

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

CSPI Calls on Congress to Impose Soft Drink Tax as Part of Health Care Reform

The Center for Science in the Public Interest (CSPI) has [written](#) to Senate Finance Committee Chair Max Baucus (D-Mont.) requesting that the federal government "levy a tax on non-diet soft drinks to recoup some of the costs incurred by the government from the consumption of these drinks, as well as to reduce consumption."

Others signing the June 17, 2009, letter are the American Public Health Association, Consumers Union, Physician's Committee for Responsible Medicine, Kelly Brownell of the Rudd Center for Food Policy and Obesity at Yale University, and Walter Willett of the Harvard School of Public Health. Claiming that "soft drinks are the only food or beverage shown to have a direct link to obesity," CSPI contends that "a new federal excise tax of one penny per 12-ounce soda could generate more than \$1.5 billion per year" and that even higher taxes "could raise roughly \$16 billion a year—an amount that would make a serious down payment on a comprehensive health care reform bill." See *CSPI Press Release*, June 17, 2009.

EPA to Move Scientific Peer Review to Independent Panels

An Environmental Protection Agency (EPA) deputy administrator reportedly told a House science oversight subcommittee that the agency plans to rely more often on independent peer review panels when seeking scientific advice or conflict resolution. According to a news source, this could potentially speed external review of EPA studies and cut agency costs. Such review would reportedly reverse a policy under the Bush administration of automatically referring problematic scientific risk studies to the National Academy of Sciences (NAS) for peer review.

EPA Assistant Deputy Administrator for Science Kevin Teichman reportedly testified during a June 11, 2009, hearing, that the agency "very carefully consider[s] the complexity of the given assessment as to which form of peer review that we would use. More times than not, we'll convene a peer review panel, which would have a face-to-face meeting, that might go through a contractor choosing the panelists, or it might be our own Science Advisory Group." Teichman suggested that recourse to the NAS would be "rare." See *Inside EPA*, June 19, 2009.

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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FDA Announces Emergency Processing for Draft Guidance of Reportable Food Registry

The Food and Drug Administration (FDA) has [announced](#) that emergency processing is underway for the draft guidance titled "Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007." When finalized, the guidance will assist industry in complying with the Reportable Food Registry requirements prescribed by the Act, which required FDA to establish within one year of enactment an electronic portal to facilitate reporting of adulterated foods. FDA has delayed until September 8, 2009, implementation of the registry to consider comments and to allow further testing of the electronic portal for reportable foods. Written comments are requested by July 16, 2009. FDA has requested approval of the emergency processing by August 17, 2009. See *Federal Register*, June 16, 2009.

United States and Canada Reach Agreement on Organic Equivalency

The U.S. Department of Agriculture (USDA) and the Canadian Food Inspection Agency have agreed to recognize each other's organic certifications. As of June 30, 2009, Canada will have national organic standards in place that have been determined to be the equivalent of U.S. National Organic Program requirements. Thus, products meeting U.S. standards can be sold as organic in Canada, and vice versa. The only exception is for products from fields in the United States treated with sodium nitrate; such crops cannot be sold in Canada as organic. The agreement, however, does away with the need for a three-year transition period from sodium nitrate use.

According to USDA, "more than 80 percent of Canada's organic consumption comes from imports, and approximately 75 percent of those imports come from the United States." The value of the total market for organic products in Canada apparently ranges from \$2.1 to \$2.6 billion. U.S. Trade Representative Ron Kirk hailed the agreement, calling it "the first of its kind in international organics trade and a real achievement for both countries." See *USDA Press Release* and *Office of U.S. Trade Representative Press Release*, June 17, 2009.

Stakeholders Expand Parameters of American National Standard for Sustainable Agriculture

According to a report from the organization that launched the concept of a voluntary consensus standard for sustainable agriculture, nearly 50 committee members met in late May 2009 in Illinois to address issues raised by task forces considering various aspects of the proposed standard. The Leonardo Academy initiated the effort with a draft "trial-use" standard, intended to be implemented while under development, that would have imposed organic requirements and employment practices, such as union organizing and collective bargaining, on every aspect of agriculture in the United States from farm to store. Operating under the American National Standards Institute consensus and transparency principles, a number of industry interests are now involved in the process, which has apparently resulted in a change of focus.

