

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

FDA to Rule on BPA Regulation in Food Packaging by November 30

The Food and Drug Administration (FDA) has announced that it will decide by November 30, 2009, whether the chemical bisphenol A (BPA) is safe for use in food packaging. FDA Acting Deputy Commissioner and Chief Scientist Jesse Goodman has reportedly told the agency's Science Board that a group of FDA scientists will conduct a new review of more than 100 studies on BPA and that the review will be assessed by a group of government scientists not affiliated with FDA. Commissioner Margaret Hamburg will review the science and recommendations, and then determine whether BPA is safe when used in food containers.

Scientific evidence on whether the levels of BPA in products are harmful has been hotly disputed. Last year, FDA said the chemical was safe because the small amounts that leach from food containers do not threaten children or adults. But its Science Board rejected that decision, apparently claiming that it was based on two studies financed by the plastics industry. New studies have also allegedly linked BPA to heart disease and diabetes, and one study has suggested the chemical interferes with the effectiveness of chemotherapy for breast cancer patients. Minnesota, Connecticut, Chicago and Long Island's Suffolk County have already banned BPA in baby bottles and sippy cups. Massachusetts has issued a health advisory to pregnant women and parents of young children, and a federal ban has been introduced in the House and Senate. See *Milwaukee Journal Sentinel*, August, 17, 2009; *E&E News PM*, August 18, 2009; *FoodProductionDaily.com*, August 19, 2009.

FDA Publishes Draft Labeling Guidance for Beer Made Without Malted Barley and Hops

The U.S. Department of Health and Human Services (HHS) has **announced** the availability of draft **guidance** titled "Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration [FDA]." The agencies have issued the document "in light of the recent ruling by the Alcohol and Tobacco Tax and Trade Bureau (TTB) (formerly The Bureau of Alcohol, Tobacco and Firearms (ATF)) clarifying that certain beers do not meet the definition of a 'malt beverage' under the Federal Alcohol Administration Act (FAA Act)." According to HHS, beers that do not fall under FAA Act jurisdiction "are subject to the labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA)."

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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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The draft guidance also “reminds manufacturers that the labeling of wine beverages containing less than 7 percent alcohol by volume, such as wine coolers, diluted wine beverages, dealcoholized or partially dealcoholized wine and ciders, is also subject to FDA labeling requirements.” FDA is accepting public comments on the draft guidance until October 16, 2009. *See Federal Register*, August 17, 2009.

HHS Announces Public Meeting to Discuss Codex Session on Nutrition and Foods for Special Dietary Uses

The U.S. Department of Health and Human Services (HHS), U.S. Department of Agriculture and Office of the Acting Secretary for Food Safety have announced a public [meeting](#) to address an upcoming session of the Codex Alimentarius Commission, the international food standards body established by the U.N. Food and Agriculture Organization and World Health Organization. Slated for October 8, 2009, the meeting will consider U.S. draft positions pertaining to the 31st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to be held November 2-6 in Dusseldorf, Germany. CCNFSDU studies nutritional problems and advises the Codex on general nutritional issues; drafts general provisions concerning the nutritional aspects of all foods; develops standards, guidelines and related texts pertaining to foods for special dietary uses; and considers provisions on nutritional aspects proposed for inclusion in Codex standards. The U.S. agencies will also hold a working group on October 31 to discuss the development of nutrient reference values for nutrients associated with increased or decreased risk of non-communicable diseases. *See Federal Register*, August 20, 2009.

LITIGATION

Stay on Water Bottle Deposits Lifted in New York

A federal court in New York has decided to allow most parts of a new state bottle-deposit law to take effect, lifting a injunction that would have delayed implementation until April 2010. *Int'l Bottled Water Ass'n v. Paterson*, No. 09-4672 (U.S. Dist. Ct., S.D.N.Y., decided August 13, 2009). Additional details about the litigation challenging the law's constitutionality appear in issue 305 of this Update. The court's decision overturns an order entered in late May 2009 granting injunctive relief.

