

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] **Wilson Center Report Calls for Greater FDA Authority over Nanotechnology**

Industry groups are reportedly questioning the conclusions of a new report about purported gaps in FDA's regulatory authority as to products made with nanotechnologies. The [report](#), titled "Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?," was written by a former FDA deputy commissioner with funding from the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts.

Author Michael Taylor also focuses on resource shortfalls that will similarly hamper FDA's ability to provide effective oversight of this emerging industry. According to the report, the FDA's authority over whole foods is generally weaker than its authority over drugs and medical devices. Taylor calls for the FDA to establish criteria that will allow manufacturers to know when they must submit their products for pre-market approval. He also calls for data on food uses, stating "In the absence of clear authority to access food industry data on pipeline products, FDA should attempt to access at least some of the food industry's safety-related data by

collaborating with industry, perhaps through a trade association, on a voluntary call for data on food uses of nanotechnology."

The report makes specific recommendations as to legal authority Congress should grant FDA, such as "administrative authority to call for the submission of specified information on emerging technologies and products under its jurisdiction," "discretionary pre-market notification authority," "post-market monitoring authority," and "adverse event reporting." Without certain legal authority or the resources to provide effective oversight, the report cautions that the agency "may miss potential safety problems or discover them too late to prevent harm, thereby jeopardizing public health and public confidence in nanotechnology."

The NanoBusiness Alliance responded to the report by claiming that FDA is "fully capable to carry out its mission to protect public health with regard to products using nanotechnologies." According to the alliance, which is a trade association for the emerging nanotechnology industry, "the FDA has robust legal authority and significant discretion in setting the protocols for testing to regulate nanotechnologies." See *dBusiness News*, October 6, 2006.

In a related development, FDA opened nanotechnology hearings on October 10. Media coverage of the hearings and the Woodrow Wilson report discusses the potential applications of the technology in the food sector. "What if the candy



maker Mars could come up with an additive to the coating of M&M's and Skittles that would keep them fresher longer and inhibit melting?," suggests a *New York Times* reporter. Written testimony submitted to FDA in advance of the hearing by the Consumers Union, states in part, "Lack of evidence of harm should not be a proxy for reasonable certainty of safety." That group, as well as others, are apparently urging FDA to automatically classify all nanoscale food ingredients as "new additives." FDA officials reportedly indicated that such an approach may not be within the agency's authority. Nanotechnology is already being used in synthetic food colorings, frying oil preservatives and food packaging, said a news source. See *The New York Times*, October 10, 2006.

[2] FBI and FDA Begin Criminal Searches in *E. Coli* Investigation

The FBI and FDA last week reportedly executed search warrants on Natural Selection Foods and Growers Express in the Salinas Valley region of California. "We are investigating allegations that certain spinach growers and distributors may not have taken all necessary or appropriate steps to ensure that their spinach was safe before it was placed into interstate commerce," Kevin Ryan, the U.S. attorney general for the Northern District of California, told the press. Although spinach processed and distributed by Natural Selection Foods has been implicated in the recent *E. coli* outbreak, Growers Express reportedly declined to speculate on why it was under investigation. Meanwhile, Natural Selection's chief operating officer was quoted as saying that the company continues "to believe that the source of the contamination was in the fields from which we

buy our spinach." See *The New York Times* and *The San Francisco Chronicle*, October 5, 2006; *Mercury News*, October 5 and 6, 2006.

Meanwhile, another Salinas company issued a voluntary recall of lettuce distributed under the Foxy label. The Nunes Co., Inc., apparently stated that the recall was initiated after irrigation water tests yielded positive results for *E. coli*. Nearly 8,500 cartons of lettuce were taken off the market, although further investigation revealed that the greens were negative for *E. coli* O157:H7. Despite farmers' fears that future recalls will erode consumer confidence, the FDA reportedly commended Nunes "because it is better to be cautious than to potentially put consumers at risk of contracting a serious foodborne illness." See *The New York Times*, October 10, 2006.

