Shook, Hardy & Bacon L.L.P.

ISSUE 460 | NOVEMBER 2, 2012

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Senators Continue to Push FDA on Energy Drinks

U.S. Senators Richard Durbin (D-Ill.) and Richard Blumenthal (D-Conn.) have for the third time this year challenged the Food and Drug Administration (FDA) "to take immediate action" to address public concerns about energy drinks. In their October 26, 2012, **letter** to FDA, the senators write that they are "extremely concerned by reports of five deaths following the consumption of Monster energy drinks and a recent study showing that many energy drinks labels do not provide caffeine information to consumers."

Durbin and Blumenthal's letter refers to a new **study** issued by Consumer Reports allegedly revealing that five of the 27 top-selling energy drinks contain caffeine at levels at least 20-percent above the listed amounts, with 11 beverages failing to specify caffeine content altogether. "We do not know enough about the effect of caffeine on children and young adults, yet energy drinks are marketed directly to kids without the oversight that beverages like soda face," conclude the senators. "The FDA needs to do more to investigate the impact of energy drinks and identify the loopholes that allow this deception to continue." Additional information about FDA's response appears in Issues **453** and **459** of this *Update*.

GAO Urges FDA to Leverage Other Countries' Oversight Resources

The Government Accountability Office (GAO) has issued a **report** recommending that the Food and Drug Administration (FDA) revise its approach when comparing foreign food safety systems with the U.S. system to better ensure the safety of imported food. Under the FDA Food Safety Modernization Act, FDA's enhanced oversight of food imports includes express authority to implement a system for accrediting third parties like foreign governments and private auditing firms to certify foreign food facilities' compliance with U.S. food safety requirements. The agency has apparently faced some challenges doing so.

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

According to GAO, FDA has already started assessing selected foreign food safety systems to determine if they provide the same level of public health protection as domestic resources. But FDA has also stated "that it needs new approaches to improve its oversight of imported food that take into account the entire food supply chain and that it needs to push prevention of food safety risks offshore and leverage the efforts of others to avoid duplication and better target its food safety efforts."

Since 1998, GAO has reported on the need for FDA to enhance its oversight of imported food products, including seafood, and has recommended that FDA use the tools available to it, such as equivalence, to leverage the resources of foreign countries to ensure exports meet U.S. requirements. "To better leverage the oversight resources of foreign countries and ensure the safety of food imports, the Secretary of Health and Human Services should direct the Commissioner of FDA to revise FDA's comparability approach to one that allows for the flexibility of assessing foreign food safety systems for particular food products, such as seafood, when a full comparability assessment of foreign countries' food safety systems may not be feasible," the GAO report concludes.

EFSA Holds BPA Consultation; UK Health Group Advocates BPA Ban

The European Food Safety Authority (EFSA) recently held a one-day meeting with scientific experts, member states and other Advisory Forum participants "to exchange each other's previous or ongoing work related to the safety assessment of bisphenol A (BPA)." Part of the agency's continuing BPA evaluation, the meeting covered previous risk appraisals and outlined EFSA's "developing approach" to the next opinion scheduled for completion in May 2013. It also featured members of other EFSA committees who discussed BPA safety assessments undertaken for medical devices and industrial chemicals, as well as experts from individual countries who described their work in the following areas: (i) "human exposure to BPA"; (ii) "current levels of BPA in food and other sources"; (iii) "analytical methods"; (iv) "non-dietary sources of exposure to BPA"; and (v) "recent studies on the toxicity of BPA, including those related to reported low dose effects of BPA."

According to EFSA, the agency decided to review its BPA data after taking into consideration new information about overall exposure to the substance from both dietary and non-dietary sources. "EFSA's new opinion will also further evaluate uncertainties about the possible relevance to human health of some BPA-related effects observed in rodents at lose dose levels," states an October 29, 2012, news release, which notes that EFSA plans on issuing a full report on the meeting in the near future. Additional details about the ongoing risk assessment appear in Issue **440** of this *Update*.

