Food & Beverage

LITIGATION UPDATE

Issue 275 • September 19, 2008

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Backs BPA Despite Questions Raised by New Human Study

FDA has reportedly defended its draft assessment of bisphenol A (BPA) despite a new study linking the chemical plasticizer to heart disease and diabetes in humans. An agency expert panel met September 16, 2008, to discuss the FDA draft document and a recent National Toxicology Program report expressing "some concern" that BPA could affect brain and reproductive development before and after birth. In particular, FDA cited comprehensive animal studies in backing its earlier safety assessment of BPA, also noting a lack of similarly reliable human studies. "A margin of safety exists that is adequate to protect consumers, including infants and children, at the current levels of exposure," FDA senior scientist Laura Tarantino said. "We recognize the need to resolve the concerning questions that have been raised." *See USA Today*, September 16, 2008.

Meanwhile, a study published in the *Journal of the American Medical Association* has allegedly found a correlation between BPA exposure and cardiovascular disease, type 2 diabetes and liver-enzyme abnormalities in adults. Iain A. Lang, et al., "Association of Urinary Bisphenol A Concentration With Medical Disorders and Laboratory Abnormalities in Adults," *JAMA*, September 17, 2008. Researchers sampled 1,455 U.S. residents ages 18 to 74, dividing them into quartiles according to urinary BPA concentrations. Compared to those in the lowest quartile, participants with the highest BPA exposure were three times as likely to develop cardiovascular disease and twice as likely to develop type 2 diabetes. "The associations all seemed pretty robust," said the lead author, who nevertheless stressed the need for more research.

A concurrent *JAMA* editorial hailed these results as the "first major epidemiologic study to examine the health effects associated with the ubiquitous estrogenic chemical bisphenol A." The commentary concluded that the study, albeit "preliminary," "should spur U.S. regulatory agencies to follow the recent action taken by Canadian regulatory agencies, which have declared BPA a 'toxic chemical' requiring aggressive action to limit human and environmental exposures." "The FDA and the European Food Safety Authority have chosen to ignore warnings from expert panels and other government agencies, and have continued to declare BPA 'safe,'" opined the editorial authors. "The report by Lang et al should stimulate further studies and reevaluations of the basic assumptions in chemical risk assessments that led to FDA assurances that BPA is safe."

Some experts, however, noted that BPA exposure

levels in the study were "far below" the safety standard set by government agencies. Steven Hentges, executive director of the Polycarbonate/BPA Global Group of the American Chemistry Council, also pointed out limitations in the study design. "Urinary concentrations tell you the exposure over the last 24 hours, but heart disease and diabetes do not occur overnight," Hentges was quoted as saying. *See Chicago Tribune* and *Environmental Health News*, September 16, 2008.

[2] FDA Warns Against Illegal Imports of Tainted Baby Formula from China

FDA last week issued a health issue advisory after Chinese authorities reported that baby formula tainted with the plasticizer melamine sickened thousands of children. Although FDA has not approved any Chinese-manufactured formula for the domestic market, the agency cautioned that some illegal products could wind up in U.S. specialty stores. Infants exposed to the melamine-tainted milk powder have developed kidney stones and other complications, resulting in at least four fatalities to date.

"This [advisory] is to assure the American public that there is no known threat of contamination in infant formula manufactured by companies that have met the requirement to sell infant formula in the United States," FDA said in a September 12 press release that advised "caregivers not to feed infant formula manufactured in China to infants." *See Law360*, September 15, 2008.

Meanwhile, the Chinese government has reportedly linked the contamination to 22 different powdered milk producers. The investigation first implicated China's seventh-largest milk distributor Shijiazhuang Sanlu Group Co., which apparently received consumer complaints as early as March, but did not discover melamine in its products until August and waited until September 8 to notify provincial officials of its ongoing recall efforts. Health officials have traced the melamine to dealers who diluted their milk and added the chemical to boost protein counts before selling it to Sanlu and others in the supply chain. In addition, the scandal has forced several major retailers, including Starbucks, to withdraw a range of dairy products from the Chinese market. The contamination has ensnared 20 percent of China's formula brands, according to the General Administration of Quality Supervision, Inspection and Quarantine, which so far has arrested four dealers in conjunction with the recall. *See The Wall Street Journal*, September 15 and 16, 2008; *Mail Foreign Service*, September 19, 2008.

