# Food & Beverage

## LITIGATION UPDATE

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# Food & Beverage

LITIGATION UPDATE

# Legislation, Regulations and Standards 110th Congress

#### [1] House Subcommittee Inserts Preemption Provision Into Farm Bill

The House Subcommittee on Livestock, Dairy and Poultry has reportedly approved a provision for inclusion in the 2007 Farm Bill that would preempt any state prohibitions against foods or agricultural products deregulated by the U.S. Department of Agriculture. Viewed as a measure aimed at recently adopted state laws restricting the planting of genetically engineered crops, the language, according to critics, could also prohibit states from taking action on food contamination outbreaks. The passage apparently states, "no State or locality shall make any law prohibiting the use in commerce of an article that the Secretary of Agriculture has inspected and passed; or determined to be of non-regulated status." See Center for Food Safety Press Release, May 24, 2007.

Meanwhile, groups ranging from the businessfriendly American Enterprise Institute to Food & Water Watch, a Washington, D.C.-based consumer rights organization, have been weighing in on the legislation. AEI recently released a <u>series</u> of papers from academics and trade group representatives opposing crop subsidies and land-use restrictions. They contend that food-aid programs are wasteful and that ending crop subsidies presents a low risk of financial calamity. They also call for reform of the Conservation Reserve Program that takes farmland out of use to advance conservation interests. On the other end of the spectrum, Food & Water Watch is calling for the farm bill to serve the interests of farmers and consumers, as opposed to "agribusiness middlemen." The organization is recommending legislation that would, among other matters, help farmers transition to organic production methods and give consumers country of origin labeling with respect to livestock.

## Department of Agriculture (USDA)

#### [2] FSIS to Discuss Upcoming Codex Alimentarius Meeting

USDA's Food Safety and Inspection Service has announced a public meeting slated for June 5, 2007, in Washington, D.C., to discuss U.S. positions on agenda items for the 30th Session of the Codex Alimentarius Commission, which will convene July 2-7 in Rome. Agenda items covered in the 30th Session will include: (i) amendments to the procedural manual; (ii) proposed draft standards; (iii) revocation of existing Codex standards; and (iv) implementation of the FAO/WHO evaluation of the Codex Alimentarius. Interested parties can find additional information on the Codex Alimentarius Web site.





#### [3] FSIS Announces Open Meeting of National Advisory Committee on Microbiological Criteria for Foods

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has announced a public meeting for the full committee and subcommittees on June 4-8, 2007, in Washington, D.C. The committees will assess: (i) the cooking parameters for safe seafood; (ii) the food safety importance of mycobacterium avium subspecies paratuberculosis; (iii) the most appropriate technologies for FSIS to adopt in performing routine and baseline microbiological analysis; and (iv) the parameters for inoculated pack challenge study protocols. NACMCF advises USDA, the Centers for Disease Control and Prevention, and the Departments of Commerce and Defense on public health issues related to food safety. A finalized agenda will also be available on the FSIS Web site.

### Food and Drug Administration

#### [4] FDA Issues Perchlorate Exposure Estimates; Claims Most Levels Consumed in Foods Fall Below EPA Standard

FDA has released its "Preliminary Estimation of Perchlorate Dietary Exposure," which is based on a study of 27 foods and beverages consumed by three population groups — everyone ages 2 and older, children ages 2 to 5 and women of childbearing age (15 to 45). Perchlorate is used to make rocket fuel and enters the food chain via contaminated water sources; it has purportedly been found to affect thyroid function. According to the National Academy of Sciences, the chemical has been detected in 35 states, and more than 11 million

people apparently consume it in their drinking water at levels of 4 parts per billion. Levels in foods studied by the FDA ranged from a high of 92.4 ppb in greens to a low of 0.15 ppb in apples.

The agency contends that even when exploratory surveys are conducted in regions where water sources are known to be contaminated with the chemical, the levels found in foods, such as fruits, vegetables, fish, and grain products are not high enough to pose a health risk to most people. It estimated that most Americans ages 2 and older consume 0.053 micrograms per kilogram of body weight daily, which is lower than the 0.7 micrograms per kilogram of body weight standard adopted by the Environmental Protection Agency in 2005. In 2006, EPA raised its standard for taking remedial action to 24.5 ppb. According to a scientist with the Natural Resources Defense Council, the EPA standard is not safe for vulnerable populations and the new FDA estimates for some food items "come perilously close to what EPA considers an unsafe level." See The Washington Post, May 31, 2007.

#### [5] FDA Publishes Interim Report on Melamine-Contaminated Animal Feed; FSIS Rules Pork and Poultry "Not Adulterated"

FDA has published a report, titled <u>Interim</u> <u>Melamine and Melamine Analogues Risk</u> <u>Assessment</u>, that describes the human health risks associated with consuming poultry, pork, fish, or eggs from animals fed salvaged pet food contaminated with melamine and cyanuric acid, ammelide or ammeline. Prepared in collaboration with the Food Safety Inspection Service (FSIS), the report concludes that the affected animals pose little or no threat to human health, even when consumed in large quantities. "The purpose of the safety/risk assessment is to assist FDA and FSIS in the ongoing





investigation of contaminated vegetable protein products imported from China that were mislabeled as 'wheat gluten' and 'rice protein concentrate,'" FDA said. The agency will accept comments on the interim report until June 29, 2007. *See Federal Register*, May 30, 2007.