Meanwhile, Breast Cancer UK has apparently used the occasion of the meeting to call for BPA's removal from all food and beverage packaging. The group has launched a petition requesting support for its effort, which urges the U.K. government to act without waiting for the results of EFSA's data collection. "A Government ban on Bisphenol A in food and drinks packaging could help to reduce our daily exposure to this hormone-disrupting chemical, which could be at the bottom of why breast cancer is fast becoming an epidemic," Breast Cancer UK Chair Clare Dimmer told reporters. "The Government must acknowledge all causes of breast cancer and cut cancer-causing chemicals." *See The Independent*, October 30, 2012.

Australian Agency Calls for Nanotubes to Be Classified as Hazardous

Safe Work Australia, a government agency lacking regulatory authority, has recommended that multi-walled and single-walled carbon nanotubes be classified as hazardous unless they can be shown, on a case-by-case basis with toxicological or other data, to merit a different classification. The agency recently released a **report** titled "Human Health Hazard Assessment and Classification of Carbon Nanotubes," which concludes that the recommended classification is supported by the available evidence. Specifically, Safe Work Australia, seeks the classification "Harmful: Danger of serious damage to health by prolonged exposure through inhalation."

LITIGATION

Court Dismisses Claims That Food Supplements Contain Undisclosed Pork Byproducts

A federal court in Illinois has dismissed a putative class action filed against a nutritional supplement company by a Muslim woman who alleged that the company misled consumers by failing to disclose that some of its products contain an animal-based product. *Lateef v. Pharmavite LLC*, No. 12C5611 (U.S. Dist. Ct., N.D. Ill., E. Div., decided October 24, 2012). The court found the consumer-fraud claim preempted and determined that the named plaintiff lacked standing to rely on allegations relating to the company's Web-based advertising because she did not visit the Website before purchasing the product. The plaintiff also abandoned her federal law-based claim.

According to the court, the plaintiff has dietary restrictions that prohibit her from eating certain animal-based food products such as pork. She allegedly purchased the defendant's Nature Made® Vitamin D tablets after carefully reading the product label to ensure it did not contain animal byproducts. Her complaint alleges that the tablets were coated with gelatin, which "is manufactured in part with extracts from animal byproducts: specifically from cattle, chicken, and pigs." The plaintiff quoted statements from the

company's Website indicating that "what is on the label is in the bottle" and other purported indicia of trustworthiness. She alleged violation of the state's consumer fraud statute, breach of express warranty, unjust enrichment, and violation of the Magnuson-Moss Warranty Act.

The defendant argued that federal law exempts it from listing gelatin as an ingredient on its labels because the law exempts the labeling of "incidental additives," extracts from food sources that have "no technical or functional effect," and are present at "insignificant levels." The plaintiff evidently agreed that her labeling claims are preempted but contended that she "seeks only to enjoin Pharmavite 'from falsely advertising that consumers can trust that [Pharmavite] identifies every ingredient on a Supplement's label.'" The court disagreed, finding that the focus of her complaint was the product label, and since she admitted that her label-related claims were preempted, the court dismissed the consumer-fraud claim. The remaining state law-based claims were dismissed for lack of standing.

ADA Class Settlement Will Require Burger King to Make Restaurants Accessible

A federal court in California has approved the settlement of class claims that will require Burger King Corp. to remove barriers to wheelchair and scooter access at more than 75 of the restaurants it leases to franchisees in the state and pay $19 million to the settlement class. *Vallabhapuapu v. Burger King Corp.*, No. C 11-00667 WHA (U.S. Dist. Ct., N.D. Cal., decided October 29, 2012). This is the second settlement of Americans with Disabilities Act claims against the company; the first involved 10 certified classes and 10 alleged non-compliant restaurants in California.

Each individual who files a claim by November 15, 2012, will take a pro rata share of the settlement for up to six visits to a Burger King restaurant "where he or she encountered a barrier to access." As of mid-October, 620 claims had been filed with an average recovery expected to be nearly $5,000 per store visit, based on an adjusted store-visit count (including the six-visit limit). The court found the agreement fair, reasonable and adequate, and also approved $4.8 million in attorney's fees and litigation costs.

