

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards 110th Congress

[1] Senate Favors Federal Pet Food Standards

Senator Richard Durbin (D-Ill.) recently introduced the Human and Pet Food Safety Act of 2007 ([S. 1274](#)), which would establish uniform federal standards for pet food ingredients and food import safety. The bill proposes an early warning surveillance system “to identify contaminations of pet food supply and outbreaks of illness,” in addition to recommending civil penalties for food importers, processors and distributors that fail to notify health officials about potential problems. The bill would also impose stricter standards, including a more rigorous certification and inspection process, on foreign governments wishing to export foodstuffs to the United States. “There is more work to be done to fix our food safety system, but today we have moved forward to address the growing concerns across our nation,” said Durbin in describing the amendments to the Federal Food, Drug, and Cosmetic Act. Representative Rosa DeLauro (D-Conn.) introduced a commensurate measure (H.R. 2108) in the House of Representatives.

Food & Drug Administration (FDA)

[2] Investigation Continues into Melamine-Tainted Wheat Flour Imported from China

FDA, the agriculture department and three other governmental agencies this week published a risk assessment finding that the maximum human exposure to melamine-tainted food would be approximately 2,500 times below the level considered safe. “In other words, it was well below any level of public health concern,” stated a joint USDA/FDA [press release](#), which also announced plans to release some swine and poultry for food processing. USDA had quarantined nearly 6,000 hogs after tests revealed melamine and related compounds in pet food salvaged as livestock feed, but the multi-agency report noted that the pet food scraps composed only a small portion of the feed. Melamine and its chemical cousin, cyanuric acid, are believed responsible for several dog and cat deaths that led to the recall of more than 100 pet food brands. Chinese exporters apparently added the nitrogen-rich compounds to low-grade feed components to boost protein counts above acceptable U.S. thresholds. See *The Washington Post*, May 7, 2007; *Reuters*, May 8, 2007; *The New York Times*, May 9, 2007.

FDA has also opened an investigation into fish meal made from the compromised ingredients. Distributed to U.S. and Canadian fish farms, the



meal contained what Chinese manufacturers represented as wheat gluten, although FDA found that both the suspect gluten and rice proteins were actually simple wheat flour. FDA Assistant Commissioner of Food Protection David Acheson told reporters that the agency will continue screening the fish for melamine contamination. "Depending on what we find in that testing, that is going to drive the next step," he was quoted as saying. *See Associated Press*, May 8, 2007.

In connection with the U.S. investigation, China has reportedly detained managers from two export companies, Binzhou Futian Biology Technology Co. Ltd. and Xuzhou Anying Biologic Technology Development Co. Ltd, the latter of which supplied adulterated products to Nevada-based ChemNutra Inc. Other China-based manufacturers, however, have apparently claimed that the practice of spiking animal feed with melamine scrap is widespread, a revelation that has focused international scrutiny on China's food supply. Meanwhile, the Chinese government has also refused to provide information on a reported epidemic that is killing pigs in southeastern China, where some sources estimate that 80 percent of the pig population has perished. The World Health Organization and the Food and Agricultural Organization routinely track swine diseases because pigs contract many of the same illnesses, such as avian influenza, as humans. "They definitely need to tell the public, but also people in the city, as to the extent of the outbreak, how the disease is being controlled and the impact on public health," said one Hong Kong official. *See The Wall Street Journal*, May 7, 2007; *The New York Times* and *Associated Press*, May 8, 2007

In a related development, the Arkansas Department of Health and Human Services this week began testing frozen catfish from Asia after neighboring states discovered the antibiotics ciprofloxacin and enrofloxacin in products imported from China. A state health department spokesperson said any lots tainted with the illegal drugs would be destroyed, while last month the Alabama Department of Agriculture and Industries placed a stop-order on all catfish from China. Alabama, Arkansas, Louisiana, and Mississippi, which lead the United States in farm-raised catfish, have reportedly struggled since 2002 against cheaper imports. *See Associated Press*, May 8, 2007.

