

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

Leahy Proposal Would Increase Penalties for Food Safety Violations

Senator Patrick Leahy (D-Vt.) has renewed his quest to increase the sentences prosecutors can seek to impose on those who knowingly sell tainted food products. He has reintroduced the Food Safety Accountability Act (S. 216) and promises to schedule hearings in the near future before the Judiciary Committee, which he chairs. While the proposal passed unanimously out of that committee in September 2010, Leahy was unable to attach it to the Food and Drug Administration Food Safety Modernization Act, approved during the lame duck session at the close of the year.

With five Democratic co-sponsors, the bill would allow prison sentences up to 10 years for the most egregious food safety violators. Referring to the nationwide *Salmonella* outbreak and recall involving an Iowa egg producer with a history of violations, Leahy said when he introduced the bill, “It is clear that fines are not enough to protect the public and effectively deter this unacceptable conduct. We need to make sure that those who intentionally poison the food supply will go to jail. . . . Current statutes do not provide sufficient criminal sanctions for those who violate our food safety laws with the intent to mislead or defraud. Doing so is already illegal, but it is merely a misdemeanor now, and the Sentencing Commission has found that it generally does not result in jail time.” See *Press Release of Senator Patrick Leahy*, January 27, 2011.

House Bill Would Require Labels for Foods with Nexus to Sewage Sludge

Representative José Serrano (D-N.Y.) recently introduced legislation ([H.R. 254](#)) that would amend several laws to require that consumers “receive notification regarding food products produced from crops, livestock, or poultry raised on land on which sewage sludge was applied.”

Titled “Sewage Sludge in Food Production Consumer Notification Act,” the proposal would consider food to be adulterated if it is produced on land to which sewage sludge has been applied or is derived from poultry or livestock

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raised on or fed with feed produced on such land. It provides several exceptions, including if the sewage sludge has been applied more than one year before the food was produced or if the food is appropriately labeled. The bill has been referred to the Committee on Energy and Commerce and the Committee on Agriculture.

Senators Push Legislation Banning "Frankenfish"

U.S. Senators Mark Begich (D-Alaska) and Lisa Murkowski (R-Alaska) have spearheaded a bill ([S. 230](#)) that would amend the Federal Food, Drug, and Cosmetic Act to prevent the approval of genetically engineered (GE) fish. Companion legislation ([S. 229](#)) would require labeling of any genetically engineered fish should such fish get approved.

Noting that the Food and Drug Administration (FDA) is considering a proposal by AquaBounty Technologies, Inc., to produce GE salmon as the first such food hybrid safe for human consumption, the senators reintroduced legislation they co-sponsored in the last congressional session in hopes of implementing a quick ban of GE fish.

Calling GE fish "Frankenfish" that is "risky, unprecedented and unnecessary," Begich said in a statement that such fish "threatens our wild stocks, their habitat, our food safety, and would bring economic harm to Alaska's wild salmon fishermen." Citing strong opposition to GE salmon, Begich added that "it is completely irresponsible for the FDA to even consider this action without evaluating the impacts on Alaska's fisheries. The FDA has not studied the environmental effects, let alone the economic impacts on the salmon and seafood markets that would result from approval." More details about GE salmon appear in [Issue 366](#) of this Update. See *Press Release of Senator Mark Begich*, January 31, 2011.

USDA Issues 2010 Dietary Guidelines for Americans

The U.S. Department of Agriculture (USDA) and Department of Health and Human Services (HHS) have released the [2010 Dietary Guidelines for Americans](#), "the federal government's evidence-based nutritional guidance to promote health, reduce the risk of chronic diseases, and reduce the prevalence of overweight and obesity through improved nutrition and physical activity." Published every five years, the guidelines are based on the findings of the Dietary Guidelines Advisory Committee and consideration of federal agency and public comments. The 2010 version encompasses "two overarching concepts" that tackle both obesity and poor nutritional content by urging Americans to (i) "maintain a healthy calorie balance over time to achieve and sustain a healthy weight" and (ii) "focus on consuming nutrient-dense foods and beverages."

