

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Issues Melamine Risk Assessment; More Tainted Candy Found in the United States

The Food and Drug Administration (FDA) this week issued the results of “its interim safety and risk assessment of melamine and melamine-related compounds in food, including infant food.” Prompted by “reports of melamine contamination in milk-derived ingredients” manufactured in China, FDA reviewed its scientific literature on melamine toxicity, pointing to “gaps in our scientific knowledge” regarding the threshold at which the industrial chemical becomes dangerous in infants. “There is too much uncertainty to set a level in infant formula and rule out any public health concern,” according to an October 3, 2008, FDA press release, which noted that for other food products, “levels of melamine and melamine-related compounds below 2.5 parts per million do not raise concerns.”

Meanwhile, U.S. officials have reportedly located more melamine-tainted candy from China in New Haven, Connecticut, where two specialty stores were selling the White Rabbit Creamy Candy brand implicated in the global dairy scandal. The state’s consumer protection commissioner, Jerry Farrell Jr.,

expressed concern that “there may have been bags sold of these before we got to them,” warning consumers to avoid any White Rabbit products not yet removed from store shelves. The investigation followed the discovery of adulterated candies in California that led the U.S. distributor, Queensway Foods Co. based in Burlingame, Calif., to voluntarily recall the sweets pending further research. *See The Los Angeles Times*, September 27, 2008; *The New York Times*, October 2, 2008.

Chinese administrators have also added 15 dairy processors to the list of companies that allegedly sold products laced with the industrial additive. More than 53,000 Chinese infants have reportedly experienced kidney stones or renal failure after consuming contaminated infant formula, leading the parents of injured children to consider filing lawsuits against the businesses. State media sources have accused these manufacturers of seeking to collude with local officials in concealing the problem before the Beijing Olympics. Chinese Premier Wen Jiabao, however, has contested these reports, saying that when the government first received word of the widespread illnesses, “there wasn’t the slightest cover-up.” He added that China will work to “deepen foreign-related economic structural reform; improve foreign-related economic laws, regulations and policies; expand market access; strengthen the protection of intellectual property rights and provide a better environment for foreign business in China.” *See The Wall Street Journal*, September 29, 2008.



In addition, several multinational companies have pulled products made with milk-derived ingredients from China and switched suppliers in emerging markets. Cadbury PLC has apparently identified melamine traces in its chocolates sold in Asian stores, leading the company to recall products originating at its Beijing plant. H.J. Heinz Co. also reportedly announced that it will no longer use the implicated milk in infant formula destined for Hong Kong, while Nestle SA has initiated a review of its milk-buying procedures in China. “Nobody can look for everything,” one Cadbury spokesperson said, pointing to preliminary tests that “cast doubt on the integrity of a range of our products manufactured in China.” See *The Wall Street Journal*, September 30, 2008.

[2] FDA Amends Labeling Regulations for Health Claims Pertaining to Calcium, Osteoporosis and Vitamin D

FDA has [issued](#) a final rule “amending its labeling regulation authorizing a health claim on the relationship between calcium and a reduced risk of osteoporosis to include vitamin D so that, in addition to the claim for calcium and osteoporosis, an additional claim can be made for calcium and vitamin D and osteoporosis.” Effective January 1, 2010, the rule would also eliminate (i) “the requirement that the claim list sex, race, and age as specific risk factors for the development of osteoporosis”; (ii) “the requirement that the claim does not state or imply that the risk of osteoporosis is equally applicable to the general U.S. population, and that the claim identify the populations at particular risk for the development of osteoporosis”; (iii) “the requirement that the claim identify the mechanism by which calcium reduces the risk of osteoporosis and instead make it optional”; and (iv) “the require-

ment that the claim include a statement that a total dietary intake greater than 200 percent of the recommended daily intake (2,000 milligrams (mg) of calcium) has no further benefit to bone health when the food contains 400 mg or more of calcium per reference amount customarily consumed or per total daily recommended supplement intake.” In addition, the rule would “allow reference for the need of physical activity in either of the health claims to be optional rather than required.”

