apparently found that FDA has "added few details on the resources and strategies required to implement the plan," in part because the Department of Health and Human Services (HHS) has delayed publishing a draft progress report promised in April 2008. As a result, "neither Congress nor the public can gauge the plan's progress or assess its likelihood of success in achieving its intended results," stated Lisa Shames, GAO director of natural resources and environment, in her June 12 testimony before the House Oversight and Investigations Subcommittee. "One had to ponder how serious the administration was"

in backing the plan, subcommittee chair Bart Stupak (D-Mich.) was quoted as saying.

Although the Bush administration has since proposed an additional $275 million to supplement next year's FDA budget, critics have countered that the amount is insufficient and long overdue. Gail Cassel, who serves on the FDA Science Board, told the House committee that FDA needs $375 million in 2009 to "meet current and emerging regulatory responsibilities." In addition, Senator Arlen Specter (R-Penn.) contended that the administration "is drastically hindering necessary immediate relief by denying the funding for over nine months." *See The New York Times*, *The Wall Street Journal, The Baltimore Sun*, and *CQ Healthbeat News*, June 12, 2008.

Food and Drug Administration

[4] FDA Reopens Comment Period on Petition to Revise Regulatory Status of Salt

FDA has reopened until August 11, 2008, a comment period related to a citizen's petition to revoke the generally recognized as safe (GRAS) status of salt and sodium. FDA initially held a November 29, 2007, meeting and 60-day comment period to address a 2005 petition submitted by the Center for Science in the Public Interest, which has argued for increased salt and sodium regulation since 1978. Although the initial comment period expired on March 28, 2008, FDA received a request on behalf of interested parties to provide additional response time. The agency is soliciting public feedback on its current salt and sodium policy framework, as well as recommendations for future approaches. *See Federal Register*, June 11, 2008.

State and Local Governments

[5] Massachusetts House Passes Legislation Banning Artificial *Trans* Fat

The Massachusetts House of Representatives this week passed legislation (**H.B. 4346**) that would prohibit the use of partially hydrogenated oils in all state restaurants. The bill would prohibit restaurateurs from preparing or serving foods with artificial *trans* fats unless the product is served in the manufacturer's original packaging. The legislation proposes fines ranging from $25 to $1000 for the establishments that fail to phase out *trans* fat in frying and spreads within six months of enactment or to eliminate *trans* fats in baked goods within 12 months. A recent poll conducted by 7News/Suffolk University reportedly found that two-thirds of Massachusetts residents support the proposal, which now heads to the Senate under the auspices of Susan Fargo (D-Third Middlesex). "Though Boston, Brookline, and other jurisdictions around the country have phased out restaurants' use of artificial *trans* fat, Massachusetts would be the first to do it statewide," stated the deputy director of health promotion policy at the Center for Science in the Public Interest. "That would be a big boost for the heart-health of Massachusetts residents. And it would send a strong wake-up call to the slow-moving officials at the Food and Drug Administration, who have refused to revoke their approval of this heart-attack inducing chemical." *See CSPI Press Release,* June 4, 2008.

In a related development, a study has reportedly alleged that *trans* fat health risks may pass from a mother to her infant during breast feeding. F. Silveira Osso, "*Trans* fatty acids in maternal milk lead to cardiac insulin resistance in adult offspring,"

Nutrition, June 3, 2008. Researchers apparently found that rat offspring weaned by mothers on a high *trans* fat diet exhibited decreased heart function for glucose transport and insulin sensitivity problems. "Our data strongly suggest that *trans* fats ingestion during early life is particularly related to insulin resistance and to the consequent impairment of cardiac glucose metabolism in adulthood," said study author Fernanda Silveira Osso from the State University of Rio de Janeiro. *See FoodNavigator-USA.com*, June 5, 2008.

South Korea

[6] South Korean Government Faces Strong Opposition to U.S. Beef Imports

South Korean President Lee Myung-bak's Cabinet offered to resign this week after thousands of demonstrators flooded Seoul to protest the government's decision to reinstate U.S. beef imports, which were banned in 2003 over fears of mad cow disease. Opponents have reportedly leveraged these concerns to accuse Lee's administration of sacrificing public safety to further his own agenda as an "authoritarian leader" eager to please the United States. Lee has also faced increasing discontent stemming from the country's lackluster economy, the North Korean nuclear missile crisis, and the anti-American sentiment fostered by his predecessor. "Lee has behaved too much like a chairman of the board, acting imperiously and with little regard for public opinion on a number of issues, the most prominent of which has been the U.S. beef-import decision," opined Leonardo Martinez-Diaz, a political economy fellow for the Brookings Institution.

