# Food & Beverage

## LITIGATION UPDATE

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## Food & Beverage

LITIGATION UPDATE

## Legislation, Regulations and Standards

## Food and Drug Administration (FDA)

#### [1] FDA Announces Public Hearing to Address Salt and Sodium in Food

FDA this week **announced** a public hearing, slated for November 29, 2007, to address agency policy regarding salt and sodium in food and to solicit comments on a 2005 citizen petition, submitted by the Center for Science in the Public Interest, that requests changes to the regulatory status of salt. CSPI has reportedly argued that FDA should revoke salt's "generally recognized as safe" (GRAS) status, require limits on salt in processed foods and establish health messages related to salt and sodium. FDA has also recognized that other public health advocates have echoed the CSPI recommendations, referring in its Federal Register notice to a 2006 American Medical Association (AMA) report that advocated a similar approach to restricting salt in foods. "Excessive sodium has been cited by the scientific community as a contributory factor in the development of hypertension and cardiovascular disease," stated the agency, adding that it is "very much interested in hearing the views of other interested parties, including the AMA." See FoodNavigator-USA.com, October 24, 2007.

In addition, CSPI and the Grocery Manufacturers Association (GMA) recently held a conference, "Getting to 2,300: Balancing Health with Consumer Preferences and Industry Challenges," that discussed strategies for reducing consumer salt intake to the recommended 2,300 milligrams of sodium per day. Food industry leaders, health professionals and government officials, including FDA representatives, gathered in Washington, D.C., to discuss industryrelated experience in cutting sodium levels, consumers' taste expectations, salt substitutes, and research and educational needs. "I am proud of the efforts of the food manufacturers to reformulate their products and reduce the amount of salt," said GMA President and CEO Cal Dooley. "The industry has made great progress and we are committed to continuing our efforts to provide consumers with great tasting and lower sodium products that can help them reach their dietary goals and live healthy lives." See CSPI/GMA Press Release, October 23, 2007.

Meanwhile, a British lobbying group has claimed that one meal from Pizza Hut contained four to six times the daily salt limit of 3 grams recommended for a 6-year-old. Consensus Action on Salt and Health (CASH) analyzed "hundreds of food items" from popular fast-food restaurants, including KFC, McDonald's and Burger King, with a Pizza Hut meal deal shared by four people topping the charts at an alleged 12.3 grams of salt per person. CASH has reportedly urged all restaurants to make salt content and other nutritional information available at the





point of sale, although many companies have already significantly reduced the salt in their products in response to consumer demand. "How can these companies justify selling food that contains more than the maximum daily limit for adults and children in a single meal," opined a CASH spokesperson. *See BBC News*, October 18, 2007.

### 110th Congress

#### [2] Connecticut Lawmaker Introduces Food Import Legislation

U.S. Representative Rosa DeLauro (D-Conn.) this week introduced a bill (H.R. 3937) that would amend the Federal Food, Drug and Cosmetic Act to improve the safety of imported food. The bill aims to strengthen the Food and Drug Administration (FDA) "to reflect the needs of an increasingly global food supply and ensure the agency has the authorities and tools necessary to verify the safety of imported food products," according to a press release issued by DeLauro. In addition, the Food Import Safety Act includes provisions that would (i) require foreign facilities to meet standards equivalent to those in the United States; (ii) give the Health and Human Services secretary "the authority to deny food imports from countries that demonstrate a pattern of violations;" (iii) "authorize FDA to inspect overseas plants and make access to foreign plants a condition of entry" into the United States; and (iv) "provide the FDA with mandatory recall authority." "The FDA's response to contaminated products being imported from China was tragically slow, and this bill would address the shortfalls in the FDA's authority that prevents it from ensuring the safety of food imports," DeLauro said. See DeLauro Press Release, October 24, 2007.