ABC News Seeks to Dismiss $1.2 Billion "Pink Slime" Lawsuit

After removing to federal court a defamation lawsuit brought by the company that makes lean finely textured beef (LFBT), ABC News has reportedly filed a motion to dismiss claiming that its news stories referring to the product as "pink slime" are protected speech under the First Amendment. *Beef Products, Inc. v. Am. Broadcasting Cos., Inc.*, No. 2012cv04183 (U.S. Dist. Ct., D.S.D., filed October 24, 2012). Additional information about the lawsuit appears in Issue 453 of this *Update*. According to the news company's motion, "Pink slime is exactly the sort of 'loose, figurative, or hyperbolic language' that courts recognize demands protection under the First Amendment." ABC reportedly contends that the lawsuit challenges the rights of news organizations to "explore matters of obvious public interest—what is in the food we eat and how that food is labeled." *See Reuters*, October 31, 2012.

Court Says Only Chemicals Known to Cause Cancer May Be Added to Prop. 65 List

A California appeals court has determined that the Office of Environmental Health Hazard Assessment (OEHHA) may not add styrene or vinyl acetate to the Proposition 65 (Prop. 65) list of chemicals known to the state to cause cancer because they have been identified as "possible" but not known carcinogens. *Styrene Info. & Research Ctr. v. OEHHA*, No. C064301 (Cal. Ct. App., 3d Dist., decided October 31, 2012). Styrene is used in food packaging.

The International Agency for Research on Cancer (IARC) had categorized the substances as Group 2b chemicals, which are "possibly" carcinogenic to humans, based on less than sufficient evidence of carcinogenicity in experimental animals. The court acknowledged that the California Health and Safety Code requires that the Prop. 65 list contain "at a minimum, the substances identified by reference in Labor Code section 6382, subdivision (d)," which addresses "hazardous substances" that extend "beyond those that cause cancer or reproductive toxicity." And it was on this basis that OEHHA announced its intent to list the chemicals. Noting that this Labor Code reference "must be read in conjunction with the prior language requiring the Governor to publish a list of chemicals known to the state to cause cancer or reproductive toxicity," the court ruled that chemicals included in a 2b IARC listing "may not qualify for Proposition 65 listing on that basis alone."

The court expressly accorded OEHHA's interpretation of Prop. 65 "little or no deference." According to the court, OEHHA did not use the Labor Code method for listing chemicals in the first 15 years after Prop. 65's enactment. "This has been OEHHA's practice only during the last 10 years or so. '[A]n agency's vacillating practice—i.e., adopting a new interpretation that contradicts a prior interpretation—is entitled to little or no weight.' And OEHHA has not adopted any formal regulations to this effect." The court also noted that administrative agencies may not "alter or amend" a statute or "enlarge or impair its scope."

Thus the court concluded, "the Proposition 65 list is limited to chemicals for which it has been determined, either by OEHHA through one of the methods described in section 25249.8, subdivision (b), or through the Labor Code method of adopting findings from authoritative sources, that the chemical is known to cause cancer or reproductive toxicity." Finding no other basis in the record for listing the chemicals, the court affirmed a trial court decision granting the trade group and chemical manufacturer's motion for judgment on the pleadings.

LEGAL LITERATURE

FTC Accepts FDA-Compliant Advertising for Foods

University of Wyoming College of Law Professor Mary Dee Pridgen has updated a treatise titled *Consumer Protection and the Law* to reflect recent developments in Federal Trade Commission (FTC) enforcement of its 1995 policy statement on food advertising. As she notes, although FTC and the Food and Drug Administration (FDA) have overlapping authority to police food advertising claims, they have generally divided their duties with FDA concentrating on food labels and FTC addressing advertising claims. FTC indicates in the policy statement that it will give advertisers "a bit more leeway in advertising than the FDA allows on labels," but if an advertising claim complies with FDA labeling regulations, it will "generally be safe from FTC scrutiny."

Pridgen discusses FTC enforcement actions since the mid-1990s, involving Stouffer Foods, Haagen-Dazs, the Isaly Klondike Co., Mrs. Fields Cookies, Dannon, Gerber, and Kellogg, as well as companies that sell dietary supplements. She concludes, "In reported settlements that have come out since the Food Advertising Statement, the FTC continues to provide a safe haven for advertisers to make claims that *do* comport with FDA label requirements."