Lee has not announced whether he plans to accept the resignations, but his trade minister has warned that backing out of the beef deal could endanger a separate free trade agreement with the United States. Trade Minister Kim Jong-hoon has agreed to meet with U.S. trade representatives to seek a "mutually agreeable path forward," which may include limiting U.S. beef imports to cattle under 30 months of age. "We have to consider whether it would be a good thing to insist on renegotiation and risk trade retaliation," Kim was quoted as saying. *See The New York Times*, June 11, 2008; *NPR* and *Reuters UK*, June 12, 2008; *BBC News*, June 13, 2008.

Litigation

[7] FDA Files *Amicus* Brief Supporting NYC Fast-Food Menu Board Regulation; Argues Against Federal Preemption

In the New York State Restaurant Association's challenge to New York City's regulation requiring fast-food restaurants to post calorie content information on menu boards, the Food and Drug Administration (FDA) has filed an *amicus* brief urging the Second Circuit Court of Appeals to affirm the lower court's finding that the local law is not preempted by federal law nor does it violate restaurateurs' First Amendment rights. *N.Y. State Rest. Ass'n v. NYC Bd. of Health*, No. 08-1892 (2d Cir., *amicus* brief filed May 29, 2008). While the FDA disagrees with some aspects of the lower court's ruling, it essentially argues that calorie-content information requirements are not the types of "nutrient content claims" that could be preempted under federal law. FDA also contends that a rational

connection exists between the disclosure requirement and the city's purpose in imposing it, thus, meeting the test for constitutional limitations on commercial speech.

In a related development, the Center for Science in the Public Interest (CSPI) claims that a new poll indicates that 80 percent of New York voters who were asked about the calorie content of popular fast-food items would support statewide legislation similar to the city regulation. Many of those surveyed were unable to correctly identify which of an array of fast-food items had the most or the fewest calories. According to Zogby International, which conducted the survey for CSPI, "Majorities of respondents from across the state, from rural to urban areas, and across age groups, are strongly in favor of chains and fast food restaurants being required to display calorie information." *See CSPI Press Release*, June 11. 2008.

Meanwhile, a *Wall Street Journal* article discusses legislative proposals pending in California and New York that would require chain restaurants to post calorie-content information on their menu items. The article notes that related initiatives have been adopted or are being considered mostly at the local level. Should California and New York pass such legislation, they would apparently be the first states to impose such requirements. A similar measure, however, was vetoed by California's governor in 2007. Restaurant interests reportedly oppose these measures, citing logistical issues, the lack of evidence that such information reduces obesity and the utility of providing calorie counts in terms of healthfulness. A California Restaurant Association official was quoted as saying, "Diet Pepsi has no calories. Low-fat milk has 130 calories. What's healthier?" *See The Wall Street Journal*, June 11, 2008.

[8] California Low-Cal Menu Deceptive Claims Class Action Withdrawn; Similar Claims Filed in Texas

The Washington state resident who filed false advertising claims against the company that franchises and operates Applebee's Neighborhood Grill & Bar restaurants in a California federal court has withdrawn the suit. Further details about the complaint, which focused on the fat and calorie content of items on Applebee's Weight Watchers® menu, appear in issue 262 of this Update. According to her lawyer, the suit was dropped due to "procedural concerns" and would be re-filed in a California state court with a named plaintiff from California. *See Product Liability Law 360*, June 10, 2008.

Meanwhile, the original named plaintiff, Anne Paskett, has also filed litigation in Texas against the Delaware-based company that operates Chili's Grill & Bar, Romano's Macaroni Grill and On the Border Mexican Grill & Cantina restaurants throughout the United States. *Paskett v. Brinker Int'l, Inc.*, No. 08-942 (U.S. Dist. Ct., N. D. Tex., Dallas Div., filed June 5, 2008). Seeking to certify a nationwide class of those who ordered from the "Guiltless Grill, Sensible Fare or Border Smart menus," the plaintiff raises similar claims in this lawsuit, alleging that the fat and calorie content of items on the "healthier and less fattening" menu was far higher than that advertised. She brings causes of action for unjust enrichment and deceptive trade practices and requests the equitable remedy of restitution and an order enjoining defendant's "methods, acts or practices."