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To this end, the current guidelines [feature](#) 23 key recommendations for the general population and six key recommendations for specific populations, as well as tips “to help consumers translate the *Dietary Guidelines* into their everyday lives.” The 23 key recommendations include advice such as (i) “reduce daily sodium intake to less than 2,500 milligrams (mg);” (ii) “consume less than 10 percent of calories from saturated fatty acids;” (iii) “consume less than 300 mg per day of dietary cholesterol;” (iv) “reduce the intake of calories from solid fats and added sugars;” (v) “limit the consumption of foods that contain refined grains;” and (vi) “increase vegetable and fruit intake.” In addition, pregnant women should “choose foods that supply heme iron” and “consume 400 mg per day of synthetic folic acid,” while those who are pregnant or breastfeeding should “take an iron supplement” and “consume 8 to 12 ounces of seafood per week” but “limit white (albacore) tuna to 6 ounces per week” and avoid tilefish, shark, swordfish, and king mackerel. Individuals ages 50 or older should also consume foods “fortified with B12,” and roughly one-half of the U.S. population—those ages 51 or older, African Americans of any age, and people with hypertension, diabetes or chronic kidney disease—should reduce sodium intake to 1,500 mg.

“The 2010 Dietary Guidelines are being released at a time when the majority of adults and one in three children is overweight or obese, and this is a crisis that we can no longer ignore,” said USDA Secretary Tom Vilsack in a January 31, 2011, press release. “These new and improved dietary recommendations give individuals the information to make thoughtful choices of healthier foods in the right portions and to complement those choices with physical activity. The bottom line is that most Americans need to trim our waistlines to reduce the risk of developing diet-related chronic disease. Improving our eating habits is not only good for every individual and family, but also for our country.”

Meanwhile, consumer groups like the Center for Science in the Public Interest (CSPI) have lauded USDA’s “[selected messages for consumers](#)” that break down the 29 key recommendations into actionable steps. These tips exhort consumers to “eat less;” “avoid oversized portions;” “make half your plate fruits and vegetables;” and “drink water instead of sugary drinks,” among other things. As CSPI Nutrition Policy Director Margo Wootan told *The New York Times*, “For them to have said ‘eat less’ is really new... Before, the dietary guidelines said, ‘Eat more fruits and vegetables,’ but that could mean add a slice of tomato to your hamburger.”

CSPI has also praised the policy implications of the 2010 Guidelines, which call for “an immediate, deliberate reduction in the sodium content of foods” and “effective policies to limit food and beverage marketing to children.” Food & Water Watch (FWW), however, drew attention to the guidelines’ failure to address genetically engineered (GE) crops and ingredients. “[T]he USDA and HHS need to take into account the evidence that the public is concerned

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about the potential health, environmental and economic threats of GE foods and they should not infiltrate our food supply,” opines a January 31 FWW press release. See *CSPI Press Release, MSNBC.com* and *The New York Times*, January 31, 2011; *Food Politics*, February 1, 2011.

Meeting Slated for Codex Committee on Fats and Oils

The U.S. Department of Agriculture, the Food and Drug Administration and the Office of the Under Secretary for Food Safety have [announced](#) a February 9, 2011, public meeting in College Park, Maryland, to provide information and receive public comments on draft U.S. positions to be discussed at the 22nd session of the Codex Committee on Fats and Oils (CCFO) on February 21-25 in Penang, Malaysia. CCFO “is responsible for elaborating worldwide standards for fats and oils of animal, vegetable, and marine origin, including margarine and olive oil.”

Agenda items include (i) “Draft Amendment to the Standard for Named Vegetable Oils; Inclusion of Palm Kernel Olein and Palm Kernel Stearin”; (ii) “Code Practice for the Storage and Transport of Edible Fats and Oils in Bulk”; (iii) “Proposed Draft Amendment to the Standard for Olive Oils and Olive Pomace Oils: Linolenic Acid Level”; (iv) “Proposal for New Work on a Standard for Fish Oils”; and (v) “Proposal to Amend the Standard for Named Vegetable Oils: Sunflower Seed Oils.” See *Federal Register*, January 28, 2011.

EPA to Declare Prions a Pest Under FIFRA

The Environmental Protection Agency (EPA) has [issued](#) a proposed rule that would declare a prion a pest under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), thereby requiring products “intended to reduce the infectivity of any prion on inanimate surfaces” to register as pesticide. According to EPA, the proposed rule would codify the agency’s current interpretation of FIFRA and implement a 2003 decision that expressly includes proteinaceous infectious particles within the regulatory definition of “pest.”

