Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Nation Toxicology Program (NTP)

[1] NTP Concludes Bisphenol A Poses "Some Risk" to Children

The NTP Center for the Evaluation of Risks to Human Reproductive Health (CERHR) has announced the final results of its research on bisphenol A (BPA). The NTP-CERHR Monograph on Bisphenol A includes (i) an NTP brief on BPA and (ii) the conclusions of the CERHR expert panel regarding the potential reproductive and developmental health risks associated with BPA. The brief is based on "information about [BPA] provided in the expert panel report, public comments, comments from peer reviewers of the draft NTP brief, and additional scientific information available since the expert panel meeting." Noting that most human EPA exposure occurs via food and beverages, the monograph concludes that the agency "has some concern for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A," as well as "minimal concern for effects on the mammary gland and an earlier age for puberty for females in fetuses, infants, and children at current human exposures to bisphenol A." In addition, NTP expressed (i) "negligible concern" that BPA exposure in pregnant women would result in

"fetal or neonatal mortality, birth defects, or reduced birth weight and growth in their offspring;" (ii) "negligible concern" that non occupationally exposed adults would experience "reproductive effects;" and (iii) "minimal concern for workers exposed to higher levels in occupational settings." *See FoodNavigatorUSA.com*, September 4, 2008.

The NTP-CERHR findings have reportedly prompted both the Environmental Protection Agency (EPA) to reevaluate its policies regarding BPA exposure. EPA earlier this year added BPA to its Integrated Risk Information System (IRIS) database and initiated a literature review to update its 1993 assessment of chemical. In light of the NTP report and other similar investigations, however, "EPA's IRIS Program is currently evaluating the need for a health assessment for [BPA] and may begin assessment development in the near future," according to an EPA spokesperson. *See Inside EPA*, September 9, 2008.

In a related development, a Yale School of Medicine study has purportedly linked BPA to memory loss, learning impairment and depression. Csaba Leranth, et al., "Bisphenol A prevents the synaptogenic response to estradiol in hippocampus and prefrontal cortex of ovariectomized nonhuman primates," *PNAS*, September 3, 2008. Researchers gave monkeys 50 micrograms/kg of BPA per day, an amount analogous to the level that EPA deems safe in humans, as well as estradiol, a hormone that modulates nerve cell connection in the brain. After





looking at nerve cell connections in the brain under an electron microscope, the study authors "found that BPA inhibits creation of the synaptic connections in the hippocampus and prefrontal cortex, areas of the brain involved with regulation of mood and formation of memory," according to a September 3, 2008, press release issued by Yale University. "Our primate model indicates that BPA could negatively affect brain functions in humans," one co-author was quoted as saying. "Based on these new findings, we think the EPA may wish to considering lowering its 'safe daily limit' for human BPA consumption." *See Law360*, September 4, 2008.

European Union

[2] GM Soybeans Approved for Import

The European Commission has reportedly announced that import of a genetically modified (GM) soybean has been approved by the EU's executive. Member state ministers were apparently unable to agree about whether to allow the product, which is used for the protein added to animal feed and will be widely planted across the United States in 2009. GM crop opponents contend that the European Food Safety Authority, which approved the soybean as safe for import in 2007, is biased in favor of the biotechnology industry and bases its investigation on data the industry provides. *See euobserver.com*, September 9, 2008.

United Kingdom (UK)

[3] FSA Publishes Acrylamide Survey

The UK Food Standards Agency (FSA) this week published the first <u>results</u> of a three-year rolling survey that tracks acrylamide levels in food products. In addition to acrylamide, the study looked at 3-MCPD (3-monochloropropanediol), furan and ethylcarbarnate in food products purchased at local retailers. After analyzing 178 food product samples for acrylamide, FSA stated that the "results were all within previously reported ranges with the highest mean concentration of acrylamide found in the prefabricated potato snacks at $1143~\mu g/kg$." The agency noted that "jarred/processed cereal-based baby foods, and bread, contained very low levels of acrylamide in comparison."

In addition, the survey found that all four chemical byproducts occurred in amounts supported by previous research. Based on these results, the agency did not recommend any dietary changes and concluded that "the occurrence and levels found do not increase concern about the risk to people's health." *See FSA Press Release*, September 10, 2008.