U.S. Department of Agriculture (USDA)

[3] USDA Seeks to Revoke Accreditation of Sustainable Agriculture Standard Developer

USDA has [requested](#) that the American National Standards Institute (ANSI) revoke the standards-development accreditation of the Leonardo Academy, the entity behind the development of a sustainable agriculture standard that was published as a draft standard for trial use in ANSI’s *Standards Action* in April 2007. Details about an initial stakeholder meeting held in November to discuss the draft standard appear in issue 237 of this Update. USDA has also asked ANSI to withdraw the draft standard for trial use.

In its September 2008 letter to ANSI, USDA contends that (i) the draft standard exceeds the scope of the academy’s approved scope of standards activities by straying into fair labor practices, community benefits, product quality, and product safety and purity; (ii) the academy failed to develop or publicize “its procedures with respect to draft standards for trial use”; (iii) the academy “failed to afford materially affected interests the opportunity to challenge the decision to register a [draft standard for trial use] with ANSI”; (iv) flawed



procedures have led to a flawed process that cannot be administered, and consensus will be impossible to attain on “too many issues”; (v) interested stakeholders did not provide input into the standards development committee’s formation; thus, certain industry segments are over-represented and others are under-represented; (vi) the academy lacks the ability to administer its announced standards development procedures; and (vii) the academy’s operations do not comply with ANSI’s requirements for coordination/harmonization, due process or with “normative American National Standards policies and administrative procedures.”

The Leonardo Academy [responded](#) to USDA’s appeal with a document that exceeds 200 pages, essentially contending that the agency’s appeal is “without foundation.” It suggests that its newly minted standards committee is “very diverse and experienced” and that it has diligently followed ANSI’s essential requirements.

Thereafter, on September 29, the academy issued a press release to announce that the development of a sustainable agriculture standard has moved into “high gear.” Its standards committee met, identified issues that need to be resolved, agreed to form work groups, and outlined future tasks. Among the issues to be addressed are “the relationship between organic, mainstream and sustainable agriculture”; “the place of genetically engineered crops in sustainable agriculture”; “the strength of labor protections”; “the intersection of product safety and sustainability”; and “whether the scope of the standard should extend beyond plant agriculture to include livestock and other sectors of agriculture.”

According to the academy, the standards committee agreed to set aside the draft standard for trial use, noting that it would serve as one of several reference documents in future standards develop-

ment deliberations. The academy also solicited contributions “to fund its work on this standard development initiative and to support active participation by the full range of stakeholders in the process.” See *Leonardo Academy Press Release*, September 29, 2008.

[4] COOL Regulations Take Effect

Country-of-origin labeling rules, long-delayed for fresh, perishable foods other than fish and shellfish, went into effect on September 30, 2008. They require supermarkets and mass-merchandise outlets to label or display the country of origin for meats, poultry, produce, and some nuts. Small food outlets, such as butcher shops and restaurants are exempt, and the rules do not apply to processed foods, like smoked salmon and cooked shrimp, or mixes, like bagged mixed salad greens, trail mix and fruit salad. Meats blended with products from several countries are not required to list the countries in any particular order. Any covered foods produced or packaged before September 30, do not have to include the COOL information.

For many years, foods packaged in another country have been required to carry origin labeling; with the latest COOL implementation, almost all food should carry this information. Consumer groups have hailed the mandatory rule change, calling it a “great benefit for consumers.” Some critics have apparently expressed concerns about loopholes that could allow meat packers to choose from among the countries represented in their products for purposes of labeling them. Senator Jon Tester (D-Mont.) reportedly complained to USDA that the loophole “gives consumers the impression that there is no domestically born, raised and slaughtered livestock and denies our American livestock producers the opportunity to focus on



promoting U.S. beef, lamb, pork, chicken, or goat meat.” See *Consumers Union Press Release*, September 12, 2008; *The Wall Street Journal*, September 23, 2008; and *Product Liability Law 360*, September 29, 2008.