In a related development, FSIS has determined that "pork and poultry products from all animals identified as having been fed animal feed containing contaminated pet food scraps are 'not adulterated' and are thus eligible to receive the mark of inspection." FSIS based its assessment on FDA's interim report and testing conducted on tissue samples taken from hogs and poultry exposed to melamine-contaminated feed. The agency has released all quarantined animals for use in human food and will accept comments on its action until August 28, 2007.

Meanwhile, Chinese officials have reportedly announced plans to develop a food recall system for unsafe or unapproved products. "All domestic and foreign food producers and distributors will be obliged to follow the system," said Wu Jianping, the director general of the General Administration of Quality Supervision, Inspection and Quarantine. The effort to improve food regulation comes after international allegations of plasticizer-tainted feed ingredients and toxic solvent in toothpaste, in addition to domestic reports of substandard products from duck eggs enhanced with industrial dye to medicines laced with diethylene glycol. The Beijing No. 1 Intermediate People's Court has also sentenced to death the former head of the State Food and Drug Administration (SFDA) for accepting US\$850,000 in alleged bribes from eight pharmaceutical companies. "The Chinese government has always seriously regarded consumer products, especially with regard to the safety of food and medicines, and we treat the protection of our citizens' lives and safety as an important responsibility," a Foreign Ministry spokesperson was quoted as saying. *See The Independent*, May 25, 2007; *The Wall Street Journal, Reuters* and *China Daily*, May 29, 2007.

### **European Commission**

#### [6] EU White Paper Calls for Obesity Strategy

Commenting that if the EU fails to act on obesity, "today's overweight children will be tomorrow's heart attack victims," EU Health Commissioner Markos Kyprianou has released a white paper on nutrition and obesity adopted by the European Commission on May 30, 2007. The paper calls for public action that takes into account: (i) individuals are responsible for their lifestyles, "while recognizing the importance and the influence of the environment on [their] behavior"; (ii) "only a well-informed consumer is able to make rational decisions"; and (iii) optimal responses will require an integration of different policy areas in the public and private spheres. Strategies to combat obesity would include voluntary approaches on the part of the food and beverage industry, with labeling initiatives, product reformulations and standards for youth advertising primary among them. The commission will apparently decide in 2010 whether such approaches are working.

Promoting the consumption of fruits and vegetables and increased physical activity are also among the white paper's recommendations. The EC plans to establish monitoring programs on macro and micro levels to determine the effectiveness of obesity-related campaigns and initiatives.

Recognizing that some 30 percent of the continent's children are overweight, the commission clearly





acknowledged that action is necessary, but consumer advocacy groups harshly criticized the policy paper as a "disappointing, unambitious and minimalist response to the problems of obesity and diet-related diseases." Such groups advocate food-advertising restrictions and regulations requiring that product labels warn consumers about high-salt, -fat or -sugar content. The food and beverage industry reportedly applauded the paper; one lobbying group was quoted as saying, "We think the Commission is taking a very sensible and good approach towards obesity. It is giving industry time to show that self-regulation measures are working." *See Financial Times*, May 30, 2007

# Litigation

#### [7] USDA Plans to Appeal BSE Test Kit Case

The U.S. Department of Agriculture has reportedly indicated that it will appeal a U.S. district court's March 2007 decision allowing a Kansas beef processor to test the animals it slaughters for bovine spongiform encephalopathy (BSE). Creekstone Farms Premium Beef, L.L.C. v. USDA, No. 06-1544 (D.C. District Court, decided March 29, 2007). The ruling was to have taken effect June 1, but the testing may be delayed until the appeal is decided. USDA contends that it has the authority to regulate the use of BSE test kits under the Virus-Serum-Toxin Act. The court rejected that argument, reasoning that because the kits are used on dead animals, they do not fit within the definition of "analogous products," i.e., those products used for the treatment of domestic animals. Additional details about the court's ruling appear in issue 209 of this Report. See The Wichita Eagle, May 30, 2007.

#### [8] Federal Court Allows Benzene Suit Against Soft Drink Makers to Proceed

A U.S. District Court in Kansas has denied a motion to dismiss a lawsuit that seeks to halt the sale of beverages with ingredients that can form benzene when exposed to light and heat. Gonzalez v. PepsiCo, Inc., No. 06-2163 (D. Kan., decided May 24, 2007). Defendants PepsiCo, Inc., Sunny Delight Beverages Co. and Rock Star, Inc. contended that the court lacked subject matter jurisdiction over the claims and that the complaint failed to state a claim for which relief can be granted. According to the plaintiffs, all defendants have manufactured and/or distributed their beverage products deliberately and notwithstanding their knowledge that such products have a tendency to contain benzene at levels in excess of 5 parts per billion, the level EPA deems safe in drinking water. The plaintiffs claimed they would not have purchased the products if the defendants had disclosed their tendency to contain benzene. While they alleged breach of implied warranty of merchantability, unfair trade practices and unjust enrichment, plaintiffs did not allege that any of the beverages they purchased and consumed actually contained benzene or that drinking the beverages caused them any personal injury.