U.S. Department of Agriculture (USDA)

[3] USDA Nutritionist Finds Children's Foods Marketed as Healthy Are High in Fat, Salt and Sugar

A USDA Agricultural Research Services (ARS) survey has reportedly determined that of 9,105 food products marketed to children, nearly 80 percent carried a nutrient claim and 60 percent of those were also high in saturated fat, sodium or added sugar. ARS nutritionist Sarah Colby presented her research at the 2007 Experimental Biology meeting held last week in Washington, D.C., where she stressed a need for balanced nutrition offerings. Colby and her team reviewed 57,000 food items from six major grocery stores, categorizing foods marketed to children according to package design, graphics and lettering, and promotions. They reported that 4,370 products claiming to be a "good source" of nutrients failed to meet the 2005 Dietary Guidelines for Americans in other areas. *See Food Production Daily USA.com*, May 7, 2007.



Department of Health and Human Services (HHS)

[4] NTP Invites Nominations for Expert Panel

The National Toxicology Program has [invited](#) expert panel nominations for a review of the agency's *12th Report on Carcinogens (12th RoC)*, a congressionally mandated document that lists substances "known to be human carcinogens or reasonably anticipated to be human carcinogens." The nominees should have expertise relevant to evaluating the carcinogenic hazards of the candidate substances, which include di (2-ethylhexyl) phthalate and formaldehyde. Expert knowledge applicable to the review process might cover biostatistics, carcinogenesis, chemistry, epidemiology, exposure assessment, molecular biology, pathology, toxicokinetics, or toxicology. Nominations for scientific experts must be received by June 8, 2007. Further details on the *12th RoC* appear in issue 211 of this Report.

International Trade Commission (ITC)

[5] Investigation Launched in Sucralose Import Case

The ITC has agreed to [investigate](#) a number of sucralose products from China to determine whether their importation violates the Tariff Act by infringing U.S. company patents. The action was taken in response to a complaint filed by Tate & Lyle Sucralose, Inc., which is requesting that the ITC issue a permanent general exclusion order and a permanent cease and desist order. Further details about the complaint appear in issue 210 of this Report. At issue are the artificial sweetener sucralose, sweeteners containing sucralose and

related intermediate compounds. The ITC has identified 25 respondents, including companies in China, Hong Kong, the United Kingdom, California, Illinois, Indiana, New Jersey, and New York. The case has been assigned to an administrative law judge, who will make an initial determination which will be reviewed by the commission and the U.S. Trade Representative. *See ITC News Release*, May 7, 2007.

In a related development, the International Alliance of Dietary Food Supplement Associations has been working through the Codex Alimentarius Commission to establish permissible levels of sucralose and other additives in food supplements. The organization, which represents 57 national trade associations on six continents, has proposed a level for sucralose of 2,400 mg/kg. Other proposed additive levels on which the association has focused its attention relate to castor oil, polysorbates, aspartame, cyclamates, and saccharin. The industry hopes to prevent the deletion of, or raise the allowed levels for, specific additives through the Codex process by providing its subcommittees with health-related evidence. Codex establishes food-related standards and guidelines that are relied on by governments worldwide to regulate the industry. *See FoodUSANavigator.com*, May 7, 2007.

State/Local Initiatives

[6] California Moves Forward with Legislation to Prohibit Diacetyl

Concerned about the food-flavoring industry's slow response to respiratory problems allegedly experienced by workers exposed to diacetyl, a chemical used in microwave popcorn and other products, California Assemblywoman Sally Lieber introduced [legislation](#) (A.B. 514) that would



require the state to ban the additive by 2010. The measure has been approved by two committees and is expected to be taken up by the full assembly in summer 2007. It would not affect diacetyl that naturally occurs in foods.