U.S. Department of Agriculture (USDA)

[3] USDA Recommends Improvements to FSIS Review System for State Meat and Poultry Inspection Programs

USDA published an [audit report](#) last month on Food Safety and Inspection Service (FSIS) oversight of state meat and poultry inspection (MPI) programs. According to the report, 28 states have entered into cooperative agreements with FSIS to ensure that "meat and poultry products sold intrastate meet inspection standards 'at least equal to' Federal laws and regulations." USDA found that since FSIS initiated a comprehensive review process in 2003, the agency has only completed eight initial onsite reviews of state MPI programs. USDA also said that the FSIS determinations in those cases "may be inappropriate," partly because the agency failed to properly document how it arrived at its conclusions.



USDA recommended that FSIS develop “clear and uniform criteria” for (i) weighting deficiencies in its evaluation of state MPI programs; (ii) analyzing state staffing requirements; (iii) verifying that effective employee performance systems are in place; and (iv) ensuring that laboratories “adhere to standards that are ‘at least equal to’ Federal regulations.” FSIS was also directed to resume its triennial fiscal review of state MPI programs.

State/Local Initiatives

[4] New Jersey Senator Proposes Statewide *Trans* Fat Ban in Restaurants

Following the lead of health officials in New York City and Chicago, Senator Ellen Karcher (D-Freehold) has announced a bill that would ban *trans* fat in all New Jersey restaurants. According to Karcher, the proposed legislation would really “take a bite out of the problem of obesity” while also cutting state health care costs. The New Jersey Restaurant Association, however, has reportedly criticized the impending bill, claiming its message is potentially misleading because other alleged causes of obesity, such as sugar, will not be restricted as well. “Moderation,” a restaurant association official said, “that’s what we should be talking about.” See *Associated Press*, October 5, 2006.

Meanwhile, a writer for the *The New York Times* recently considered whether the data on *trans* fat consumption is sufficiently up-to-date. Michael Mason noted that while researchers agree that *trans* fat consumption increases “bad” (LDL) cholesterol, new evidence suggests that the relationship between *trans* fat and heart disease is not straightforward. Recent studies apparently show that “good” (HDL) cholesterol, once thought to be

negatively affected by *trans* fat intake, is “significantly diminished only in subjects who consumed *trans* fat in the greatest amounts – nearly 7 percent of their daily calories – and even then just barely.” According to Mason, “This finding and others like it suggest that for consumers eating modest amounts of *trans* fat, the gain from reduced intake may not be as great as some might hope.” He added that the suggested alternatives to *trans* fat – saturated fats like coconut oil and butter – “are the very ingredients health advocates shooed us away from not so long ago.” See *The New York Times*, October 10, 2006.

Litigation

Deceptive Trade Practices

[5] McDonald’s Fries Blamed for Aggravation of Autism in California Lawsuit

According to a news source, the guardian of an autistic boy has filed suit on his behalf in Los Angeles Superior Court seeking damages from McDonald’s Corp. for injury allegedly caused by consumption of the company’s fries. Plaintiff Richard Brown apparently claims that after the youngster ate fries at a McDonald’s restaurant in Valencia, his autism symptoms of aggression and tantrums increased while his ability to communicate and take care of himself decreased. The boy and his guardian later learned that McDonald’s flavors its fries with gluten and casein, yet advertised the product as gluten- and casein-free. The complaint reportedly states, “In most cases, elimination of gluten and casein from an autistic child’s (diet) results in dramatic improvements in the child’s condition, often enabling the child to attend



mainstream educational programs in a matter of months.” Sounding in fraud, false advertising and negligent misrepresentation, the suit seeks \$15,000 for the child’s medical costs, a share of McDonald’s profits and unspecified compensatory and punitive damages. See *KNX 1070 Newsradio*, October 9, 2006.

GM Contamination

[6] Second Suit Alleging Damage from GM Rice Crop Contamination Filed in Louisiana

A putative class action filed against Bayer CropScience, LP in a Louisiana federal court on behalf of rice growers and processors alleges that the company negligently allowed an experimental genetically modified (GM) rice crop to contaminate non-GM rice crops. *Simon v. Bayer CropScience, LP* (U.S. District Court, Western District, Louisiana, filed October 9, 2006). According to the complaint, “[t]he scope of Bayer’s alleged wrongdoing is astronomical.” Referring to bans and restrictions on rice exports to the European Union and Japan, the complaint contends that the GM rice, which was never approved by oversight agencies, “is now present in virtually *all* milled rice grown in the United States.” The complaint further alleges, “This widespread LL601 rice cross-pollination and contamination has had a broad and adverse impact on Plaintiff and all rice farmers. Bayer’s wrongful conduct has rendered hundreds of millions of bushels of U.S. rice, grown on tens of millions of acres of U.S. farmland, unfit for human consumption or otherwise suspect in the global rice markets, which has resulted in worldwide market value loss for U.S. rice.”