“This amendment, together with the formal declaration that a prion is a pest, will eliminate any confusion about the status of prion-related products under FIFRA,” states the proposed rule, which would direct any company seeking to sell or distribute a prion pesticide in the United States to obtain “a section 3 registration, section 24(c) registration, or a section 18 emergency exemption.” EPA will accept comments on the proposed rule until March 28, 2011. See *Federal Register* and *EPA Pesticide News Story*, January 26, 2011.

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LITIGATION**Court Issues Summary Judgment Rulings in Remanded GM Rice Contamination Suits**

A federal court in Missouri has denied in part and granted in part the summary judgment motions filed by Texas and Louisiana rice farmers as well as the company they sued in the first group of cases in this multidistrict litigation (MDL) to be remanded to their transferor courts for trial. *In re: Genetically Modified Rice Litig.*, MDL No. 1811 (U.S. Dist. Ct., E.D. Mo., E. Div., decided February 1, 2011). The litigation involves claims that conventional U.S. rice farmers sustained market losses when other countries learned that the U.S. rice supply had been contaminated with a genetically modified (GM) rice variety and then prohibited all U.S. imports. To date, the company has lost a number of bellwether trials and has entered settlements with some purportedly affected farmers.

Relying on previous dispositive rulings, the court dismissed the Louisiana plaintiffs' claims under the North Carolina Unfair Trade Practices Act and their claims for punitive damages. The court allowed both groups of plaintiffs' claims for negligence to proceed, "as well as the Texas plaintiffs' claims for punitive damages and the Louisiana plaintiffs' claims for trespass." The court further dismissed the Louisiana plaintiffs' claims for public and private nuisance, negligence *per se*, and to recover damages for mental anguish. The court also dismissed the Texas plaintiffs' claims for fraud, fraudulent non-disclosure, tortious interference with contract, and tortious interference with prospective business relations.

In addition, the court reiterated that the Plant Protection Act does not preempt plaintiffs' claims "and that the regulations do not allow for low level or adventitious presence of regulated genetically modified rice in the commercial rice supply." The court denied plaintiffs' motions to establish the defendant's liability "for the actions of its cooperators under various theories of vicarious liability," finding that genuine disputes of fact remain as to agency, joint venture and nondelegable duty liability. And the court determined that the economic loss doctrine does not apply to bar these plaintiffs' claims

The court also issued rulings on a number of the defendant's affirmative defenses, determining that it could not assert intervening and legal cause, and compliance with applicable statutes and regulations. The rulings will bind the trial courts hearing the individual claims of some two dozen Louisiana rice farmers and nearly 20 Texas farmers.

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California Plaintiff Shocked to Learn Nutella® Contains Sugar and Fat

A California resident who purportedly bought the hazelnut spread Nutella® to provide a nutritious snack or breakfast for her 4-year-old daughter has filed a putative class action against its manufacturer alleging violations of consumer protection laws. *Hohenberg v. Ferrero U.S.A., Inc.*, No. 11-0205 (U.S. Dist. Ct., S.D. Cal., filed February 1, 2011).

Seeking to represent a nationwide class of consumers who purchased the product since 2000, Athena Hohenberg claims that she relied on the company's product advertisements and representations that Nutella® is a "healthy breakfast" and "nutritious." According to the complaint, she did not learn until December 2010 "through friends what ingredients were in the Nutella® that she was feeding her family. She was shocked to learn that Nutella® was in fact not a 'healthy' 'nutritious' food but instead was the next best thing to a candy bar," containing "about 70% saturated fat and processed sugar by weight."

Characterizing herself as a "reasonably diligent consumer," Hohenberg also asserts that she "is not a nutritionist, food expert, or food scientist; she is a lay consumer who did not possess the specialized knowledge Ferrero had which otherwise would have enabled her to associate high levels of saturated fat and refined sugar with disease." She contends that even with reasonable diligence, she "could not have discovered Ferrero's deceptive practices earlier because, like nearly all consumers, she does not read scholarly publications or other materials describing the negative impact of consuming foods high in saturated fat and refined sugars."

