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LEGISLATION, REGULATIONS AND STANDARDS

Ohio Lawmaker Introduces GE Bill Package

Representative Dennis Kucinich (D-Ohio) has introduced a package of bills that would require foods with genetically engineered (GE) ingredients to provide that information on product labels (H.R. 3553); affect how GE pharmaceutical and industrial crops are grown, while establishing a tracking system from cultivation to disposal (H.R. 3554); and protect farmers and ranchers from economic harm purportedly caused by GE seeds, plants or animals (H.R. 3555).

Introduced on December 2, 2011, the bills were referred to a number of committees; the co-sponsors are mainly Democrats, although Republican Representative Don Young (Alaska) signed onto the "Genetically Engineered Food Right to Know Act." In a December 9 statement, Kucinich referred to examples of cross-contamination, stating "We must take steps to prevent genetically engineered organisms from being grown in a way that could do irreversible damage to our food supply. Under pressure from profit-minded industry, we have already allowed the spread of genetically modified crops into our agriculture at great cost to our economy and with unknown effects on our bodies." See Press Release of Congressman Dennis Kucinich, December 9, 2011.

Senators Urge FDA to Declare Gulf Seafood Safe

Eight U.S. Senators have <u>urged</u> the Food and Drug Administration (FDA) to "publicly and vigorously" defend the safety of Gulf seafood in the wake of last year's oil spill. Led by Senator David Vitter (R-La.), the lawmakers signed a December 1, 2011, letter to FDA Commissioner Margaret Hamburg asserting that although "rigorous testing" has revealed that Gulf seafood is safe for human consumption, many consumers believe otherwise because of "misinformation and unscientific claims." Vitter wrote a similar letter to Hamburg in November.

The effort was prompted by opposing claims made by the Natural Resources Defense Council (NRDC), whose scientists assert that FDA's safety thresholds



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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);

for Gulf seafood "significantly" underestimate cancer risks from seafood contaminants. NRDC published a <u>study</u> in *Environmental Health Perspectives* concluding that "FDA risk assessment methods should be updated to better reflect current risk assessment practices and to protect vulnerable populations such as pregnant women and children."

Agency IG Chastises FDA for Lax Food-Facility Inspection Oversight

The Office of Inspector General (IG) of the U.S. Department of Health and Human Services has issued a <u>report</u> that "identified significant weaknesses in FDA's [the Food and Drug Administration's] oversight" of its contracts for state inspections of food facilities. In recent years, FDA has increasingly shifted to the states its responsibility for conducting inspections, and has apparently "failed to ensure [in eight states] that the required number of inspections was completed," "did not ensure that all State inspections were properly classified and that all violations were remedied," and "failed to complete the required number of audits for one-third of the States and did not always follow up on systemic problems identified."

Based on an analysis of FDA inspection data and interviews with agency officials, the report, titled "Vulnerabilities in FDA's Oversight of State Food Facility Inspections," opens by noting that annually "128,000 Americans are hospitalized and 3,000 die after consuming contaminated beverages and foods." As an example of possibly faulty oversight, the IG cites the 2009 Salmonella-contaminated peanut outbreak, which led to a massive food recall. According to the IG, the peanut processing facility responsible for the outbreak "was inspected multiple times by a State agency working on behalf of FDA."

The IG has recommended changes to address the problems, including ensuring that (i) "all contract inspections are completed, properly documented, and appropriately paid for," (ii) "contract inspections are properly classified in accordance with FDA guidance," (iii) "all inspection violations are remedied by routinely tracking all actions taken to correct violations," and (iv) "the minimum audit rate is met in all States." The IG also recommended that FDA "[a]ddress any systemic problems identified by audits." While FDA apparently concurred in the first four recommendations, it agreed only in part with the last, noting that "it will continue to develop processes and procedures to ensure that systemic problems are identified and that corrective action plans are implemented."

APHIS Reopens Comment Period for Proposed Amendments to Bioterrorism Protection Act

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has <u>reopened</u> the comment period until January 17, 2012, on a proposed rule that would amend and republish the Agricultural Bioterrorism



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Protection Act's "list of selected agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products." Details of the proposed rule were covered in Issue 412 of this Update. See Federal Register, December 15, 2011.