State and Local Governments

[4] Los Angeles City Council Drafts Law to Require Calorie Counts on Menus

The Los Angeles City Council has reportedly voted to draft an ordinance that would require chain restaurants to post calorie counts on menus, a measure similar to those before the Los Angeles County Board of Supervisors and the state Legislature. The council could implement the measure next month in an effort to reduce the city's adult obesity rate, which has reportedly increased 46 percent over eight years. The California Restaurant Association, however, has challenged the policy's effect on public health. "If we're going to fight obesity we need to teach folks about nutrition and proper eating," a CRA spokesperson was quoted as saying. "I question whether this ordi-





nance will have a real meaningful impact on people's behavior in terms of what they eat and how much they exercise." *See Associated Press*, September 10, 2008; *Reuters*, August 8, 2008.

Litigation

[5] Ban on GM Alfalfa Continues While USDA Completes Environmental Assessment

The Ninth Circuit Court of Appeals has affirmed a district court injunction stopping the sale and planting of genetically modified (GM) alfalfa pending the government's completion of an environmental impact statement under the National Environmental Policy Act (NEPA). Geertson Seed Farms v. Johanns, No. 07-16458 (9th Cir., decided September 2, 2009). The suit involved a challenge to the U.S. Department of Agriculture's (USDA) decision to deregulate Monsanto Co.'s Roundup Ready® alfalfa, a GM seed created to tolerate the active ingredient in the company's Roundup® herbicide. The agency did so on the basis of an environmental assessment that led the government to conclude that the GM alfalfa would not have a significant impact on organic farming.

Organic and conventional alfalfa growers, concerned about inadvertent gene transmission in the field, contended that some markets would not accept products that "cannot be guaranteed to be non-genetically engineered" and urged a full environmental evaluation under NEPA. The district court entered a permanent injunction in May 2007, agreeing that the USDA's Animal Plant Health and Inspection Service (APHIS) violated NEPA by deregulating Roundup Ready® alfalfa without first preparing an environmental impact statement. "The court ruled that APHIS had failed to take the

required 'hard look' at whether and to what extent the unconditional deregulation of Roundup Ready alfalfa would lead to genetic contamination of nongenetically engineered alfalfa."

Finding no error in the district court's exercise of discretion, the court affirmed the injunction by a 2-1 majority. The dissenting judge would have ruled that the district court failed to conduct a required evidentiary hearing before issuing a permanent injunction.

[6] Delaware Resident Refiles Claims Against Applebee's in Kansas; Seeks Treble Damages Under RICO and Certification of Nationwide Class

A Delaware resident who filed then withdrew false advertising claims in California against the company that owns the Applebee's Neighborhood Grill & Bar franchise has filed a new putative class action in a Kansas federal court. Valiente v. DineEquity, Inc., No. 08-2416 (U.S. Dist. Ct., D. Kan., filed September 9, 2008). Also named as defendants in this federal RICO action are Applebee's International, Inc. and Weight Watchers International, Inc. According to the complaint, the restaurateur defendants misrepresent the amount of fat and calories in the dishes on their "healthy" Weight Watchers® menus, and Weight Watchers, which markets the menus on its Web site, also participated in the fraudulent activity. The plaintiff claims, "Defendants formed an enterprise, with which they were and are associated, and conducted the affairs of that enterprise through a pattern of racketeering activity, in violation of the Racketeer Influenced and Corrupt Organizations Act."

The complaint recites how laboratory tests found higher fat and calorie content for specific menu





items than advertised and claims that plaintiff relied on the alleged misrepresentations to his detriment, that is, "the price paid for the falsely and fraudulently advertised meals." The complaint, which also alleges violations of the Kansas Consumer Protection Act, civil conspiracy and unjust enrichment, seeks to certify a class of "all persons who ordered from and purchased a meal from the Weight Watchers® Menu at Applebee's between September 5, 2004 and September 5, 2008." The plaintiff requests injunctive relief, treble damages, costs, and attorney's fees. Details about similar litigation filed in other jurisdictions appear in issues 262, 263 and 266 of this Update.

[7] Meatpacking Plant Owners Face Child Labor Charges

A kosher meatpacking plant in Iowa that was raided by immigration officials has been charged with more than 9,000 misdemeanor counts relating to violations of child labor laws. *Iowa v. Agriprocessors, Inc.*, No. 3MCR009340-9345 (Iowa Dist. Ct., Allamakee County, filed September 9, 2008). According to the complaint, 32 employees under age 18 worked at the meatpacking facility in Postville, Iowa, on multiple dates in 2007 and 2008. Among them were seven who were allegedly under age 16. Named as defendants are the company, its principal owner and president, a corporate officer and manager, and three human resources personnel.

