

# Food & Beverage

## LITIGATION UPDATE

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## LITIGATION UPDATE

### Legislation, Regulations and Standards

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

##### [1] Agriculture Secretary Mike Johanns Resigns to Campaign for Senate Seat

Agriculture Secretary Mike Johanns this week resigned his Cabinet post to enter the U.S. Senate race in Nebraska, where Senator Chuck Hagel (R) will vacate his seat in 2008. President George W. Bush reportedly said in a recent press conference that Johanns “brought focus and energy to the department” but was “serious about going home and possibly serving the nation in a different capacity.” Johanns will seek the GOP nomination in what some political pundits have called a “premier Senate showdown” that could match him against former Senator Bob Kerrey (D), according to the *Lincoln Journal Star*. Deputy Agriculture Secretary Charles Conner will serve as acting secretary until the president appoints a permanent replacement. See *Lincoln Journal Star*, September 19, 2007; *Associated Press* and *The New York Times*, September 20, 2007.

##### [2] APHIS Publishes Final Rule for Importing Livestock from BSE Minimal-Risk Areas

USDA's Animal and Plant Health Inspection Service (APHIS) this week published a [final rule](#), effective November 19, 2007, that amends the regulations governing the importation of animals and animal products from “regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States.” The amendments affect regulations pertaining to (i) “live bovines for any use born on or after a date determined by [AHPIS] to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export;” (ii) “blood and blood products derived from bovines;” and (iii) “casings and part of the small intestine derived from bovines.” APHIS, which identifies Canada as the only country currently recognized as a BSE minimal-risk region, based its risk assessment on the importation of Canadian cattle and cattle by-products. The agency specifically responded to concerns that it had underestimated the transmission risk posed by Canadian cattle, arguing in part that ruminant-to-ruminant feed bans and other barriers will result in the continued decline of BSE worldwide.

APHIS also addressed the monitoring of imported cattle 30 months of age or older and stressed that current regulations require the removal of all Specified Risk Materials (SRMs) from cattle slaughtered in the United States regardless of their country of origin. SRMs include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column



(excluding the tail vertebrae, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from cattle 30 months of age or older. In keeping with this definition, APHIS lifted the rule requiring the removal of the entire small intestine and instead specified that only “80 inches of the uncoiled and untrimmed small intestine, as measured from the cecocolic junction” must be eliminated to ensure removal of the distal ileum. APHIS will also allow the importation of bovine blood and blood products from BSE minimal-risk regions provided certain conditions are met regarding (i) “the health of the animal from which the blood or blood products are derived, or – in the case of blood collected from a fetal calf – the health of the dam”; (ii) the slaughter method; (iii) how the blood is collected; and (iv) certification of compliance with the regulations.

The agency further noted that “a large number of commentators addressed the potential economic impact of the proposed rule,” but emphasized that APHIS “lacks the statutory authority to restrict trade based purely on its potential economic impact, market access effects, or quantity of products expected to be imported.” Commentators had argued that the final rule would result in a significant influx of cattle from Canada over a short period of time.

## Food and Drug Administration (FDA)

### [3] Food Industry Calls for Increased FDA Regulation

The Grocery Manufacturers Association (GMA) this week released an [action plan](#) titled “Commitment to Consumers: The Four Pillars of

Food Safety” that calls for increased FDA regulation and a risk-based approach to import safety. The plan specifically recommends that food companies: (i) adopt a foreign supplier quality assurance program to verify that products meet FDA standards; (ii) share their testing and supply chain data with FDA, thus qualifying as “low-risk” operations and allowing the agency to focus on high-risk areas; (iii) build capacity within foreign governments to ensure that food safety standards align with those of FDA; and (iv) seek to expand FDA’s capacity and provide it with the resources to meet the program’s goals. In addition, GMA President Cal Dooley has asked Congress to pass legislation that would require foreign governments to adhere to U.S. safety standards. “Echoing a major theme from last week’s White House Interagency Working Group on Import Safety report, the Four Pillars program proposal is intended to improve the safety of food imports through an integrated, ‘life-cycle’ approach centering on prevention,” stated a GMA [press release](#).