OTHER DEVELOPMENTS

U.S. Food Industry Highly Consolidated, Says Food & Water Watch

Food & Water Watch has issued a **report** detailing how the consolidation of business along the entire food chain has resulted in farm losses, layoffs and higher prices with fewer choices for consumers. Titled "The Economic Cost of Food Monopolies," the report discusses the effects of consolidation in Iowa's hog sector, New York's dairy industry, Maryland's poultry production, the organic soybean market, and California's processed fruit and vegetable industry.

According to the advocacy organization, "The agriculture and food sector is unusually concentrated, with just a few companies dominating the market in each link of the food chain." The pace of consolidation is attributed, particularly in the produce sector, to international trade agreements, such as the North American Free Trade Agreement, that by facilitating "lower U.S. tariffs, combined with loosened investment rules for U.S. companies operating in other countries, encouraged U.S. food processing companies to invest in factories overseas and shutter plants in the United States."

Contending that the Department of Justice and U.S. Department of Agriculture have taken a hands-off approach to consolidation in the food system, Food & Water Watch calls for new rules that would (i) collect and report information about food-chain concentration, (ii) coordinate a competition and antitrust policy for the agribusiness sector from farm to fork, (iii) remedy and prevent distortions in hog and cattle markets, and (iv) prevent unfair and deceptive practices in agricultural contracting. Executive Director Wenonah Hauter said, "The consolidation of the food and farm sector is sucking the economic vitality out of rural America and shipping it off to Wall Street. These findings shine a much-needed light on the negative economic impact that farm and agribusiness monopolies have on farmers, consumers, and rural communities." *See Food & Water Watch News Release*, November 2, 2012.

Critics Sour on USDA's Latest Sugar Consumption Data

Nutritionists and consumer groups have reportedly criticized the U.S. Department of Agriculture (USDA) for reducing its per capita sugar consumption estimate from approximately 100 pounds per year to 76.7 pounds per year. According to an October 26, 2012, *New York Times* article, Center for Science in the Public Interest (CPSI) Executive Director Michael Jacobson "stumbled across" the agency's latest assessment "while working on a project on sugar consumption." Lowering the previous benchmark by 20 percent, the revised numbers apparently raised red flags with Jacobson, who suggested that the methodology used by USDA researchers was "built on a foundation of sand."

"The new estimate is still relying heavily on experts making what seem to me to be largely guesses," he told *Times* reporter Stephanie Strom. "Other than the 4 percent they're getting [from the National Health and Nutrition Examination Survey], what do they really know for certain?"

In particular, Strom questioned the sugar sector's hold on USDA policy, citing emails obtained by CSPI through a Freedom of Information request in which industry representatives allegedly "discussed the benefits of the lower estimate and how they might persuade the USDA to make a change that would reduce it even more." But the scientists responsible for the data have since countered that the numbers reflect an agency-wide effort to better account for "consumer-level food-loss estimates," which aim to capture "how much of various sweetener-laden foods that consumers buy is actually eaten, versus how much is thrown away."

Meanwhile, New York University Nutrition Professor Marion Nestle has faulted USDA for failing to adequately track sugar consumption trends over time. "Food availability figures also indicate declines, but suggest that Americans have access to about 65 pounds a year each of table sugar and corn syrup for more than 130 pounds per year total," writes Nestle on her *Food Politics* blog, pointing to recent reports issued by USDA's Economic Research Service. "None of these figures is precise. But if the methods for calculation are the same every year, trends should be discernible. Adjusting for waste introduces new sources of error and makes trends impossible to determine." *See Food Politics,* October 30, 2012.

Wealthy Plaintiffs' Tobacco Lawyer Ready to Pursue Food Companies

According to Hank Campbell, writing for *Science 2.0*, lawyers who made their fortunes suing cigarette manufacturers are now prepared to replace "Big Tobacco" with "Big Food." "Not because they have done anything wrong, but rather because we live in a culture where a dizzying cross-section of people assume anyone working for a corporation must be unethical. And creating nuisance laws that make it possible to sue over labels without actually having any evidence of harm are a dream for litigation attorneys," says Campbell. He suggests that the passage in California of Proposition 37 (Prop. 37), which will require foods containing genetically modified ingredients to be labeled as such, will create a goldmine for plaintiffs' lawyers.

