Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

U.S. Department of Agriculture (USDA)

[1] USDA Issues Proposed Standard for Naturally Raised Marketing Claim

USDA's Agricultural Marketing Service (AMS) is seeking comments on a proposed voluntary standard for naturally raised marketing claims. The proposed claim would apply "to livestock used for meat and meat products that were raised entirely without growth promotants, antibiotics, and mammalian or avian by-products." AMS also notes that the "naturally raised" claim, if adopted, would remain independent from the "natural" statement used by the Food Safety and Inspection Service. AMS has recommended the uniform standard for those wishing to capitalize on consumer demand for meat derived from naturally raised livestock. The agency would verify the claim through an auditing process that would require producers to maintain a documented quality management system. The agency will accept comments on the proposal on or before January 28, 2008.

Food and Drug Administration (FDA)

[2] Lack of Funding Hinders National Food and Drug Safety, Says FDA Report

An FDA subcommittee has reportedly concluded that the agency lacks the funding to adequately protect the nation's food and drug supply. The Subcommittee on Science and Technology, which this week released its year-long review of the agency's shortfalls, has found that regulators can no longer keep up with scientific advances and emerging technology. "Crisis management in FDA's two food safety centers . . . has drawn attention and resources away from FDA's ability to develop the science base and infrastructure needed to efficiently support innovation in the food industry, provide effective routine surveillance, and conduct emergency outbreak investigation activities to protect food," states the report. The subcommittee suggests the formation of a new department, the Incubator for Innovation in Regulatory and Information Science (IIRIS), to coordinate groups involved with new science programs. In addition, the report urges Congress to approve the $1.75 billion, as well as the $444 million in user fees, that the agency requested for 2008. The funding would help FDA acquire better-trained scientists, improved computer technology and an updated infrastructure to meet the increasing challenges of the global food supply, according to the subcommittee. "The imbalance is imposing a significant risk to the integrity of the food, drug, cosmetic, and device regulatory system,

and hence the safety of the public," the report authors were quoted as saying. *See Food Navigator-USA.com*, December 3, 2007.

Meanwhile, several members of Congress have apparently criticized the White House for threatening to veto the FDA funding bill. "The FDA does not have the capacity to assure the safety of food for the nation," said U.S. Senator Ted Kennedy (D-Mass.) in reference to the subcommittee report. Kennedy argued that the agency's outdated policies, technology and scientific knowledge have hindered efforts to secure the safety of food and product imports. Other experts have also stressed the need for FDA to shift its emphasis from reaction to prevention. "While a substantial increase in resources will enhance the scientific capabilities and capacity of the FDA, funding alone will not address the inherent tension between America's insatiable demand for immediate access for innovative products and an unwillingness to tolerate products that are anything but perfectly safe," opined Dr. A. Mark Fendrick, a professor of health management and policy at the University of Michigan. *See The Washington Post*, December 1, 2007; *CQ HealthBeat News*, December 4, 2007.

In a related development, several members of Congress have also questioned the recently unveiled "FDA Food Protection Plan" for failing to provide a uniform set of standards for meat, poultry and egg imports and other foods. Senator Tom Harkin (D-Iowa) posited that, due to conflicting FDA and Department of Agriculture regulations, "[m]aybe it is time to think about a single food inspection agency." Speaking before a recent Senate panel, critics also claimed that some provisions aimed at improving safety would in fact make it more difficult for regulators to act. Kennedy, referring to a proposal that would allow FDA to police high-risk foods, said this provision amounted to "a requirement that people be injured or even killed before the FDA can act." The Center for the Science in the Public Interest again called on FDA to request, in addition to mandatory recall authority, the ability to require traceability standards and impose civil penalties for ineffective recalls. Health and Human Services Secretary Mike Leavitt, however, disagreed that increased inspections and recalls would improve the current system. "We will never inspect our way to safety," he said. "We need to build quality in every step of the way." *See CQ HealthBeat News*, December 4, 2007; *The Wall Street Journal*, December 5, 2007.

