# Food & Beverage

## LITIGATION UPDATE

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# Food & Beverage

LITIGATION UPDATE

## Legislation, Regulations and Standards

### 110th Congress

**[1] Democratic Lawmakers Call for Investigation into Unsafe Food Practices**

Joined by three Democratic colleagues, the chair of the House Committee on Education and Labor has asked the Government Accountability Office (GAO) to investigate "the overall effectiveness of the federal government's effort to ensure the safety of meat in the school food supply." In a February 14, 2008, **letter**, Representative George Miller (D-Calif.) discusses the "urgent concerns" he shares with "all Americans who watched the Humane Society's disturbing videos" involving the alleged mistreatment of cattle at Westland Meat Co.

As we noted in our last Update, the U.S. Department of Agriculture (USDA) has placed an administrative hold on all Westland meat products and indefinitely suspended it from participating in the National School Lunch Program. While Miller characterizes the USDA's action as "appropriate," he calls for the GAO to examine (i) "the process for protecting our students from dangerous food"; (ii) "how quickly and accurately schools can assess and pull potentially contaminated products"; and (iii) "the information, guidance and resources about inspections, suppliers' histories, and safe handling practices the USDA provides to local authorities." According to Miller, with information from this review, Congress will be able "to determine what steps are necessary to ensure our children's health by preventing tainted beef from entering the school food supply."

**[2] GAO Reports to Congress on FDA Food Protection Plan**

The Government Accountability Office (GAO) recently delivered its **evaluation** of a Food and Drug Administration (FDA) plan, first issued in November 2007, that seeks to expand the agency's authority to police the national food supply. Testifying before the U.S. House Subcommittee on Oversight and Investigations, the GAO Director of Natural Resources and Environmental, Lisa Shames, concluded that while FDA "proposes some positive first steps," its *Food Protection Plan* lacks the specific details needed by Congress "to assess the likelihood of the plan's success in achieving its intended results." In particular, GAO noted that FDA fails to describe food safety strategies or funding requirements in depth, thus jeopardizing congressional approval for the plan. GAO further recommended that FDA leverage its current resources by (i) establishing "equivalency agreements with other countries to shift some oversight responsibility to foreign governments;" (ii) exploring certification for third-part y inspections; and (iii) "accrediting private laboratories to inspect seafood, among others." The report also advised

FDA to partner with U.S. Department of Agriculture inspectors at facilities where the two agencies perform overlapping duties if such a strategy proved to be cost-effective. Food regulators should also appoint a chief operating officer to help resolve "longstanding management problems" that undermine key strategic missions, according to GAO. "FDA's *Food Protection Plan* is a step in the right direction and proposes to implement many of the recommendations made by GAO," concluded the evaluation, which added that, "Continued congressional oversight . . .and additional legislative action are key to achieving that progress and to promoting the safety and integrity of the nation's food supply." *See Reuters*, January 29, 2008.

## Food and Drug Administration (FDA)

### [3] FDA Releases Draft Compliance Policy to Control Listeria in Ready-to-Eat Foods

FDA recently announced a draft compliance **policy** directed at agency staff and draft industry **guidance** pertaining to *Listeria monocytogenes*-control measures for ready-to-eat (RTE) foods. Categorizing RTE foods as those that support *Listeria* growth and those that do not, the draft compliance policy retains a zero tolerance rule toward the former, stating that FDA "may regard the food to be adulterated … when L. monocytogenes is present in the food, based on an analytical method that can detect 1.0 colony forming unites (CFUs) of L. monocytogenes per 25 grams (g) of food (i.e., 0.04 CFU/g)." For foods that do not support *Listeria* growth, FDA proposes to raise its zero tolerance level to 100 CFUs/g of food before the product is considered adulterated. In addition, the agency has issued draft industry guidance to "complement FDA's current good manufacturing practices (CGMP) regulations by providing specific guidance on the control of L. monocytogenes in the processing of refrigerated or frozen" FTE foods. FDA has **called** a March 28, 2008, public meeting to address the draft compliance policy.