The prosecutor contends, "All of the named individual Defendants possessed shared knowledge that Agriprocessors employed undocumented aliens. It was likewise shared knowledge among the Defendants that many of those workers were minors. The company's hiring practices encouraged

job applicants to submit identification documents which were forgeries, and known to contain false information as to resident alien status, age and identity." Each charge carries penalties of up to 30 days in jail and a \$625 fine.

According to the complaint, which was filed by the Iowa attorney general, the minors were exposed to dangerous or poisonous chemicals and assigned to operate and monitor power-driven machinery in violation of state law. The complaint also alleges that some of the minors worked more than eight hours a day and more than 40 hours in some weeks. The company has reportedly denied the allegations. A spokesperson was quoted as saying that the company, "looks forward to trial so that it may put to rest the insidious notion that it knowingly employed underage workers. All the minors lied about their age in order to gain employment at the company. In order to convict, the State is going to have to prove that the defendants willfully violated the child labor laws. The State will not be able to carry this burden of proof." The Orthodox Union, which certifies the company's products as kosher, reportedly indicated that it would revoke its certification unless the company hires new management. See USA Today and Iowa Attorney General Press Release, September 9, 2008; meatingplace.com, September 10, 2008

[8] Dannon Responds to Consumer Fraud Claims in Probiotic Yogurt Litigation

Yogurt-maker Dannon Co. has reportedly filed its answer to a consumer fraud complaint filed by a California woman who alleges that company probiotic yogurt promotions with health-benefit claims are false and misleading. *Wiener v. Dannon Co.*, No. 08-415 (U.S. Dist. Ct., C.D. Cal., answer filed Aug. 6,





2008). The putative class-action suit alleges that the company has no scientific evidence to support its claims that Activia® and DanActive® have beneficial effects on the digestive and immune systems. Dannon apparently denies that its claims are false and misleading and contends that the plaintiff cannot show any injury or money loss. *See FindLaw*, September 4, 2008.

[9] Second Lawsuit Claims Popcorn Consumption Led to Lung Disease

A Seattle businessman who allegedly ate four to six bags of microwave popcorn each day has apparently filed a lawsuit against ConAgra Foods claiming his lung disease was caused by exposure to the popcorn's butter flavoring. The second such lawsuit filed in the United States, the complaint also names the retailer who sold the product and a number of national and international companies that make the diacetyl flavoring linked to the disease. According to the plaintiff, "I was a healthy, active guy who could play golf for hours on end and haul building supplies all over the place and never get tired. Now, I can't walk up a flight of stairs without stopping halfway." His doctors were apparently stumped about what caused his condition, and then he read about popcorn plant workers who developed breathing problems. According to a news source, Allen Parmet, a nationally known occupational medicine authority, diagnosed the plaintiff with bronchiolitis obliterans on August 8, 2008. The Independence, Missouri-based lawyer handling numerous occupational exposure cases involving "popcorn lung" is reportedly representing the plaintiff. The lawsuit was filed in federal court in Spokane, Washington. See Seattle Post-Intelligencer, September 4, 2008.

[10] "Healthy Choice" Pasta Product Labeling and Promotions Challenged Due to HFCS

A California resident has filed suit against ConAgra Foods, Inc., alleging that it falsely advertises and labels its Healthy Choice® pasta sauce products as "100% Natural," "Natural" or "All Natural" despite using high-fructose corn syrup (HFCS) to make them. Lockwood v. ConAgra Foods, Inc., No. 08-4151 (U.S. Dist. Ct., N.D. Cal., filed September 2, 2008). Claiming that "[t]he complicated process used to create HFCS does not occur in nature" and that "it is misleading to consumers to label products that contain HFCS as 'Natural,'" the plaintiff seeks to certify a class of "All persons in California who purchased any of Defendant's pasta sauce products containing High Fructose Corn Syrup, yet marketed, advertised or labeled as being 'All Natural', 'Natural' or '100% Natural' during the 'Class Period.'"