[3] FDA Publishes Draft Guidance on Regulation of GE Animals

FDA this week published draft **guidance** titled "The Regulation of Genetically Engineered [GE] Animals Containing Heritable rDNA Constructions," which aims "to clarify the FDA's regulatory authority in this field, as well as the requirements and recommendations for producers of GE animals and products derived from GE animals."

FDA said it will use the animal drug provisions of the Federal Food, Drug, and Cosmetic Act to regulate recombinant DNA technology, which changes structure or function in animals and thus "meets the definition of a new animal drug, whether the animal is intended for food, or used to produce another substance." Although the agency has not yet approved animals with modified rDNA for the

human market, FDA anticipates an increase in the development of GE animals in the following categories: (i) "animals that produce human or animal pharmaceuticals (biopharm animals)"; (ii) "animals that produce high-value industrial or consumer products, such as fibers"; and (iii) "food-use animals with new traits such as improved nutrition, faster growth or lower emission levels of environmentally harmful substances (such as phosphate in their manure)." The comment period on the draft guidance closes November 18, 2008.

FDA will also coordinate with the U.S. Department of Agriculture and the Environmental Protection Agency to regulate GE livestock in accordance with the United Nations' Codex Alimentarius Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Animals. USDA's Animal and Plant Health Inspection Service has also **requested** scientific data "concerning ongoing and future research on [GE] animals." The agency seeks comments on "what types of actions and approaches APHIS should consider in addressing any such risks that would complement the Food and Drug Administration's (FDA's) oversight."

"[T]he FDA's Center for Veterinary Medicine (CVM) has been working with developers of GE animals to make them aware of their responsibilities to ensure that food from these animals does not enter the U.S. food supply unless the FDA has authorized such use," FDA stated in a September 18 press release. "Under the draft guidance, in those cases in which the GE animal is intended for food use, producers will have to demonstrate that food from the GE animal is safe to eat." *See Reuters*, September 18, 2008.

[4] Proposed FDA Rule Would Require "Refused Entry" Labels on Imported Foods Turned Away at Borders

The FDA has published a proposed **rule** that "would require owners or consignees to label imported food that is refused entry into the United States." The agency's intent is "to prevent the reintroduction of refused food into the United States, to facilitate the examination of imported food, and to implement part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Comments on the proposal must be submitted by December 2, 2008.

The FDA is authorized to refuse entry to food imports "that appear, from examination or otherwise, to be (among other things) adulterated or misbranded." The agency detains shipments of food that appears not to be in compliance with food safety laws and gives the importer an opportunity to demonstrate compliance or to recondition the food to bring it into compliance. Failure to do so results in refused admission; Customs and Border Protection ensure that such foods are destroyed if not re-exported within 90 days of refusal.

According to the *Federal Register* notice, the FDA proposed a rule in 2001 requiring "refused entry" marking "to address a practice known as 'port shopping,'" whereby "some unscrupulous persons attempt to bring the refused food back into the United States by shipping it to another port in the hopes that the food will be admitted into the United Sates at that other port." The 2001 proposal was never finalized because the bioterrorism preparedness law adopted the following year contained requirements that differed with the proposal. The new proposal accommodates the new statutory provisions. *See Federal Register*, September 18, 2008.

U.S. Department of Agriculture (USDA)

[4] ERS to Host Workshop on Lack of Access to Affordable and Nutritious Foods

USDA's Economic Research Service (ERS) will host a **workshop** on October 9, 2008, to launch a study of "food deserts," that is, those low-income and rural communities whose lack of access to affordable and nutritious foods may be affecting rising rates of obesity and chronic diseases. The 2008 Farm Bill apparently requested such a study, and the ERS workshop "will bring together key stakeholders from program, policy, research, and advocacy communities to discuss how to conceptualize and measure food deserts, implications of food deserts for public health and food assistance programs, and programs and policies to help mitigate the impact of food deserts." Registration is required due to space limitations.

State and Local Governments

[5] State AGs Call on Manufacturer to Cease Rollout of Higher-Alcohol Version of Caffeinated Energy Beverage

The attorneys general of 38 states have reportedly joined forces in an effort to stop the planned October 1, 2008, launch of a new alcoholic energy beverage with a higher alcohol content than products currently on the market. According to New York Attorney General Andrew Cuomo (D), who was one of the signatories to the AGs' September 17, 2008, letter to the company, "By introducing Sparks Red, a higher-alcohol-content and even more dangerous version of its Sparks product, MillerCoors is demonstrating an utter disregard for the safety of young consumers. Drinking is not a sport, and my office will not stand idly by as MillerCoors ramps up its efforts to market these potentially harmful products to young consumers."