Government Accountability Office (GAO)

[5] GAO Report Faults FDA Oversight of Fresh Produce Imports

A GAO report has [claimed](#) that the Food and Drug Administration (FDA) “examined less than 1 percent of the 7.6 million fresh produce lines imported from fiscal years 2002 through 2007.” “Moreover, FDA acknowledged that it has not yet been able to conduct certain fresh produce work crucial to understanding the incidence of contamination of produce by pathogens such as *E. coli* O157:H7 or *Salmonella*,” according to GAO, which attributed the failures to a lack of resources for either extramural research grant programs or internal research agendas. The report also noted that the agency “has no formal program devoted exclusively to fresh produce” and has not “reliably tracked its fresh produce spending. “What I found most interesting is that fresh produce has been a priority for FDA for nearly a decade, but all the initiatives the agency said it needs to implement to improve its oversight efforts have been delayed because of other pressing issues, like increasing response to bioterrorism and responding to food-borne outbreaks, like the jalapeno problem this summer,” the GAO director of food safety and agricultural issues, Lisa Shames, was quoted as saying. See *Law 360*, September 29, 2008.

Meanwhile, FDA Commissioner for Foods David Acheson has reportedly responded to GAO’s assess-

ment by calling on Congress to give the agency more authority to enact “preventative controls” over fresh produce processing similar to those in place for seafood and fresh juice. “Having Congress give us explicit authority makes it a much more robust approach and gives more chance of success,” Acheson said. See *The Associated Press*, September 26, 2008.

Food Safety Authority of Ireland (FSAI)

[6] Irish Report Calls for Regulation of Nanotechnology Applications in Food Industry

A recent FSAI [report](#) addresses the application of nanotechnology to the food industry and urges the European Union (EU) to provide a legislative framework for regulating nanotechnology in food.

Citing a general lack of information concerning the purported risks of nanoparticles in food, FSAI recommends the following: (i) “food business operators should conduct risk assessments on all foods involving introduction of new nanoparticles into foods and packaging”; (ii) “legal provisions should be considered at EU level to ensure that food and feed should be re-evaluated in terms of safety whenever the properties are changed/re-engineered to the nanoscale”; (iii) “the FSAI should promote the establishment of a publicly available inventory of nanotechnology-based food products and food contact materials”; (iv) “urgent consideration should be given to whether additional controls are required on the disposal and/or recycling of nanoparticle-containing food and other materials”; and (v) “food surveillance programmes should include investigation of the potential for nanoparticles . . . to migrate into foods and also to be recycled in the environment and enter the food chain indirectly.”



The report also calls for mandatory labeling of food and food packaging that contain nanoparticles.

State and Local Governments

[7] California Governor Approves Menu Labeling Legislation, Vetoes PFAO Ban

California Governor Arnold Schwarzenegger (R) this week signed legislation ([S.B. 1420](#)) requiring restaurant chains with 20 or more locations statewide to “post calorie information on menus and indoor menu boards for consumers.” Beginning July 1, 2009, “brochures containing either calorie content information or other nutritional information, such as grams of saturated fat, grams of carbohydrates, and milligrams of sodium, will be at the point of sale and drive-thrus for consumers,” according to a press release issued by the Office of the Governor. Chain restaurants must add calorie counts to their menus and menu boards by January 1, 2011. The new rules will affect approximately 17,000 establishments, and county health department officials can fine restaurateurs between \$50 to \$500 for violations. “States and cities are interested in menu labeling because of the growing role that chain food restaurants play in the American diet,” a spokesperson for the Center for Science in the Public Interest was quoted as saying. “Most Americans get a third of their calories from eating out. And, unfortunately, restaurant foods play a very problematic role in our diets.”

Schwarzenegger also approved a bill ([S. B. 441](#)) directing the operators of vending machines on state property to “satisfy the requirement that at least 35 percent of the food and at least one-third of the beverages offered in the vending machines meet accepted nutritional guidelines by January 1, 2011.”

See *Office of the Governor Press Release*, September 30, 2008; *The Washington Post*, October 1, 2008;

In a related development, Schwarzenegger vetoed a bill ([S.B. 1313](#)) seeking to prohibit the use of perfluorooctanoic acid (PFOA) in food packaging. Backed by the Environmental Working Group (EWG), the bill called for a ban on the “manufacture, sale, or distribution of any food contact substance ... that contains [PFOAs] ... in any concentration exceeding 10 parts per billion.” The proposal pointed to the Environmental Protection Agency’s classification of PFOA as a “likely carcinogen” linked to “breast tumors in animals” and “problems in pregnancy, including development complications.”

