

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards 110th Congress

[1] House Committee Holds Hearings on FDA's "Diminished Capacity"

The House Committee on Energy and Commerce this week held an oversight and investigations [hearing](#) titled "Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?." Civilian witnesses, industry representatives and health officials addressed recent disease outbreaks linked to fresh produce, peanut butter and pet food, the latter of which apparently contained melamine-laced wheat gluten imported from China. "I can't protect them from spinach – only you guys can," said one father who testified that his daughters contracted *E. coli* from tainted spinach, although industries defended their approach to food safety. "We welcome regulation in this arena, but also believe strongly that with or without regulation, it is incumbent upon the individual companies and our industry as a whole to act to improve food safety," contended a spokesperson for Natural Selection Foods, a spinach processor implicated in the *E. coli* outbreak. "Private industry can and should move faster than the regulatory process."

A second hearing will interview FDA field officials

about "their imperfect stewardship of public health," according to committee chair John Dingell (D-Mich.), in describing the agency's lack of funding and overtaxed workforce. He also alluded to reports that Chinese companies deliberately used melamine, a fertilizer and plasticizer high in nitrogen, to artificially bulk up grain proteins. "While it matters not to the victims whether they are poisoned for profit or politics, we must be particularly concerned that these profiteers have drawn a roadmap to holes in our regulatory scheme," Dingell said in his [statement](#). China, which had been resisting FDA investigators, this week agreed to allow a U.S. inquiry into at least two Chinese companies suspected of intentional contamination. Today, the Chinese Foreign Ministry issued a statement claiming the nation has banned melamine from food products, while asserting "there is no clear evidence" indicating the substance is responsible for the sickening or deaths of American pets. See *The New York Times*, April 24, 2007; *Associated Press*, April 26, 2007.

Meanwhile, several pet food manufacturers have expanded recalls after FDA detected melamine in additional grain ingredients. Natural Balance Pet Foods, the Blue Buffalo Co. and Diamond Pet Foods have pulled products containing rice proteins imported by Wilbur-Ellis, Co., which reportedly received adulterated shipments from China-based Binzhou Futian Biology Technology Co. Ltd. FDA is also investigating whether melamine has entered the human food supply via hogs raised on salvaged



pet food. Animals from California-based American Hog Farm have tested positive for melamine, although state officials maintain the operation does not supply “mainstream pork” and poses minimal risk to humans. The Food Safety and Inspection Service is currently tracking contaminated animal feed distributed to hog farms in six other states. *See Associated Press*, April 20 and 25, 2007.

In addition to its criminal investigation, FDA reportedly plans to test more Chinese imports – including wheat gluten, corn meal, soy protein, and rice bran – for melamine and related chemicals. The Center for Science in the Public Interest, however, has described U.S. pets as “the puppies in the coal mine,” calling for a ban on all grain products “until the Chinese government and producers can guarantee that these imports are free of illegal and dangerous substances.” Other critics have also pointed to gaps in U.S. regulatory oversight. “Billions of dollars’ worth of foreign ingredients that Americans eat in everything from salad dressing to ice cream get a pass from overwhelmed inspectors, despite a rising tide of imports from countries with spotty records,” charges *Associated Press* reporter Justin Pritchard in an April 23 article, which claims FDA targeted only 20 ingredients when it inspected 650 shipments last year. *See CSPI Press Release*, April 24, 2007.

[2] Proposed Legislation Would Create National Institutes for Food and Agriculture and Require Federal Government to Purchase Foods from Producers Meeting Stewardship Standards

U.S. Senator Debbie Stabenow (D-Mich.) has introduced legislation ([S. 1094](#)) that would “establish the National Institutes for Food and Agriculture as an independent agency reporting to and coordi-

nating with the Secretary of Agriculture.” Titled the Creating Research Extension and Teaching Excellence for the 21st Century (CREATE-21) Act, the bill builds on a 2004 report issued by USDA’s Research, Education, and Economics Task Force, which recommended developing an institute within USDA to support U.S. agricultural research. The proposal would integrate several new and existing programs under one umbrella agency that reports to USDA, according to a coalition of land-grant university representatives, also known as [CREATE-21](#), that is backing the measure. The National Institutes director, appointed by the president to a six-year term, would oversee six solution-focused institutes: (i) economic opportunities in agriculture and natural resources; (ii) nutrition and health; (iii) rural and urban community development; (iv) natural resources and environment; (v) food safety and agricultural security; and (vi) families, youth and communities. The bill has been referred to the Committee on Agriculture, Nutrition and Forestry.