## Environmental Protection Agency (EPA)

### [4] EPA Seeks Comments on Nanomaterial Research Strategy Draft

EPA has **published** a notice regarding the availability of its "Draft Nanomaterial Research Strategy" for public comment. Nanomaterials are used in more than 600 consumer products, including antibacterial kitchenware, food packaging and storage, vegetable oils, food supplements, and veterinary pharmaceuticals. The agency has contracted with Versar, Inc. to oversee the external peer review of the research strategy draft, and a meeting of external peer reviewers has been scheduled for April 11, 2008. Versar is a Virginia-based "global project management company" that frequently contracts with government agencies on environmental science, construction management and homeland defense projects. EPA will consider its report of the expert comments and recommendations, as well as the public comments, in finalizing the nanomaterial research strategy by mid-2008. Comments on the draft must be submitted within 30 days of the February 13, 2008, *Federal Register* notice.

The **draft** identifies research needs and discusses the in-house and external research to be conducted to understand the environmental and health effects of engineered nanomaterials. Four key research themes identified in the draft are (i) sources, fate transport and exposure; (ii) human health and

ecological risk research; (iii) risk assessment methods and case studies; and (iv) preventing and mitigating risks. The draft mentions veterinary pharmaceuticals, noting that if they are "administered using nanomaterials, these materials may be excreted and released into the environment when manure is land applied as fertilizer. Additionally, the disposal of dead animals may result in the release of nanomaterials present in the animal's body."

The draft recognizes the potential difficulty and expense of removing nanomaterials "from some media (e.g., surface waters or drinking water), potentially resulting in exposures to large segments of the population to complex mixtures of these materials." The draft also notes that nanomaterials could find their way into soil and aquatic ecosystems through manufacturing plant effluents, "the recycling or disposal of nano-based consumer products into landfills and surface/ground water." According to the draft, EPA researchers have already seen (i) "unique gene expression patterns within airway cells exposed to carbon nanotubes versus environmental particles," (ii) *in vitro* pulmonary toxicity, and (iii) cellular oxidative stress "of nano TiO2 induced toxicity in brain microglia cells."

In a related development, a nanomaterial manufacturer has announced a research grant to an Iowa State University scientist to study "the use of nanomaterials to improve the safety of the world's food supply." Byron Brehm-Stecher, Ph.D., will test the effectiveness of a QuantumSphere, Inc. product "for use in antimicrobial materials that could prevent food contamination" *See Nanotechnology News*, February 6, 2008.

# U.S. Agency for International Development (USAID)

### [5] USAID Announces International Food and Agricultural Development Meeting

USAID recently announced the 153rd meeting of the Board for International Food and Agricultural Development (BIFAD), slated for February 27, 2008, at the National Press Club in Washington, D.C. This session will include presentations on the Global Summit on Higher Education and Development, as well as the Global Development Commons initiated by USAID Administrator Henrietta Fore. In addition, BIFAD will discuss its 2008 strategic direction and the impact of the president's 2009 budget on agricultural programs. Board members will also confer with the Office of Agriculture on two new Collaborative Research Support Programs: Global Horticulture and Global Livestock-Climate Change. The meeting is free and open to the public.

# State and Local Governments

### [6] San Francisco Board of Supervisors Approves Voluntary *Trans* Fat Ban

San Francisco's Board of Supervisors has reportedly approved a voluntary program to distribute decals to city restaurants that pledge not to use *trans* fats in their cooking, baking or frying. The Department of Public Health, which will oversee the program, will require participants to pay a $250 fee and will distribute the advertising decals to those that qualify. The initiative is reportedly backed by the Golden Gate Restaurant Association, which also publicly supports a mandatory *trans* fat ban under consideration by city officials. "Since there are

reasonable alternatives, there is no reason for restaurants to continue using *trans* fats," an association spokesperson told reporters.