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The standard will initially be limited to crop production and will be extended incrementally to eventually include post-farm gate activities and other agricultural production, including livestock. While sustainability remains a significant guiding principle, the standards development committee agreed that its goal would be to “develop a standard that is based on verifiable metrics and will allow for any technology that increases agricultural sustainability.” The standard’s mission will be to “encourage the widespread adoption of agricultural production and handling practices that are ecologically responsible, equitable, economically viable, science-based, meet global demand for a full range of agricultural products and ensure that future generations are able to meet their own needs.”

One committee member, representing the academic community, stated that the agreement to move forward using “any technology,” “sends a message to all segments of the agricultural community that we are not excluding any appropriate technologies from our considerations as we develop standards that will help all of agriculture become more sustainable.”

Industry representatives were reportedly encouraged by the meeting’s outcome. A spokesperson for the Western Growers was quoted as saying, “These basic guiding tenets, and the discussions leading up to the Standards Committee approval, set the stage for a modular approach to building a performance-oriented sustainability standard.” An American Soybean Association representative reportedly said, “It is encouraging to work with a diverse group of individuals that represent many sectors of agriculture to create a standard that will have a positive affect on how we produce food, feed and fiber.”

The next phase of the project will involve subcommittee work on the following focused issues: (i) developing criteria for economic, social and environmental sustainability; (ii) compiling a reference library and information; (iii) preparing a structure and process for standard development; (iv) raising funds to carry the work forward; and (v) communicating with stakeholders and the public. All interested parties may participate on the standard’s subcommittees. *See Leonardo Academy Press Release, June 5, 2009.*

European Regulators Conclude MRSA-Tainted Food Poses Little Risk

The European Food Safety Authority (EFSA), the European Center for Disease Control and Prevention (ECDC) and the European Medicines Agency (EMA) have published a joint report on methicillin-resistant *Staphylococcus aureus* (MRSA), concluding that “food-producing animals such as pigs, veal calves and broiler chickens often carry without symptoms a specific strain of MRSA called CC398.” The report apparently warns that farm workers, veterinarians and their families face the greatest risk of contracting CC398, which has been “associated, albeit rarely, with serious skin and soft tissue infections, pneumonia and blood poisoning in humans.” EFSA has noted, however, that even if food becomes tainted with MRSA, “there is currently no evidence that eating or handling contaminated food can lead to an increased risk for humans.”

The agencies have also stated that “as animal movement and contact between live animals and humans are likely to be important factors in the transmission of MRSA,

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the most effective control measures will be at farm levels." They have urged those with prolonged exposure to livestock to adopt basic hygiene measures and to limit the use of antimicrobial veterinary medicines when possible to ensure their efficacy in humans. See *EFSA Press Release*, June 16, 2009; *FoodProductionDaily.com*, June 18, 2009.

Connecticut AG Seeks Details of "Apparent Campaign" to Fight BPA Regulation

Connecticut Attorney General Richard Blumenthal has reportedly launched an investigation into chemical and packaging lobbyists who allegedly sought to thwart regulation banning the use of bisphenol A (BPA) in baby bottles, infant food jars and other products. Blumenthal is seeking details about a series of joint trade association meetings held in April and May 2009, during which industry officials purportedly discussed a public relations strategy to counter efforts to regulate BPA. According to Blumenthal, this "apparent campaign" aimed to use "fear tactics, political manipulation, and misleading marketing" to stymie BPA legislation pending in several state and local governments, including Connecticut. The attorney general has also called on the North American Metal Packaging Alliance (NAMPA) and other key stakeholders to denounce these efforts. "Colluding in a campaign of confusion and concealment – potentially endangering children and pregnant women – is appalling and possibly illegal," Blumenthal was quoted as saying. "We are demanding details about industry giants plotting to use deceptive, and possibly illegal, tactics to blur the truth about BPA dangers." See *The Connecticut Post and Courant.com*, June 15, 2009; *FoodProductionDaily.com*, June 17, 2009.

Meanwhile, The Endocrine Society issued a scientific statement concerning "endocrine-disrupting chemicals" at its 91st annual meeting, ENDO 09, held June 10-13 in Washington, D.C. The society listed BPA, phthalates, pesticides, and other chemicals as a "significant concern for public health" and urged legislators to reduce human exposure to these agents. "From chemicals in pesticides, food, plastic bottles and other items that we use every day, the concern is real," stated Endocrine Society President Robert Carey, pointing to evidence that endocrine disruptors affect "male and female reproduction, breast development and cancer, prostate cancer, neuroendocrinology, thyroid disease, metabolism and obesity, and cardiovascular endocrinology." See *The Daily Green*, June 11, 2009; *The Endocrine Society Press Release*, June 16, 2009.