According to a news source, the ruling means that soft drink and beer makers must now give the state 80 percent of the unclaimed 5-cent deposits, and store and redemption handling fees will increase from 2 cents to 3.5 cents per container. Water companies making products containing flavored water, vitamin water and artificial sweeteners have apparently been given until October 22 to comply with the law, unless they can prove compliance is impossible. They did succeed in preventing the implementation of a provision requiring New York State-specific bar codes; the court's order prevents it from taking effect. Beverage makers had argued that it would have been costly and onerous to implement.

Environmental activists are reportedly planning to seek an extension of the law to iced teas, sports drinks and other non-carbonated beverages. The water companies

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had argued that by exempting beverages containing sugar from the law, the state violated the Constitution's Equal Protection Clause. *See Star Gazette*, August 15, 2009.

New Lawsuit Claims Deceptive Marketing of Pomegranate Juice

In the wake of lawsuits filed by the manufacturer of a pomegranate-juice based product line, consumers have now begun seeking damages against the same defendants for alleged deception and fraud in the sale of pomegranate juice purportedly containing "little or no pomegranate juice." *Burcham v. Welch Foods, Inc.*, No. 09-05946 (U.S. Dist. Ct., C.D. Cal., filed August 14, 2009). Additional information about the lawsuits filed by POM Wonderful LLC against Welch Foods, Inc. and Ocean Spray Cranberries, Inc. appears in issues 290 and 313 of this Update.

According to plaintiff Maryam Burcham, seeking damages for herself and a class of "All persons residing in California who purchased Welch's 'White Grape Pomegranate Juice,'" the defendant's product "purports to combine white grape and pomegranate into a single juice product. However, the truth is that the main ingredients in Defendant's White Grape Pomegranate Juice are actually cheap white grape and apple juice, instead of pomegranate juice, which is one of nature's most potent antioxidants."

Discussing the purported health benefits of pomegranate juice, the plaintiff details how the defendant allegedly misleads consumers with its advertising and labeling by focusing "on the pomegranate in the product, while downplaying the cheaper juices it primarily contains." The complaint refers to the POM Wonderful litigation, noting that a court has ruled that its state law claims are not preempted by federal law. According to the plaintiff, the defendant also makes misleading and deceptive claims about the juice on its Web site.

The complaint alleges unlawful, unfair and deceptive business practices and false and misleading advertising in violation of California's Business & Professions Code. The plaintiff seeks injunctive relief to halt defendant's advertising, marketing and packaging of its product "as containing a significant quantity of pomegranate juice"; to require an immediate public information campaign; and to correct "any erroneous impression consumers may have derived concerning the nature, characteristics, or qualities of its juice product." The plaintiff also seeks restitution, interest, attorney's fees, and costs, and asks for "[d]istribution of any moneys recovered on behalf of members of the Class via fluid recovery or *cy pres* recovery where necessary and as applicable, to prevent Defendant from retaining the benefits of their [sic] wrongful conduct."

NAFTA Tribunal Awards Damages in HFCS Dispute

A North American Free Trade Agreement (NAFTA) tribunal has reportedly awarded \$58 million in damages to Corn Products International's Mexican affiliate after finding that Mexico imposed discriminatory taxes on beverages sweetened with high-fructose corn syrup (HFCS). The tribunal determined in January 2008 that Mexico had breached its NAFTA obligations to favor its domestic sugar industry by requiring a 20 percent tax on HFCS-sweetened beverages. According to a news source, the tax was also imposed in retaliation for U.S. curbs on surplus Mexican sugar imports in the 1990s, an anti-dumping practice declared illegal by the World Trade Organization. *See FoodNavigator-USA.com*, August 29, 2009.

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Pennsylvania AG Sues Township for Stance on CAFOs

Pennsylvania Attorney General Tom Corbett (R) has filed a lawsuit against a York County township that denied a farmer's request to put a 4,400-hog confined animal feeding operation (CAFO) on his family's property. Peach Bottom Township, located about 60 miles south of the state capitol in Harrisburg, reportedly has an ordinance requiring such uses to be placed on low-quality farm land. The township zoning board apparently determined that Eric Gemmil's 120-acre farm was not low-quality land.

