

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards 110th Congress

[1] Harkin Introduces Fresh Produce Safety Bill

Senator Thomas Harkin (D-Iowa) has introduced a bill ([S. 2077](#)), titled the Fresh Produce Safety Act of 2007, that would establish a national program “to assure the safety of fresh produce intended for human consumption.” In addition to giving the Food and Drug Administration the authority to enforce its voluntary guidelines, the bill would require the agency to establish national standards and conduct more stringent inspections of fresh produce operations. The bill would also set up a surveillance system to identify the sources of food-borne illness outbreaks and a research program designed to “identify, mitigate and prevent” the contamination of produce. Imported produce would also need to meet FDA standards before being admitted into the United States. “Americans should be consuming more fresh fruits and vegetables; instead we are scanning our refrigerators looks for bags to discard,” Caroline Smith DeWaal, the food safety director for the Center for Science in the Public Interest, stated in a press release supporting the bill. “These continuous outbreaks and recalls

are eroding Americans’ confidence in fresh produce. It’s time for a food safety system that applies the same scrutiny to our farms as we have for other high-risk produces like meat and poultry.” *See Press Release of U.S. Senator Tom Harkin and CSPI Press Release, September 20, 2007.*

In a related development, Harkin’s bill ([S. 771](#)) to revise school nutrition standards has reportedly ignited debate over how the government should set new standards for the foods and drinks sold outside the cafeteria.

The bill, which would extend the Child Nutrition Act of 1996 to all foods sold on school campuses, would also require the agriculture department to redefine “foods of minimal nutritional value” in accordance with “current nutrition science.” Public health advocates have contended that these standards should exclude sports drinks and sweetened water as containing two-thirds the sugar of full-calorie sodas, which soft drink makers have already agreed to phase out by 2009. Harkin has also apparently indicated that continuing to allow sports drinks and enhanced waters in schools might be a “deal-breaker.” “Our most recognized national health watchdog – the Institute of Medicine – said sports drinks are equivalent to flavored water, noting especially their high sugar content,” he was quoted as saying.

The legislation has gained the support of 25 senators and more than 100 organizations, while industry groups such as the Grocery Manufacturers



Association and the American Beverage Association have agreed to discuss federal standards. “These drinks are low in calories and the portion sizes are capped,” said the beverage association’s vice president for communications. “They have benefits to the student. Where you have students competing in athletics throughout the day, it’s an essential beverage to make available. These are very reasonable, common-sense things.” *See The Washington Post*, September 26, 2007.

[2] Congress Passes 2007 Food and Drug Administration Amendment Act

The U.S. Senate has reportedly passed by unanimous consent the 2007 Food and Drug Administration Amendment Act ([H.R. 3580](#)), which primarily reauthorizes the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act. In addition, the legislation includes a section on food safety (Title X) that would require FDA to protect pet food by establishing (i) ingredient standards and definitions; (ii) processing standards; (iii) updated labeling standards that include nutritional and ingredient information; and (ix) an “early warning” surveillance system to detect adulterations in the pet food supply. Title X would also mandate an Adulterated Food Registry, accessible via electronic portal, to gather reports from health officials and food companies about adulterated foods. Under the food safety provision, FDA would need to meet improved communication requirements during a recall of human or pet food and create a consolidated, searchable database on the FDA Web site that the public could use to identify recalls. “This important bill should give every American greater peace of mind every single day – every time we eat, take our

medicine or see our doctor,” Senator Edward Kennedy (D-Mass.) was quoted as saying. *See The U.S. Law Week*, September 25, 2007.

[3] GMA Asks Congress to Increase Budget for Food Import Inspections

The Grocery Manufacturers Association, which last week called for increased regulation, has reportedly asked Congress to expand the Food and Drug Administration’s budget for food import safety. GMA representative Joseph Levitt testified on Tuesday before the U.S. House Appropriations’ Subcommittee on Agriculture that the globalization of the food supply has presented a “unique problem” for the industry. In addition, Representative Rosa DeLauro (D-Conn.) has requested that FDA receive \$28 million to improve its food safety record, although she noted at the hearing that the agency has not used funds efficiently in the past and does not want to “appropriate further money into a black hole.” According to the reported testimony of FDA Assistant Commissioner David Acheson, however, the FDA currently lacks the authority to effectively police import safety and may ask Congress for new powers as a result. Other critics have also pointed to the agency’s failure to act on more than 100 proposals that advocated changes to the system. “Given these circumstances, increasing funding to support the FDA’s current import paradigm without requiring significant change in its approach would produce far too much additional waste, result in even more shipping delays for compliant and safe import shipments,” a former FDA official was quoted as saying. *See The Associated Press*, September 25, 2007; *The Wall Street Journal* and *Reuters*, September 26, 2007.