In a related development, two separate animal studies presented at ENDO 09 have purportedly linked BPA to abnormal heartbeats and low fertility. University of Cincinnati (UC) researchers apparently exposed live cultures of mouse and rat cardiac cells to BPA and/or estrogen, finding that "both compounds caused striking changes in the activity of cardiac muscle cells from females but not males." Their results showed that "these cellular changes in activity caused improperly controlled beating in the female heart," stated the UC team, which noted the implications for women's health. "It's very clear that BPA is acting like estrogen," the researchers concluded. "If we give estrogen at physiological concentrations, then add BPA, it's actually a synergistic effect. It's not like adding the two together. It's worse." See *University of Cincinnati Press Release*, June 10, 2009.

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Yale University scientists also put forth research suggesting that low doses of BPA could decrease fertility in both mice and humans. Led by Professor Hugh Taylor, the group examined DNA from the offspring of mice injected with BPA during pregnancy. According to Taylor, BPA exposure *in utero* affected the genes (HOXA10) responsible for uterine development and fertility in mice and humans, altering both the DNA code and the ability of DNA to express these genes. "A little transient exposure during a brief period in pregnancy could permanently alter the DNA of the uterus," Taylor told ENDO 09 attendees. "We don't know what a safe level of BPA is, so pregnant women should avoid BPA exposure. There is nothing to lose by avoiding items made with BPA – and maybe a lot to gain." See *FoodProductionDaily.com*, June 11, 2009.

42 Nebraska Herds Quarantined over Concerns of Bovine Tuberculosis

The Nebraska Department of Agriculture has reportedly quarantined 42 herds involved in an ongoing bovine tuberculosis outbreak, which the department says may have already spread to Colorado and South Dakota because animals from quarantined herds were sold to cattle producers in those states. Transmitted through contact and respiration, bovine tuberculosis is easily transmitted within herds and in rare cases can be transmitted to humans who work directly with the animals or who consume unpasteurized milk and cheese. The U.S. Department of Agriculture (USDA) is apparently collaborating with state officials to determine the source and extent of the outbreak.

Greg Ibach, director of the Nebraska Department of Agriculture, predicts that the quarantine, which includes approximately 15,000 cattle, is likely to continue growing in the weeks ahead because investigators are still tracking down the animals that may have had contact with an infected herd over the last two years. "It's important to remember that at this time, only one herd has had animals test positive for TB," he was quoted as saying in a statement issued June 16, 2009. "We are pulling together all the resources we have at our disposal to address this situation. The beef industry is a cornerstone of our state's agricultural foundation, so we recognize the importance of handling this matter efficiently and effectively for our state and region."

In a related development, Texas officials have reportedly quarantined a West Texas dairy herd and slaughtered several cattle from the herd that tested positive for tuberculosis. They apparently have not identified the source of the disease. See *Nebraska Department of Agriculture Press Release*, June 16, 2009, *The Associated Press*, June 17, 2009.

LITIGATION

Waffle Fraud Plaintiffs File Motion to Certify Nationwide Class

Consumers who sued the company that makes Van's brand frozen waffles and a number of retailers, alleging that the calorie and nutrition information on the packaging did not accurately reflect what was in the products, have filed a motion

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to certify a nationwide class. *Hodes v. Van's Int'l Foods*, No. 09-01530 (U.S. Dist. Ct., C.D. Cal., motion filed June 15, 2009). Additional information about the complaint appears in issue 295 of this Update.

According to the motion, the defendants have filed motions to dismiss since the suit was filed in March 2009, and thus, no discovery has taken place. The named plaintiffs discuss how their complaint fulfills class certification requirements, contending that all class members were injured in the same way, that is, "they purchased Van's waffles products in the belief that the waffles had the nutritional value represented by the labeling."

The plaintiffs argue that no conflicts of laws issues arise because they are suing under California law; they cite cases that purportedly allow a nationwide class action for fraud to be maintained "where the misrepresentations at the core of the claims emanated from California." They also assert that "class members do not need to prove individual reliance on the misrepresentations for any cause of action," because claims under California's Business & Professions Code are assessed under a "reasonable consumer" standard and do not require proof that "each individual plaintiff or class member was deceived."