If approved, the *trans* fat ban would join similar regulations in New York City, Philadelphia and other areas that took effect in 2007. The New York City measure has apparently met little resistance from restaurant owners, despite some initial confusion registered by "mom and pop" establishments over the restrictions. "My feeling is that *trans* fats are bad and should be gone, but they are not that bad," New York University Professor Marion Nestle was quoted as saying. "It's not like you're going to eat them and die on the spot." *See San Francisco Chronicle*, January 30, 2008.

In a related development, the San Francisco Rules Committee last week heard a proposed menu-labeling ordinance that would require chain restaurants with 14 or more branches in the state to post calorie, sodium, carbohydrate, and saturated fat content on menus or menu boards. Sponsored by Supervisor Tom Ammiano, the ordinance would apply to locations within city limits, although critics have opposed the mandate as unnecessary and potentially ineffective. Proponents such as Harold Goldstein, executive director of the California Center for Public Health Advocacy, and Patricia Wakimoto, chair of the Wellness Team for the California division of the American Cancer Society, have countered that even "would-be healthy diners" make poor choices when dining out, in part because current labeling laws do not require eateries to prominently display nutrition information. "Given today's obesity crisis, diners can no longer afford to play a guessing game when choosing the food they eat," argue Goldstein and Wakimoto in a February 7, 2008, opinion piece published in the *San Francisco Chronicle.* "While menu labeling alone will not solve the problem of obesity, it can play a vital role in a multi-pronged effort to combat the epidemic."

### [7] Ohio Adopts Temporary Rule on Labeling Growth Hormone-Free Dairy Products

Ohio Governor Ted Strickland (D) has reportedly issued an emergency rule that will allow dairies to label their products as free of synthetic growth hormones if they can verify the claim and include a disclaimer indicating that "no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows." Verification includes farmer-signed affidavits, farm weight tickets and processing plant audit trails. The issue apparently generated significant debate among those advising the state's agriculture department, which drafted the rule. Some farmers reportedly did not want any claims about hormone use, and others contend that the disclaimer is excessive. The rule will apparently remain in effect for 90 days, while a statutory rulemaking process is completed. According to a news source, the final rule will likely mirror the temporary one. *See The Columbus Dispatch*, February 7, 2008; *Dayton Daily News*, February 8, 2008.

### [8] Hawaiian Legislature Ices Aspartame Bill

The Hawaiian House of Representatives has reportedly postponed a vote on aspartame legislation (H.B. 2680) seeking to prohibit the substance in the state as early as January 1, 2009. Several proponents of the bill had submitted written testimony alleging that the artificial sweetener, which is widely used in diet soft drinks, chewing gun and other non-sugar products, causes a range of side effects, including neurological and cardiovascular symptoms, as well as severe diseases such as multiple sclerosis.

The attempted ban also received national attention, soliciting remarks from New Mexico state Senator Gerald Ortiz y Pino, who blamed "corporate lobbyists' theories of federal pre-emption" for killing similar efforts in his state's legislature. Critics of the ban, however, noted that the measure would require strong evidence of a severe public health risk to override federal approval for the product. "Aspartame is one of the most thoroughly test and studied food additives the (U.S. Food and Drug Administration) has ever approved," a spokesperson for the state Department of Health was quoted as saying. *See The Honolulu Advertiser*, February 10, 2008; *Hawaiian Reporter*, February 13, 2008.

## European Union (EU)

### [9] EU Adopts Voluntary Nanotechnology Code of Conduct

The European Commission has adopted a "**Code of Conduct for Responsible Nanosciences and Nanotechnologies Research**," recommending that all EU member states be guided by its tenets. The code is based on seven general principles, including sustainability, the precautionary principle, transparency, and best scientific practices. While the code acknowledges the importance of intellectual property rights, member states and researchers "are encouraged to make easily accessible and understandable to lay people as well as by the scientific community all N&N [nanosciences and nanotechologies] scientific knowledge as well as related information such as relevant standards, references, labels, research on impacts, regulations and laws."