Meanwhile, other industry groups, including Florida tomato growers and seafood companies, have reportedly lobbied Congress for improved regulatory oversight. U.S. Representative John Dingell (D-Mich.) and U.S. Senator Richard Durbin (D-Ill.) have also drafted separate bills that would support user fees on imports of seafood, fruits and vegetables regulated by FDA, but GMA apparently opposes the program because it might unfairly burden companies and consumers. “Today’s announcement by the food industry reaffirms that the current system is not working,” Durbin was quoted as saying. “FDA does not have the resources, tools and oversight ability necessary to prevent dangerous imported products from slipping into our food supply.” See *The Wall Street Journal*,



September 17, 2007; *CQ HealthBeat News* and *National Journal's CongressDaily PM*, September 18, 2007; *The Washington Post*, September 19, 2007.

#### [4] **FDA Changes Food Labeling Regulation on Noncariogenic Carbohydrate Sweeteners**

The FDA has issued an interim final [rule](#) that amends the regulation “authorizing a health claim on noncariogenic carbohydrate sweeteners and dental caries, i.e., tooth decay, to include isomaltulose, a noncariogenic sugar.” Isomaltulose is a disaccharide sugar intended for use as a nutritive sweetener. Foods containing the substance will now be allowed to carry labels stating that it “does not promote tooth decay” or “may reduce the risk of tooth decay.” The agency took the action in response to a petition filed on behalf of Cargill, Inc. and after finding that isomaltulose “is not fermented by oral bacteria to an extent sufficient to lower dental plaque pH to levels that would contribute to the erosion of dental enamel.” While written comments may be submitted until December 3, 2007, the amendment took effect September 17. See *Federal Register*, September 17, 2007.

## State and Local Governments

#### [5] **California Considers Taking Action on Bisphenol-A and Caffeine**

The Office of Environmental Health Hazard Assessment (OEHHA) of California's Environmental Protection Agency has [announced](#) that it is considering whether to prepare hazard identification materials for a number of chemicals including bisphenol-A and caffeine. OEHHA is the lead agency for implementing Proposition 65, a 1986 law that requires the state to identify chemicals known to the state to cause cancer or reproductive toxicity. Public

comments on this initiative must be submitted to OEHHA on or before November 6, 2007; the agency will consult with the Developmental and Reproductive Toxicant Identification Committee on December 10 to decide whether any of the chemicals mentioned in the notice should be further assessed.

Bisphenol-A is used to manufacture plastics and epoxy resins; consumer exposure may result from its use in eyeglass lenses, baby and water bottles, reusable food and drink containers, dental composites, paints and adhesives, and protective coatings in food and beverage containers. According to OEHHA, a number of epidemiologic and animal studies have reported adverse developmental or reproductive outcomes related to bisphenol-A exposure.

#### [6] **California Senate Shelves Diacetyl Bill; Cloning Bill Awaits Governor's Action**

According to a news source, last-minute legislative maneuvering in California's Senate has stalled a [bill](#) (A.B. 514) that would have prohibited the use of diacetyl, a butter-flavored chemical added to microwave popcorn and other foods and beverages, in any workplace in the state. The bill was expected to pass, but a key vote broke a tie and allowed an opponent of the measure to successfully call for its reconsideration. The proposal will not be considered again until January 2008.

Meanwhile, the California Legislature has passed a [bill](#) (S.B. 63) that would require labels on meat or dairy products produced from animal clones or their offspring. If signed into law by Governor Arnold Schwarzenegger (R), the legislation would require (i) livestock producers to disclose cloning information to buyers and (ii) manufacturers, processors and importers to “label the food to indicate that the food includes the product of a cloned animal or its progeny.” Anyone who



resold such food to another would also have to ensure the food was properly labeled. The governor has until October 15 to either sign or veto the measure. While several other states are apparently considering adopting similar measures, the Food and Drug Administration has announced its intention to approve the sale of unlabeled food from clones by the end of 2007. See *Center for Food Safety Press Release*, September 14, 2007; *The Sacramento Bee*, September 18, 2007.

## Legal Literature

- [7] **Michael Roberts, "Role of Regulation in Minimizing Terrorist Threats Against the Food Supply: Information, Incentives and Penalties," *Minnesota Journal of Law, Science and Technology* (2007)**

This article outlines the laws and regulatory initiatives that have been adopted to counter potential terrorist attacks on the U.S. food supply. Because there are numerous points from "farm to fork" where food safety can be compromised and because food imports are increasing dramatically, the author observes that minimizing acts or threats of deliberate contamination can be difficult. He also notes that the piecemeal development of the U.S. food regulatory system has created a complicated organizational structure "plagued by gaps, overlaps and inconsistencies." The article concludes that while "the regulatory response to threat of food terrorism has been impressive and deserves recognition," the absence of a single food safety regulatory authority and reliance on voluntary cooperation continue to make the food system easy prey for a terrorist attack.