In a related development, U.S. Representatives Peter DeFazio (D-Ore.) and Christopher Shays (R-Conn.) have introduced the Farm Animal Stewardship Purchasing Act ([H.R. 1726](#)), which would require the federal government to purchase meat, dairy and egg products from producers that meet animal-welfare standards. “Increasingly, Americans are demanding we curb the most abusive factory farming practices,” said DeFazio in a press release. “As a significant buyer of farm animal products, the federal government can and should help lead the way by requiring produces to meet basic federal animal welfare requirements.” *See Press Release of U.S. Representative Christopher Shays*, March 28, 2007.



Food and Drug Administration (FDA)

[3] FDA Rejects Italian Aspartame Study Results

Based on the limited data available from the authors of a study on the potential for the artificial sweetener aspartame to cause cancer in animals, the FDA has [determined](#) that “significant shortcomings in the design, conduct, reporting, and interpretation of this study” compromised its reliability. Details about the 2005 study, conducted by the European Ramazzini Foundation in Bologna, Italy, appear in issue 134 of this Report. According to the FDA, it could not conduct a complete review of the study because the foundation did not provide the full study data. Nevertheless, because a large number of studies have not shown an association between the use of aspartame and the occurrence of tumors, “FDA finds no reason to alter its previous conclusion that aspartame is safe as a general purpose sweetener in food.”

Department of Health and Human Services

[4] Bisphenol A Draft Report Available for Public Comment

The National Toxicology Program’s Center for the Evaluation of Risks to Human Reproduction (CERHR) has announced the availability for public comment of an interim draft expert panel [report](#) on bisphenol A. Written comments must be received by May 14, 2007, and time will be set aside on May 21, during CERHR’s expert panel meeting, for oral public comments. The second [meeting](#) of the bisphenol A expert panel will be held May 21-23. The panel is considering whether the chemical,

which is used in polycarbonate plastic and resins, is harmful to human reproduction or development. According to CERHR, humans come into frequent contact with bisphenol A through food and drink packaging, electronic equipment, automobiles, and water-supply pipes. The National Institutes of Health fired the company that was operating CERHR for conflicts of interest. Additional details about the controversy appear in issue 211 of this Report. It is unknown if NIH’s action will affect the meeting schedule. *See Federal Register*, April 2, 2007.

Litigation

[5] KFC and California AG Resolve Acrylamide Issues

California’s attorney general has announced the [settlement](#) of claims that KFC Corp. violated Proposition 65 (Prop. 65) by failing to warn the public that its fried and baked potatoes contain acrylamide. Prop. 65 requires warnings to the public about exposure to chemicals “known to the state to cause cancer or reproductive toxicity.” Two lawsuits were filed against KFC, other fast-food companies and snack makers in 2005, seeking to force them to comply with the warnings law. Further details about the litigation appear in issues 132 and 140 of this Report.

Under the agreement, KFC does not admit wrongdoing, but agrees to display prominent warnings in its restaurants and to pay \$341,000 in civil penalties and funding for Prop. 65 enforcement. KFC can provide the prescribed warnings with signs, a combination of signs and brochures or posters. Attached to the settlement agreement are samples of warnings the attorney general finds adequate. The agreement contains three approved warning



messages, stating, in part:

Fried potatoes, including both french fries and potato chips, contain acrylamide, a chemical known to the State of California to cause cancer. This chemical is not added to our foods, but is naturally created when certain foods are browned. It is created in fried and baked potatoes made at all restaurants, by other companies, and even when you bake or fry potatoes at home. . . . The FDA has not advised people to stop eating baked or fried potatoes.

The settlement requires KFC to provide its franchisees with signs or brochures and to inform them of their obligations under the agreement. Other defendants in the case include Frito-Lay Inc., PepsiCo Inc., H.J. Heinz Co., Kettle Foods Inc., and McDonald's Corp. Counsel for a number of the defendants reportedly noted that some of them are not yet negotiating with the attorney general's office; snack makers with a nationwide market do not apparently have the same options as restaurants with a presence in the state, she contends. The parties to the agreement, which is subject to court approval, will appear before the Los Angeles County Superior Court on May 29, 2007. *See The Los Angeles Times*, April 25, 2007.