[9] Class Action Alleges Fraud in Packaging and Promotion of Breakfast Cereal

Claiming that Cap'n Crunch Crunch Berries® cereal "contains no actual berries of any kind," a California consumer has filed a putative class action in a California federal court seeking injunctive relief and compensatory and punitive damages against PepsiCo, Inc. *Sugawara v. PepsiCo., Inc.*, No. n/a (U.S. Dist. Ct., E.D. Calif., filed May 27, 2008). According to the complaint, "The use of the word 'Berries' in the Product name, coupled with the brightly depicted fruit-shaped cereal on the PDP [principal display panel], constitutes the 'characterizing flavor' of the Product. This is reinforced by the use of such representations as '[c]runch Berries is a combination of Crunch biscuits and colorful red, purple, teal and green berries' used in the Product's advertising, marketing, promotion and sale." The plaintiff alleges that the only fruit in the cereal is "a nominal amount of strawberry fruit concentrate," and thus, that defendant should place "Strawberry artificially flavored cereal" after the name of the food on the product package.

Seeking to certify a statewide class of product purchasers, the plaintiff alleges unlawful, unfair and deceptive practices as well as false and misleading labeling and advertising under California's Business and Professions Code; negligent and intentional misrepresentation; breach of express warranty; breach of implied warranty of merchantability; and violations of the Consumer Legal Remedies Act. The plaintiff contends that she purchased the cereal at issue for the preceding four years and only learned that it was not a fruit-based product after reading news accounts and a study in January 2007 that raised questions about the content of foods and beverages marketed to children. Colorado lawyer Howard Rubinstein is one of plaintiff's lawyers; he also represented the woman who sued cereal makers and retailers in 2005, alleging that their low-sugar cereals offered no significant nutritional advantage because the sugar had been replaced with other carbohydrates. Further details about that case appear in issue 120 of this Update. Rubinstein reportedly represents a woman who filed a putative class action in May 2008 against the maker of plastic sports bottles that contain bisphenol A. *See FindLaw.com*, May 2, 2008.

[10] Missouri Resident Seeks Certification of Nationwide Bisphenol A Class

In the latest litigation to claim that the manufacturers of plastic baby bottles containing bisphenol A misled the public by marketing and labeling their products as safe, a Kansas City, Missouri, mother of two is seeking to certify nationwide and statewide classes in a Missouri federal court. *Thornberry v. Avent Am., Inc.*, No. 08-418 (U.S. Dist. Ct., W.D. Mo., W. Div., filing date unknown). The complaint cites research about purported health risks from bisphenol A exposure and a study measuring levels of bisphenol A leaching into liquids contained in a variety of baby bottles. The complaint alleges intentional and negligent misrepresentation as to the national class and Missouri subclass, violation of the Missouri Merchandising Practices Act as to the Missouri subclass and violations of other state consumer protection statutes as to the national class. The plaintiff seeks punitive damages, restitution, an order enjoining further sales and advertising "by all defendants who do not include a bold face disclosure indicating the contents of Bisphenol-A in the above-described products," corrective advertising, attorney's fees and costs.

Other Developments

[11] Documents Reveal Infrequent *E. Coli* Tests and Slipshod Practices at Beef Processing Plant

Documents obtained by *The Associated Press* about the massive ground beef recall that precipitated Topps Meat Co.'s bankruptcy in 2007 reportedly reveal that the company rarely tested its product for *E. coli* and allowed unsanitary conditions to exist at its New Jersey plant. The documents apparently also raise questions about the adequacy of U.S. Department of Agriculture inspections. Food plaintiffs' lawyer William Marler, asked to review the documents, was quoted as saying, "This report clearly shows that [Topps'] safety procedures and testing procedures were definitely below par and led to this outbreak and ultimately to their bankruptcy. My point is, these things are so obvious, where was the inspector in July and August 2007?" Responding to the criticism, a USDA official reportedly acknowledged that the inspections could have been better, but assured that the agency has "put in place some changes to make sure that [the Topps' beef contamination and recall] doesn't happen again."