According to the plaintiff, a number of common questions predominate over individual issues, including whether defendant misrepresented its ingredients, mislabeled its products or engaged in unfair and deceptive conduct, among other matters. The complaint alleges misleading and deceptive advertising; untrue advertising; unlawful, unfair and fraudulent business acts and practices; and violations of the state's Consumer Legal Remedies Act. The plaintiff seeks injunctive relief, corrective advertising, restitution, disgorgement, punitive damages, attorney's fees, and costs. The injuries alleged include "millions of dollars in losses," because the defendant's marketing "caused Plaintiff and other members of the putative Class to purchase, purchase more of, or pay more for, these 'All Natural' products."





[11] Almond Industry Challenges USDA's Raw Product Treatment Protocol

According to the Cornucopia Institute, a natural and organic foods advocacy organization, a group of 15 U.S. almond growers and wholesale nut handlers has filed a federal court challenge to the U.S. Department of Agriculture's (USDA's) rule that raw almonds be fumigated with propylene oxide or steam-heated before they can be sold. *Koretoff v.* USDA, No. N/A (U.S. Dist. Ct., D.D.C., filed September 9, 2008). Apparently, foreign-grown almonds are exempt from the rule, which has purportedly "devastated" domestic framers, particularly in California. The institute contends that propylene oxide is recognized as a carcinogen by the Environmental Protection Agency and that consumers are "outraged" about the lack of any requirement to label raw almonds as treated with the fumigant.

The USDA initiated the treatment rule in 2007, calling it a necessary food safety requirement. Raw almonds have twice caused *salmonella* outbreaks in the last decade, but government investigators were allegedly unable to determine how they became contaminated. The attorney representing the almond growers claims that the USDA did not allow them to fully participate in the regulation's development. *See Cornucopia Institute Press Release*, September 10, 2008.

[12] CSPI Sues Maker of Alcohol Energy Beverage

The Center for Safety in the Public Interest (CSPI) has filed a lawsuit in Washington, D.C., against the MillerCoors Brewing Co., seeking a court order to halt the sale of Sparks®, a caffeinated alcoholic beverage. *CSPI v. MillerCoors LLC*, No. N/A (D.C. Super. Ct., filed September 8, 2008). According

to CSPI Litigation Director Steve Gardner, "MillerCoors is trying to hook teens and 'tweens on a dangerous drink. This company's behavior is reckless, predatory, and in the final analysis, likely to disgust a judge or a jury." The beverage is apparently higher in alcohol by volume than regular beer and contains caffeine and other additives and flavorings that make it taste like candy or soda. CSPI contends that the beverage's Web site is appealing to juveniles and proposes consuming it for breakfast with an omelet. CSPI's director of alcohol policies project was quoted as saying, "Sparks is a drink designed to mask feelings of drunkenness and to encourage people to keep drinking past the point at which they otherwise would have stopped. The end result is more drunk driving, more injuries, and more sexual assaults."

The company reportedly declined to comment on the litigation, but stated, "[I]t is important to note that the Federal Alcohol and Tobacco Tax and Trade Bureau has approved all product formulations and labels for Sparks, Sparks Light, Sparks Plus and Sparks Red. We have and we will continue to ensure that the labeling, marketing and product formulations of all our brands meet all applicable federal regulations and that our brands are marketed responsibly to legal drinking age adults." CSPI's lawsuit alleges that it is illegal to use caffeine, guarana, ginseng, and taurine in alcoholic beverages, because the Food and Drug Administration has given only limited approval for the use of caffeine and guarana in food products—with none allowed in alcoholic beverages—and no approval for ginseng in any food or beverage. Taurine is allegedly allowed only in chicken feed. See CSPI Press Release and Advertising Age, September 8, 2008.





Legal Literature

[13] David Plunkett & Caroline Smith DeWaal, "Who Is Responsible for the Safety of Food in a Global Market? Government Certification v. Importer Accountability as Models for Assuring the Safety of Internationally Traded Foods," Food and Drug Law Journal, Vol. 63 (2008)

Co-authored by representatives from the Center for Science in the Public Interest, this article suggests that the best way to ensure food safety in international markets its to establish systems that rely on government certification before export and use government-accredited certifying agents to conduct the required inspections. The authors explore weaknesses in existing inspection programs that have allowed tainted foods to enter the U.S. market and describe various food-safety systems currently in use around the world. According to the article, the U.S. approach "is weaker than the European approach of applying a HACCP [Hazard Analysis and Critical Control Points] standard uniformly, and enforcing it through importers." Yet, the authors contend that the EU system has given rise to private certification schemes that may be too costly. They endorse the approach of the Food and Drug Administration Globalization Act, released in draft by a House committee in March 2008, for its incentives and accreditation programs for thirdparty certifying agents.