## Other Developments

- [8] **Sessions on Alcohol Industry, Youth and Minority Marketing and TV Ads on APHA Agenda**

The American Public Health Association (APHA) will be gathering in Washington, D.C., for its 135th annual [meeting](#), November 3-7, 2007. Expected to attract some 13,000 participants from health-related fields, the meeting and expo will include scientific sessions with speakers who have been active in the food and beverage arena in recent years. Michele Simon, who has participated in Richard Daynard's Public Health Advocacy Institute programs and is now with the Marin Institute, an alcohol industry watchdog group in California, will present on marketing to children. She has submitted three abstracts, "Alcohol Industry 101: Understanding the Major Players," "Targeting Minority Kids: A Cross-Disciplinary Approach to Regulating Harmful Marketing," and "Regulating Marketing to Children: Dispelling Corporate Myths and Creating Partnership Opportunities."

Other abstracts that will be presented include Ameena Batada & Margo Wootan, "SpongeBob SugarPants? The Imbalance of Foods Advertised on Children's Television"; Elena Lingas & Lori Dorfman, "Television Food and Beverage Advertising in 2006"; and Marice Ashe, "Lessons Learned from Tobacco Control: Affecting Product Marketing by Regulating the Marketplace." Among the objectives listed for the Ashe abstract are (i) "Understand the importance of avoiding, or carefully drafting around, First Amendment issues" (ii) "Recognize the legal difference between regulating marketing



(i.e., advertising) and regulating the marketplace (i.e., how a product is sold)”; and (iii) “Identify five focus areas for nutrition policy intervention that do not infringe First Amendment rights.”

#### [9] CSPI Creates Online Database of Foodborne Illness Outbreaks

The Center for Science in the Public Interest (CSPI) has decided to make its offline [database](#) of foodborne illness outbreaks available to the public. Covering the years 1990 to 2004, the new online database includes 541 poultry outbreaks, 639 produce outbreaks, and 948 outbreaks associated with multi-ingredient foods like sandwiches, salads and pasta. Associated illnesses purportedly number in the tens of thousands. CSPI compiles the data from the Centers for Disease Control and Prevention, state health departments, peer-reviewed medical journals, and verified media reports. The database can be searched by pathogen, food or state, and CSPI indicates that its researchers can “run custom searches for journalists who need trend-lines or historic information about foodborne illness.” CSPI Food Safety Director Caroline Smith DeWaal contends that “no one is really in charge” and points to a plunge in consumer confidence over the safety of our food supply. CSPI is reportedly working with Congress to “modernize federal food safety laws.” See *CSPI Press Release*, September 17, 2007.

Meanwhile, CSPI, a consumer interest group, has sent a letter, co-signed by the Corn Refiners Association, to President Bush criticizing a recent report that distinguishes between the human health effects of consuming high fructose corn syrup (HFCS) and sugar. The unlikely allies call this a “myth” and “[w]hile CSPI certainly thinks Americans are consuming far too much sugar from cane and beet sources and HFCS, research demonstrates that

the body treats those sweeteners the same way. It is time to kill the urban ‘myth’ that HFCS is more harmful than sugar.” The president’s cancer panel report apparently suggests that the body processes HFCS differently than sugar and is a uniquely important contributor to obesity, a risk factor for cancer. CSPI and the corn refiners trade group conclude by calling for a corrected edition of the report “to provide the public with science-based facts regarding high fructose corn syrup.” See *FoodUSAnavigator.com*, September 19, 2007.

#### [10] CSPI Criticizes Continued Availability of Sugary Drinks in Schools

The Center for Science in the Public Interest (CSPI) this week issued a press statement criticizing the failure of state and local policies to curb the sale of sugary beverages in schools. Although CSPI praised the efforts of the soft drink industry to self-regulate, it called on Congress to pass U.S. Senator Tom Harkin’s (D-Iowa) bill advocating national standards for the food and drinks sold in schools. “Given that two-thirds of high school beverage sales are still sugary drinks, voluntary industry action and a patchwork of state and local policies are not enough to solve the problem,” CSPI contended, adding that nutrition standards should “clearly exclude sports drinks, as the Institute of Medicine has recommended.” See *CSPI Press Release*, September 17, 2007.