Should the court choose not to certify a nationwide class, the plaintiffs request, in the alternative, that the court reform the class to certify only those plaintiffs "who purchased Van's waffles in California."

New Jersey Court Finds Insurance Contract Ambiguous; Insurer Liable for Tainted Food-Related Claims

A New Jersey Superior Court judge has denied insurers' request for summary judgment in a case brought by Taco Bell Restaurant franchisees seeking "protection from the consequences of publicity about contaminated food served at restaurants." *In re: Quick Service Mgmt., Inc. v. Underwriters of Lloyds*, No. 4861-07 (N.J. Super. Ct., decided June 12, 2009). The court also granted plaintiffs' motion for partial summary judgment as to coverage.

According to the court, the franchisees specifically sought insurance in 1999 to protect against revenue losses from food contamination outbreaks. They purchased "Food Borne Illness" and "Trade Name Restoration, Loss of Business Income and Incident Response Insurance for Food Borne Illness" policies from defendants. The latter policy, which was in force in 2006-2007, apparently contained an "Aggregate Supplier Incident Sublimit" of \$0, and plaintiffs claimed that no one explained that the sublimit would exclude coverage previously provided under the former policy, which had been discontinued in 2002. "They apparently believed that the Policy would provide reimbursement for revenue losses from reports (true or not) of food borne illness arising out of their restaurant operations."

An *E. coli* outbreak in 2006 was traced to food sold at Taco Bell restaurants in the northeast, and the Centers for Disease Control and Prevention traced the source of the contamination to lettuce sold and delivered to the restaurants by other parties. Plaintiffs sought indemnification for lost income following the outbreak, and the insurers refused coverage, relying on the sublimit provision. According to

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the court, “[a]ny exclusion must be clear,” and where “an insurance policy is less than scrupulously clear, the insurer must provide coverage consistent with a reasonable interpretation of the policy.” The court determined that the franchisees were entitled to coverage under the policy because it was open to interpretation and “an average, reasonable insured would expect coverage for the Outbreak.”

Guilty Plea Entered in Melamine-Tainted Pet Food Case

The U.S. attorney for the Western District of Missouri has [announced](#) that a Nevada company and its owners entered guilty pleas in federal court “to distributing a tainted ingredient used to make pet food, which resulted in a nationwide recall of pet food and the death and serious illness of countless pets across the United States in 2007.”

Sally Qing Miller, her husband Stephen Miller and their company Chemnutra, Inc. reportedly pleaded guilty to some of the charges in a February 2008 indictment, admitting that “melamine was substituted wholly or in part for the protein requirement of the wheat gluten” they imported from China and distributed in the United States and Canada and that “the labeling of wheat gluten was false and misleading.” The Millers are apparently each subject to a sentence of up to two years in prison without parole, fines of up to \$200,000 and an order of restitution. Sentencing will occur at a later date. *See U.S. Attorney Press Release*, June 16, 2009.

OTHER DEVELOPMENTS

AMA Declines to Label Obesity a Disability

The American Medical Association (AMA) has reportedly voted against a policy that would describe obesity as a disability, citing concerns over patient care and litigation. In particular, some AMA members noted that a disability designation might curb the willingness of physicians to openly discuss weight issues with their patients. “If obesity is designated as a disability, physicians could be sued or reprimanded for discrimination under the Americans with Disabilities Act if a patient takes offense at the physician discussing obesity,” stated the resolution adopted at AMA’s recent annual meeting. *See The Associated Press* and *ABC News*, June 18, 2009.

Meanwhile, the Obesity Action Coalition (OAC) has issued a statement calling for a continued discussion around this topic, urging physicians to take a proactive approach to obesity with their patients. “The determination of obesity should be based on scientific and medical factual data and not fear of litigation,” OAC said in a June 17, 2009, press release. “Every individual who is affected by obesity is not disabled, but this does not mean that obesity does not and cannot contribute to disability. We believe that obesity should be treated like any other disease or medical condition in regard to determining disability.”