The named plaintiff will be seeking to certify a class of “All persons and entities who cultivated and/or harvested and/or milled rice in Louisiana during the period from January 1, 2006, forward and who suffered damages from depression of rice prices, and/or the inability to sell or mill rice due to the contamination of U.S. rice supply with genetically engineered rice LL601.” The suit seeks compensatory damages and injunctive relief “requiring that Bayer decontaminate their farming, harvesting and transportation equipment, and their on-farm storage facilities, to prevent future contamination for the 2006 growing season and beyond.” Plaintiff also seeks punitive damages for reckless and willful conduct.

Similar litigation has been filed in Arkansas. Additional information about that case appears in issue 183 of this Report.

Other Developments

[7] Five Food Companies Agree to Provide Healthier Snacks in Schools

Campbell Soup Co., Dannon, Kraft, Mars, and Pepsico have agreed to replace foods high in fat, sugar and salt with more nutritious options in school vending machines and cafeterias. In an agreement with the Alliance for a Healthier Generation, a joint initiative of the William J. Clinton Foundation and the American Heart Association, the five companies will limit products to 150 calories for elementary school children, 180 calories for middle school children and 200 calories for high school students. Eliminating all *trans* fat and restricting sodium to fewer than 230 milligrams, a serving would get no more than 35 percent of its



calories from fat and 10 percent from saturated fat, and would be no more than 35 percent sugar by weight.

Food industry critics such as Commercial Alert have called the agreement “a public relations stunt,” while others reportedly lauded the effort but still believe federal legislation is necessary. See *Newsday* and *The New York Times*, October 6, 2006; *The Washington Post*, October 6 and 7, 2006.

[8] Campbell Soup Cans Go Pink for Breast Cancer Awareness Month

Campbell Soup Co. introduced pink Breast Cancer Awareness labels this month, doubling sales to Kroger stores nationwide as part of a \$3 million Susan G. Komen Breast Cancer Foundation promotion. Campbell reportedly sold 7 million cans, up from 3.5 million the previous year, to 2,500 Krogers for the month of October. Campbell's has pledged \$250,000 to breast cancer initiatives from its pink ribbon campaign. See *Advertising Age*, October 3, 2006; *Food Navigator USA.com*, October 9, 2006.

Critics of the pink labels, however, claim that Breast Cancer Awareness month is being exploited to foster brand loyalty. Blythe Berhard, a writer for the *Orange County Register*, charged that “In some cases, companies spend more on the marketing than they donate to the cause.” A Breast Cancer Action [project](#) now asks consumers to “Think Before You Pink,” citing examples of pink ribbon products that allegedly contain chemicals suspected of causing cancer. Public health lawyer Michele Simon also questioned Campbell on her blog, [Big Food Watch](#), writing “the pink label is only for the really salty stuff,” not the low-sodium varieties. See *The Orange County Register*, October 6, 2006; *Time*, October 8, 2006.

Scientific/Technical Items

Soft Drinks

[9] Researchers Allegedly Link Cola Consumption to Osteoporosis in Women

According to researchers studying 2,500 men and women near age 60, women who drank just four cola beverages weekly, but not other soft drinks, had lower mineral bone density in the hips than women who rarely drank such beverages. Katherine Tucker et al., “Colas, but not other carbonated beverages, are associated with low bone mineral density in older women: The Framingham Osteoporosis Study,” *84 Am. J. Clinical Nutrition* 936 (October 2006). The effect was apparently seen whether diet or full-sugar beverages were consumed; the effect, however, was not observed in men. The researchers adjusted their results for factors such as body mass index, height, age, energy intake, physical activity score, smoking, alcohol use, total calcium intake, total vitamin D intake, caffeine from noncola sources, season of measurement, and menopausal status and estrogen use in women. While the study did not identify what ingredient in cola drinks could trigger such effects, other studies have reportedly suggested that phosphoric acid may cause calcium loss. See *Daily Mail*, *Independent* and *FoodNavigator.com*, October 6, 2006.



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