Among the priorities for nanotechnology research in the code are the encouragement of standard measurement procedures, the development of methods and tools for risk assessment and "research aiming to protect the public and the environment, consumers or workers and aiming to reduce, refine or replace animal experimentation."

## Germany

### [10] German Authorities Investigate Suspected Chocolate Price-Fixing Scheme

The German Federal Cartel Office has reportedly opened an investigation into several chocolate companies, including Nestle S.A. and Ritter, suspected of colluding over price increases. German cartel officials apparently became suspicious when the cost of chocolate confections allegedly outpaced rising milk and cocoa prices, which several manufacturers have blamed for cutting profits in 2007. As a result of these accusations, these companies could face numerous lawsuits filed by their smaller competitors. The International Cocoa Organization, however, has confirmed that a worldwide cocoa deficit is now estimated at 242,000 tons, compared with an earlier projected figure of 156,000 tons. Similar allegations are also under investigation in the United States and Canada. *See Food Navigator-USA.com*, February 12, 2008.

## Litigation

### [11] Federal Court Allows ADA Suit to Continue Against Fast Food Establishments

The Second Circuit Court of Appeals has determined that a legally blind woman has standing to bring claims against several fast food restaurants under the Americans with Disabilities Act (ADA). ***Camarillo v. Carrols Corp.*, No. 06-4909 (2d Cir., decided February 8, 2008)**. Alice Camarillo,

who is able to read enlarged writing, claimed that the fast food restaurants she patronized did not have large print menus, and when she "asked for employees to read her the menu items, she has been made fun of, stared at, and forced to wait until other customers behind her in line were served, and the employees have often read her only part of the menus." A district court in New York dismissed her claims for lack of standing, finding that because she was always permitted to eat at the defendants' restaurants, she had suffered no harm and failed to state a claim under the ADA.

Reversing, the appeals court found that Camarillo alleged more than mere rudeness or insensitivity and had, indeed, stated cognizable claims under the ADA. "A reasonable inference to be drawn from her complaint is that defendants failed to adopt policies or procedures to effectively train their employees how to deal with disabled individuals." As such, according to the court, "Camarillo cannot experience 'full and equal enjoyment' of defendants' services." Because she had alleged past injury under the ADA and it was reasonable to infer that the discriminatory treatment would continue and that she intended to return to these establishments in the future, the court also determined that she had standing to pursue her claims under both state and federal law.

### [12] State Court Finds Artificially Colored Salmon Complaints Not Preempted

The California Supreme Court has determined that federal law does not preempt claims brought under state deceptive marketing laws that were allegedly violated by grocery stores which sold farmed salmon without disclosing to customers that the fish had been fed chemicals to simulate the coloration of wild salmon. ***Farm Raised Salmon Cases*, No. 147171 (Cal., decided February 11, 2008)**. Two lower courts dismissed the claims, finding them preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), which requires salmon fed with color additives to be appropriately labeled.

The supreme court reversed, finding nothing in the federal law precluding the states from enacting identical food labeling provisions or proscribing private actions for violations of those state laws. The court found the state labeling laws identical to the federal law and upheld the plaintiffs' right to bring suit under state law. The court noted, "while allowing private remedies based on violations of state laws identical to the FDCA may arguably result in actions that the FDA [Food and Drug Administration] itself might not have pursued, Congress appears to have made a conscious choice not to preclude such actions."

In a footnote, the court described the options available to salmon farmers who wish to add the petrochemical-based additives to their feed and, quoting a *New York Times* article, wrote "one of the dye manufacturers 'offers salmon farmers the SalmoFan, a sort of paint wheel with assorted shades of pink, to help them create the color they think their customers want.'" Details about the court of appeals decision that the supreme court reversed can be found in issue 183 of this Update.

### [13] California Raw Milk Dairy Sued for *E. Coli* Outbreak

Plaintiff's lawyer Bill Marler has reportedly filed two lawsuits against Organic Pastures, a California-based raw milk dairy, for injuries allegedly caused by a 2006 *E. coli* 0157:H7 outbreak that purportedly sickened six children in the state. While a communicable disease-control agency apparently failed to find the outbreak strain at the dairy, it concluded

nonetheless that "the source of infection for these children was likely raw milk products produced by the dairy." The children who Marler represents were allegedly hospitalized for more than a month with complications from *E. coli* 0157:H7 infection. *See The Ethicurean*, February 8, 2008.