## National Toxicology Program (NTP)

#### [3] NTP Announces Scientific Counselors Meeting; to Consider Phthalates

NTP's Board of Scientific Counselors will meet December 6, 2007, to consider, among other matters, review of NTP study nominations and proposed research and testing for diethyl phthalate and to provide comment on a research concept for a phthalates initiative. The board, which includes public and private sector scientists, provides oversight to NTP's director and evaluates the scientific merit of NTP's intramural and collaborative programs. Also on the board's agenda is an update on the process and timelines for the *Report on Carcinogens*. Written statements or comments must be submitted by November 21, and meeting participants must pre-register by November 29. *See Federal Register*, October 17, 2007.

## U.S. Department of Agriculture (USDA)

## [4] USDA Announces "Aggressive Actions to Combat *E. Coli* O157:H7"

USDA's Food Safety and Inspection Service (FSIS) this week **announced** "new, ongoing and upcoming actions to protect public health against the risk of *E. coli* O157:H7, including expanded testing and more rapid recalls." There have already been 15 recalls related to *E. coli* this year compared to eight last year, according to USDA Undersecretary for Food Safety Richard Raymond, who added that the recent Topps Meat Co. recall "emphasized the need for us do even more to strengthen our policies and procedures." FSIS, which reportedly increased *E. coli* testing by 75 percent in July, will also boost by 50 percent routine targeted samplings at slaughter





plants, especially "high-volume" operations, starting in January 2008. In addition to testing more domestic and imported ground beef components, the agency has agreed to (i) test and analyze beef trim, which FSIS has identified as a common contamination source; (ii) require all beef plants, as of November, to verify effective *E. coli* controls; (iii) review both suppliers and processors according to a new checklist that will track significant changes in plants' production controls; (iv) establish routine targeted testing for E. coli O157:H7 at slaughter and grinding facilities; (v) issue more rapid recalls based on a complete range of evidence; and (vi) ensure the safety of imported beef. FSIS has also stressed the importance of improved communication with federal and public health partners, industry stakeholders and small beef processors. See The Washington Post and Meatingplace.com, October 24, 2007.

In a related development, an October 23 New York Times article reportedly documents the "many red flags" that preceded the Topps recall, which involved 21.7 million pounds of ground beef and allegedly caused 40 illnesses. The Topps Meat Co. reportedly "cut its microbial testing on finished ground beef from once a month to three times a year, a level the [USDA] considers inadequate," but federal inspectors failed to cite the company for failing to test raw beef and for mixing tested and untested meat in its grinding machines. Public interest groups have since criticized USDA for adopting a "catch as catch can" approach and for allowing small and mid-sized plants to avoid implementing the most advanced testing available. "They just lay it out and make recommendations" that are "summarily ignored," U.S. Representative Rosa DeLauro was quoted as saying.

Meanwhile, plaintiffs' lawyer William Marler recently authored a piece titled "Food Safety & the CEO: Keys to Bottom Line Success" in the October/November 2007 issue of Food Safety Magazine. Marler, who represents plaintiffs in E. coli litigation, gives a history of the disease first recognized as a human pathogen in 1982 and recommends strategies that owners can use to protect their businesses. Although Marler identifies the market, the government and the legal system as potential venues for managing foodborne illness, he urges CEOs to take a proactive approach to food safety. He specifically advises businesses to (i) "put qualified people in charge of food safety;" (ii) "listen to the qualified food safety professionals you've hired," (iii) "use contracts with your vendors to protect your customers and indemnify your company of liability if something goes wrong;" (iv) "understand why information management (IT) is important to your company, especially as it related to the food safety mission;" and (v) "stay current with regulatory and code compliance for every jurisdiction in which your company operates." Marler ultimately attributes the rise in foodborne illness cases to a centralized food system vulnerable to widespread contamination and improved tracing technology, but adds that "if somebody gets sick then somebody like me will be waiting at his or her doorstep. And I will do my best to make it a very costly mistake."