LITIGATION

Court Recognizes Severe Obesity as Disability Under ADA

Denying an employer's motions for summary judgment in an employment discrimination suit, a federal court in Louisiana has determined that severe obesity, regardless of its basis, qualifies as a disability under the Americans with Disabilities Act. *EEOC v. Res. for Human Dev., Inc.*, No. 10-03322 (U.S. Dist. Ct., E.D. La., decided December 7, 2011). The court did not decide whether the employer had terminated the obese employee's employment because she was regarded as disabled, finding that the matter presented a genuine issue of fact to be decided by a jury.

The employee, now deceased, weighed more than 400 pounds when she was hired by the defendant, which owned and operated a long-term residential treatment facility for chemically dependent women and their children. Some eight years later, the employee was terminated from her position; at the time, she weighed 527 pounds. She filed a discrimination claim with the Equal Employment Opportunity Commission (EEOC) alleging that she was terminated because her employer regarded her as disabled due to her obesity. She died in 2009, and EEOC filed suit on behalf of her estate in September 2010, alleging that she "had severe obesity, which is a physical impairment under the Americans with Disabilities Act ('ADA') and that Defendant regarded her as disabled because of it."

The court provided an overview of case law from various federal circuits and EEOC regulations on whether obesity is an ADA impairment and concluded that "severe obesity qualifies as a disability under the ADA and that there is no requirement to prove an underlying physiological basis." The court also held that EEOC would not be "judicially stopped" from bringing an ADA claim despite potentially inconsistent statements the employee made when applying for Social Security Disability Insurance.

Federal Court Issues Ruling on Jurisdiction in Food Packaging Dispute

A federal court in Georgia has determined that it has personal jurisdiction over a Michigan food-packaging company that was sued as a third-party defendant in litigation over a recalled baby food product. *IPN USA Corp. v. Nurture, Inc.*, No. 11-501 (U.S. Dist. Ct., N.D. Ga., Atlanta Div., decided December 12, 2011). A Food and Drug Administration investigation appar-



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ently concluded that the third-party defendant (Liquid) had violated agency regulations on the manufacture of acidified and acid food products. While the baby food manufacturer (Nurture) allegedly sustained millions in damages in the recall, it was the packaging supplier (IPN) that brought the lawsuit against Nurture for breach of contract.

According to the court, Liquid had sufficient contacts with Georgia for the court to exercise jurisdiction over the company. For purposes of packaging Nurture's baby food, Liquid had purchased a machine, packaging supplies and other equipment from IPN's Georgia-based entity, which referred a "significant number" of prospective customers to Liquid. The contracts between IPN and Liquid contained Georgia choice-of-law and forum-selection clauses. Because the "alleged failure of the packaging at issue in this case is directly related to the cont[r]acts between Liquid and IPN," the court concluded that Liquid has "minimum contacts" with Georgia and that it would not offend due process to exercise jurisdiction over the company.

Jurisdictional Discovery to Proceed in Deceptive-Trade Suit Against OJ Maker

A federal court in Alabama has granted in part a motion to stay discovery in litigation alleging that an orange juice (OJ) maker misrepresented that its product is not made from juice concentrate, but is rather "100% pure Florida squeezed." *Leftwich v. TWS Mktg. Group, Inc.*, No. 11-1879 (U.S. Dist. Ct., N.D. Ala., S. Div., order entered December 12, 2011). The court will allow discovery as to "general personal jurisdiction" over the non-resident beverage maker to proceed, while staying discovery as to all other matters.

Residents of Indiana and Alabama brought the putative class action after the Food and Drug Administration warned the company in November 2010 that its labeling violated the Federal Food, Drug, and Cosmetic Act. According to the court, if jurisdiction over the defendant is lacking, it will dismiss the Indiana plaintiff, "leaving [the Alabama plaintiff] to proceed only on the count of unjust enrichment—which itself is still subject for consideration in [the defendant's pending] motion to dismiss."