The article discusses attorney Don Barrett, "who forced a settlement that cost tobacco companies more than $200 billion." Barrett contends that money is not motivating him to target food manufacturers. "I'm 68 years old, frankly I don't need the cash, the law's been good to me," Barrett reportedly said. "This is my job, but here we have an opportunity to really help people." Campbell opines, "So he is going to make food more expensive for the poorest." He also notes that Barrett intends to sue food companies even if voters do not approve Prop. 37. "[H]is tactics will be the same the lawyers like him have always used—if you can't prove your food is 'healthy,' you will have to cut him a check." *See Science20.com*, November 1, 2012.

Australian Health Experts Urge "Junk Food" Regulations

Two health experts who recently appeared on Australia's ABC *Lateline* have reportedly called for additional government regulation to help combat rising obesity levels. University of Melbourne Professor Rob Moodie, who previously chaired Australia's Preventative Health Taskforce, reportedly suggested that because voluntary programs have failed to curb obesity and diabetes rates, the government should step in with mandatory policies designed to tackle "the junk food industry the same way it confronted the tobacco industry."

"What they've failed to do is bring in the policies to reduce the obesigenic food environment," Deakin University Professor Boyd Swinburn told *Lateline's* Margot O'Neill. "Restrict marketing of junk foods to children, take fiscal policies, taxes, subsidies to make healthy foods cheaper and so on. That's where the failure is: not addressing the unhealthy food environment."

But a representative from the Australian Food and Grocery Council countered that childhood obesity rates have already stopped increasing thanks, in part, to the voluntary efforts being criticized by Moodie and Swinburn. "If you look overseas to where more direct intervention in the market has happened in advertising, it hasn't worked," said a council spokesperson. "And therefore we should be looking at the evidence and getting back to the facts, not opting for overly simplistic approaches." *See Lateline,* October 29, 2012.

MEDIA COVERAGE

Mother Jones Provides Public Access to Sugar Industry Documents

Following publication of an article titled "Sweet Little Lies," *Mother Jones* magazine has made available online the **documents** underlying the authors' assertions of sugar-industry influence over government dietary policy and scientific health effects research. Additional details about the article appear in Issue **459** of this *Update*. Among the documents is one from 1942 that purportedly "encouraged sugar cane and sugar beet producers to create a joint research foundation to counter the 'ignorance' the industry was facing." It discusses World War II sugar rationing and campaigns "derogatory to sugar." A **video** featuring one of the article's authors is also available online.

In a related development, writing in the Harvard College *Global Health Review,* Dylan Neel calls for strict regulation of sugar, including taxation, reduced availability, control of the location and density of retail markets, and tightened vending machine and snack bar licensing. He claims in his October 24, 2012, article "The Sugar Dilemma" that "[f]ailure to curb global sugar consumption will condemn the world to yet another decade of rampant obesity, diabetes and cancer." According to Neel, non-communicable diseases contribute to 35 million deaths annually throughout the world and "[d]eveloping countries must now bear the crippling double burden of both non-communicable and communicable disease." He contends that the recent surge in the incidence of heart disease, cancer and diabetes is "undisputedly" attributable to "increased dietary use of refined sugar."

Daily Beast Examines Food Addiction Theories

"[T]he theory that the brain responds to high-fat, high-calorie foods similarly to how it responds to drugs is now gaining scientific muscle, led by renowned names in the field of addiction," reports *The Daily Beast's* Laura Beil in an October 28, 2012, article describing so-called food addiction as "one of the hottest topics in obesity research." In particular, Beil recounts the work undertaken by former tobacco researchers such as Mark Gold, who now chairs the University of Florida's Department of Psychiatry, as well as animal studies that examine how brain chemicals respond to "highly palatable" foods. The article also explains human brain scans that have led scientists to focus attention on dopamine receptors, which "can reveal a great deal about the dynamics of pleasure, reward motivation, and addiction," and hormones such as ghrelin that help regulate the desire to eat.