Environmentally Focused Investment Managers Publish Nano Risk Report

The Investor Environmental Health Network has issued a [report](#) urging federal regulators to change shareholder reporting requirements to close loopholes that are

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allowing corporations to use nanotechnologies without disclosing their potential long-term risks to investors. Titled "Bridging the Credibility Gap, Eight Corporate Liability Accounting Loopholes That Regulators Must Close," the report explores two case studies, asbestos and nanotechnology, to show how Securities and Exchange Commission (SEC) rules allow companies to underreport or fail to report product risks and liabilities until after they have become targets of litigation and may be on the verge of bankruptcy.

The network describes itself as an organization that encourages companies through dialogue and shareholder resolutions "to adopt policies to continually and systematically reduce and eliminate the toxic chemicals in their products." Its members and advisory panel include groups such as the As You Sow Foundation, Sierra Club Mutual Funds, Friends of the Earth, and Campaign for Safe Cosmetics.

Discussing nanotechnology, the report notes that most companies do not openly advertise that their products contain nanoparticles and contends that current annual research investment in nanotechnology exceeds \$9.6 billion worldwide with more than 2 million people working in its development, production or use. While the report discusses nanotechnology's potential benefits, it also refers to a number of studies that purportedly show adverse effects on health and the environment.

The report specifically addresses how nanotechnology is being applied in the food industry in five categories: (i) "food contact materials or coatings designed to interact with the food or environment surrounding the food"; (ii) "food ingredients processed at the nanoscale to form nanostructures or nano-textures"; (iii) "nano-sized additives and processing aids such as flavorants or colorants"; (iv) biosensor packaging utilizing nanotechnology"; and (v) "nanosized pesticides or agro-chemicals used in food production."

Among the reforms that the network advocates are requiring SEC filings to disclose trends in scientific studies that may relate to public health or environmental risks; describe measures the company is taking to prevent, reduce or mitigate potential long-term liabilities; and allow the placement of shareholder resolutions requesting disclosure of the risks of concern to investors on annual proxy ballots.

In a related development, *FoodNavigator-usa.com* recently discussed differing views over nanotechnology. The president of nanoAgri Systems, which is developing vegetable packaging with nanosilver to prevent *Salmonella*, *Listeria*, and *E. coli* contamination, reportedly said during a nanoscience conference in California that restrictive regulation could "kill" the industry. He apparently claimed that environmentalists are lobbying the Environmental Protection Agency to impose barriers on the development of nanotechnology.

A toxicologist reportedly told *FoodNavigator-USA* that the food industry's use of nanotechnology could make it "the new asbestos." According to George Burdock, manufacturers do not understand how particles change when they are used at nano-size. He is reportedly concerned that nanoparticles could cross cellular membrane barriers and create health and safety risks. Still, he believes that federal agencies have the tools they need to effectively test nano-product safety. See *FoodNavigator-USA.com*, June 16 and 17, 2009.

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SCIENTIFIC/TECHNICAL ITEMS

Neurologist Claims Farmed Fish Might Pose Risk for Mad Cow Disease

A University of Louisville neurologist has published a report questioning the safety of farmed fish that are fed cattle byproducts, which could allegedly present a risk of transmitting mad cow disease to humans. Robert P. Friedland, et al, "Bovine Spongiform Encephalopathy and Aquaculture," *Journal of Alzheimer's Disease* (June 2009). Friedland and his co-authors have urged government regulators to ban feeding cow meat or bone meal to fish until the safety of this common practice can be confirmed.

"We have not proven that it's possible for fish to transmit the disease to humans," Friedland was quoted as saying. "Still, we believe that out of reasonable caution for public health, the practice of feeding rendered cows to fish should be prohibited. Fish do very well in the seas without eating cows." Although no cases of mad cow disease have been linked to eating farmed fish, the report claims that this does not assure that feeding rendered cow parts to fish is safe. The incubation period of mad cow disease, Friedland says, "may last for decades, which makes the association between feeding practices and infection difficult."

While the risk of transmitting mad cow disease to humans who eat farmed fish appears to be low, Friedland alleges it is possible for a disease to be spread by eating a carrier that is not infected itself. He asserts that eating diseased cow parts could cause fish to experience a pathological change that allows the infection to be passed between two species.

Creutzfeldt-Jakob disease, the human form of transmissible spongiform encephalopathy, is an untreatable fatal disease that can be contracted by eating parts of an infected animal. Most countries have outlawed feeding rendered cow material to other cattle because the disease is so easily spread within the same species. In the United Kingdom, 163 people have reportedly died from eating infected beef. See *Science Daily*, June 17, 2009.

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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.