#### [5] USDA Schedules AC21 Meeting to Address Diverse Agricultural Systems

USDA's Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) has announced a meeting, slated for November 28-29, 2007, to complete all substantive work on a paper addressing the question, "What issues should USDA





consider regarding coexistence of diverse agricultural systems in a dynamic, evolving and complex marketplace?" The committee consists of 23 members representing the biotechnology industry, farmers, food manufacturers, commodity processors and shippers, livestock handlers, environmental and consumer groups, and academic researchers. The meeting agenda will also cover (i) the Biotechnology Quality Management System proposed by the Animal and Plant Health Inspection Service and (ii) the initial plans for AC21 work related to transgenic animals.

In addition, AC21 has requested nominations for 13 committee seats set to expire in 2008. Nominees should possess expertise in one or more of the following areas: recombinant-DNA research and applications using plants, animals or microbes; food science; silviculture and related forest science; fisheries science; ecology; veterinary medicine; the broad range of farming or agricultural practices; weed science; plant pathology; biodiversity; applicable laws and regulations relevant to agricultural biotechnology policy; risk assessment; consumer advocacy and public attitudes; public health/epidemiology; ethics, including bioethics; human medicine; biotechnology industry activities and structure; intellectual property rights systems; and international trade. Written nominations must be received by fax or postmarked before November 23, 2007.

### European Union

#### [6] European Union Approves Genetically Engineered Corn and Sugar Beets

According to a news source, the European Union (EU) has given Monsanto Co., Dow Chemical Co.

and DuPont Co. 10-year authorizations for genetically modified corn and sugar beets for use in food and animal feed. The European Commission issued a statement saying, "All of the genetically modified organisms received positive safety assessments." Individual EU countries, such as Italy, Poland, Hungary, Austria, Greece, Cyprus, and Luxembourg, reportedly oppose biotech crops, and surveys show that more than one-half of European consumers worry about health and environmental risks. Since the EU ended its moratorium on genetically engineered products in 2004, it has apparently issued some 15 authorizations for biotech foods and crops. *See Bloomberg.com*, October 24, 2007.

Meanwhile, The Los Angeles Times recently ran a lengthy story discussing biotech foods, noting that "largely unbeknownst to most consumers, more than 70% of processed foods on grocery store shelves contain genetically engineered or biotech ingredients." The main sources of such ingredients are oil, flour, sweetener, and lecithin, which come from corn, soy and canola, "engineered to do two things: withstand sprayings of herbicides and resist pests." The article discusses scientific and technical challenges in bioengineering and highlights the concerns people have about the development of super-weeds, new allergies and antibiotic resistance. Apparently, company researchers test their new products to ensure they do not produce allergens. A spokesperson for Monsanto was quoted as saying, "If it even has the potential, it's dead. It doesn't go into the plant."

The article discusses the fractured nature of federal government oversight, with a number of agencies involved in various growing and production stages. The Center for Science in the Public Interest (CSPI) has reportedly concluded, after studying the data, that "the current crops on the



market aren't harmful to humans." CSPI, comparing the regulatory controls over biotech foods and crops to the types of regulations that are applicable to pharmaceuticals, believes that the voluntary system the Food and Drug Administration uses to oversee whether crops are safe for humans to eat is sufficient. The executive director of the Center for Food Safety, however, is calling for food labels so consumers have a choice as to whether they will eat biotech foods or not. *See The Los Angeles Times*, October 22, 2007.

