

# Food & Beverage

## LITIGATION UPDATE

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# Food & Beverage

## LITIGATION UPDATE

### Legislation, Regulations and Standards 110th Congress

#### [1] Harkin Legislation Would Revise School Nutrition Standards

Senator Tom Harkin (D-Iowa) has introduced legislation ([S. 771](#)) that would extend the Child Nutrition Act of 1966 to all foods sold on school campuses. The proposal would also require the agriculture department to redefine “foods of minimal nutritional value” in accordance with “current nutrition science.”

“We must bring nutrition guidelines for foods sold outside of the cafeteria in line with those required for food sold inside of the cafeteria,” Harkin said of the measure, which has gained support among policymakers and health advocates since it was first proposed in the 109th Congress. Senator Richard Lugar (R-Ind.), who serves on the Senate Agriculture, Nutrition and Forestry Committee with Harkin, also condoned the revisions but noted that “Revenue is a concern. We need to get more data on that.” If passed, the legislation would displace voluntary agreements the Alliance for a Healthier Generation recently brokered with major beverage and snack food producers. See *Press Release of Senator Tom Harkin*, March 6, 2007; *The Washington Times*, March 7, 2007; *Food Navigator USA.com*, March 9, 2007.

### Food and Drug Administration (FDA)

#### [2] Peanut Butter Recall Expanded as ConAgra Plans Recovery

FDA announced this week that ConAgra has expanded its recall of Peter Pan and Great Value peanut butters with product code 2111, asking consumers to discard items purchased since October 2004. The lot number has been implicated in a *Salmonella* outbreak under investigation by the FDA, which identified bacteria strains at the Georgia plant that manufactures all Peter Pan peanut butter. “When it is in the environment you have to assume that it’s all over the place – whether it is or not – and clean up everywhere,” an FDA chief medical officer told the press. ConAgra, which has pledged to reopen the Peter Pan facility, reportedly estimates that the recall will have cost the company \$50 to \$60 million by the end of April. See *FDA Press Release*, March 9, 2007; *Atlanta Journal-Constitution*, March 13, 2007.

#### [3] FDA Publishes Draft Guidance for Fresh-Cut Produce Industry

FDA has published [draft final guidance](#) for processing fresh-cut produce, especially fruits and vegetables sold as “ready-to-eat.” A complement to FDA’s manufacturing practice requirements, the guidance recommends that food processors adopt a “state-of-the-art” Hazard Analysis and Critical Control Point (HACCP) program to minimize microbial contamination. Specific areas covered by the guide



include: (i) “personnel hygiene” and training; (ii) “building and equipment”; (iii) “sanitation”; (iv) “processing controls from product specification to packaging”; and (v) recall and traceback procedures. FDA also emphasizes that others in the supply chain, from growers to consumers, should follow safe handling practices and report disease outbreaks as soon as possible. “Once the product is contaminated, it’s very difficult to get this contamination off, so our focus is on prevention,” the director of FDA’s Office of Food Safety said about the voluntary measure. *See FDA Press Release*, March 12, 2007; *Federal Register* and *The Wall Street Journal*, March 13, 2007.

Meanwhile, policymakers and consumer advocates have reportedly criticized the step as inadequate. “At a time when the country is experiencing numerous foodborne illness outbreaks, and the industry is looking for the government’s help to repair their image, it is disappointing that the FDA issues a nonbinding, voluntary guidance document that does nothing and merely tells growers what they already know,” Representative Rosa DeLauro (D-Conn.) opined in a press statement. The Center for Science in the Public Interest (CSPI) also faulted FDA for “rushing in after the fact,” according to a *Brandweek* article on the potential for regulatory action. CSPI demanded mandatory auditing at a congressional field hearing held this week by Senate Agriculture Appropriations Subcommittee Chair Herb Kohl (D-Wis.). “All growers and fresh-cut processors should have written plans in place that describe how they will meet FDA standards for use of manure, water quality, farmer hygiene, and sanitation in the plants,” a CSPI spokesperson charged. *See CQ Healthbeat News and Brandweek.com*, March 12, 2007; *The New York Times* and *Reuters*, March 13, 2007.