[3] FDA Considers Regulating Sodium Content in Foods

FDA last week held a hearing to discuss whether to revoke the "generally recognized as safe" (GRAS) status of sodium. The meeting responded in part to a 2005 petition submitted by the Center for Science in the Public Interest, which recently convened a joint conference with the Grocery Manufacturers Association to encourage food companies, restaurants, health professionals, and government agencies to help Americans limit sodium in their diets. In addition, the American Medical Association (AMA) has urged the agency to restrict the sodium content of processed and prepared foods. "Reducing the salt in our diets by 50 percent over the next 10 years could save at least 150,000 lives each year," stated Dr. Stephan Havas, the AMA vice president for science, quality and public health, in written testimony. Other experts, however, have questioned whether the agency should focus its regulatory efforts on a single nutrient. "It's important to encourage the FDA to move forward on these changes, but it's just one part of the whole

picture," Tufts University Professor Alice Lichtenstein said in response to the hearing. The Salt Institute has also called on FDA to review alleged evidence that salt is directly linked to heart attack deaths and mortality. *See The New York Times*, November 19, 2007; *CSPI Press Release* and *Food & Drink-Europe.com*, November 27, 2007; *The Washington Post*, November 30, 2007; *The Wall Street Journal*, December 3, 2007.

In related news, a recent U.K. study has reportedly estimated that reducing salt intake by 15 percent could prevent nearly 9 million deaths across the globe between 2006 and 2015. P. Asaria, et al., "Chronic disease prevention: health effects and financial costs of strategies to reduce salt intake and control tobacco use," *The Lancet Chronic Diseases Series*, December 5, 2007. The study examined figures from low- and middle-income countries, which carry 80 percent of the world's chronic disease burden, in tabulating the effects of sodium on cerebrovascular and hypertensive disease mortality. The authors concluded that simple dietary changes could account for a 30 percent reduction in salt intake, but instead focused their analysis on a 15 percent reduction achieved through health policy changes. "The main costs of the strategy to reduce salt consumption would be awareness campaigns through mass-media outlets and regulation of food products by public health officers, with a total cost ranging from 4 cents to 32 cents per person for the countries analyzed," the authors said. *See Food Navigator-USA.com*, December 5, 2007.

[4] FDA Extends Comment Period on Nutrition Information Symbols

FDA has **extended** until January 15, 2008, the comment period for a **notice of public hearing** that addressed the use of symbols to communicate nutritional information. The July 20, 2007, notice announced a September 10-11 public meeting to discuss the many nutrition symbol programs now available in the domestic and international marketplace. The agency specifically requested that attendees consider how symbols could help consumers make food choices and whether symbols could introduce confusion into the decision-making process. FDA also sought comments on the economic impact of nutritional symbol programs on both industry and consumers. Respondents initially had until November 15 to submit comments, but FDA has extended this period by 60 days to encourage "meaningful or thoughtful" reactions.

Meanwhile, *New York Times* writer Andrew Martin discussed the advantages and disadvantages of nutrition symbols in a December 1, 2007, article, titled "Is It Healthy? Food Rating Systems Battle It Out." Martin notes that various groups, from supermarkets to health experts, have developed food rating systems that aim to simplify "the nutritional labels required by the government and the plethora of logos and slogans meant to signify good nutrition." Using numerical scales, star ratings or letter grades, these systems are designed to "reflect the aggregate nutritional value of the food," but some critics have reportedly cautioned that most ratings are proprietary and therefore cannot be adequately evaluated. As a result, some manufacturers and grocers have expressed a desire to develop a uniform rating system based on a European model that has so far met with mixed results. The Center for Science in the Public Interest has also urged FDA to consider implementing nationwide standards for nutrition symbols. "With Hannaford giving a food no stars but it has the American Heart Association logo on it, what is a consumer supposed to make of that?," a CSPI spokesperson was quoted as saying. "I think we are going to have competing systems until the federal government steps in."

Department of Health and Human Services (HHS)

[5] U.S. and Chinese Officials to Sign Import Safety Pacts

Health and Human Services Secretary Mike Leavitt has reportedly confirmed that the United States expects to sign two agreements with China to ensure that Chinese exports of food, animal feed, drugs, and medical devices meet U.S. standards. Leavitt stated in remarks before the U.S. Chamber of Commerce that the pacts would make the countries' different regulatory systems more compatible, despite several recent recalls that have jeopardized the reputation of Chinese products in the American marketplace. China's food inspection system "is substantially more mature than their regulatory system for drug and devices," according to Leavitt, who added that Chinese officials have traditionally set stringent rules for products sold domestically but have failed to uphold those standards for exported goods. "Any country who desires to produce goods for American consumers needs to produce them in accordance with American standards – American standards of quality, American standards of safety," he concluded. *See Reuters*, December 3, 2007.