The state's Department of Occupational Safety and Health (DOSH) Standards Board has directed an advisory committee to develop an emergency or permanent standard to regulate diacetyl in the workplace; a draft was circulated to stakeholders, and the advisory committee has scheduled its next meeting for May 18. Opponents of A.B. 514 include the California Chamber of Commerce, the California Restaurant Association and the Grocery Manufacturers/Food Products Association. The groups contend that the proposal is premature and unnecessary and constitutes "an unwarranted attempt to bypass the effective process and statutory authority of DOSH and the Standards Board." As we noted in issue 213 of this Report, critics have expressed their concerns about the failure of federal regulators to take action on diacetyl despite studies linking the exposure to a life-threatening form of obstructive lung disease. One such critic, who formerly served in the Clinton administration's Department of Energy accused the federal occupational and safety agency of "regulatory paralysis." See *The Washington Post*, May 7, 2007; *The New York Times*, May 6, 2007.

Litigation

[7] Legal Actions Force Cocaine® Makers to Withdraw Beverage from Market

Redux Beverages has reportedly withdrawn the energy drink it markets as Cocaine® from stores nationwide. While the Food and Drug Administration (FDA), which had warned Redux that it was violating the law by purportedly marketing

the beverage as a drug and threatened to take enforcement action against the company, no such action had yet been taken. Nevertheless, company officials were facing legal issues in several states, including Connecticut and Texas. Additional details about the FDA's initiative appear in issue 210 of this Report.

The Connecticut Department of Consumer Protection entered an agreement with Redux on May 7, 2007, under which the company withdrew its product from the state and ceased marketing there. The department had embargoed 300 cases of the beverage in April "in response to an investigation initiated by complaints related to misbranding of the product." Texas Attorney General Greg Abbott filed a [request](#) for an *ex parte* temporary restraining order against the company, asserting violations of the state's Food, Drug and Cosmetic Act and the Deceptive Trade Practices Act.

A district court judge [granted](#) the request on May 2, temporarily banning its distribution in the state. The Texas Department of State Health Services detained \$200,000 worth of the product at warehouses in the Dallas area.

The company reportedly intends to announce a new name for the product within a week and hopes to return it to store shelves shortly thereafter. A spokesperson continues to contend that the company is making a legal product, but acknowledged it cannot distribute the product "when regulators in the states and the FDA are saying that if you do this, you could go to jail." Beverage fans have apparently been leaving profanity-laced messages on Myspace.com, complaining about its withdrawal from the market. See *The Port Arthur News*, May 2, 2007; *Connecticut Dept. of Consumer Protection Press Release*, May 7, 2007; and *The Miami Herald*, May 8, 2007.



[8] Food-Processing Plant Fined for Wastewater Violations

California water regulators have reportedly fined Natural Selection Foods \$95,000 for violating wastewater-discharge rules. The company, which was involved in the *E. coli* outbreak that affected hundreds who consumed fresh bagged spinach in 2006, has apparently been subjected to heightened scrutiny since the outbreak. According to a news source, a company plant in San Juan Bautista was discharging more water used to wash vegetables than its permits allowed. The threat posed by discharging chlorinated wastewater into waterways is to the fish living there and apparently had nothing to do with the *E. coli* problems. The company also reportedly failed to file required reports and expanded its disposal area without the proper permits and approvals. State regulators could have imposed fines as high as \$6.24 million; they are also focusing on other facilities and believe the problem “could be a widespread issue.” See *The Californian*, May 9, 2007.

Other Developments

[9] Distilled Spirits Company Imposes Stricter Youth Marketing Rules

Beam Global Spirits & Wine, Inc., which makes Jim Beam and Maker’s Mark bourbon and Canadian Club whiskey, has reportedly announced that it would begin restricting its print, TV and radio advertising to media whose audience is composed of at least 75 percent drinking-age consumers. The voluntary industry standard is 70 percent. The company has also apparently decided not to market at “Spring Break” events, to restrict the use of its brand in video games, not to market or sell flavored malt beverage products, and not to advertise

outdoors within 500 feet of playgrounds. Thirty-seven state attorneys general reportedly wrote to the company to applaud its initiative and called on others to follow suit. According to *The New York Times*, other alcohol companies have not indicated that they will follow Beam’s lead. See *The New York Times* and *MediaPost Publications*, May 8, 2007.