Connecticut's attorney general called the new product a "recipe for disaster," and the attorney general for Illinois said, "I am extremely disappointed with MillerCoor's decision to introduce Sparks Red to the marketplace. The scientific evidence clearly shows the grave dangers these products pose, especially to young consumers. I urge MillerCoors to reverse its decision and keep this product off store shelves." A company spokesperson was quoted as saying that the company "goes to great lengths to ensure all of our products are marketed in a very responsible manner to legal drinking-age adults" and that its Sparks® beverages "have all been approved for sale by the federal government."

Sparks Red® will reportedly contain 8 percent alcohol; most conventional beers contain 4 to 5 percent alcohol. Similar beverages with caffeine contain 6 or 7 percent alcohol. The $4.8 billion market for alcoholic energy drinks has apparently grown more than 400 percent since 2003. According to a news source, other high-profit-margin Sparks® products lead the industry. Details about a lawsuit involving Sparks® products that the Center for Science in the Public Interest filed against MillerCoors appear in issue 274 of this Update. *See Advertising Age* and *New York* and *Illinois Attorneys General Press Releases*, September 17, 2008; *Chicago Tribune*, September 18, 2008

Litigation

[6] Pet Food Class Members Challenge Proposed $24 Million Settlement

Two class members who brought claims against pet food companies over the melamine contamination that led to the deaths of family pets in 2007 and a massive recall of cat and dog food have reportedly objected to the proposed $24 million settlement and will move for permission to intervene on October 14, 2008. *In re Pet Food Prods. Liab. Litig.*, MDL No. 1850 (U.S. Dist. Ct., D.N.J.) Margaret Picus and Daniel Kaffer are apparently plaintiffs in other lawsuits against the companies, filed on behalf of individuals who purchased non-contaminated food that was not recalled, and raising issues related to product labels that claim the pet foods are "Made in the United States." They contend that the contamination settlement will preclude them from seeking relief with respect to their mislabeling allegations. According to their brief, "The settlement provides no consideration for the purported release of such claims" and that "certain settling defendants sought to use this settlement to foreclose the 'Made in the USA' claims which are pending in other districts." *See Product Liability Law 360*, September 15, 2008.

[7] Fast-Food Chain Sued for Allegedly Overcharging

A Texas resident has sued McDonald's Corp. in an Illinois state court, alleging that the company systematically overcharges consumers when they ask to super-size items on its "value meals" menu. *Guindi v. McDonald's Corp.*, No. 08-33972 (Cook County Circuit Court, Illinois County Dept., Chancery Div., filed September 12, 2008). According to plaintiff Nathan Guindi, McDonald's allows customers to super-size items in their value meals for an additional $.39 and "further represents that its computers are programmed to charge that amount and not a greater amount." Instead, the super-sized meals are overcharged in small amounts, says the complaint, "and calculated to escape the notice of the customer." Guindi claims that he "discovered the overcharges because he paid by credit card and kept the receipts."

Guindi, who specifies 17 different occasions on which he was allegedly overcharged, seeks to certify a class of "all persons who were charged by McDonald's Corporation a greater amount for 'supersized' meals than the additional charge advertised." He contends that common questions include "[w]hether the defendant engaged in the practices complained of," and whether the practices constitute fraud. Guindi alleges breach of contract, common law fraud, negligent misrepresentation, and restitution; he requests compensatory and punitive damages and costs.

[8] Non-Profit Seeks to End Disposal of Sewage Sludge on Farmland

The Center for Food Safety has reportedly announced plans to sue the Environmental Protection Agency (EPA) in an attempt to force the agency to set a moratorium on the land application of sewage sludge until more scientific study is conducted on the possible harm to people and animals from contaminants and heavy metals that may be in the sludge. Under EPA's biosolids program, sludge, a byproduct of sewage treatment, may be disposed of on public lands, including parks and farms. It is often used as an alternative to commercial fertilizers. The Center, which was founded in 1997 to address concerns about the

nation's food production system on health and the environment, unsuccessfully petitioned EPA in 2003 to end the program.

Expected to be filed within 60 days, the Center's lawsuit will apparently seek an order requiring that permits issued under the Clean Water Act National Pollutant Discharge Elimination System (NPDES) mandate a method of sludge disposal other than land application. It will also ask the court to order EPA to issue a rule eliminating land application as an acceptable practice for sludge disposal. When it denied the center's 2003 petition, the agency said that current scientific evidence did not support a ban. *See BNA Daily Environment Report*, September 15, 2008.