National Toxicology Program (NTP)

[6] Comments Sought on Final Bisphenol A Expert Panel Report

NTP's Center for the Evaluation of Risks to Human Reproduction has released its final expert panel **report** on the reproductive and developmental toxicity of bisphenol A, a chemical with endocrine-disrupting properties used in plastic food and drink packaging, food cans and dental sealants. Written **comments** must be submitted by January 25, 2008.

The panel, chaired by a scientist from Pfizer, Inc., concluded that it had some concern about neural and behavioral effects of exposure for infants and children and minimal concern about accelerated puberty effects. The panel's concerns were "negligible" for birth defects and malformations and for "adverse reproductive effects following exposures in the general population to Bisphenol A. For highly exposed subgroups, such as occupationally exposed populations, the level of concern is elevated to minimal." *See Federal Register,* November 30, 2007.

United Nations (U.N.)

[7] Food and Beverage Companies Press for Climate Change Agreement

A coalition of companies from various industry sectors are apparently calling on U.N. environment ministers to enter a binding agreement to address climate change by imposing carbon dioxide emissions targets. The call reportedly coincided with the United Nations Climate Change Conference that got underway in Bali, Indonesia, on December 3, 2007. Companies supporting the Corporate Leaders Groups on Climate Change initiative include Nestle, Kingfisher, Unilever, Cadbury Schweppes, and Diaego, in addition to British supermarket chains and packaging suppliers. The coalition's communiqué states, "As business leaders, it is our belief that the benefits of strong, early action on climate change outweigh the costs of not acting." *See FoodUSAProductiondaily.com*, December 3, 2007.

Litigation

[8] *Pelman v. McDonald's Corp.*, No. 02 Civ. 7821 (S.D.N.Y., filed September 30, 2002)

U.S. District Court Judge Robert Sweet has issued an order scheduling argument on the motions filed by both parties relating to class certification and to compel discovery. They will be heard January 16, 2008. Discovery has been ongoing since the court issued a scheduling order in March 2007 that included an April 16, 2008, trial date. The claims, which have been amended and appealed twice, allege on behalf of teenage plaintiffs that the company's misleading and deceptive marketing caused their obesity and obesity-related health problems. The named plaintiffs purport to represent a class of consumers under the New York Consumer Protection Act. Additional details about the most recent developments in the case appear in issues 155, 186 and 205 of this Update.

[9] Indiana Couple File Organic Milk Class Action Against Target

An Indiana couple, who allegedly purchased milk labeled as organic and sold by Target Corp., have filed a putative class action lawsuit against the company in a federal district court in Minnesota, claiming that the milk, supplied by Aurora Organic Dairy, is not organic. *Hudspeth v. Target Corp.*, No. n/a (U.S. Dist. Ct., D. Minn., filed December 4, 2006). The complaint outlines the U.S. Department of Agriculture's (USDA's) investigation into Aurora's herd management and practices and the consent decree the company entered with the USDA in August 2007 after the agency found it had not complied with federal organic food regulations. Plaintiffs seek the certification of a nationwide class of consumers who purchased the milk from Target and also identify an alternative statewide class of all Minnesota consumers who purchased Archer Farms® organic milk from Target. The complaint alleges unfair competition or unfair or deceptive acts or practices under the laws of the 50 states and the District of Columbia, common law unjust enrichment and breach of express warranty. Plaintiffs seek unspecified compensatory and punitive damages in addition to statutory damages, attorney's fees and costs.

[10] Salmon-Labeling Argument Scheduled in California Supreme Court

The California Supreme Court was reportedly scheduled to consider arguments the week of December 4, 2007, in a case raising consumer claims against food retailers for their failure to label the salmon they sell as wild or farmed. Federal and state regulators are apparently lax about enforcing rules requiring sellers to clearly label salmon containing dye, and the plaintiffs argue they should be able to sue to ensure better labeling in the absence of effective regulation. According to a news source, the original complaint, filed in 2004 by 11 named plaintiffs, alleged that consumers bought unlabeled salmon and had the right to know exactly what they were buying. Their putative class claims, which apparently have the support of California's attorney general and local prosecutors, have been rejected by the state's lower courts. *See The Los Angeles Times*, November 29, 2007.