Seeking damages in excess of \$5 million, the plaintiff alleges unlawful and fraudulent business acts or practices, false advertising, violations of the Consumer Legal Remedies Act, and breaches of express warranty and implied warranty of merchantability. She requests an order enjoining Ferrero from making health or balanced nutrition claims for the product, corrective advertising, disgorgement, the destruction of "all misleading and deceptive advertising materials and products," restitution, damages, punitive damages, costs, expenses, and attorney's fees.

CSPI Backs Suit Charging Safeway with Recall Notification Shortcomings

Montana and California residents have sued Safeway, Inc. in a California state court on behalf of a putative nationwide class of customers that the company allegedly failed to notify about tainted food recalls despite the ability to contact purchasers of contaminated products through its "club card" loyal customer program. *Hensley-Maclean v. Safeway, Inc.*, No. n/a (Cal. Super. Ct., Alameda County, filed February 2, 2011). Backed by the Center for Science in the Public Interest (CSPI), the plaintiffs allege that they purchased *Salmonella*-tainted peanut butter and egg products from the grocery and learned only

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by chance on the news or from neighbors that the products were subject to a recall.

According to the complaint, the company's club card program gives the grocery contact information for participating customers and a history of the purchases they have made. The plaintiffs allege, "Many of Safeway's competitors already use their own customer data to notify their customers of Recalled Products and to offer refunds, reducing the risk of harm to their own customers [and] all routinely issue food safety alerts directly to customers using a variety of methods."

Alleging purely economic injury, the plaintiffs contend that the company has violated the Consumers Legal Remedies Act, by selling unsafe goods while leading customers to believe they were safe for consumption and of a particular quality, and the Unfair Competition Law; they also allege breach of a duty to warn, breach of implied warranty of merchantability and unjust enrichment, denominated in the complaint as "money had and received." They seek injunctive relief requiring Safeway to post accessible warnings online and in stores and to contact each customer by any means "to advise them not to consume the product and credit the amount paid for the product if possible, or, in the case of cash purchases, offer a refund." They also seek monetary damages, statutory or punitive damages, an order for restitution and disgorgement of all profits from the sale of recalled products, costs, and attorney's fees.

OTHER DEVELOPMENTS

NYC Health Department Airs Controversial Ad Campaign

The New York City Department of Health and Mental Hygiene has announced a new advertising campaign designed "to educate New Yorkers about the potentially serious health effects of consuming sugary drinks." With the tagline "Pouring on the Pounds," the health department's latest installment features [subway advertisements](#) and a new [TV commercial](#), the latter of which has sparked debate over its allegedly graphic content, including a close-up of a diabetic's decaying toes. According to a January 31, 2011, press release, the 30-second spot aims to illustrate "how a daily routine of just a few sweetened drinks can cumulate to a whopping 93 packets of sugar by the end of the day."

"Too many sugar-sweetened drinks are fueling the obesity epidemic. Obesity and the serious health consequences that result are making hundreds of thousands of New Yorkers sick or disabled," said New York City Health Commissioner Thomas Farley. "This new campaign shows how easy it is to drink a staggering amount of sugar in one day without realizing it. We hope that

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this campaign will encourage people to make the simple switch to healthier alternatives such as water, seltzer or low-fat milk. If this campaign shifts habits even slightly, it could have real health benefits.”

MEDIA COVERAGE

Jane Brody, “Scientists See Dangers in Energy Drinks,” *The New York Times*, January 31, 2011

This article summarizes recent research, including a November 2010 literature review in *The Mayo Clinic Proceedings*, that has questioned the effectiveness and safety of energy beverages (E.B.’s). According to *Times* journalist Jane Brody, the *Mayo* study “noted that the drinks contain high levels of caffeine and warned that certain susceptible people risk dangerous, even life-threatening effects on blood pressure, heart rate and brain function.” In addition to recording “four documented cases of caffeine-associated death,” the authors also expressed concern about “whether long-term use of E.B.’s by [teens and young adults] will translate into deleterious effects later.” As one of the contributors, Troy Tuttle, reportedly said in an interview, “Almost all the studies done on energy drinks have involved small sample sizes of young, healthy individuals in whom you’re unlikely to see short-term ill effects. But what about the long term? What about liver and cardiovascular disease, insulin resistance and diabetes?”