In related developments, *The Wall Street Journal’s* Jane Zhang reported in an article titled “Trailing Virulent Veggies” that processors have started using radio-frequency identification tags and global-positioning systems to track greens from farm to fork. “If a foodborne outbreak occurs, the processor could end up holding the bag,” Zhang concludes of the paper trail required by the Bioterrorism Act. “Such records often fall short in helping determine the sources of contamination.” *See The Wall Street Journal*, March 13, 2007.

## U.S. Department of Agriculture (USDA)

### [4] AMS Schedules National Organic Standards Board Meeting

The Agricultural Marketing Service has announced a National Organic Standards Board (NOSB) meeting, slated for March 27-29, 2007, to continue the sunset review process for materials on the National List of Allowed and Prohibited Substances. The National List describes synthetic substances (exemptions) permitted for producing organic-certified foods and banned non-synthetics. NOSB in its last meeting recommended renewal for 166 of 169 listed items set to expire this year. The board will now hear assessments on 13 items expiring in 2008, including (i) copper sulfate, (ii) ozone gas, (iii) peracetic acid, (iv) inerts of unknown toxicity on Environmental Protection Agency List 3, (v) calcium chloride, (vi) agar-agar, (vii) tartaric acid, (viii) animal enzymes, (ix) calcium sulfate, (x) glucono delta-lactone, (xi) ethylene, (xii) cellulose, and (xiii) potassium hydroxide. *See Federal Register*, March 12, 2007.



### [5] **USDA Announces Advisory Committee Meeting on Biotechnology**

USDA has announced the 15th meeting of the Advisory Committee on Biotechnology and 21st Century Agriculture (AC21), which will convene March 26-27, 2007, to discuss the agency's approach to managing "coexistence among increasingly diverse agricultural systems." AC21 includes members involved in biotechnology industries, agriculture and food processing, environmental groups, and academic research. Interested parties must register five business days in advance. *See Federal Register*, March 9, 2007.

## European Commission

### [6] **European Food Safety Experts to Consider Animal Cloning**

The European Commission has reportedly asked the European Food Safety Authority (EFSA) to assess the impact of animal cloning on food safety, animal welfare and the environment. EFSA, which intends to issue a report in six months, announced that the agency has "already begun considering how best to address this issue in anticipation of the possibility of such a request."

The cloning debate gained momentum earlier this year after FDA released its statement on the safety of cloned livestock. "According to experts," the European Commission said in its request to EFSA, "animal cloning is on the verge of widespread commercial use and expected to spread within the global food chain before 2010." The European Group of Ethics will also look into cloning, which European food regulators have apparently decided to treat as a novel food similar to genetically modified organisms. *See BBC News*, March 8, 2007; *Food Production Daily Europe.com*, March 9, 2007.

## State/Local Initiatives

### [7] **California Assembly Health Committee Approves *Trans* Fat Ban**

The California Assembly Health Committee has approved, by a 9-4 vote, [legislation](#) that would prohibit *trans* fats in restaurants and other food facilities statewide by 2010. Introduced by Assemblyman Tony Mendoza (D-Artesia), who reportedly called *trans* fat "the leading cause of heart disease and diabetes," the law would apply to all foods not sold in original packaging and allow for fines as high as \$1,000. The Appropriations Committee will now review the proposal before sending it to the full Assembly.

While health advocates contend that even saturated fats are a preferable alternative, restaurants have criticized the lawmaking as impractical. "We see larger chains being able to move away from *trans* fat," a California Restaurant Association spokesperson was quoted as saying. "Small mom-and-pop restaurants cannot do this. They cannot afford to buy bulk oils that will not change the taste of their food." *See Contra Costa Times*, March 7, 2007.

## Litigation

### [8] **Federal Court Orders Halt to Planting of GE Alfalfa Seed**

The federal district judge in California who ruled that USDA violated the National Environmental Protection Act by failing to prepare an environmental impact statement before de-regulating genetically engineered (GE) alfalfa has preliminarily enjoined all future plantings of Roundup Ready® alfalfa beginning March 30, 2007. [Geertson Farms, Inc. v. Jobanns, No. 06-01075 \(U.S. Dist. Ct., N.D. Calif., order issued March 12, 2007\)](#).



Further information about the case appears in issues 202 and 205 of this Report. In addition, while the court allowed growers who have already purchased GE seed to plant it, the order prohibits any further seed sales.