[11] European Commission Accuses Poland of Violating GMO Regulations

The European Commission (EC) has reportedly instituted legal action against Poland for refusing to bring its laws on genetically modified products

(GMOs) into conformity with EC regulations. The Polish government apparently has 20 days to respond; if it continues to prohibit GMOs, it faces fines of as much as $381,407 a day. Should the EU court rule in the EC's favor, Poland would also apparently be exposed to lawsuits filed by GMO trading firms. According to a spokesperson for Poland's Environment Ministry, "There is no final opinion from the new minister yet. As a general rule, we do not want to admit genetically modified crops in Poland, as they threaten biodiversity." The EU's Court of First Instance has already ruled against Austria for its anti-GMO stance and warned Italy of adverse legal consequence for passing a law banning GMO crops until legislation to address the segregation of GMO, organic and conventional crops is in place. *See AHN*, December 4, 2007.

Legal Literature

[12] Comment, "What's in That Guacamole? How *Bates* and the Power of Preemption Will Affect Litigation Against the Food Industry," *George Mason Law Review*, Fall 2007

This student-authored comment argues that state food-labeling lawsuits should not be preempted by federal law and would be socially beneficial "because manufacturers with truly misleading labels will be discouraged from continuing their deceptive practices, while manufacturers who provide sufficient product information for consumers to make informed food choices will escape liability and, in these cases, consumers will maintain responsibility for their health." The article includes an analysis of federal and state laws addressing food labeling and discusses cases involving claims about the labels on bottled water, advertisements for french fries and farm-raised salmon, and failures to warn about the risks of milk to the lactose intolerant. Also included is a brief summary of litigation that caused a manufacturer to change its labels for guacamole. The author suggests that proliferating food-labeling litigation is following the same progression as lawsuits against cigarette manufacturers, "[o]nce consumers realized state laws might allow for private causes of action."

[13] Food Journal Profiles U.S. and EU Animal ID and Tracing Systems

The most recent issue of the *Journal of Food Law & Policy* (Fall 2006) contains articles about the animal identification and traceability laws in the United States and European Union. University of Illinois Agricultural Law Professor Margaret Rosso Grossman discusses the issue from the perspective of bovine spongiform encephalopathy (BSE) and argues that cost, liability and privacy issues are outweighed by the need to establish an effective traceability system. She provides an overview of laws in some other countries and details the requirements recently implemented in the United States. Dutch law professors Bernd van der Meulen and Annelies Freriks characterize the EU's system as a "beastly bureaucracy" because of its paperwork requirements, but note that its goals include speedy identification of the source of a food safety problem and "well aimed recalls to take affected products from the market."

Media Coverage

[14] Milwaukee Newspaper Produces "Watchdog Report" on Bisphenol A

The Milwaukee *Journal Sentinel* ran a two-part series, November 24 and December 2, 2007, discussing chemicals that are ubiquitous in the envi-

ronment and, as endocrine disruptors, can disrupt biological development. The second in the series focused on bisphenol A, produced at a rate of 6 billion tons a year in the United States and detected in the urine of 93 percent of Americans tested. As part of the investigation, the paper reviewed 258 scientific studies which purportedly show overwhelmingly that "the chemical is harmful – causing breast cancer, testicular cancer, diabetes, hyperactivity, obesity, low sperm counts, miscarriage and a host of other reproductive failures in laboratory animals."

The article is highly critical of the work done by a National Toxicology Program (NTP) panel that "found adults have almost nothing to worry about" from exposure to the chemical. Additional information about the panel's report can be found elsewhere in this Update. According to the article, "panel members gave more weight to industry-funded studies and more leeway to industry-funded researchers," rejecting academic studies that found harm and missing dozens of publicly available studies.