Occupational Safety & Health Administration (OSHA)

[4] OSHA Schedules Stakeholder Meeting on Diacetyl; House Passes Bill to Require Agency Action

OSHA has [announced](#) that it will convene an informal stakeholder meeting October 17, 2007, to exchange data, ideas and points of view about occupational exposure to diacetyl, a butter flavoring used in microwave popcorn and other food products, and food flavorings containing diacetyl. Those wishing to attend are asked to submit a notice of intention to attend; should a sufficient number of individuals register, the agency will schedule a second meeting October 18. As background, OSHA notes that in July 2006 labor unions sought an emergency temporary standard for employees exposed to diacetyl, citing evidence that exposure is associated with the development of bronchiolitis obliterans, a debilitating and potentially fatal airways disease. The agency calls for stakeholders to be prepared to discuss (i) uses of diacetyl and food flavorings containing diacetyl, (ii) approaches to exposure assessment, (iii) available exposure data, (iv) controls used to minimize exposures, and (v) medical screening and surveillance.

Meanwhile, apparently impatient with OSHA's progress regulating diacetyl the House passed [legislation](#) (H.R. 2693) on September 26 by a vote of 260-154 requiring the agency to adopt an interim standard within 90 days of enactment.

While the White House reportedly “strongly opposes” the measure, the administration has not threatened to veto it. Referred to as the “Popcorn Workers Lung Disease Prevention Act,” the bill states “[t]here is compelling evidence that diacetyl pres-

ents a grave danger and significant risk of life-threatening illness to exposed employees.” Should the bill become law, the interim standard “shall provide no less protection than the recommendations contained in the NIOSH Alert ‘Preventing Lung Disease in Workers Who Use or Make Flavorings.’” The final standard, which the bill calls for not later than two years after enactment, would have to contain worker protection provisions, a short-term exposure limit “and a permissible exposure limit that does not exceed the lowest feasible level.” The National Institute for Occupational Safety (NIOSH) would be required to conduct a study on food flavorings that could be used as diacetyl substitutes.

Public health representatives, while welcoming OSHA's latest diacetyl initiative, questioned the timing of the stakeholder meeting, suggesting that it was an effort to preempt legislation. They complain that the agency should have begun gathering information in 2002 when NIOSH first issued warnings about diacetyl exposure. The National Association of Manufacturers and other business groups reportedly oppose congressional action, claiming that no data exist that could be used to set a permissible exposure limit. See *CQ Today* and *The Pump Handle*, September 26, 2007.

U.S. Department of Agriculture (USDA)

[5] Public Interest Groups Target Organic Fish and Dairy Issues

The Cornucopia Institute and the Organic Consumers Association have recently communicated with USDA about issues related to the national organic program. In a letter dated September 13, 2007, the Cornucopia Institute filed a formal complaint concerning alleged violations of the



program's standards by two USDA-accredited certifying agents, Quality Assurance International and the Colorado Department of Agriculture. The institute is requesting a full investigation into their activities as certifiers of the Aurora Organic Dairy, characterized as "the nation's largest organic factory-farm dairy operator" located in Colorado and Texas.

According to the institute, which has targeted the dairy with several USDA complaints since 2005 for allegedly violating rules on adequate access to pasture, the USDA announced in August 2007 that it had taken enforcement actions against the dairy for willful violations involving the sale, labeling and representation of milk as organically produced when the milk was not produced and handled in accordance with the law. Yet, "hours before the USDA made their announcement, [Aurora] issued its own news release . . . [that] sought to frame the issue in the most positive light" and included "quotes in the same news release from principals associated with its two organic certifiers . . . designed to mislead the organic community and downplay the severity of the findings by USDA's investigators." The institute **contends** that it has a document from the director of USDA's national organic program notifying Colorado of a formal notice of proposed suspension of its accreditation as a certifying agency for organic livestock.

Meanwhile, an online nonprofit public interest organization that promotes the interests of organic consumers, has **asked** the USDA not to include carnivorous fish species used in aquaculture in national organic standards. According to the Organic Consumers Association, "the use of fish meal and fish oil to grow carnivores supports the ecologically unsustainable practice of over-fishing

forage fisheries that are one of the most important foundations of healthy marine ecosystems." As well "[a]ltering carnivorous fish diet to include plant based foods in aquaculture practices violates the principle of adhering to the natural diet of the species" and "[t]he use of open net-pens in carnivorous aquaculture production has been responsible for the death of thousands of seals and sea lions . . . in direct violation of organic principles."