The court has allowed intervenors, including seed manufacturer Monsanto, to participate in the litigation and has given them the opportunity to present evidence “to assist the court in fashioning the appropriate scope of whatever relief is granted.” Because there was evidence that some growers had already purchased and begun planting the GE alfalfa seed, the court determined, after “weighing the balance of harms,” that they would not be ordered to remove the alfalfa from their fields. The court ordered the government and intervenors to file their evidence and legal briefing as to the court’s permanent injunctive relief on or before March 23. Plaintiffs must file their response, if any, by April 6, and the court scheduled oral argument for April 27. While the court has given the parties the option of providing live testimony, it has ordered that no discovery take place.

## Legal Literature

### [9] Legal Journal Publishes Symposium on Childhood Obesity

The Spring 2007 [issue](#) of the *Journal of Law, Medicine & Ethics* has devoted more than 150 pages to symposium articles about childhood obesity. Editor Ted Hutchinson sets the tone for the symposium by noting in his letter, “Children’s weight is clearly a result not only of diet and exercise but more specifically of what they are offered for food in schools, how foods are marketed to them in the media, and how children are able to function in the ‘built environment’ that exists around them.” As

anti-tobacco activist Richard Daynard contends in a symposium [article](#) he co-authored, obesity has been framed by industry as an individual choice issue when it is actually a result of legal policy that has shaped “the situational and environmental influences that drive both dietary intake and physical activity.” He continues to believe that litigation will have a role in addressing the nation’s problems with obesity but argues that it must “focus on the needs of the population rather than of individual clients.” The article also discusses the obstacles facing those who turn to government for legislative and regulatory solutions.

The symposium articles are divided into sections. The first addresses potential causes for childhood obesity; the second contains articles outlining possible strategies “for stemming the epidemic.” Among the articles in the second section is a [piece](#) by food activist and psychology professor Kelly Brownell who claims that the issue must be reframed from one of personal responsibility to that of “a toxic environment.” Brownell states that humans are innately predisposed to overeat fatty, salty and sweet foods, and live in an environment that makes such foods easy to find and ready to eat. He calls for a major research effort and “sensitivity to global factors that affect diet and activity and take into account broad social forces such as economics and the influence of industry.”

McDonald’s Corp. Vice-President Catherine Adams was given an opportunity to [contribute](#) to the symposium and reinforces the company’s commitment to food quality, nutrition information and educational messages. According to Adams, the company’s current “focus is on the foods that experts around the world generally agree people should eat more often – fruits and vegetables.” She emphasizes that the company relies on the advice of nutrition experts and has demonstrated



its commitment to customer health and well-being. “We do not offer ‘fast food’; rather, we provide ‘good food fast.’” Adams concludes by stating, “McDonald’s has taken a seat at the table of the obesity discussion, but our role is not apologetic – it is as a partner equally dedicated to sensible, responsible and sustainable solutions.”

## Other Developments

### [10] Anti-Tobacco Activist Targets “Industry Front Groups”

Anti-tobacco activist Lisa Bero has co-authored an article that calls for policymakers and the media to be skeptical of organizations that “purport to reflect popular disaffection” with government regulation. In “The Creation of Industry Front Groups: The Tobacco Industry and ‘Get Government Off Our Back,’” Bero draws on the millions of documents, made available to the public in litigation against cigarette manufacturers, to describe how the R.J. Reynolds Tobacco Co. created and funded an organization that lobbied against government regulation in the mid-1990s without revealing its tobacco connections or purported agenda. She contends that the successful development of industry front groups “has implications beyond tobacco regulation. Similar public health issues arise in debates about food policy and obesity.”

Bero states that organizations learn from each other and that other industries facing “new restrictions have developed similar kinds of front groups to advocate on their behalf.” Because “few of these other industries have been required to release the kinds of internal documents that would make the creation of such groups evident to outside observers,” Bero suggests that policymakers and advocates “research newly formed coalitions” to discover whether some industry is actually behind what otherwise appears to be a grass-roots organization. See *American Journal of Public Health*, March 2007.