### [14] BSE Claims Against Feed Company Settle in Canada

An animal feed company based in both Minnesota and Manitoba has reportedly agreed to settle class action claims filed in Canada seeking damages for losses to the cattle industry when a bovine spongiform encephalopathy (BSE) outbreak resulted in international bans on trade in Canadian beef. Feed company Ridley Inc. reportedly agreed to pay plaintiffs CAN$6 million but admitted no wrongdoing. "Resolving these lawsuits now minimizes the costs associated with defending an already lengthy litigation, eliminates the uncertainty and allows us to move our business forward," its CEO was quoted as saying.

Filed by Canadian ranchers in 2005, the lawsuit will continue against the Canadian government, which allegedly failed to act with sufficient speed to regulate cattle feed after BSE was diagnosed in an Alberta cow in 2003. *See Meatingplace.com*, February 8, 2008.

## Other Developments

### [15] FDA-Sanctioned Energy Drink Returns to Market

Redux Beverages LLC has reportedly initiated a new advertising campaign to herald the return of its Cocaine™ energy drink, which the Food and Drug Administration last year pulled off the market for violating federal labeling laws. To comply with FDA regulations, Redux has apparently removed from labels a tagline exalting Cocaine™ as "the legal alternative" and replaced it with an anti-drug warning. In addition, Redux has deleted from its Web site several health benefit claims that were not approved by FDA. The renewed promotion will purportedly pursue music tour sponsorships, viral marketing through Web pages and branding opportunities with video game companies, as well as traditional print, radio and television media. "We have also built a social network, kind of like MySpace but built solely for Cocaine™ energy drink at drinkcocaine.com/social," a Redux spokesperson was quoted as saying. This network will also feature contests and giveaways that include free cases of Cocaine™ and branded merchandise. *See Media Post's Marketing Daily*, February 6, 2008.

### [16] Health Advocates Red Flag Caffeinated Candy

Candy manufacturers have reportedly started designing product lines to cash in on the energy drink craze, creating jelly beans, chocolate bars and breath mints that contain as much caffeine as a cup of coffee, in addition to ingredients such as B vitamins, electrolytes, taurine, guarana, and ginseng. While confectioners are not marketing these products to children and often include warnings for pregnant women or the caffeine-sensitive, health professionals have apparently questioned the increase in energy-enhanced products now available to school-aged kids. In addition, consumer activists have decried the illegal drug references made by some candies in their marketing and labeling practices.

Like the energy drink known as Cocaine™, candies such as Buzz Bites™ and Crackheads™ have

raised eyebrows among public heath advocates, as well as industry representatives who reportedly believe the tongue-in-cheek allusions tarnish the candy-making business. Moreover, state legislatures have already considered numerous measures to prohibit the sale of caffeinated products and energy drinks in schools. "It blurs the distinction between legal and illegal drugs, and it normalizes the use of performance-enhancing drugs," Professor Roland Griffiths of the Johns Hopkins University School of Medicine was quoted as saying. *See The Wall Street Journal*, February 15, 2008.