In a related development, the American Beverage Association has published its 2006-2007 [“School Beverage Guidelines Progress Report.”](#) which details the effects of an industry initiative signed in May 2006 that aims to eliminate non-diet soft drinks from public and private schools over a three-year period. The report found that in 2006-2007, non-diet soda accounted for 32 percent of drinks for sale



at schools, compared with 47 percent in 2004. There was also a 56.2 percent reduction in the volume of sugary fruit drinks shipped to schools and a 22.8 increase in the volume of bottled water. In addition, the 2006-2007 beverages reportedly contained two-fifths total fewer calories than their 2004 versions. "Through these guidelines, the beverage industry is cutting calories in schools in a dramatic way across the country," ABA President Susan Neely was quoted as saying. *See Associated Press*, September 18, 2007.

## Media Coverage

### [11] CNN to Air Special Report on Obesity in America

CNN has announced that it will air a [special investigation](#) titled "Fed Up: America's Killer Diet" on September 22-23, 2007, at 8 p.m. Eastern Standard Time. Hosted by CNN's Chief Medical Correspondent Sanjay Gupta, M.D., the report will cover topics such as "Junk Food Making Immigrant Children Fat" and "Liquid Calories Are No. 1 Enemy," the latter of which contends that "the rise in soft drink consumption mirrors the national march towards obesity." Nutritionists cited in the online report that accompanies publicity for the upcoming TV program also point to the high-fructose corn syrup in most non-diet sodas as a contributing factor in obesity and diabetes. "Soda pop is a quintessential junk food," Michael Jacobson, the director of Center for Science in the Public Interest, told CNN. "It's just pure calories, and no nutrients. It's like a bomb in our diet."

The program's segment on immigrant children's food consumption will apparently focus on a boy who gained 30 pounds after moving from Jamaica to

America, putting him at risk for hypertension, high cholesterol and type 2 diabetes. The online report argues that the sudden availability of cheap, unhealthy foods can lead to weight gain in both children and adult immigrants lured by "the fascination of all the new foods." "We really would like to encourage immigrant families to continue the kinds of eating that they ate in their country of origin because our studies show that the longer they've been in this country the more likely that their children are going to get fat," said Pat Crawford, the co-director of the University of California-Berkeley's Center for Weight and Health.

## Scientific/Technical Items

### [12] British Researchers Issue Findings on Salt Consumption and High Blood Pressure in Children

British children taking part in the 1997 National Diet and Nutrition Survey reportedly consumed higher than recommended levels of salt, and those who consumed the most salt had the highest blood pressure levels. F.J. He, et al., "Salt and Blood Pressure in Children and Adolescents," *The Journal of Hypertension*, September 2007. Children as young as age 4 consumed 4.7g of salt per day, while 18-year-olds registered a salt intake of about 6.8g per day. Not accounted for was the salt added in cooking or at the table; thus, actual salt intake was apparently underestimated. According to the researchers, for each additional gram of salt eaten by participants, a related 0.4mmHg increase in systolic blood pressure was measured. Nutritionists reportedly recommend that parents check processed food labels and choose lower salt options for their children. *See BBC News and FoodUSANavigator.com*, September 7, 2007.



In a related development, a University of Limerick research team has reportedly found that reducing the amount of salt in processed foods does not increase the risk of food spoilage from bacteria. Researcher Edel Durack was quoted as saying, “low salt foods are just as safe as conventionally processed ones.” See *HealthDay News*, September 6, 2007.

### **[13] Study Links Cured Meats to Increased Risk of Lung Disease**

A recent study has claimed that men who frequently consume cured meats may be at an increased risk of developing chronic obstructive pulmonary disease (COPD). R. Varraso, et al., “Prospective Study of Cured Meats Consumption and Risk of Chronic Obstructive Pulmonary Disease in Men,” *American Journal of Epidemiology*, September 4, 2007. Researchers followed 42,915 men involved in the Health Professionals Follow-up Study and identified 111 self-reported cases of newly diagnosed COPD, gauging the cumulative average intake of cured meats through food frequency questionnaires issued in 1986, 1990 and 1994, and divided according to servings per week. The study concluded that men consuming cured meats daily had more than 2.5 times the risk for COPD compared with those who rarely consumed processed meats, bacon or hot dogs. In contrast, however, cured meat consumption was not similarly associated with the risk of adult-onset asthma. Researchers speculated that the nitrites contained in cured meats “generate reactive nitrogen species that may cause damage to the lung.” See *PCRM News Release*, September 12, 2007.





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