[6] Contaminated Spinach Cases Settle

The families of three elderly women who filed wrongful death lawsuits against the companies purportedly responsible for the 2006 sale of *E. coli*-contaminated spinach have reportedly settled their claims. Mission Organics (the grower), Natural Selection Foods (the processor) and the Dole Food Co. (the marketer) were described as "very apologetic" during the mediation process, and

negotiations centered on which company was the more culpable. The women who died were all in their 80s; they were from Nebraska, Washington and Maryland. Only one of the women was included as one of the three deaths counted during the outbreak by the Centers for Disease Control and Prevention. A second was counted as one of those taken ill. Food plaintiffs' attorney William Marler represented the families and was quoted as saying, "They didn't die immediately after eating it, but they got sick. But there's no question that it came from Dole baby spinach, or else there wouldn't have been a settlement." *See Santa Cruz Sentinel*, April 21, 2007; *The Los Angeles Times*, April 23, 2007.

[7] Chocolate Contamination Generates Criminal Prosecution

The *BBC News* is reporting that Cadbury Schweppes will be prosecuted for three alleged offenses relating to its sale of *salmonella*-contaminated chocolate in the United Kingdom during 2006. The Birmingham City Council is apparently planning to charge the confectionary company with two breaches of the General Food Regulations of 2004 and one breach of the Food Hygiene (England) Regulations of 2006. The charges specifically allege that the company (i) placed unsafe chocolate products on the market, (ii) failed to immediately inform authorities about the alleged contamination, and (iii) failed to identify critical control points and corrective actions. Each offense carries a maximum penalty of an unlimited fine and/or two years' imprisonment. The firm will appear before Birmingham magistrates on June 15, 2007. The company has already incurred £30 million in expenses to recall the product and for loss of consumer confidence. Herefordshire Council is reportedly investigating possible environmental



health breaches at the company's Marlbrook site. See *BBC News*, April 24, 2007.

Other Developments

[8] Honeybee Exodus Continues to Confound Apiarists

"As with any great mystery, a number of theories have been posed, and many seem to researchers to be more science fiction than science," writes *New York Times* reporter Alexei Barrionuevo in an April 23 article chronicling what some are calling "the rapture of the bees," a honeybee disappearance afflicting more than one-quarter of the nation's commercial hives. Known as colony collapse disorder, the phenomenon has affected beekeepers in 27 states and threatened \$14 billion in pollinated crops, although entomologists have been unable to find an explanation for the vanishing insects. Theories range from poor diet and stress to cell phone interference, but new evidence suggests that a viral infection, fungus or pesticide might be compromising the bees' immune systems. More than 60 North American scientists met this week to discuss these possibilities in light of preliminary DNA results, which identified unknown microorganisms in affected colonies. They also considered rare fungi discovered in bees for the first time, as well as the effect of a pesticide ban in France. "This is like 'C.S.I.' for agriculture," one researcher was quoted as saying. "It is painstaking, gumshoe detective work."

[9] Advertisers Tap Into Cheerleading Spirit

"Putting in an appearance on the cheerleading circuit is becoming mandatory for marketers hoping to connect with teens through word-of-mouth marketing," according to a recent *Wall Street Journal* article on Varsity Spirit, a cheerleading

organization that has brokered sponsorships agreements with Proctor & Gamble Co. and PepsiCo Inc. Through its deal with Varsity, PepsiCo has reportedly peddled its Propel® water to more than 500,000 cheerleaders who attended the beverage maker's workshops on nutrition and the importance of hydration. The athletes are apparently more susceptible to sponsorships because "they lose some of that wall they put up" against traditional marketing, a PepsiCo spokesperson was quoted as saying. Nevertheless, some sports marketers have warned against overly aggressive tactics at teen-centered events. "High school has become a big bulls-eye for lots of marketers," said one advertising executive, pointing to the fine line between subtle word-of-mouth marketing and message overkill. See *The Wall Street Journal*, April 19, 2007.