Although Beil notes that experts have cited data inconsistencies in the food addiction literature, she nevertheless concedes that this preliminary research "is beginning to change the way some scientists are thinking about the approach to weight loss." For those who support the food addiction narrative, categorizing "calorie- and fat-dense foods as addictive" could not only lead to better weight loss drugs and programs but widespread efforts like "cigarette-style taxes and warning labels" designed to curb exposures to highly palatable foods. As former Food and Drug Administration Commissioner David Kessler reportedly told Beil, regulators and policymakers could learn "from the anti-tobacco model" and use food addiction research to better address "'cue-induced wanting,' or a sudden need triggered by the sight of something."

"What's changed in the last four decades?," Kessler asked. "We changed our environment. We increased the number of cues. We made it socially acceptable to eat any time." His point was echoed by Rudd Center for Food Policy & Obesity Director Kelly Brownell, who highlighted concerns about food marketing to children. "If parents start to believe that these foods are having a negative effect on the brains of their children, they might very well want to keep them away from their kids," said Brownell about the practical consequences of an accepted food addiction model. "They may not want schools to be selling them. To me, these are the big implications."

Farm Labor Laws Back in Spotlight

In a recent article detailing the safety risks faced by underage farm workers, *New York Times* journalist John Broder examines thwarted efforts to broaden farm labor regulations after reports of silo, bin and grain elevator fatalities at both large commercial enterprises and smaller family operations not currently covered by federal law. "Experts say the continuing rate of silo deaths is due in part to the huge amount of corn being produced and stored in the United States to meet the global demand for food, feed and, increasingly, ethanol-based fuel," writes Broder. "That the deaths persist reveals continuing flaws in the enforcement of worker safety laws and weaknesses in rules meant to protect the youngest farm workers. Nearly 20 percent of all serious grain bin accidents involve workers under the age of 20."

In particular, the article describes agricultural child labor rules proposed by the U.S. Department of Labor (DOL) that not only would have "barred young workers from entering silos and other enclosed spaces," but would have prohibited teenagers "from doing a broad array of farm tasks, including herding livestock and driving large farm vehicles." But after receiving complaints from farming communities and pressure from embattled politicians in agricultural states, DOL eventually withdrew the proposals despite protests from farm worker advocacy groups. "They needed to address new technology and new equipment," said Purdue University Agricultural and Biological Engineering Professor William Field, who viewed DOL's failure as a squandered opportunity. "But in my mind, the Department of Labor, or whoever was pushing it, took it as an opportunity to throw everything, including the kitchen sink, at this thing."Additional details about the proposed regulations and their subsequent withdrawal appear in Issues **425** and **438** of this *Update*.

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 460 | NOVEMBER 2, 2012

NPR Blog Highlights Efforts to Curb Food Label Proliferation

A recent post on *NPR's* "The Salt" blog has highlighted a sharp increase in the number of food labels designed to signal a product's nutritional content and environmental status, raising questions about whether "the proliferation of 'pick me!' logos has become somewhat overwhelming." According to the October 29, 2012, post, the International Ecolabel Index has counted 432 "green" marks "administered by governments, nongovernmental organizations and industry alliances" without even tracking those labels addressing nutrition or humane handling practices. "The Index's Anastasia O'Rourke says this sea of stylized leaves and bean sprouts is confusing not only to individual consumers but to major purchasers like universities trying hard to do the right thing," reports "The Salt," which notes that some entities like the European Commission, United Nations and International Organization for Standardization have already embarked on efforts to standardize "the whole labeling game."

Meanwhile, some countries like Denmark have started moving toward their own systems with an eye toward weeding out "some of the labels (to the extent that's legally possible)." As one European Commission spokesperson purportedly explained, "The tug of war between informing consumers and making them want to bury their heads in the sand is nothing new… Before, it was a discussion about whether the letters on labels should be 1-millimeter tall or less. There's always a trade-off. It's a constant discussion."

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400