The association urges the organic standards board "to uphold the principles of organic standards and to continue to exclude carnivorous finfish from the organic realm." It was apparently prompted to act after the National Organic Standards Board Livestock Committee recommended that "fish raised in open-net cages and those using wild caught fish in their diets be excluded from national organic standards for aquaculture." While the association agrees with this decision, it extended its opposition to "the development of national organic standards that include carnivorous fish species such as salmon raised in open and closed systems."

Legislation, Regulations and Standards

Environmental Protection Agency (EPA)

[6] EPA to Seek NAS Review of Bisphenol-A Assessment Practices

According to a news source, EPA is poised to request that the National Academy of Sciences (NAS) review its toxicological assessment practices



regarding an array of phthalates, including bisphenol-A, a plasticizer chemical believed to have human endocrine effects at low-exposure levels. While the review will delay agency efforts to finalize assessments for these chemicals, EPA apparently needs the input before it can include the assessments in its Integrated Risk Information System (IRIS) database. IRIS has risk data on thousands of substances and is relied on to set health and cleanup standards. A 2006 EPA draft assessment for dibutyl phthalate apparently proposed to weaken the current safe exposure level from 0.1 milligram per kilogram of body weight per day to 0.3 mg/kg-day. Senator Barbara Boxer (D-Calif.) reportedly criticized this proposal in a June 29, 2007, letter, contending that it is 2,000 times weaker than California's standard. She apparently challenged EPA's failure "to consider cumulative exposures to multiple phthalates that have similar threats and are present in individuals nationwide." See *Inside EPA*, September 21, 2007.

U.K. Food Standards Agency (FSA)

[7] FSA Seeks Comments on Updated Country-of-Origin Labeling Guidance

The FSA has issued proposed [changes](#) to its 2002 Country of Origin Labeling Guidance and is requesting comments by December 13, 2007. Among the changes proposed are (i) updates of relevant legal information, (ii) advice on avoiding misleading labeling regarding products of a particular culinary style and for origin declarations for products from Northern Ireland, (iii) best practices for providing voluntary information about where a product is produced or packed that could otherwise mislead consumers, and (iv) best practices to avoid misleading product presentation and display in

stores. According to FSA, the proposals will improve country-of-origin labeling practices, enhance consumer confidence and provide enforcement authorities with the means to improve labeling advice. The agency has also reformatted the document and plans to publish a summary of responses received.

Litigation

[8] Taco John's Sues Food Suppliers for Negligence

Taco John's corporations in Iowa, Minnesota and North and South Dakota have reportedly filed a putative class-action lawsuit against several named and unnamed food suppliers for negligence. Because a federal district court in Sioux Falls has sealed the complaint, little more is apparently known about the litigation other than that a jury trial has been sought and damages of \$5 million are alleged. The cause of action was described on the cover sheet of the filing as "negligence in the handling of food." Contaminated lettuce was blamed for making a number of the fast-food company's customers sick in 2006. See *Argus Leader Media News*, September 24, 2007.

Other Developments

[9] Animal Health Industry Leaders Extol Logistical Advantages of Locating in the Midwest

Shook, Hardy & Bacon Chair [John Murphy](#) last week welcomed more than 275 animal health and nutrition executives to Kansas City as they convened for an annual event known as the KC Animal Health Homecoming.



The September 17, 2007, gathering celebrated the continuing success of the KC Animal Health Corridor in recruiting U.S. and international animal health and nutrition companies to locate in the bi-state region flanked on the east by Columbia, Missouri, and the west, by Manhattan, Kansas. Among other things, the region boasts world-class research facilities in Kansas City, Columbia and Manhattan and superior transportation and distribution capabilities.

Highlights of the Homecoming program included remarks from the director of the Missouri Department of Economic Development and the lieutenant governor of Kansas, as well as the recognition of 2007 Iron Paw Award honoree Wes Remington, chair of Pete & Mac's Pet Resorts, for his leadership in the animal health industry. SHB was a presenting sponsor of the Homecoming event; please click [here](#) for more information about the KC Animal Health Corridor.

[10] Authors Balk at Famous Characters Hawking Food Products

Two famous British authors have recently published letters in *The London Times* criticizing the use of iconic children's book characters in food and beverage advertisements. "It is galling to find that the innocent character one has created for young children is being used to promote junk food and drink, and also to decorate the packaging of lavatory paper," wrote Raymond Briggs, author of *The Snowman*, in registering "dismay" that his character "has been used to promote Irn-Bru, and in Japan, Kentucky Fried Chicken." Snowman Enterprises, which manages the copyright of the 1982 animated version, apparently sold the movie's song rights to Irn-Bru manufacturer A.G. Barr PLC, which then created an "affectionate homage" to *The Snowman*

that included the lyrics: "Now I'm falling through the air / I wonder where I'm going to land / He nicked my Irn-Bru / And let go of my hand." Despite receiving a royalty check from Snowman Enterprises, Briggs nevertheless called the advert an example of "crass exploitation" designed to "cast a charming glow over products which are so charmless." See *The London Times*, September 21 and 22, 2007; *BBC News*, September 23, 2007.