In vetoing the proposed ban, Schwarzenegger instead opted to pass two bills ([A.B. 1879](#) and [S.B. 509](#)) creating the “Green Chemistry Initiative,” which requires the California Environmental Protection Agency to “establish a process by which chemicals or chemical ingredients in products may be identified and prioritized for consideration as being chemicals of concern.” The initiative also requires the agency to create a Toxics Information Clearinghouse “for the collection, maintenance, and distribution of specific chemical hazard traits and environmental and toxicological end-point data.” The governor said that this initiative “puts to an end the less effective ‘chemical-by-chemical’ bans of the past.” See *United Steelworkers Press Release*, September 30, 2008; *Food Product Daily.com*, October 1, 2008.

[8] Utah Bans Flavored Malt Beverages from Gas Stations and Grocery Stores

The Utah Legislature has reportedly prohibited the sale of so-called “alco-pops” like Smirnoff Ice and Zima at all grocery stores and gas stations.



While state-run liquor stores can still sell the sweetened alcoholic beverages, the Utah Department of Alcoholic Beverage Control now requires the drinks to bear new labels that prominently display the alcohol content on the front of the product. Because no labels have yet received approval, the department anticipates that the current supply of these alcoholic beverages will run out and that many companies will choose not to spend substantial funds on new labels. *See The Associated Press*, October 1, 2008.

Litigation

[9] PCRM Seeks Processed-Meat Plaintiffs

The Physicians Committee for Responsible Medicine (PCRM) has launched a campaign warning consumers of the purported cancer risks posed by the consumption of processed meats, such as hot dogs, salami, sausage, pepperoni, bacon, and deli meats. Through train station posters in Newark, New Jersey, and a nationally aired TV spot, the group contends that processed meats, even in small amounts, increase the risk of cancer.

The poster campaign invites those who have purchased and eaten processed meat to join PCRM's hot dog lawsuit. It is not known if such litigation has yet been filed or in what venue. According to PCRM, the primary remedy sought will be product label and advertising warnings in New Jersey. The organization bases its cancer claims on a 2007 report from the American Institute for Cancer Research and the World Cancer Research Fund allegedly showing that processed meats increase the risk of colorectal cancer by 21 percent for every 50 grams of such foods eaten daily.

PCRM's Cancer Project [surveyed](#) school breakfast and lunch menus and found that they "are packed

with processed meats." According to the Cancer Project, "Some of the school districts with the highest rates of processed meat are in states with the highest rates of colorectal cancer." *See PCRM Press Release*, August 27, 2008; *PCRM Online*, October 2008.

[10] Chinese Courts See First Lawsuit over Melamine-Tainted Milk Powder

The parents of a boy allegedly sickened by consuming a dairy product contaminated with melamine have reportedly filed suit in China against Shijiazhuang Sanlu Group Co. Believed to be the first of its kind, the suit seeks compensation for hospital fees, travel expenses, lost work time, and other costs for a total of 150,000 yuan (US \$21,900). The parents, who are represented by lawyers from Beijing's Deheng Law Office, allege that their 1-year-old son developed kidney stones from drinking Sanlu and claim they have more than 90 empty bags of the company's milk powder as evidence. While product liability litigation has apparently been on the rise in China, the government has taken steps to keep the tainted-milk scandal out of the courts. According to a news source, lawyers who indicated they were available to assist families with sick children have been pressured by local government officials to avoid the issue. *See The Wall Street Journal*, October 1, 2008.

Other Developments

[11] Yum Brands to Provide Calorie Counts Nationwide

Yum Brands, parent to KFC, Taco Bell, Pizza Hut, Long John Silver's, and A&W All-American, has announced that it will add calorie information to menu boards in its company-owned restaurants



across the nation. The counts will be linked to individual serving sizes, and the company plans to encourage its franchisees to provide the same information. Of its 20,000 restaurants, some 4,000 are company-owned, according to a news source. The information will be placed next to the product's name and price on indoor menu boards. Michael Jacobson, executive director of the Center for Science in the Public Interest, reportedly lauded the initiative and called on "other major chains to follow this bold example." *See Associated Press*, October 1, 2008.



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