Defendants argued that the (i) plaintiffs lack standing because they have not "suffered any injury in fact"; (ii) the complaint does not state a claim for relief because state product liability law does not permit recovery of economic damages, the parties lack privity, and no allegation of present defect was alleged; and (iii) the court should defer primary jurisdiction to the Food and Drug Administration.

Because plaintiffs alleged that they "suffered economic damages resulting from the difference between the purchase price of the beverage products





as warranted and their actual value considering the potential presence of benzene in those products," the court found that they had alleged an injury. The court disagreed that plaintiffs' claims were foreclosed under state product liability law and agreed with plaintiffs that privity is not required for breach of warranty claims in a consumer transaction. Whether the defendants' products probably or possibly contained benzene was not, said the court, properly resolved on a motion to dismiss. The court further declined to defer primary jurisdiction to the FDA, finding that, on a motion to dismiss, it was sufficiently qualified to make a decision as to the sufficiency of the allegations "without impinging on the FDA's regulatory scheme or area of expertise."

#### [9] Court Orders Pet Food Company to Cease Contacting Pet Owners

A USA Today report indicates that a U.S. District Court in Camden, New Jersey, has entered an order to stop Menu Foods from contacting pet owners involved in litigation against the company unless their attorneys are involved in the discussion. The company, which manufactured pet food that allegedly sickened or killed thousands of cats and dogs nationwide, is defending hundreds of class action and individual lawsuits filed across the country. Many are seeking consolidation before the Judicial Panel on Multidistrict Litigation, which considered argument on the issue May 31, 2007. Menu Foods representatives reportedly called pet owners, asking probing questions about the foods they were feeding their pets and making references to a settlement of their claims. Plaintiffs' lawyers have referred to the conduct as abusive and harassing. The court reportedly said, "It seems to me that Menu Foods is out to do whatever Menu Foods wants to do in a way that could adversely

impact the rights of possible members of a class action suit against the company." *See USA Today*, May 28, 2007.

#### [10] Judge Dismisses Claims in French Fry MDL Suit Against McDonald's

According to a news source, U.S. District Judge Elaine Bucklo has dismissed without prejudice three of five claims filed by plaintiffs who alleged that McDonald's Corp. misled the public by failing to disclose that its french fries and hash browns contain wheat and gluten. In re McDonald's French Fries Litig., MDL No. 1784 (N.D. Ill., decided May 30, 2007). The court reportedly determined that the complaint contained insufficient detail about an alleged scheme to conceal the existence of gluten and dairy in the company's products. She was quoted as saying that the claims "allege that the potato products were advertised and marketed as milk-, wheat- and gluten-free, but no specific instances or locations of the advertisements are identified." Allowing claims for breach of warranty and unjust enrichment to proceed, the court gave the plaintiffs 28 days to amend their complaint. See Bloomberg News, May 31, 2007

# Other Developments

#### [11] New Studies Suggests Sodium Benzoate Damages Living Cells

A U.K. study has reportedly linked sodium benzoate, a preservative also known as E211 in Europe, to the destruction of mitochondrial DNA in living cells. "The mitochondria consumes the oxygen to give you energy and if you damage it – as happens in a number of diseased states – then the





cell starts to malfunction very seriously," said lead researcher and Sheffield University Professor Peter Piper, in speculating that sodium benzoate could negatively affect the aging process and contribute to neurodegenerative diseases such as Parkinson's. Recent studies have also suggested that food additives, including sodium benzoate, can cause hyperactivity and allergic reactions in children. "No one really knows what this chemical cocktail could be doing, particularly in the early stages of development," one University of Ulster researcher told the consumer affairs correspondent for *The Independent*, which also reported on claims that sodium benzoate can form benzene when combined with ascorbic acid in soft drinks.

Meanwhile, Piper's findings have reportedly prompted several Members of Parliament to call for an inquiry into the safety of sodium benzoate in foods. The United States, European Union and World Health Organization have both approved the preservative for widespread use in food and beverages. *See The Independent*, May 27 and 29, 2007; *Food Production Daily Europe.com*, May 29, 2007.

# Scientific/Technical Items

#### [12] New Zealand Scientists Breed Crows That Produce Low-Fat Milk

A New Zealand-based biotechnology company is reportedly breeding a herd of cows capable of producing low-fat milk that is also high in omega-3 fatty acids. Vialactia apparently discovered the dominant gene in a Friesian cow whose milk contained only 1 percent fat, as opposed to the 3.5 percent fat generally found in whole milk. In addition to the elevated protein count, products made from the milk "maintain the positive taste with other desirable benefits," according to a company representative, also describing a butter that spreads as easily as margarine. Vialactia, which has already bred offspring with the trait, expects the first commercial herd to be supplying low-fat milk and butter by 2011. See MSNBC.com, May 29, 2007.



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Leo Dreyer and Mary Boyd in the Kansas City office of SHB.

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