### [11] Former FTC Official to Direct Food and Beverage Advertising Initiative

According to news sources, 25-year Federal Trade Commission veteran Elaine Kolish has been chosen to lead The Children’s Food and Beverage Advertising Initiative, a voluntary industry project intended to ensure that marketers meet or exceed youth-advertising principles. Companies such as Cadbury Schweppes USA, Campbell Soup Co., Hershey Co., and Kraft Foods launched the project in November 2006, pledging, among other matters, to (i) devote at least one-half of their children’s advertising to promote good nutrition and healthy lifestyles, (ii) stop advertising in elementary schools, (iii) cease product placements in editorial and entertainment content, and (iv) place only healthier foods and drinks in interactive games. See *Advertising Age*, March 9, 2007; *Promo*, March 13, 2007.

## Media Coverage

### [12] Biotech Book Author Calls for Exploration of the Unknowns

In a *Salon.com* [interview](#), technology writer Denise Caruso discusses her new book, *Intervention: Confronting the Real Risks of Genetic Engineering and Life on a Biotech Planet*. According to Caruso, scientists and government regulators will never be able to understand the risks of new technologies until they are willing to explore the issues for which there are no data and start researching the unknown unknowns. As she addresses a scenario-based assessment paradigm that could have prevented substances like DDT from damaging the ecosystem, Caruso discusses genetically engineered crops, cloned animals and traditional approaches to risk assessment. Her book makes the case for collaborative risk assessment, or “the analytic deliberative process,” that would bring together individuals from a broad spectrum of scientific disciplines to



explore the uncertainties of a new technology, ask questions, conduct additional research, and then determine whether the risks are worth the benefits. Caruso contends that biotechnology may or may not be “bad” for humans and the environment; we just “*don’t know*. And it behooves us to find out.”

### [13] FDA Responds to *Washington Post* Article on Cattle Antibiotic

Stephen Sundlof, director of the Food and Drug Administration Center for Veterinary Medicine, has responded to an article in *The Washington Post* about a cattle antibiotic the agency has been asked to approve. Information about the article appears in issue 205 of this Report. According to Sundlof, the article contained “a key factual error” and, based on that error, implies “that approval of cefquinome is a foregone conclusion.” He identifies the error as assigning “excessive importance to an FDA document titled ‘Guidance for Industry 152,’” which is apparently guidance for animal antibiotic developers – not the agency. Sundlof contends that the agency is reviewing the scientific evidence and “will reach no conclusions until that review is completed.” He concludes, “If the use of an antibiotic in livestock poses a health threat to people, the FDA will act to protect human health, either by not approving a new antibiotic for livestock or by taking one off the market.” See *The Washington Post*, March 11, 2007.

## Scientific/Technical Items

### [14] Scientists Suspect Link Between Bisphenol A and Obesity

Findings about environmental exposure to chemicals such as bisphenol A and their potential to trigger fat-cell activity were reportedly presented

during the recent annual meeting of the American Association for the Advancement of Science. A developmental and cell biologist from the University of California at Irvine apparently refers to these chemicals as “obesogens,” or chemicals that promote obesity. Bisphenol A, identified as an endocrine disruptor for its ability to cause abnormal changes in animals’ sexual development, is similar in that respect to tributyltin, which is used as a marine and agricultural fungicide. A researcher studying tributyltin’s effect on genetic mechanisms was quoted as saying, “Exposure to tributyltin is increasing the number of fat cells, so the individual will get fatter faster as these cells produce more of the hormones that say ‘feed me.’” He contends that exposed animals remain predisposed to obesity for life. Similar effects have reportedly been seen with regard to diethylstilbestrol (DES).

Scientists are reportedly concerned about this research because bisphenol A is so widely used in food-packaging materials and has been detected in 95 percent of nearly 400 adults and children tested in the United States. A top official with the National Institute of Environmental Health Sciences reportedly said that a suspected link between obesity and exposure to endocrine disruptors is “plausible and possible.” Fat cells are apparently considered to be an endocrine organ. Additional information about recent regulatory activity on the chemical appears in issue 205 of this Report. An American Chemistry Council spokesperson said the group’s review of the scientific literature indicates that a preponderance of studies have shown no adverse health effects, including no increase in body weight. See *FoodUSA Production Daily.com*, March 8, 2007; *The Washington Post*, March 12, 2007.



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## LITIGATION UPDATE

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