

Food & Beverage

LITIGATION UPDATE

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Table of Contents

Legislation, Regulations and Standards

- [1] House Subcommittee Holds Hearing Targeting Food Recalls1
- [2] Consent Decree Bars Health Claims by Fruit Concentrate Suppliers2
- [3] New Jersey Considers Banning Phthalates and Bisphenol A in Kids' Products3
- [4] Maine Considers Prohibiting the Sale of Energy Drinks to Minors3

Litigation

- [5] CSPI Announces Intent to Sue over Caffeinated Alcohol Beverages3
- [6] Humane Society Challenges USDA's BSE Rule4
- [7] CSPI *Trans* Fat Claims Against Burger King Remanded to D.C. Court5

Other Developments

- [8] Scientists Develop Independent Nutritional Ratings for Food Products5

Media Coverage

- [9] U.K. Workers' Health Magazine Highlights Diacetyl Inhalation Risks6
- [10] Natalie Zmuda, "Fortified Water Has Gone to the Dogs," *Advertising Age*,
February 25, 20086

Scientific/Technical Items

- [11] Researchers Demonstrate Respiratory Injury in Diacetyl-Exposed Mice7
- [12] Pharmaceuticals and Personal Care Products Detected in Earthworms7
- [13] Study Questions Role of Salty Foods in Children's Soft Drink Consumption8

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LITIGATION UPDATE

Legislation, Regulations and Standards 110th Congress

[1] House Subcommittee Holds Hearing Targeting Food Recalls

The House Energy and Commerce Subcommittee on Oversight and Investigations this week convened a hearing to question food industry representatives, the Humane Society of the United States and other stakeholders about a recent spate of recalls affecting the food supply. The fifth in a series of similar meetings, the hearing included testimony from executives at ConAgra Foods, Inc., Bumble Bee Foods, LLC, Dole Food Co., and Butterball LLC. In particular, ConAgra CEO Gary Rodkin discussed specific measures that his company has taken to improve food safety, such as instituting a food safety advisory committee; upgrading its food testing programs; installing new processing equipment; and clarifying preparation instructions on packaged foods. Rodkin also noted that ConAgra removed diacetyl from its popcorn brands in response to public concern about the butter-flavoring's alleged effect on the respiratory system.

Several witnesses went on to testify about how the lack of federal funding has undermined efforts to bolster food safety. Dole Foods President David DeLorenzo called on the government to provide

more financing for foodborne illness research. "The fact that our industry has had recalls should not be viewed as an indication of our complacency," DeLorenzo told the lawmakers, many of whom have openly supported stricter food and agriculture regulation. Grocery Manufacturers Association Vice President Robert Brackett also spoke in support of granting the Food and Drug Administration mandatory recall authority. He further suggested that Congress and the Bush administration have failed to adequately sustain the nation's food safety infrastructure. "Because FDA food-related funding has not kept pace with inflation, more than 800 scientists, inspectors and other critical staff have been lost in the past four years," Brackett was quoted as saying. See *CNNMoney.com* and *The Wall Street Journal*, February 26, 2007; *Product Liability Law 360°* and *Omaha World-Herald*, February 27, 2008.

The subcommittee also heard from the Humane Society's Michael Greger about videotape shot by the group that allegedly shows illegal slaughtering practices at the Westland/Hallmark Meat Co. in Chino, California. The video launched the largest beef recall in U.S. history, threatening to permanently close the Westland/Hallmark facility that in 2004-2005 was named "Supplier of the Year" for the federal school lunch program. Lawmakers, however, criticized the Human Society for failing to notify the U.S. Department of Agriculture about the violations. USDA Secretary Ed Schafer reportedly complained that "for four months, theoretically, animals were not being properly treated, and the Humane Society



stood by and allowed it to happen.” Contending that federal prosecutors requested the delay to conduct their own investigation, the Human Society also hinted at forthcoming exposés against other meat processors and declined to identify their undercover videographer. See *Meatingplace.com*, February 25, 2008; *National Journal’s CongressDailyPM*, *Humane Society Press Release* and *Meatingplace.com*, February 26, 2008; *The New York Times*, February 27, 2008.