#### State and Local Initiatives

#### [7] New York City Revamps Calorie Posting Ordinance

The New York City Board of Health has reportedly taken a first step toward enacting a new rule that would require fast-food restaurants to list the calorie content of their menu offerings as prominently as the price. The board's previous effort stalled when a judge struck it down in September 2007, finding that it conflicted with federal food labeling laws. He suggested that the rule, which would have applied only to restaurants that were already providing nutritional information to their customers, could be adjusted to withstand a preemption challenge. The board has apparently done so by proposing that all restaurants subject to the rule be required to post calorie information regardless whether they had provided it in the past. Only chain restaurants with 15 or more outlets in the city would be covered and only those restaurants serving standardized portion sizes. The city's health commissioner was quoted as saying, "People deserve to have more information when they are ordering food." The New York State Restaurant Association has weighed in against the new

proposal, and news sources expect a legal challenge if it is adopted. The board voted to publish the revamped proposal and hold a public hearing. Final action on the measure would apparently be taken in January 2008. *See Associated Press*, October 24, 2007.

## Litigation

#### [8] Organic-Law Violation Complaints Mount Against Aurora Dairy

A putative class action has been filed against Aurora Dairy Corp. in federal court in Denver alleging that the company violated statutory and common law by marketing its milk and dairy products as organic without complying with federal organic regulations. *Still v. Aurora Dairy Corp.*, No. 07-2188 (U.S. Dist. Ct., D. Colo., filed October 18, 2007). It follows by two weeks a somewhat similar complaint filed in the Eastern District of Missouri. Details about that case, *Mothershead v. Aurora Dairy Corp.*, appear in issue 234 of this Update.

The Denver complaint, filed on behalf of named plaintiffs from 30 states and the District of Columbia, seeks to certify a nationwide class as to alleged violations of Colorado's consumer protection and deceptive trade practices statutes and individual statewide classes as to, for the most part, alleged violations of their respective consumer protection laws, express and implied warranties, negligence per se, and unjust enrichment. The Iowa and Kansas classes do not include allegations as to violations of statutory law, and the Texas class does not include allegations as to negligence per se. The California class additionally includes a claim for damages under the state's false advertising law.





Recently, a federal district court in Ohio found that class-action plaintiffs would not run afoul of choice-of-law conflicts where they seek to certify single state subclasses. *In re Welding Fumes Prods. Liab. Litig.*, MDL Docket No. 1535 (U.S. Dist. Ct., N.D. Ohio, Eastern Div., decided September 14, 2007).

The Still plaintiffs seek injunctive relief, compensatory damages, triple or multiple damages in those states where available, costs, and fees. Unlike the Missouri plaintiffs, they do not ask for punitive damages. While both complaints include recitations of Aurora's alleged violations of organic regulations, mention the U.S. Department of Agriculture's investigation of the company and set forth common questions of law and fact, the Missouri complaint contains more common questions. Additional cases against the dairy have been filed in federal court in California, Gallardo v. Aurora Dairy Corp., No. 07-5331 (U.S. Dist. Ct., N.D. Calif., filed October 18, 2007); Colorado, Freyre v. Aurora Dairy Corp., No. 07-2183 (U.S. Dist. Ct., D. Colo., filed October 17, 2007); and Florida, Fiallos v. Aurora Dairy Corp., No. 07-22748 (U.S. Dist. Ct., S.D. Fla., filed October 17, 2007).

#### [9] Wisconsin Court Dismisses Marketing Claims Against Beverage Interests

The Wisconsin Court of Appeals has dismissed a putative class action seeking recovery for money given to children by their parents and guardians and purportedly misspent on the purchase of alcoholic beverages. *Tomberlin v. Adolph Coors Co, et al.*, No. 2006-1302 (Wisc. Ct. App., decided October 25, 2007). The appeals court affirmed the lower court's dismissal of the claims filed against "numerous entities engaged in the manufacture and sale of alcohol," for plaintiff's failure to allege an actionable injury and lack of standing. According to the

court, there is no authority supporting "the proposition that a parent may recover damages from one who persuades a child to spend the child's own money for a product or purpose the parent disfavors." The court also found that the defendants' alleged youth marketing did not "actionably interfere with the parent-child relationship." This case was one of 10 marketing class actions that alcohol manufacturing and retail companies and their trade associations have faced in federal and state courts across the country. To date, no court has allowed the claims to proceed.