Putative Class Alleges Walgreen Beverages Contain High Levels of Lead and Arsenic

A California resident is seeking to certify a nationwide class in a lawsuit alleging that Walgreen Co. 100% Grape Juice and 100% Apple Juice contain "dangerously high levels" of lead and arsenic. *Boysen v. Walgreen Co.*, No. 11-6262 (U.S. Dist. Ct., N.D. Cal., filed December 13, 2011). According to the complaint, the levels of lead and arsenic in these beverages are higher than FDA limits on these chemicals in bottled water, and the company fails to disclose information about the contaminants on product labels or in advertising. The plaintiff alleges that California includes lead and arsenic on the list



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of those substances known to the state to cause cancer or reproductive harm, but does not otherwise include a Proposition 65 claim.

Alleging unfair business acts or practices and false or misleading advertising under California law, breach of implied warranty, and unjust enrichment, the plaintiff seeks restitution; actual, statutory and punitive damages; injunctive relief; attorney's fees; and costs. The plaintiff contends that he "suffered injury in fact and lost money as a result of the unfair competition and material omissions described in this Complaint" and that "Defendant has generated substantial sales of the Contaminated Juices," which neither the plaintiff nor the class would have purchased if the company had made disclosures about lead and arsenic in its juices.

"All Natural" Chips and Snacks Challenged for Containing GE Ingredients

A California resident who claims economic injury from purchasing Frito-Lay snack and chip products advertised as "All Natural" while allegedly containing genetically engineered (GE) corn and vegetable oil seeks to certify a nationwide class in a consumer fraud action filed in a California federal court. **Gengo** v. Frito-Lay N. Am., Inc., No. 11-10322 (U.S. Dist. Ct., C.D. Cal., filed December 14, 2011).

According to the complaint, the company's tortilla chips, sun chips and multigrain snacks are prominently labeled as "made with ALL NATURAL ingredients." Because they are instead purportedly made with corn, soybean and canola oils "made from genetically modified plants and organisms," the plaintiff contends that "she did not get the 'all natural' Tostito's and SunChip's products that were advertised and she paid for."

Alleging violations of the California Business & Professions Code (misleading advertising and unfair competition) and Consumers Legal Remedies Act, breach of express warranty, and violation of the Magnuson-Moss Act, the plaintiff alleges damages in excess of \$5 million, including restitution, disgorgement, compensatory and statutory damages, injunctive relief, attorney's fees, and costs.

OTHER DEVELOPMENTS

Anti-Tobacco Law Professor Claims Credit for Food Litigation Explosion

George Washington University Law Professor John Banzhaf has issued a press release highlighting recent action the Food and Drug Administration took against a food company that purportedly misbrands one of its products by declaring it "All Natural" while making the product with a synthetic chemical preservative ingredient. According to Banzhaf, the agency's warning letter is "likely to lend support to and encourage an ever-growing number of major



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class action law suits being filed on these grounds, says the public interest law professor whose earlier movement to use legal action as a weapon against obesity apparently inspired these new legal actions."

He claims that *The American Lawyer* recognized how he started this litigation movement, noting in an article that he used the courts to address obesity, "just as he had earlier done in leading the use of legal action as a weapon against smoking." Banzhaf further states, "The movement which Banzhaf started has now resulted in at least ten successful fat law suits which have forced food companies to fork out more than \$20 million and make major changes in the way their products are advertised, promoted, and sold. 'The newer "natural" law suits should force companies to think twice before simply slapping an "all natural" label on their products and their advertising, seeking to take advantage of vagueness in the definition of the world "natural," and in the hopes that people will be tricked into thinking that an "all natural" product is safer or healthier, says Banzhaf."

Banzhaf suggests that lawsuits challenging "all natural" labeling are easy to win because (i) "plaintiffs may not necessarily have to show that the claim is expressly false, and/or that some identified people were in fact mislead to their detriment"; (ii) judgments are based "not on the brightest and most educated consumer, but rather on those who, because they may not be quite as smart or as educated, may be deceived by the wording"; and (iii) consumers cannot verify whether a product is actually "natural," thus "the burden to avoid misrepresentation by properly labeling its product must be on the advertiser." See Press Release of John Banzhaf, December 7, 2011.