In addition, plaintiffs’ lawyer Bill Marler testified before both the House subcommittee and the California Senate, which is conducting an inquiry into events at Westland/Hallmark. The California Senate Select Committee on Foodborne Illness will apparently interview the California Department of Public Health and the California Department of Food and Agriculture, as well as explore several state-based initiatives to close loopholes in the federal food safety system. California Senator Dean Florez has advocated that the state health and agriculture departments install cameras at slaughterhouses, and called on the governor to reimburse school districts using Westland/Hallmark funds. Marler specifically proposed that state and federal officials: (i) “create a local, state and national public health system that catches outbreaks before they balloon into personal and business catastrophe;” (ii) “actually inspect and sample food before it is consumed;” (iii) “consider mandatory recall authority on all food products;” (iv) “merge and then adequately fund the three federal agencies responsible for food safety;” and (v) “invest in solid research . . . to help producers manufacturer food that is safe, nutritious and the envy of the world.”

In his testimony before Congress, however, Marler apparently questioned the effectiveness and necessity of the Westland/Hallmark recall. “Although

stunned by the video . . . I am more stunned that the recall has ballooned to 143 million pounds of meat and is quickly encompassing products that might contain trace amounts of the meat. No people have been sickened. I wonder if resources are better spent elsewhere,” Marler was quoted as saying. Two major food companies this week recalled processed food products after learning that some suppliers used Westland/Hallmark beef. See *Marler Blog*, February 25, 2008; *Meatingplace.com*, February 26, 2008; *The Wall Street Journal*, February 27, 2008.

Food and Drug Administration (FDA)

[2] Consent Decree Bars Health Claims by Fruit Concentrate Suppliers

A federal court in Michigan has approved a consent decree between the FDA and two companies that apparently made unauthorized health claims including that their cherry-derived products “may help fight diabetes.” According to FDA, Brownwood Acres Foods Inc. and Cherry Capital Services Inc. (dba Flavonoid Sciences) agreed to remove unauthorized health claims from their product labels, brochures and Web sites. They will also cease linking to other Web sites containing such claims and will hire independent experts to review their product claims and certify that all violative claims have been omitted. The companies, which make and distribute an array of products such as juice concentrates, soft fruit gel capsules, fruit bars, dried fruits, liquid glucosamine, and salmon oil capsules, will have to pay \$1,000 per violation per day if they run afoul of the consent decree in the future. See *FDA News*, February 22, 2008.



State and Local Governments

[3] New Jersey Considers Banning Phthalates and Bisphenol A in Kids' Products

A [bill](#) (A2332) has been introduced in New Jersey's Assembly to make it unlawful for anyone in the state to sell or manufacture products, intended for use by children, containing phthalates or bisphenol A. Introduced February 26, 2008, by Assemblywoman Linda Greenstein (D-Mercer and Middlesex), the "Toxic-free Children's Products Act" sets forth findings that these substances are found in "virtually everyone," they may pose a health hazard, and they are used in a variety of plastics like reusable plastic storage containers and baby bottles. A state senator from Bergen County is reportedly expected to introduce companion legislation in the next week. According to a news source, similar bills that would prohibit one or both substances are pending in Connecticut, New York, Pennsylvania, Maryland, Maine, and Minnesota. *See Star-Ledger*, February 26, 2008.

In a related development, the British Food Standards Agency (FSA) has reportedly begun working with food and beverage manufacturers to ensure they will be able to comply with the phthalate specifications in EU directives (2002/72/EC, modified by 2007/19/EC) applicable to plastic food packaging. As a first step, manufacturers must indicate their awareness of EU compliance deadlines to FSA by March 21. *See Foodproductiondaily.com*, February 26, 2008.

[4] Maine Considers Prohibiting the Sale of Energy Drinks to Minors

The Maine Legislature is reportedly considering a bill ([LD 2034](#)) to prohibit the sale of some energy

beverages to minors younger than age 18. The legislature held a public hearing this week before the state Health and Human Services Committee to debate the terms of the bill, which would require proof of age to purchase energy drinks containing 80 or more milligrams of caffeine per 8 fluid ounces. At least 40 beverage brands would fall into this category, although some Maine residents apparently questioned the difference between regular coffee and other caffeinated beverages. While the bill's sponsor, Representative Troy Jackson (D-Allagash), reportedly contended that energy drinks are more dangerous because they are being "funneled" by minors, one store owner noted that most sales were to men between the ages of 20 and 30. "I don't have kids lining up to buy energy drinks," said one market owner from North Berwick. "And we don't see kids pounding 12 of them." The store owner also pointed to the difficulty in policing the proposed regulation, suggesting that a schoolwide ban on soft drinks and energy beverages would better serve the community. *See Fosters.com*, February 23, 2008.