The reporters note that the NTP asked two groups to review the risks of bisphenol A; the group of academics, who were experts on the chemical, reportedly found strong cause for concern, while the scientists without detailed knowledge about bisphenol A were less alarmed about its effects. The head of the latter panel dismissed criticisms leveled against it claiming "the panel bent over backwards to apply standards of good scientific conduct. My accusers have a great deal more bias than I do." A toxicologist with Pfizer, Inc., he reportedly claimed that many studies have been done poorly, explaining why the panel did not accept any studies finding an effect at low doses of exposure. *The Journal Sentinel* concluded that consumers should try to minimize their exposures.

In a related development, the Environmental Working Group (EWG), an advocacy and research organization, has released its **findings** about the presence of bisphenol A in infant formula. The chemical is used in the linings of metal cans holding liquid formula and in powered formula containers. According to EWG, powdered formulas are a better choice because "babies fed reconstituted powered formula likely receive 8 to 20 times less [bisphenol A] than those fed liquid formula from a metal can." EWG also recommends that parents not use plastic bottles or plastic bottle liners when feeding their babies.

[15] Ken Wheaton, "On the Media: Edwards Views Alcohol Ads as Threat; Romney Sees Sea of Perversion," *Advertising Age*, December 5, 2007

This article discusses a Common Sense Media survey of presidential candidates, quizzing them about a number of issues including advertising and obesity. Only four candidates apparently responded: Senator Barack Obama (D-Ill.), Governor Mitt Romney (R-Mass.), former Senator John Edwards (D), and Governor Bill Richardson (D-N.M.). Edwards reportedly supports government action to curtail childhood obesity when voluntary approaches fail and called for "the alcohol industry to quit making millions encouraging teen drinking that destroys thousands of lives each year." Obama apparently prefers to address obesity with information and education. Richardson claims to be fighting childhood obesity in his state by banning junk food in schools and reinstituting mandatory physical education. Romney was quoted as saying, "I want to restore values so children are protected from a societal cesspool of filth, pornography, violence, sex and perversion."

Other Developments

[16] Eleven Pork Plant Workers Contract Rare Neurological Disease

Eleven workers at Quality Pork Processors Inc. in Austin, Minn., have reportedly contracted a rare neurological disease known as chronic inflammatory demyelinating polyneuropathy (CIDP) that typically strikes one in 100,000 people. Occupational health nurses at the plant first reported workers with odd neurological symptoms to local physicians and eventually connected with the Mayo Clinic in Rochester, where CIDP experts diagnosed the disease. CIPD is caused by damage to the myelin sheath of the peripheral nerves, resulting in weakness, tingling, arm and leg numbness, and extreme fatigue. The Minnesota Health Department has not ruled out any chemical, bacterial or viral contamination, but has advised the plant to temporarily stop harvesting swine brains with its new air compressor, which was located near the affected employees. Officials will also continue to monitor conditions at other pork plants and in the surrounding community. All but two of the workers have since returned to the plant after receiving treatment for their symptoms. *See The Star Tribune*, December 4, 2007; *Meatingplace.com*, December 5, 2007.

[17] Consumer Groups Criticize McDonald's Sponsorship of Report Cards

Consumer groups have reportedly criticized McDonald's for placing Happy Meal® coupons on report cards issued by the Seminole County, Fla., school district. Although McDonald's covered the report card printing costs for the 2007-2008 school year, the Campaign for a Commercial-Free Childhood has called the coupons, which reward good grades, attendance and behavior with a free Happy Meal®, "a new low" that "bypasses parents and targets children directly." A school district spokesperson, however, has pointed out that the report cards have relied on corporate sponsorship for more than a decade without drawing more than one complaint. In addition, other companies like Pizza Hut, which backs the popular "Book It" program, have a long history of providing funds for educational initiatives. Nevertheless, consumer advocates have urged schools to end these types of incentives. "It basically shows when you get down to it, how corporations are doing everything they can to keep their brands in front of kids' eyeballs," opined public health attorney and activist Michele Simon, who said the district is "selling kids' health for chump change." *See Advertising Age* and *The Chicago Tribune*, December 5, 2007.