Despite the American Beverage Association’s contention that most mainstream E.B. brands “voluntarily put statements on their containers, including advisories about use by people sensitive to caffeine,” Tuttle has urged the Food and Drug Administration to “step in and regulate this market.” His call for tighter marketing restrictions has also drawn support from health advocates who have cautioned consumers against mixing E.B.s with alcohol.

“Caffeine is being treated as a flavoring agent, not a drug,” one doctor of pharmacy was quoted as saying. He added that while the “average healthy person who consumes one serving of an energy drink is unlikely to encounter difficulty,” “toxic jocks” and those with underlying heart conditions are “most likely to get into trouble.”

Jerome Groopman, “The Peanut Puzzle,” *The New Yorker*, February 7, 2011

“People with food allergies live under a constant threat, in a society that is still poorly informed about the condition,” writes *New Yorker* medical correspondent Jerome Groopman about this rapidly evolving branch of immunology. His article traces the history of food allergy studies, which at first recommended restricting common allergens—milk, corn, soy, citrus, wheat, eggs, peanuts, and fish—during pregnancy, nursing and the first two years of life. In theory, according to Groopman, this measure would keep babies “away from

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potentially allergenic foods until their immune systems had developed sufficiently.” But the increasing number of diagnosed food allergies in the United States and other developed countries has since cast doubt on this practice, leading specialists to consider alternative causations and subsequently overturn the infant dietary advice issued in 2000 by the American Academy of Pediatrics.

“From an evolutionary-biology point of view, food allergy makes no sense at all. It seems pretty clear that food allergy is a condition that resulted from the environment we created,” Mount Sinai Professor of Pediatrics Scott Sicherer is quoted as saying. As Groopman explains, some researchers have suggested that “germ-free” environments make mice more prone to food reactions, while others have focused on how geography, diet and exposure pathways, such as skin contact or inhalation, influence allergy rates. In January 2008, Sicherer released a clinical report concluding that current evidence “does not support a major role for maternal dietary restrictions during pregnancy or lactation,” nor does it support “delaying the timing of the introduction of complementary foods beyond four to six months of age.”

In the wake of these findings, allergists have evidently turned their attention to desensitizing people or vaccinating them against food allergies in controlled experiments. In the meantime, however, restaurants and other food preparation establishments reportedly remain ill-informed about potentially life-threatening allergies. For example, a 2007 survey conducted by Sicherer apparently found that “about a quarter of managers and workers believe that consuming a small amount of the allergen would be safe; thirty-five percent believe that frying would destroy it; and a quarter thought it was safe to remove an allergen from a finished meal.” Despite these misconceptions, adds Groopman, “nearly three-quarters of food workers believed that they knew how to ‘guarantee’ a safe meal.”

SCIENTIFIC/TECHNICAL ITEMS

NRC Report Suggests Past Smoking, Obesity Behind Shorter Lifespans

The National Research Council (NRC) recently issued a report suggesting that past smoking and current obesity levels are major reasons why U.S. life expectancy at age 50, though still rising, has not kept pace with that of other high-income countries, such as Japan and Australia.

Sponsored by the National Institute on Aging’s Division of Behavioral and Social Research, the report explained that the health consequences of smoking, which 30 to 50 years ago was “much more widespread in the U.S. than in Europe or Japan,” continue to influence today’s mortality rates. It anticipated, however, that “life expectancy for men in the U.S. is likely to improve relatively rapidly in coming decades because of reductions in

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smoking in the last 20 years," while women's mortality rates "are apt to remain slow for the next decade."

The report also concluded that current obesity rates "may account for a fifth to a third of the shortfall in longevity in the U.S. compared to other nations," although "no clear-cut marker exists for obesity, physical inactivity, social integration, or other risks." Nevertheless, NRC has warned that "if the obesity trend in the U.S. continues, it may offset the longevity improvements expected from reductions in smoking." The agency has thus urged the continuation of studies "that take advantage of natural experiments, such as increased cigarette taxes or a dramatic change in the use of hormone therapy," to complement randomized controlled trials. See *The National Academies News Release*, January 25, 2011.

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Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.