Pew Report Questions Seafood Eco-Labels

A recent <u>report</u> funded by the Pew Environment Group has suggested that many seafood products bearing eco-labels are "not much better than conventional farmed seafood options when it comes to protecting the ocean environment." Titled "How Green is Your Eco-label? A Comparison of the Environmental Benefits of Marine Aquaculture Standards," the study evidently relied on the 2010 Global Aquaculture Performance Index "to determine numerical scores of environmental performance for 20 different eco-labels for farmed marine finfish, such as salmon, cod, turbot and grouper." Researchers then ranked voluntary organic, retailer and industry standards in terms of both absolute and value-added performance based on 10 environmental impact measures, including antibiotic and parasiticide use, the ecological impact of escaped pen fish, and the sustainability of feed fish.

Intended as "a kind of *Michelin* guide for standards," the report did not assess individual farms but instead asked "how poorly a farm could perform and still meet the written standards relevant to each impact category." The results reportedly indicated that while organic standards led all others in both abso-



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lute and value-added performance, other kinds of eco-labels often "ignore major environmental impacts or fail to set measurable limits." In particular, the researchers noted that "scale is a big challenge" because eco-labels awarded to individual farms can overlook "the cumulative environmental effects of many farms [that] can quickly overwhelm the benefits of reductions in impacts by a single farm or small group of certified farms."

"Our research shows that most eco-labels for farmed marine fish offer no more than a 10 percent improvement over the status quo," said the report's lead author in a December 7, 2011, press release. "With the exception of a few outstanding examples, one-third of the eco-labels evaluated for these fish utilize standards at the same level or below what we consider to be conventional or average practice in the industry."

Obese Child Placed in Foster Care Ordered into Uncle's Custody

A Cleveland judge has reportedly decided that an obese third grader who was removed from his mother's custody after she was apparently unable to control his weight can now be removed from foster care. County child welfare officials had convinced the court in October 2011 that the 218-pound child was in imminent danger; they had been working with the family for more than a year after the boy was taken to a hospital with breathing problems. According to a news source, the court found that the boy had lost about 25 pounds during his two months in foster care. He ordered the honor student to live with his uncle following a hearing that took place on the child's ninth birthday. See The Slatest, November 29, 2011; msnbc.com, December 14, 2011.

MEDIA COVERAGE

New Book on Olive Oil Industry Presses for Change

According to a December 7, 2011, New York Times book review, a new tome by freelance writer Tom Mueller has claimed that 50 percent of the olive oil sold in America "is, to some degree, fraudulent." Based on an August 13, 2007, New Yorker article, Extra Virginity: The Sublime and Scandalous World of Olive Oil apparently aims "to demonstrate the brazen fraud in the olive oil industry and to teach readers how to sniff out the good stuff." To this end, Mueller reportedly explains how unscrupulous suppliers "frequently adulterate olive oil with low-grade vegetable oils and add artificial coloring," resulting in "a urine-colored and musty butter substitute."

But aside from such "alarming" statistics, *Times* critic Dwight Garner ultimately found the prose too "unctuous" for his taste. "The Food and Drug Administration considers this adulteration a low priority. Grody olive oil is not killing



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anyone. We're talking about a first-world problem here," Garner concluded. Additional details about Mueller's work on olive oil appear in <u>Issue 227</u> of this *Update*.

SCIENTIFIC/TECHNICAL ITEMS

Animal Study Explores Behavioral Changes Linked to Early BPA Exposure

A recent study has allegedly concurred with theories suggesting that newborn mice exposed to bisphenol A (BPA) exhibit signs of behavioral changes as adults. Henrik Viberg, et al., "Dose-dependent behavioral disturbances after a single neonatal Bisphenol A dose," *Toxicology*, December 2011. After administering a single dose of BPA to three groups of 10-day-old male mice, researchers reportedly found that the two groups exposed to the highest BPA concentrations behaved differently than normal mice when placed in new environments at 2 and 5 months of age.

According to the study abstract, these findings suggest that "a single neonatal exposure to [BPA] causes adult disturbances in spontaneous behavior in a novel home environment" that are both dose-related and long-lasting. In particular, the authors noted that the apparent effects of neonatal BPA exposure on the cholinergic system are similar to those seen "after a single postnatal exposure to other [persistent organic pollutants], such as PBDEs, PCBs and PFCs."

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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.