[18] U.K. Ad Campaign Links Meat and Dairy Consumption to Global Climate Change

Claiming that "meat and dairy animals produce more greenhouse gases than all the world's transport combined," the British vegetarian group Viva! has launched a billboard ad campaign featuring model Heather Mills who lost a leg in a motorcycle accident and is married to former Beatle Paul McCartney. In the midst of her tabloid-chronicled divorce, Mills posed for the provocative ads, one of which states, "You haven't got a leg to stand on. So, you're an environmentalist? Not if you eat meat and dairy because livestock are destroying the Earth." *See Reason*, November 27, 2007.

Scientific/Technical Items

[19] Scientific Working Group Explores Weaknesses in Epidemiology; Cites Caffeine and Alcohol Studies

The Academy of Medical Sciences, composed of the UK's "leading medical scientists from hospitals and general practice, academia, industry and the public service," has published a working group report, *Identifying the Environmental Causes of Disease: How Should We Decide What to Believe and When to Take Action?*, intended to produce principles and guidelines for the assessment of causal claims and provide a basis for recommending that a causal inference is sufficiently strong to require action.

The report notes that an "astonishing range of supposed disease causing agents" has been identified in the press, including hair products, coffee, eating red meat, and living near overhead power lines. According to the authors, few such claims are confirmed by additional research. While they agree that "environmental influences are both strong and important in the causal processes leading to most common diseases," they call for stringent criteria for non-experimental research (such as epidemiology), replication of study findings, carefully considered communication of risk to the public, and making funding contingent on accurate communication of results.

The report includes detailed recommendations and guidelines specific to researchers, journal editors, science writers and journalists, policy-makers, clinicians and health care practitioners, and funders. They also discuss the types of research shown to be both reliable and unreliable and explain why the results should or should not give rise to causal inferences. Among the examples of reliable causal claims, according to the report, is fetal alcohol syndrome. Examples of research with "probably misleading causal claims" include caffeine and lower birth weight babies and early use of alcohol and later alcohol abuse or dependency. As to caffeine, the report notes, "the non-experimental findings were inconsistent," "the supposed effects were relatively small," and "women with a high caffeine intake in pregnancy were known to smoke more, have a higher alcohol intake, and have attained a lower level of education."

The authors contend, "By far and away the main explanation of misleading claims that have not stood up to scrutiny is that they were based on small-scale weak, pilot studies that involved inadequate controls and highly specialized samples. Often, too, they were undertaken by researchers with a very limited research track record and sometimes they represented pressure groups seeking to push a particular viewpoint." The report also criticizes the tendency to publish research before peer review, which is characterized as "the most satisfactory first sieve" for establishing reliability.

[20] Researchers Link Distillers' Grain to Increased Prevalence of *E. Coli* in Cattle

Kansas State University researchers have claimed that cattle fed distillers' grain from ethanol production plants have an increased prevalence of *E. coli* 0157 in their digestive systems. This form of *E. coli* can sicken humans who contract it by consuming undercooked meat, raw dairy products and fresh produce contaminated with cattle manure. The study found that "the prevalence of 0157 was twice as high in distillers' grain-fed cattle compared with those cattle that were on a diet lacking the ethanol byproduct." Predicting that the results would have

"profound implications in food safety," the researchers have hypothesized that the grain may change the cattle's digestive process or provide a nutrient for the bacteria. Ethanol plants have reportedly started building next to feedlots because it is economically advantageous to recycle the grain as animal feed. "We realize we can't tell cattle producers, 'Don't feed distiller's grain,'" said lead researcher T. G. Nagaraja, a professor of diagnostic medicine and pathobiology at Kansas State's College of Veterinary Medicine. "What we want to do is not only understand the reasons why 0157 increases, but also find a way to prevent that from happening." *See Kansas State Press Release*, December 4, 2007.

Meanwhile, plaintiffs' lawyer Bill Marler has also noted this study on his blog, which recently discussed the apparent spike in *E. coli* cases. "It's the microbial equivalent of Genghis Khan marching across Asia, except the violence is silent and insidious," says Marler of this year's recalls involving 30 million pounds of contaminated meat. In addition to the Kansas State research, Marler addresses a range of theories that attempt to explain the increase in reported *E. coli* cases, but appears to favor the idea that food producers "have consciously or unconsciously slacked off." He ultimately dismisses the distillers' grain study and other expert opinions suggesting that better reporting, environmental factors and even bacterial changes could be behind the recent outbreaks of disease. *See Marler Blog*, December 4, 2007.

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