Shook, Hardy & Bacon lawyers took the lead in briefing the issues for the appeals court.

## [10] Lawsuits filed Against Cargill for *E. Coli* Contamination

Plaintiff's lawyer Bill Marler has reportedly filed two E. coli lawsuits in Minnesota against Cargill on behalf of state residents who allegedly became ill after eating the company's ground beef patties. The first lawsuit, filed on October 15, 2007, on behalf of the Gustafson family, alleges that two children were sickened with E. coli, one seriously enough to be hospitalized with acute kidney failure. The second lawsuit, filed on behalf of John and Barb Reber alleges that their son was hospitalized for three days with symptoms typical of *E. coli* infection and tested positive for E. coli O157:H7. According to Marler, Cargill has recalled 1 million pounds of frozen hamburger patties, and E. coli cases tied to the company have also turned up in Wisconsin, North Carolina and Tennessee. Marler, who has sued Cargill on behalf of clients in the past, claims that "Cargill has made no effort to compensate my clients for medical expenses or lost wages even though its product has been definitively linked to their illnesses." He called on the company to listen





to him and "put me out of business." *See Marlerblog.com*, October 14 and 25, 2007; *MeatProcess.com*, October 17, 2007.

#### [11] FTC Files Appeal in Wild Oats/Whole Foods Merger

The Federal Trade Commission (FTC) has reportedly asked the D.C. Circuit Court of Appeals to review a district court ruling allowing Whole Foods Market Inc. and Wild Oats Markets Inc. to merge. Characterizing the move as "unusual" because it could affect a deal that has been completed, *The Wall Street Journal* reported that the FTC argued in its motion for an expedited ruling that an appeal is still warranted because Whole Foods apparently continues to operate Wild Oats stores separately. The FTC challenged the merger on the grounds that it would stifle competition and raise prices in the natural-foods grocers market. *See The Wall Street Journal*, October 24, 2007.

## Other Developments

## [12] Advergaming Expenditures Expected to Increase

With the number of online gamers expected to increase in the United States from 6.9 million in 2007 to 18.5 million by 2012, advertising insiders reportedly expect that companies will spend more than ever for in-game advertising, around-game ads, advergames, and product placement. As noted by *MediaPost*, "Advertising can be displayed both before and after gameplay, in the launch and exit windows, with digital video ads running while the game is loading." Burger King's "Sneak King" is cited as an example of an advergame specifically designed around a product or service. In-game advertising expenditures are expected to accelerate

to nearly \$1 billion by 2013. See Center for Media Research's Research Brief, October 24, 2007.

#### [13] IBM Announces Plans for Childhood Obesity Program

The International Business Machines Corp. (IBM) has reportedly announced that it will launch a program to provide cash incentives to employees whose children enroll in and complete a 12-week online program of diet and exercise training. The N.Y.-based company has apparently succeeded in getting nearly two-thirds of its 128,000 U.S. employees to sign up for an annual fitness program and called the voluntary children's program a logical next step. IBM apparently estimates that its wellness programs have saved the company between \$100 million and \$130 million annually in avoided health-care costs. *See The Wall Street Journal*, October 24, 2007.

## Media Coverage

#### [14] Alice Miles, "Tubby or Not Tubby: Get Ready for Action," *The London Times*, October 24, 2007

"Ministers should be targeting the junk and fast-food industries with far tougher guidelines on which foods are marketed at young children, and the fat and additives contained within them," opines *Times* columnist Alice Mills in a recent op-ed piece criticizing a government plan to notify the parents of "obese" 5-year-olds. Mills, who contends that the proposed letter campaign will prove ineffective, suggests that anti-obesity policy should instead require supermarkets, bakeries and fast-food restaurants to adopt a "traffic-light" system that codes fat, sugar and salt content in an easy-to-read format. In addition, she argues that the government should





"tackle the activity deficit" affecting children because "parents cannot be forced to provide nutritious fresh food for their kids." "But that would mean taking on 'big business' in a way which the Government is loath to do," she concludes, claiming that "there isn't any great mystery" to obesity when the built environment precludes exercise and time constraints make ready-made meals an increasingly attractive option.