Briggs' commentary followed a September 19 letter written by Paddington Bear creator Michael Bond, who defied allegations that he had written a Marmite advertisement in which the marmalade-loving bear tries the sandwich spread made from yeast extract. Karen Jankel, Bond's daughter and the managing director of Paddington & Co., reportedly sold Paddington's image to Unilever for an undisclosed sum but did not tell her father until "the point of no return," according to his own account. For the record, Bond concluded, "although Paddington found the sandwich interesting, bears are creatures of habit... Besides, Squeezy Marmite may spread well, but it doesn't have any chunks." See *The London Times*, *Reuters* and *American Free Press*, September 19, 2007; *The Independent*, September 28, 2007.

Media Coverage

[11] L.A. Times Hosts Point-Counter Point on Obesity

Professors Paul Campos and Kelly Brownell recently exchanged comments on various aspects of obesity in a *Los Angeles Times* series. Brownell, who teaches psychology and public health at Yale University, criticized government policies that "promote poor diet and inactivity." He also targets



“relentless advertising of unhealthy foods to children” and industry-sponsored approaches that blame individuals for their expanding waistlines.

Campos, a law professor at the University of Colorado, points to myths about obesity and overweight that, he contends, do nothing to promote improvements to public health. He believes that “it isn’t necessary to make people thinner to improve their health”; rather, the goal should be something achievable like “getting people to be less sedentary and eat a nutritious array of foods that they enjoy.” Campos challenges much of the data used to support misconceptions about obesity and the merits of dieting. He further suggests, “Americans are obsessed with fat because fatness has become a symbol for poverty, downward mobility, nonwhiteness and socially marginal status in general.” See *The Los Angeles Times*, September 18-21, 2007.

[12] As Cupcake Wars Heat Up, Students Buy and Sell Contraband Sweets

“Edible icon of Americana, frosted symbol of comfort and innocence, it may not have faced such an identity crisis since first appearing in cookbooks sometime in the 18th century,” *New York Times* journalist Sarah Kershaw writes of the cupcake, which has attained cult status as “retro-food chic” while “marching to the front line of the fat wars” as a frequently banned treat on school campuses. Many districts have reportedly forbidden parents to bring cupcakes to classroom celebrations, citing new nutritional regulations enacted on both the federal and state levels. Kershaw argues, however, that the cupcake’s place in the national consciousness has inspired some aficionados to wage a legal battle to save the confection. She particularly notes the “Safe Cupcake Amendment,” which was passed by the Texas Legislature in 2005 after parents

complained about the bans. “[C]upcakes are deal breakers,” said New York University Professor Marion Nestle, who supports limiting school sweets. “It sounds like a joke, but it’s a very serious problem on a number of levels. You have to control it.”

Meanwhile, some Canadian students have reportedly started a “black market” operation to sell the soda, chips and candy bars recently prohibited by their schools’ strict nutrition policy. The Kelvin High School students, who advertised their enterprise on the Facebook Web site, also alleged that administrators confiscated treats brought from home despite the fact that the school policy does not cover such food items. In addition, the students have apparently attempted to organize a sit-in at the school division’s 77 campuses in protest of the draconian measures. “Winnipeg School Division does not deal with issues that are raised on Facebook, unless it impacts on the safety of our students and staff,” a school official was quoted as saying. See *Winnipeg Free Press*, September 19, 2007.

Scientific/Technical Items

[13] Survey Suggests That Consumers Would Avoid Nanotechnology in Food Products

A Woodrow Wilson International Center report has reportedly concluded that 70 percent of consumers have little or no knowledge of nanotechnology, while only 7 percent of consumers said they would consider buying food products developed using nanotechnology. Of those adults who stated that they were confident in their knowledge of nanotechnology, however, 31 percent said they would buy nanotech food products. “Efforts to inform the public have not kept pace with the



growth of this new technology area,” said David Rejeski, director of the Wilson Center’s Product on Emerging Nanotechnologies, in explaining that the percentage of people aware of nanotechnology fell 4 percent from last year. He added that the lack of public understanding could have significant repercussions in the future: “The slightest bump – even a false alarm about safety or health – could undermine public confidence, engender consumer mistrust, and, as a result, damage the future of nanotechnology, before the most exciting applications are realized.” *See FoodNavigator-USA.com*, September 25, 2007.



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