[10] Rachael Ray to Work with Alliance for a Healthier Generation

Celebrity chef Rachael Ray recently announced a cooperation between her culinary education initiative, [Yum-O Organization](#), and the Alliance for a Healthier Generation, a foundation started by former President Bill Clinton to combat childhood obesity and diabetes. The Yum-O Organization will reward schools that improve lunchroom fare and physical education classes, in addition to supporting programs such as Nickelodeon’s “Go Healthy Challenge.” Critics, however, have argued that Rachael Ray’s contract with Dunkin’ Donuts undermines her health message, despite the company’s contention that she will be promoting a line of “good for you” options. “[I]f seeing fun, peppy Rachel [sic] Ray hawk Dunkin’ Donuts encourages fans to drink a few hundred extra calories each day, then I would say this is a poor choice,” said one commentator for the Rudd Center for Food Policy & Obesity. See *The New York Times*, April 25, 2007; *Rudd Sound Bites*, May 7, 2007.

Media Coverage

[11] Sugar Levels Rise in Foods Considered “Healthy”

The *Daily Mail* reports that levels of sugar in foods such as breakfast cereals, whole grain breads and soups, traditionally considered healthy products, have been increasing dramatically over



the past three decades. For example, Kellogg's Special K® now has 17g of sugar per 100g of cereal, which doubles the amount of sugar present in 1978. According to reporter Peter Stebbings, this means "in crude terms" that "breakfast cereal now has almost as much sugar in it as vanilla ice cream." As well, "a typical wholemeal loaf" contained an average 2.1g of sugar per 100g in 1978, but now contains 2.8g. The U.K.'s Food Standards Agency called for food companies to reduce the salt levels in their foods two years ago, "but one apparent spin-off of that has been companies putting in more sugar to make up for the lower salt levels." The article quotes a *British Medical Journal* article that claimed in 2005, "Sugar is as dangerous as tobacco and, in terms of world health, far more important." See *Daily Mail*, May 6, 2007.

Scientific/Technical Items

[12] Study Shows Close Association Between Barbecued Meat and Breast Cancer Risk

A University of South Carolina-Columbia study claims a "close association" between post-menopausal women's lifetime consumption of grilled, barbecued or smoked red meat and an increased risk of developing breast cancer. Steck, Susan E., et al., "Cooked Meat and Risk of Breast Cancer-Lifetime Versus Recent Dietary Intake," *Epidemiology*, May 2007. The researchers compared the lifetime and recent cooked meat intake of 1,508 women with breast cancer and 1,556 healthy women, finding that those who consumed the most grilled, barbecued or smoked meats over their lifetimes had a 47 percent increased risk of developing breast cancer compared with women who ate meat once a week or less. The study also concluded that, although recent dietary patterns had little associa-

tion with breast cancer occurrence, women in the highest two-thirds for lifetime consumption that consumed fewer than five servings of fruits and vegetables daily had a 74 percent risk increase. While Steck cautioned that the study did not show a causal relationship, her team nevertheless noted that two byproducts of the grilling process, polycyclic aromatic hydrocarbons and heterocyclic amines, are known carcinogens. See *Reuters*, May 3, 2007.

In a related development, University of Mississippi Medical Center researchers have apparently mimicked human alcohol-induced breast cancer in genetically engineered laboratory mice fed the equivalent of two alcoholic beverages per day. The study reportedly found that, when compared to the control group, (i) moderate consumption resulted in a 1.96-fold increase in tumor weight; (ii) alcohol intake caused a 1.28-fold increase in tumor microvessel density; and (iii) alcohol did not affect body weight in mice. The researchers presented their results this month at the American Physiology Society annual meeting in Washington, D.C. See *Forbes.com*, April 28, 2007.



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