Litigation

[5] CSPI Announces Intent to Sue over Caffeinated Alcohol Beverages

The Center for Science in the Public Interest (CSPI) has reportedly served several brewing companies with [notices](#) that it intends to sue them for selling beer with "stimulant additives" including caffeine, taurine, ginseng, or guarana.

Characterizing such beverages as "alcospeed," CSPI claims that these are "adulterated products" and alleges that the companies engage in acts and practices that are unfair and deceptive as to the products' marketing and sale. The group contends



that consumption of such beverages leads to risky behavior and cites a study showing that college students “who drank alcohol mixed with energy drinks were more likely to experience alcohol-related consequences than were those students who drank only alcohol.” According to CSPI, the additives have neither been approved for use in alcoholic beverages nor “generally recognized as safe for use in alcoholic beverages.” In its February 28, 2008, letters, CSPI demands the entry of a permanent injunction prohibiting the companies from making or selling alcoholic beverages with stimulant ingredients and the disgorgement of profits from the sale of such beverages from the time they were introduced “into a *cy pres* fund to be used for charitable purposes.” CSPI’s “settlement offer” is open for 30 days. *See CSPI Press Release*, February 28, 2008.

[6] **Humane Society Challenges USDA’s BSE Rule**

The Humane Society of the United States has filed a lawsuit against the U.S. Department of Agriculture (USDA) calling for a court order to “close a dangerous loophole in the agency’s regulations that contributed to the recent recall of more than 143 million pounds of beef – much of which was fed to schoolchildren in at least 40 states and the District of Columbia.” [*The Humane Society of the U.S. v. Schafer, No. 1:08-cv-00337 \(U.S. Dist. Ct., D.C., filed February 27, 2008\)*](#). The society seeks a declaration that the agency’s final rule on the use of non-ambulatory cattle in the food supply is arbitrary and capricious, a remand for a new rule-making and a permanent injunction to stop the agency “from allowing downed cattle to be slaughtered for human consumption.”

According to the complaint, the USDA adopted an

interim rule in 2004 requiring that all non-ambulatory disabled cattle presented for slaughter be condemned. Such cattle, also referred to as “downed” or “downer” cattle, pose a risk of bovine spongiform encephalopathy (BSE) infection which can be passed to humans who consume their meat. In humans, the disease is “invariably fatal” and has no known cure. The interim rule was adopted after BSE-infected cattle were discovered in the United States. The Humane Society alleges that the agency then issued a “Final Rule,” which “quietly reversed course” and amended the interim rule to “permit some downed cattle to be slaughtered for human consumption” by providing, in relevant part, “FSIS [Food Safety and Inspection Service] personnel will determine the disposition of the cattle that become non-ambulatory after they have passed ante-mortem inspection on a case-by-case basis.” Further details about the USDA’s final BSE rule appear in issue 223 of this Update, July 20, 2007.

The complaint further states, “The extreme danger associated with the Final Rule’s failure to prohibit all downed cattle from being slaughtered for consumption is confirmed by [plaintiff’s] recent investigation of the federally inspected Hallmark/Westland slaughtering establishment, and the resulting recall of millions of pounds of potentially tainted ground beef.” Characterizing the interim rule’s amendment as a “regulatory loophole,” the Humane Society alleges that “the meat industry has an economic incentive to use whatever means it deems are necessary to force downed cattle to stand and walk, even if only for the brief period of time necessary to slaughter them for human consumption.” According to the complaint, the incubation period for BSE in humans “can be long” and thus, “the full impact that the consumption of Hallmark/Westland beef has had on



consumers, including Plaintiffs members' children in the National School Lunch Program, may not be known for many years."

The Humane Society claims that USDA violated the Administrative Procedure Act by changing its rule "without providing adequate advance public notice and an advance opportunity to comment on this new loophole," and by acting "arbitrarily and capriciously and not in accordance with law." While the final rule that the USDA published in July 2007 contained commentary that appeared to "continue the complete prohibition on slaughtering downed cattle for human consumption, the binding portions of the Final Rule do not," according to the complaint. A representative of the American Meat Institute reportedly said that the interim rule imposed too broad a ban because it included cattle that became disabled due to a physical injury, such as a broken leg, after inspection. The institute and other industry groups were apparently among those seeking the rule's amendment. *See Humane Society Press Release*, February 27, 2008; *The New York Times*, February 28, 2008.