According to the state, the township's ordinance and CAFO application denial violated the Agriculture, Communities and Rural Environment Act, which prohibits local municipalities from passing ordinances limiting "normal" agricultural practices. The AG's lawsuit also reportedly alleges that the township has violated the state Nutrient and Odor Management Act, Agriculture Security Area Act, Right to Farm Act, Clean Stream Law, and Municipalities Planning Code.

A township official apparently refused to comment on the lawsuit other than to say that legal counsel is reviewing the complaint and will make recommendations to the board of supervisors. The next board meeting will be held September 9, 2009. See *The York Daily Record*, August 19, 2009; *U.S. Agricultural & Food Law and Policy Blog*, August 20, 2009.

Illinois AG Sues Makers of Acai Berry Products for Fraud

Illinois Attorney General Lisa Madigan has filed [lawsuits](#) against companies that make, market or supply acai berry products, touted as weight loss dietary supplements, charging that they are scamming consumers with aggressive marketing campaigns, prematurely billing their credit cards, not always supplying the product ordered, and making it nearly impossible to cancel once a "free trial" has been implemented. The product ads purportedly feature images of celebrities such as Rachel Ray, Oprah Winfrey, Mehmet Oz, M.D., Gwyeth Paltrow, or Courtney Love, despite their alleged lack of a promotional contract with the companies. The complaints seek injunctive relief, restitution and civil penalties.

MEDIA COVERAGE

Steve Stecklow, "Fraud by Trial Lawyers Taints Wave of Pesticide Lawsuits," *The Wall Street Journal*, August 20, 2009

"After responding to a radio commercial seeking former banana-plantation workers for a lawsuit against Dole Food Co., Marcos Sergio Medrano thought he might be entitled to some money," begins this article exploring fraud allegations against lawyers and plaintiffs in banana-pesticide litigation. "He says an American law firm convinced him that a pesticide used on the Dole-operated banana plantation where he had worked years ago had made him sterile. Lawyers for the 49-year-old peasant produced tests that purported to prove it. But DNA testing by Dole revealed that he had fathered three children—something Mr. Medrano says was news to him."

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Stecklow writes that Medrano, of Chinandega, Nicaragua, is part of the “sorry fallout from a group of U.S. personal-injury and other lawyers who descended on this small, impoverished city, seeking to recruit thousands of clients and earn up to 40 percent of any awards. Emboldened by a developing-world legal system that heavily favored plaintiffs, they filed an avalanche of lawsuits here against California-based Dole and eventually won \$2.1 billion in local judgments.”

But Stecklow reports that a California judge has ruled that plaintiffs and their lawyers deployed fraudulent tactics, which included faking sterility tests and using plaintiffs who never worked on banana plantations. “As a result,” he writes, “actual workers who may have been hurt may receive nothing, even though Dole continued using a dangerous pesticide called DBCP after it had been linked definitively to male sterility.”

Stecklow chronicles the saga of litigation, ending by reporting that Dole still faces nearly 250 DBCP lawsuits, mostly in Nicaragua. He quotes an attorney who says he’s “not optimistic” plaintiffs will prevail because if fraud did occur “that would cause any reasonable person to question all the cases.”

Bryan Walsh, “America’s Food Crisis and How to Fix It,” *Time*, August, 20, 2009

Describing an Iowa pig’s miserable, short life as “the state of your bacon—circa 2009,” this author recaps the “horror stories about the food industry” and how he believes things have gotten worse. “The U.S. agricultural industry can now produce unlimited quantities of meat and grains at remarkably cheap prices,” Walsh writes. “But it does so at a high cost to the environment, animals and humans. Those hidden prices are the creeping erosion of our fertile farmland, cages for egg-laying chickens so packed that the birds can’t even raise their wings and the scary rise of antibiotic-resistant bacteria among farm animals. Add to the price tag the acceleration of global warming—our energy-intensive food system uses 19 percent of U.S. fossil fuels, more than any other sector of the economy. And perhaps worst of all, our food is increasingly bad for us, even dangerous.”