Other Developments

[14] Companies Pledge Not to Use Ingredients From Cloned Animals

Twenty food companies have pledged to reject ingredients derived from cloned livestock, according

to a recent Center for Food Safety (CFS) and Friends of the Earth joint press release. The agreement includes major food and beverage manufacturers such as Kraft Foods Inc., Smithfield Food Inc. and Tyson Foods Inc., the latter of which also agreed not to use meat and milk from cloned animals' offspring despite the lack of a tracking system for these animals. Although none have announced plans to market their products as "clone-free," several signatories pointed to negative consumer response as the reason underlying their decision to forgo ingredients from cloned animals. "This rejection of food from clones sends a strong message to biotech firms that their products may not find a market," said CFS Campaigns Coordinator Lisa Bunin. "American consumers don't want to eat food from clones or their offspring, and these companies have realistically anticipated low market acceptance for this new and untested technology." See CFS Press Release, September 3, 2008; The Wall Street Journal, September 4, 2008.

Meanwhile, The Wall Street Journal has reported that animal clones' offspring have already entered the food supply. The Food and Drug Administration earlier this year declared products from cloned cattle, pigs and goats safe for human consumption, but regulators have declined to implement a tracking system to monitor clones and their offspring. At least one rancher quoted by the Journal estimated that "hundred, many thousands, of offspring of [beef cattle] clones" already exist in the United States, further noting that his own ranch has sold approximately 30 clones' offspring for slaughter for food. The FDA decision has drawn fire from consumer advocates and animal welfare activists who cite health and environmental concerns, as well as evidence that clones and their offspring suffer from more birth defects and





diseases than conventionally-bred animals. "As a mom of two young children, it makes me very uneasy, very nervous that these things are in the food supply," said one consumer. "It just doesn't feel right." *See The Wall Street Journal*, September 2, 2008.

In a related development, 662 members of the European Parliament (MEPs) have reportedly issued a resolution calling for their governing body to ban animal cloning for food. In addition to barring meat and milk from clones and their offspring, MEPs demanded "an embargo on importing cloned livestock, their offspring, semen or embryos," according to the *Belfast Telegraph*. The MEPs apparently argued that cloned livestock would not only threaten the safety and integrity of the food supply, but would damage Europe's reputation for high-quality farming. *See The Belfast Telegraph*, September 3, 2008.

[15] Web Retailer Amazon Announces Foray into Wine Sales

Amazon.com Inc. has reportedly announced plans to begin selling domestic wines through its retail Web site as early as October 2008. Amazon will partner with Napa-based New Vine Logistics Inc. to ship wine to 26 states, although varying distribution laws will complicate the new business venture. According to a September 11, 2008, article in *The Wall Street Journal*, a 2005 Supreme Court decision "struck down bans on out-of-state wine shipment in New York and Michigan," thus opening the doors for wineries to sell directly to consumers. Amazon's decision also highlighted the Web site's 41 percent increase in second-quarter sales despite a struggling retail market. "The world's largest retailer is saying that wine is important – that's very exciting for

American consumers," a spokesperson for Napa Valley Vitners was quoted as saying.

Scientific/ Technical Items

[16] Study Claims That Exercise Thwarts Effects of "Fat Gene"

A recent study claims that three to four hours of daily moderate activity could overcome the effects of a "fat gene" variant believed to affect 30 percent of people with European ancestry. Evadnie Rampersaud, et al., "Physical Activity and the Association of Common FTO Gene Variants With Body Mass Index and Obesity," Archives of Internal Medicine, September 8, 2008. Researchers took blood samples from 704 Amish people in Lancaster County, Pennsylvania, finding that those with the gene variant linked to obesity were no more likely to be overweight than their peers. The study authors attributed these results to the physical activity level of the Amish community, which adheres to a 19th century rural lifestyle free of modern conveniences like cars, appliances or TV. "These findings emphasize the important role of physical activity in public health efforts to combat obesity, particularly in genetically susceptible people," the authors stated. See Associated Press, September 8, 2008.



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