## Media Coverage

**[17] Tom Spears, "Chemical Reaction," *The Ottawa Citizen*, February 10, 2008**

"The debate about BPA [bisphenol A] is much like disputes over other environmental chemicals, from dioxin to manure from factory farms," writes *Ottawa Citizen* reporter Tom Spears in this article about the contentious history of the ubiquitous plasticizer, which some studies have linked to reproductive harm in laboratory animals. Although he concedes that it is difficult to replicate human risk factors in animal populations, Spears nevertheless notes that among existing studies, "there is a nasty split, all based on how each scientist chose to give BPA to rats." In its review of BPA scientific literature, the U.S. National Institute of Environmental Health Sciences apparently excluded several independent studies because researchers injected the rats with BPA or observed adverse affects *in vitro*, not in live animals. By contrast, several of the industry-backed studies fed BPA to the rats by mouth, a closer approximation of how humans are exposed to the substance. Moreover, according to Spears, "the 'pathway' of exposure makes a difference. When we eat it, our metabolism breaks down and excretes a lot of it. That doesn't happen as readily if the chemical is shot directly into the bloodstream." As a result, government reviewers have tentatively registered only mild concern over BPA because the chemical's effects appear negligible in adult humans. Several industries that rely on BPA, such as food canneries, have apparently supported this assessment as further evidence that the chemical's unique benefits outweigh its risks.

Anti-BPA campaigners, however, have countered these findings with new research claiming that BPA poses a unique threat to rat fetuses and babies, who might process the chemical differently. For example, Spears points to a recent University of Missouri study, published in *Reproductive Toxicity*, that gave high and low doses of BPA to three-day-old female mice, either by injection or by mouth. The study results allegedly found that the mice injected with BPA had the same blood levels as the mice that received oral doses. "It shows that for baby animals, it doesn't matter whether they get the dose orally or they get the dose through the blood," one anti-BPA advocate explained to Spears, arguing that pregnant women should avoid the substance. Spears also observes that, apparently in response to this study, the National Toxicology Program released a letter "promising to consider all views about different methods of exposure in making its decision" about the safety of BPA.

Meanwhile, University of Missouri researchers have reportedly found that BPA leaches from baby plastic bottles heated to 80 degrees Celsius. The study results are compiled in a 20-page report, titled ***Baby's Toxic Bottle: Bisphenol A Leaching from Popular Baby Bottles***, commissioned by The Work Group for Safe Markets, a coalition of U.S. public health and environmental organizations. Among

other things, the coalition recommends that (i) states adopt BPA restrictions for all food and beverage containers; (ii) the Food and Drug Administration and all baby bottle manufacturers respond "with full disclosure to the landmark investigation by Reps. Dingell/Stupak into BPA leaching from infant formula cans," and (iii) the federal government reform America's "outdated chemical policies," including the Toxic Substances Control Act. "The test results of our study indicate that the United States' current lack of regulation of bisphenol A exposes infants and children to potentially dangerous levels of this unnecessary toxic chemical," the report authors conclude. *See Kansas City Star* and *ABC News*, February 7, 2008.

# Scientific/Technical Items

### [18] Study Questions Role of Artificial Sweeteners in Weight Loss

A recent U.S. **study** based on laboratory animals has suggested that artificial sweeteners, such as saccharin, may increase body weight and fat build-up in humans. S. E. Swithers and T. L. Davidson, "A Role for Sweet Taste: Caloric Predictive Relations in Energy Regulations by Rats," *Behavioral Neuroscience*, February 2008. After feeding 27 male Sprague-Dewey rats a sweet taste from glucose or no-calorie saccharin, Purdue University researchers reportedly observed that the saccharine-fed rats subsequently consumed more calories, increased in weight and adiposity, and exhibited a blunted thermic response to sweet-tasting diets. Although these findings contradict a 2007 European study supporting the role of artificial sweeteners in human weight loss, the researchers theorized that because sweet foods generally cause the body to anticipate calories, non-caloric sweeteners might confuse the body's ingestive and digestive reflexes. "This interference could lead to reduced energy utilization and, ultimately, to increased weight gain," the study surmised. Cautioning that the results should be further tested, the authors nevertheless concluded that, "it is conceivable that just as exposure to non-predictive sweet taste-caloric relationships in the laboratory appears to promote increased body weight and adiposity in rats, the widespread use of non-caloric sweeteners in the food environment of humans may have similar effects on the predictive validity of sweet tastes and ultimately on the normal ability to control their intake and body weight." *See Food Navigator-USA.com*, *The Daily Mail* and *The London Times*, February 11, 2008.

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## LITIGATION UPDATE

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