Some Americans are working to transform the way the country eats, Walsh notes, citing as examples ranchers and farmers who are raising sustainable food, scathing documentaries like *Food Inc.* and investigative journalists like Eric Schlosser and Michael Pollan. But he believes that for most people, the price of food will remain the biggest obstacle to how willing they are to rethink the way they shop for—and eat—food.

“What we really need to do is something Americans have never done well, and that’s to quit thinking big,” Walsh writes. “We already eat four times as much meat and dairy as the rest of the world, and there’s not a nutritionist on the planet who would argue that 24-ounce steaks and mounds of buttery mashed potatoes are what any person needs to stay alive.”

OTHER DEVELOPMENTS

Food Producer Coalition Issues Report on Animal Antibiotics

The American Veterinary Medicine Association (AVMA) has submitted a [report](#) to Congress that challenges the 2008 findings of the Pew Commission on Industrial Farm

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Animal Production, which supports legislation (H.R. 1549 and S. 619) seeking to prohibit or limit the use of low-level antibiotics in agriculture. Signed by 20 food producer organizations, an introductory [letter](#) states that the PEW Commission and other supporters of the Preservation of Antibiotics for Medical Treatment Act (PAMTA) “offer no new information or data to make their case, but rather echo inaccurate messages.” The signatories have called on the Obama administration to honor its pledge to base its regulatory decisions on “the best available science,” not the opinions of “PhD issue advocates or animal rights activists.”

AVMA specifically faults the PEW Commission for failing to “incorporate the findings and suggestions of a significant number of participating academicians.” Focusing on the areas of antimicrobial resistance, the environment and animal welfare, AVMA discovered that the report’s details contained “significant shortfalls” and lacked “comprehensive idea development” about how to execute a new plan or program for reform. According to the veterinary association, PEW’s recommendations “for highly restrictive bans on antibiotic use, which are also being used to advocate for PAMTA, have not been proven beneficial to public health” and do not take into account less restrictive bans implemented in Denmark and the Netherlands, where scientists found “that even a small decrease in antibiotic use severely diminished animal health and welfare without significantly improving human health.”

“Both in substance and in approach, therefore, the PEW report contains significant flaws and major deviations from both science and reality,” concludes the AVMA response. “The report is, in many ways, a prolonged narrative designed to romanticize the small, independent farmer, while vilifying larger operations, based simply upon their size.” See *American Feed Ingredients Association Press Release*, August 14, 2009; *AVMA Press Release*, August 17, 2009; and *Meatingplace.com*, August 17 and 19, 2009.

SCIENTIFIC/TECHNICAL ITEMS

Chinese Researchers Find Nanoparticles in Human Lung Tissue

Chinese researchers studying seven women purportedly exposed to nanoparticles in the workplace for 5-13 months sought to determine if their shortness of breath and pleural effusions could be linked to their exposure. Y. Song, et al., “Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma,” *European Respiratory Journal*, August 20, 2009. According to the abstract of their article, “polyacrylate, consisting of nanoparticles, was confirmed in the workplace,” and electron microscopy revealed nanoparticles in “the cytoplasm and caryoplasm of pulmonary epithelial and mesothelial cells,” as well as in the chest fluid of the subjects. The researchers have concluded that the cases “arouse concern that long-term exposure to some nanoparticles without protective measures may be related to serious damage to human lungs.”

The research has generated debate among nanotech researchers and scientists. Two of the women studied have reportedly died. Working in an unidentified Chinese printing factory, they were apparently exposed in a small, unventilated room without appropriate workplace health and safety protections while they

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inhaled fumes from heated polystyrene boards that had previously been sprayed with a polyacrylic ester paste. Some respiratory toxicologists reportedly doubt that nanoparticles were to blame for the serious illnesses and deaths experienced by the workers, believing that the symptoms were more typical of chemical exposure. Occupational medicine experts agree that the study is not definitive and blame the "total failure in health and safety procedures" for the adverse health effects.