Marler is reportedly representing two of the three families known to have filed lawsuits against Topps for injuries allegedly caused by *E. coli* in its hamburgers. Because most of the company's assets were used to satisfy a bank debt, the families are reportedly seeking shares of insurance payments that could purportedly reach $22 million.

Among the deficiencies identified at the Topps plant were (i) "re-working" beef, that is, adding meat ground one day to meat used during another production cycle; (ii) the company's failure to require that every batch of meat received from slaughterhouses be certified as free of *E. coli*; (iii) reductions in the number of end-of-line tests for *E. coli* from monthly to only three times each year; (iv) an inadequate plan to identify where contamination could occur and establishing procedures to prevent such contamination; and (v) sanitary measures that allowed "product residues observed on product contact surfaces" and "recurring deficiencies of unsanitary equipment," such as "gouges, cracks and tears" on conveyor belts. *See The New York Times*, June 8, 2008.

[12] Public Watchdog Issues Report on Alleged Health Risks of GM Crops

The Institute for Responsible Technology (IRT) has issued a report, titled ***State-of-the-Science on the Health Risks of GM Foods***, alleging that conflicts of interest among regulators led to the approval of genetically modified (GM) crops despite purported health risks. In particular, IRT contends that large agricultural corporations influenced the Food and Drug Administration's decision to declare GM crops "generally recognized as safe" (GRAS). "[The] overwhelming consensus among the agency scientists was that GM crops can have unpredictable, hard-to-detect side effects," according to the report, which claims that adverse events include: (i) higher death rates, organ damage, reproductive failures, and infant mortality in animal studies; (ii) sick, sterile and dead livestock; and (iii) toxic and allergenic reactions to GM foods. In addition, IRT points to the possibility of "gene transfer" from GM foods to human DNA in arguing that "numerous scientific assumptions used as the basis for safety claims have since been proven false."

The consumer watchdog also faults privately-funded studies for "rampant, unrelenting industry

bias" unmitigated by government regulators charged with promoting biotechnology at the expense of adequate oversight. The report specifically points to the media's role in "manipulating" public opinion and its failure to expose attacks on independent scientists who reportedly disputed the safety of GM crops. IRT ultimately concludes that its findings represent "a very large community of research scientists who are horrified by the on-going deception that 'GM foods have never been shown to be harmful.'" *See Organic Consumers Association*, June 4, 2008.

[13] Institute of Food Technologists Announces 2008 Nanotechnology Meeting

The Institute of Food Technologists (ITF) has announced its third annual meeting, "International Food Nanoscience Conference: Advances in Nanoscale Science and Technology of Food," slated for June 27-28, 2008, in New Orleans. The conference will discuss nanotechnology prospects, tools and applications for agricultural development; food ingredients; food safety protocol; nutraceuticals, pharmaceuticals and cosmeceuticals; and food packaging and contact materials. In addition, speakers will address ethical and societal considerations pertaining to nanoparticles in consumer products. To view the conference agenda and registration materials, please click **here**.

Scientific/Technical Items

[14] Study Links Obesity and Smoking to Hearing Loss

A Belgian **study** has reportedly claimed that obesity and smoking are risk factors for permanent age-related hearing loss. Erik Fransen, et al., "Occupational Noise, Smoking, and a High Body Mass Index for Age-related Hearing Impairment and Moderate Alcohol Consumption Is Protective: A European Population-based Multicenter Study," *Journal of the Association for Research in Otolaryngology*, June 2008. After interviewing more than 4,000 men and women ages 53 to 67, University of Antwerp researchers concluded that hearing loss in this population was "proportional to how much you smoke and your body mass index," according to lead author Erik Fransen. Fransen speculated that as obesity and smoking disrupt blood flow around the body, the lack of oxygen and toxic waste build-up in the ear can lead to hearing impairment in both low and high frequencies. The study also noted that "moderate alcohol consumption was inversely correlated with hearing loss," suggesting that "a healthy lifestyle can protect against age-related hearing impairment." *See BBC News*, June 9, 2008.

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