In a related development, EPA has issued a **notice** of public comment and external peer-review workshop as to its draft "Problem Formulation for Human Health Risk Assessments of Pathogens in Land-Applied Biosolids." Public comments must be submitted by November 3, 2008; and the workshop will occur November 19. According to the notice, the draft document is a response to the National Research Council's 2002 report, *Biosolids Applied to Land: Advancing Standards and Practice*. The draft reportedly "aims to improve problem formulation and strengthen the analysis plans associated with the conduct of quantitative microbial risk assessments on land-applied biosolids." *See Federal Register*, September 19, 2008.

[9] Lawsuits Allege Fertilizer Price-Fixing

Farm chemical suppliers have reportedly filed putative class claims with federal courts in two states, alleging that the world's two biggest fertilizer companies have fixed prices and colluded to more than double the price of fertilizer ingredients such as phosphate and potash over the last year. Minn-Chem, Inc. filed its claims in federal court in Minneapolis, while Gage's Fertilizer & Grain, Inc. filed similar claims before a Chicago tribunal. The defendants, including Potash Corp. of Saskatchewan, Inc., Mosaic Co. and Agrium, Inc., apparently pointed to tight supplies and increased demand by farmers as reasons for the higher prices and their generous profits over the past two years. According to a news source, the Minnesota claims allege that the companies exchanged "sensitive, nonpublic" information relating to pricing and demand, allocated market shares and coordinated production output. Their conduct apparently attracted scrutiny in Washington, D.C., with a Democratic congressman calling for a Federal Trade Commission investigation that reportedly turned up nothing untoward. *See The Wall Street Journal*, September 16, 2008.

Media Coverage

[10] Julia Moskin, "Superfood or Monster From the Deep?," *The New York Times*, September 17, 2008

"Orange juice laced with anchovies is one example of the latest way major food companies are competing for health-conscious consumers: plugging one food into another and claiming the health benefits of both," writes *New York Times* reporter Julia Moskin in this article examining nutraceuticals, "broadly defined as ingredients that are derived from food." Moskin attributes the growth in this market to new technologies in food processing and a 1999 court decision "giving the makers of supplements broad leeway to advertise their health benefits." In addition, rising food prices have reportedly prompted companies to develop "inexpensive 'value-added' products" that capitalize on nutri-

tional trends while avoiding costly whole ingredients, such as "sun-dried tomatoes or honey-roasted almonds."

Moskin also points to lax Food and Drug Administration (FDA) standards, which require "significant scientific agreement" before food processors can make unqualified health claims but make no specific rules for the labeling of functional foods. Although she acknowledges the public health successes of fortified products like vitamin-B-enriched flour and vitamin-D-enriched milk, Moskin notes that FDA does not conduct its own nutritional research, a fact raising doubt among industry critics who question whether the health benefits of whole foods can be extrapolated into additive form. "[R]ecent studies on supplemental vitamin E, beta-carotene and folate (all of which fall into the broad category of 'antioxidants') surprised everyone by showing no benefits whatsoever for cardiovascular disease," according to Moskin.

Upcoming Conferences and Seminars

Lorman Education Services, Kansas City, Missouri – September 25, 2008 – "Document Retention and Destruction in Missouri." SHB Partner **Christopher Cotton** will present an "E-Discovery Update," focusing on evolving law, litigation issues and coordination within a company.

American Conference Institute, Scottsdale, Arizona – October 28, 2008 – "Positioning the Class Action Defense for Early Success." Joining a faculty that includes federal and state judges, SHB Partner **Gary Long** will participate in a panel discussion titled "Foregoing Settlement and Taking the Class Action to Trial."

American Bar Association, New York, New York – November 7, 2008 – "12th Annual National Institute on Class Actions." SHB Partners **Laurel Harbour** and **Jim Muehlberger** will join panels addressing the latest developments in class action law. Harbour will discuss "Class Actions Sans Frontières," while Muehlberger will explore the "Rigorous Analysis" standard that courts apply when evaluating whether to certify a class.

American Conference Institute, Scottsdale, Arizona – December 4-5, 2008 – "2nd National Forum on Food-Borne Illness Litigation: Advanced Strategies for Assessing, Managing and Defending Claims of Food Contamination. SHB Partner **Paul La Scala** will participate in a discussion about "Deceptive Trade Practices Claims: Strategies for Responding to a Growing Trend."

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Food & Beverage Litigation Update is distributed by
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