[7] CSPI *Trans* Fat Claims Against Burger King Remanded to D.C. Court

A federal court has remanded claims filed by the Center for Science in the Public Interest (CSPI) against Burger King Corp. to a D.C. superior court and rejected as moot the fast-food company's attempt to dismiss the lawsuit. [*CSPI v. Burger King Corp., No. 07-1092 \(U.S. Dist. Ct., case remanded on February 19, 2008\)*](#). The complaint, which was filed in May 2007 and removed by Burger King to federal court, alleges that the company's continuing use of *trans* fats in its French fries, baked goods and other foods violates D.C. consumer protection laws. Further details about the

litigation appear in issue 215 of this Update, May 18, 2007.

Noting that the jurisdiction of federal courts is limited to "cases" and "controversies," U.S. District Judge Richard Leon determined that CSPI lacked standing to sue in federal court because neither it nor its members have suffered "an actionable injury-in-fact." CSPI's complaint does not allege any personal or economic injury. Because the plaintiff lacked standing to pursue a "general grievance" in federal court, the court ruled that it lacked jurisdiction to address Burger King's arguments over the merits of the litigation. Burger King had argued that the court should dismiss the suit because it would be dismissed on remand for the same reason, i.e., lack of standing. According to the court, the courts in the D.C. Circuit have not recognized a "futility exception" that would allow it to rule on the merits in the absence of subject-matter jurisdiction, thus, "remand, not dismissal, is the appropriate course of action here."

CSPI contends that some of Burger King's fare is "alarmingly high in *trans* fat," with an order of Chicken Tenders and fries containing some 8 grams "of the harmful fat." CSPI seeks an injunction to either stop the company from using *trans* fats or requiring prominent warnings. *See CSPI Press Release*, February 25, 2008.

Other Developments

[8] Scientists Develop Independent Nutritional Ratings for Food Products

Several food producers, retailers and research groups have developed independent "nutritional profiling" systems to help consumers synthesize the complex calorie, fat, fiber, and sugar information



found on food labels, according to a recent *Washington Post* article, which describes multiple approaches that use complicated algorithms “to allocate simple scores to foods.” The Nutrient Rich Foods Coalition, for example, has reportedly pioneered a system that ranks foods not just by nutrient content, but also by serving size and cost; while the scientists with the Yale-Griffin Prevention Research Center have created the Overall Nutritional Quality Index (ONQI) to give food items a score ranging from 1 to 100. In addition, Hannaford Bros. Co. in 2006 introduced the “Guiding Stars” program in all of its New England supermarkets. Designed by researchers from Tufts University, Dartmouth Medical School, the University of North Carolina, the University of California at Davis, and Harvard University, the “Guiding Stars” system gives foods one star for good nutritional value, two stars for better nutritional value and three stars for best nutritional value. Hannaford has reported that since the program took effect, “sales of packaged foods with stars rose 2.5 times more than those without the icon.” “This is just the opening of the door,” said Adam Drewnowski, the head of the Nutrient Rich Food Coalition, in imagining a day when hand-held PDAs or “smart” shopping carts could do the work of such labeling systems. *See The Washington Post*, February 26, 2008.

Media Coverage

[9] U.K. Workers’ Health Magazine Highlights Diacetyl Inhalation Risks

An article appearing in “an independent, union-friendly” publication focuses on the diagnosis in North Yorkshire of a flavorings company worker with bronchiolitis obliterans. Apparently, while

“popcorn lung” has been an issue among workers in the United States for some 10 years, health authorities in the United Kingdom and European Union have yet to address the matter. According to the article, titled “Food Flavouring Wrecked My Lungs,” authorities outside the United States do not know what foods contain the flavoring, and exposed workers with respiratory problems are reportedly “misdiagnosed” with chronic obstructive pulmonary disease. This apparently occurred in the Netherlands, where four “severe cases of bronchiolitis obliterans” were identified through a study conducted after a factory had closed. *See Hazards Magazine*, January-March 2008.

[10] Natalie Zmuda, “Fortified Water Has Gone to the Dogs,” *Advertising Age*, February 25, 2008

“According to *Beverage Marketing*, the value-added water category has grown to wholesale sales of \$1.4 billion in 2006 . . . from \$114 million in 2001,” writes Natalie Zmuda in this *Advertising Age* article tracking the exponential growth of the “‘enhanced’ water” market. Zmuda notes that niche brands are breaking into pet and kid sales with products such as FortiFido™ and Bot™ Beverages, the latter of which targets the “tots to tweens” age group, while the former is described by manufacturer Cott Corp. as the “first-ever fortified water for pets with real functional benefits.” Cott Corp. reportedly spent \$80,000 and 18 months developing its product in flavors such as spearmint, parsley and peanut butter, but Zmuda suggests that the concept is not all that far-fetched. As sales from carbonated beverages begin to stagnate, companies are seeking to diversify their portfolios and leverage their existing facilities and assets, according to Zmuda. She further argues that “for those who



would snicker at the idea of a major beverage company moving into the pet category,” Cott Corp. predicts that FortiFido™ will become a “significant contributor both in terms of volume and profit.”