Nanotechnology expert Andrew Maynard, with the Woodrow Wilson International Center of Scholars, discussed the study's limitations in several science blogs. He was quoted as saying, "The study raises the bar for doing appropriate research as fast as possible to find out where the dangers might lie when working with nanomaterials." Maynard reportedly suggested that the patients' symptoms were similar to those seen in animals intentionally exposed to nanoparticles. He concluded that despite the noted limitations, "this is a strong clinical study, and if viewed appropriately, will most likely help avoid similar incidents in the future." He agreed that long-accepted occupational practices would have prevented the illnesses and deaths.

Polyacrylates are plastics that come in a variety of forms, including those that make Plexiglas and "super glue," serve as binders for indoor and outdoor latex house paints, absorb fluids in disposable diapers, provide the "instant snow" used as set decoration for movie studios, and assist with seed germination, soil conditioning and hydroponics. See *Nature News*, *SafeNano Blog*, and *ICON Blog*, August 18, 2009.

Study Authors Urge Regulatory Reform of Food Allergen Labeling

A recent audit of food allergen labeling practices has reportedly concluded that "deficiencies and ambiguities are prevalent," calling on federal agencies to back the "strict enforcement of labeling laws as well as additional regulation." M.M. Pieretti, et al., "Audit of manufactured products: use of allergen advisory labels and identification of labeling ambiguities," *Journal of Allergy and Clinical Immunology*, August 2009. In their review of 20,241 products, researchers identified 25 different allergen advisory terms including "may contain," "shared equipment" and "within plant." They also noted that "nonspecific terms, such as 'natural flavors' and 'spices,' appeared on 65 percent of products and were not linked to a specific ingredient for 83 percent of them."

The study specifically raised questions about the labeling of soy-derived lecithin and refined oils containing soy. The Food Allergen Labeling and Consumer Protection Act (FALCPA) requires manufacturers to list "soy" as an ingredient in lecithin-containing products, but does not require the same advisory on products using refined oils that contain soy. Nevertheless, producers often use a soy allergen warning for refined oil ingredients even though neither lecithin nor refined oil is likely to trigger an allergic reaction because they contain only trace amounts of soy proteins. Other ambiguities highlighted by the audit included the nonspecific labeling of tree-nut types and the failure to indicate the origin of gelatin, which may come from fish, pork or beef. "Additional allergen labeling regulation could improve safety and quality of life for individuals with food allergy," stated the study authors. See *FoodNavigator-USA.com*, August 17, 2009; *Atlanta Gluten-Free Food Examiner*, August 18, 2009.

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Researchers Develop Index to Evaluate Nutrient-Dense Foods

U.S. researchers have reportedly developed a nutrient-density classification system that offers “a positive, scientific approach to inform people about what to eat rather than what not to eat.” V.L. Fulgoni 3rd, et al., “Development and validation of the nutrient-rich foods index: a tool to measure nutritional quality of foods,” *Journal of Nutrition*, August 2009. The researchers apparently compared several formulas, or nutrient-rich food (NRF) indices, to the Healthy Eating Index (HEI) set by the U.S. Department of Agriculture’s 2005 Dietary Guidelines for Americans Committee, which called for “a scientifically valid definition of nutrient density to help with nutrition guidance.” This definition would help consumers choose nutrient-dense foods better suited to fulfill the HEI recommendations.

According to the study, the NRF index most closely aligned with HEI is based on 100 calories and weighed nine “nutrients to encourage” (calcium, fiber, iron, magnesium, potassium, protein, and vitamins A, C and E) against three “nutrients to limit” (added sugars, saturated fats and sodium). “These results confirmed that better diets do not necessarily come from just restricting certain nutrients; the addition of beneficial nutrients is critical for a higher diet quality,” stated the study authors, who concluded that more research is “still necessary to determine how best to present nutrient profiling to consumers in a way that will actually lead to selection of foods that improve the overall diet.” See *FoodNavigator-USA.com*, August 18, 2009.

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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.