In a related development, BBC News has reported that the "largest ever U.K. study into obesity" has concluded that excess weight has become the norm in modern society. Backed by the government and compiled by 250 experts, the study speculated that the majority of British citizens would become obese by 2050 and cost the country an estimated \$46 billion in health services for weight-related illnesses such as type 2 diabetes, cancer and stroke. In addition, researchers argued that the "notion of obesity simply being a product of personal over-indulgence had to be abandoned for good," according to the BBC. The authors apparently characterized obesity as the "inevitable consequence of a society in which energy-dense and cheap foods, labor-saving devices, motorized transport, and sedentary work were rife." Although the study did not offer any concrete suggestions, it covered several policy options and warned that a failure to act could mire the United Kingdom in a health crisis for decades to come. See BBC News, October 17, 2007.

Meanwhile, a study by Hertfordshire University researchers has reportedly declared that a woman's battle against food cravings is "pointless." After asking 134 female students to either suppress all thoughts of chocolate or talk about how much they liked it, scientists recorded the quantity of chocolate subsequently consumed by the women and found that those in the first group ate 50 percent more

than the students encouraged to discuss their cravings. Men, however, exhibited the opposite effect, with the group that talked about food consuming more. "There is a lot of evidence into the idea that when you suppress a thought you end up thinking about it more," the lead author was quoted as saying. "However, this is the first concrete evidence of how this works in relation to food choices." *See BBC News*, October 22, 2007.

#### [15] Lisa Young, "Fast-Food Portions Keep Getting Bigger, But You Might Not Know It," MSNBC, October 19, 2007

"Not only are servings getting larger, some top fast-food chains are engaged in a sleight-of-name game – marketing ploys that only confuse customers who think they're ordering less than they actually are," charges MSNBC contributor Lisa Young, Ph.D., R.D., in this article summarizing a portion-size study that she recently co-authored with New York University Professor Marion Nestle. Young writes that although some major chains have dropped labels such as "Biggie" or "Supersize," many restaurants have introduced 1,000-calorie-plus sandwiches and increased portion sizes across the board. Ordering a small or medium, she contends, no longer guarantees a portion size appropriate to a healthy diet. Young concedes, however, that restaurants' efforts to scale back on serving sizes often leaves a bad taste in the mouths of their customers. "But that's because consumers are programmed into thinking that bigger size means bigger value," she concludes, suggesting several ways to avoid falling victim to "portion distortion."

Meanwhile, a recent *Wall Street Journal* article titled "Treating Diabetes and Understanding Cultures" also focuses on portion sizes in the context of food consumed by different ethic groups.





Theo Frances reports that "New York's 11 public hospitals have mounted a campaign to tailor treatment and counseling to their ethnicities" with tactics ranging from multilingual handouts to on-site cooking classes. Dr. Huajin Huang at the Elmhurst Hospital in Queens, N.Y., for example, created a photograph menu that compares typical Chinese and Indian take-out dishes to the single serving his diabetic patients should be eating. The article, which replicates his experiment, notes that many patients require specialized nutritional information that takes cultural cuisines into account and lifestyle advice adapted "to the needs of an ever-more-polyglot population." "It's not hard to imagine that if you choose a typical [American] diet and you're speaking to someone who's Latino or Chinese, it's not going to be very helpful," said the chief of ambulatory medicine at Elmhurst Hospital, where 50 percent of diabetic patients have blood-sugar levels close to that of a healthy adult, compared with 25 percent just five years ago. See The Wall Street Journal, October 23, 2007.



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#### LITIGATION UPDATE

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