Scientific/Technical Items

[11] Researchers Demonstrate Respiratory Injury in Diacetyl-Exposed Mice

North Carolina researchers who exposed laboratory mice to inhaled diacetyl at several concentrations and durations, or by direct oropharyngeal aspiration, have reportedly concluded that it can cause “significant epithelial injury, peribronchial lymphocytic inflammation, or fibrohistiocytic lesions in the terminal bronchioles,” depending on the route and duration of exposure. [Daniel L. Morgan, et al., “Respiratory Toxicity of Diacetyl in C57BL/6 Mice.” *Journal of the Society of Toxicology* \(forthcoming 2008\).](#) According to the researchers, exposures were designed to replicate the types of acute and chronic exposures that workers in microwave popcorn and flavorings manufacturing facilities experience. They estimated a “maximum tolerated dose” (six-hour daily exposures) for mice of between 50 and 100 ppm. Exposures to diacetyl concentrations in excess of 100 ppm “resulted in morbidity and mortality.” The article concludes, “these results indicate that relevant diacetyl exposures result in a pattern of injury that replicates features of human OB [obliterative bronchiolitis].”

[12] Pharmaceuticals and Personal Care Products Detected in Earthworms

A recent [study](#) claims that pharmaceuticals and personal care products (PPCPs) left over from wastewater treatment processes are ending up in

biosolids used as fertilizer for both industrial and small-scale agriculture. Chad A. Kinney, et al., “Bioaccumulation of Pharmaceuticals and Other Anthropogenic Waste Indicators in Earthworms from Agricultural Soil Amended with Biosolid or Swine Manure,” *Environmental Science & Technology*, February 2008. Researchers from Colorado State University at Pueblo and the U.S. Geological Survey reportedly collected earthworms and soil samples from “three sites several times during a growing season: a soybean field amended biosolids (which were not tilled into the soil) from a wastewater treatment plant, a corn field treated with swine manure that was tilled into the soil, and a soybean field not amended with biosolids or manure.” Earthworms from both the biosolid- and manure-treated fields contained high levels of PPCPs in their tissue, where some chemicals accumulated in concentrations “several orders of magnitude higher” when compared to the soil samples. The scientists also found varying concentrations of wood preservatives and PAHs in the amended fields, noting that triclosan (an antimicrobial used in soaps) and the synthetic musks galaxolide and tonalide occurred at “surprisingly high levels.” These latter chemicals also appeared at high concentrations in the untreated field, which was intended as a control site.

The study results have apparently raised questions in the scientific community about the potential for PPCPs to enter the food chain. In addition, at least one researcher unaffiliated with the study has pointed to the possibility of using earthworms to monitor soil contamination. Because the worms appear to concentrate compounds that may be undetectable in the soil, they can be “a sort of sentinel, or magnifying glass of what’s in the soil,” Stockholm University’s Cynthia De Wit was quoted



as saying. See *Environmental Science & Technology Online News* and *U.S. Geological Survey Office of Communication News Release*, February 20, 2008.

[13] Study Questions Role of Salty Foods in Children's Soft Drink Consumption

A recent U.K. study claims that children who consume salty foods also increase their intake of sugar-sweetened soft drinks, thus compounding the risk factors for childhood obesity. Feng J. He, et al., "Salt Intake Is Related to Soft Drink Consumption in Children and Adolescents," *Hypertension*, March 2008. Researchers assessed a cross-section of 1,688 participants, ages 4 to 18, enrolled in the National Diet and Nutrition Survey, finding that "salt is a major determinant of fluid and sugar-sweetened soft consumption during childhood. The study speculates that "[i]f salt intake in children in the United Kingdom was reduced by half (mean decrease: 3 g/d), there would be an average reduction of [approximately] 2.3 sugar-sweetened soft drinks per week per child." In addition, the researchers conclude, "[a] reduction in salt intake could, therefore, play a role in helping to reduce childhood obesity through its effect on sugar-sweetened soft drink consumption."



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