Media Coverage

[10] U.S. News Features American Caffeine Craving

The cover story of the April 23, 2007, issue of [*U.S. News & World Report*](#) discusses the growing numbers of U.S. adults and children who are drinking beverages with high caffeine levels. Titled "Over the Limit? Americans Young and Old Crave High-Octane Fuel, and Doctors are Jittery," the article focuses on the high-energy beverages that have become a multi-billion-dollar-a-year industry and can pose risks to those unaccustomed to the levels of caffeine they contain. While caffeine has been found to reduce the risk of Parkinson's disease and may reduce the risk of colon cancer, gallstones, liver cancer, and type 2 diabetes, it may contribute to increasing problems with sleeplessness and lack of sleep, and researchers are concerned about long-term effects on children who consume caffeine. The article mentions the efforts of the American



Medical Association and the Center for Science in the Public Interest to get manufacturers to provide caffeine content labels, and several beverage makers are reportedly re-labeling their high-energy drinks to include such information.

Scientific/Technical Items

[11] Dairy Linked to Parkinson's Disease, Prostate Cancer in Men

U.S. researchers have reported that men consuming high amounts of dairy products had an increased risk of developing Parkinson's disease, although the same did not appear true for women. Honglei Chen, et al., "Consumption of Dairy Products and Risk of Parkinson's Disease," *American Journal of Epidemiology*, May 2007. The study, which compiled data on 57,000 men and 73,000 women for nine years, claims that "dairy product consumption was positively associated with risk of Parkinson's disease" for men only. The researchers, however, also caution that more investigation is necessary to "explore underlying mechanisms." "Further considering some of the health benefits of dairy consumption, it is not wise to make advice to consumers based on this finding," lead researcher Honglei Chen, M.D., Ph.D., told the media. See *Food Navigator USA.com*, April 24, 2007.

Meanwhile, a Finnish study has concluded that high-calcium consumers are more likely to contract prostate cancer. Panagiota Mitrou, et al. "A prospective study of dietary calcium, dairy products and prostate cancer risk," *International Journal of Cancer*, June 2007. Of the 29,133 men in the survey, those with calcium intake exceeding 2,000 milligrams daily apparently had a 63 percent greater chance of developing prostate cancer, compared

with men who consumed less than 1,000 mg. daily. Previous research reportedly suggests that excess calcium inhibits the body's vitamin D, which is necessary for prostate health. See *PCRM News*, April 5, 2007.

[12] Research Shows Liquor More Damaging to Women

According to researchers from the United States and Russia, alcohol-dependent women perform worse than men on tests of visual working memory, spatial planning and problem solving, and cognitive flexibility. Barbara Flannery, et al., "Gender Differences in Neurocognitive Functioning Among Alcohol-Dependent Russian Patients," *Alcoholism: Clinical and Experimental Research*, May 2007. These effects apparently manifest despite women's shorter duration of drinking and lesser quantity of alcohol consumed. The researchers tested 78 male and 24 female Russian alcoholics, age 18-40, after four weeks' abstinence in addition to a control group of 68 men and women who were not alcoholics. It is not known what confounding factors the researchers may have considered or how the subjects were selected. A psychiatrist who works with the alcohol-dependent reportedly suggested that the study's findings could be used to help treat alcoholism in women. He apparently believes that some who know that drinking could reduce their intellectual abilities might be motivated to avoid "destructive drinking." See *Agence France Presse*, April 24, 2007.

[13] Researchers Find Overweight Children at Risk of CVD

Cincinnati Children's Hospital Medical Center researchers have reported that children with high body mass indexes (BMIs) were at a greater risk of



developing left ventricular hypertrophy (LVH), a thickening of the heart muscle that precedes coronary disease and heart attacks in adults. The study analyzed the echocardiograms of 548 children examined between 2004 and 2006, then looked at the echocardiograms of 465 children examined between 1984 and 1990. The more recent group, which had an average BMI of 18.8, experienced a 10 percent increase in left ventricular mass compared with the earlier group, which had an average BMI of 17.9.

Presenting the findings at a recent American College of Cardiology meeting, pediatric cardiologist Tom Kimball, M.D., said the hospital instigated the study after observing more LVH cases in seemingly “normal-weight” children. “We’ve grown so accustomed to an overweight child walking into an exam room that we’ve lost our visual representation of what a normal child is supposed to look like,” he said, advising pediatricians to track patients’ BMIs to identify potential problems. *See The Wall Street Journal*, April 24, 2007.



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