

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

U.S. Department of Agriculture (USDA)

[1] **USDA Establishes New Protocol for Announcing BSE Contamination**

In an effort to avoid consumer alarm and prevent undue disruption of cattle prices, USDA said last week that the agency will retest beef samples that indicate possible bovine spongiform encephalopathy before making public “inconclusive” results. Under the new protocol, if an initial test shows indication of possible infection, two secondary rapid screening tests will be conducted; agency officials will announce inconclusive results only if one of the secondary tests is not negative. USDA plans to test more than 200,000 high-risk cattle for BSE by 2005. *See Reuters*, August 4, 2004; *The Wall Street Journal*, August 5, 2004.

Food and Drug Administration (FDA)

[2] **FDA Issues Revised Bioterrorism-Related Guidance**

FDA has posted on its Web site revised [guidance](#) regarding an interim final rule that implemented section 305 of the Public Health Security and

Bioterrorism Preparedness and Response Act of 2002 by requiring domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register their facilities by December 12, 2003. The agency evidently hopes that continued clarification of the interim final rule will expedite registration by covered facilities. Interested parties can submit comments on the guidance at any time. *See Federal Register*, August 6, 2004.

United Kingdom (U.K.)

[3] **British Government Orders Inquiry into Diet Plans**

As part of the British government’s ongoing activities aimed at reducing the nation’s rate of obesity, the National Institute of Clinical Excellence will reportedly convene a group of 20 physicians, nutritionists and dietitians in September to begin a yearlong evaluation of the safety and efficacy of various diet plans, particularly low-carbohydrate regimens like the Atkins Diet. According to a news source, an estimated 10 million Britons are dieting at any one time, with one in three following low-carbohydrate plans. More than 150 stakeholders will reportedly be consulted during the panel’s inquiry, with a final report expected by fall 2005. *See The Independent*, August 8, 2004.



European Commission

[4] European Stakeholders Convene for Obesity Roundtable

The European Commission's Health & Consumer Protection Directorate-General has issued a [report](#) detailing a July 20, 2004, obesity roundtable chaired by Director General Robert Madelin. Participants in the forum included representatives of the Confederation of the Food and Drink Industries of the European Union, consumer groups and the World Health Organization (WHO). According to the report, food and beverage manufacturers reiterated their commitment to taking an active role in addressing the obesity issue and their belief in the effectiveness of self-regulation, and consumer groups encouraged development of a strategy targeting healthy eating and physical activity, with WHO officials emphasizing the role of marketing to children in any such strategy. Participants evidently agreed to meet in October 2004 for a workshop in which all stakeholders present "concrete examples" of their anti-obesity efforts.

Russia

[5] Federal Assembly Passes Legislation Restricting Beer Advertising

Russia's lower house of Parliament last week reportedly approved a bill that would prohibit television and radio advertising for beer from 7 a.m. to 10 p.m. as of January 1, 2005. The proposal would also prohibit (i) slogans that create the "illusion that drinking beer is important for the achievement of social or other success," and (ii) billboards within 100 yards of hospitals, schools, sports venues, and cultural institutions. Beer consumption in Russia

has doubled by volume since 1998 and is reportedly viewed by many "as little more than a soft drink." See *The New York Times*, August 6, 2004.

State/Local Initiatives

[6] Maine Health Commission Issues Obesity-Related Recommendations

Maine's Commission to Study Public Health last week issued more than two dozen recommendations for policies aimed at reversing obesity trends among state residents. Its recommendations reportedly include (i) taxing advertisements that promote foods of "poor nutritional value" to children age 12 and younger, (ii) requiring restaurants with 20 or more locations to provide nutritional information on menus and (iii) requiring schools to assess the body mass index of students in kindergarten and grades 1, 3, 7, and 9 every year. The 28-member group is composed of various stakeholders, including those representing the soft drink and dairy industries, school districts, and the health care and insurance industries. The group plans to gather public feedback on the proposals during a public hearing in September and present final recommendations to the legislature in November. See *Bangor Daily News*, August 4, 2004; *Portland Press Herald*, August 5, 2004.

Litigation

Genetically Modified Organisms (GMOs)

[7] Federal Court Orders USDA to Disclose Location of GM Crops

A federal judge in Honolulu has ordered the agriculture department to disclose the location of crops in Hawaii that have been genetically modified



to produce pharmaceutical substances. *Center for Food Safety v. Veneman*, No. 03-CV-621 (D. Ha. 8/4/04). Several environmental groups filed the lawsuit in November 2003 claiming that USDA's Animal and Plant Health Inspection Service failed to consider potential environmental and human health impacts when it approved open-air test plots for the GM crops. "Biopharming could have disastrous effects on human health and the environment and should not be shielded from public scrutiny," an Earthjustice attorney was quoted as saying. "At least now, plaintiffs can find out if these crops are being grown near conventional crops that can be cross-pollinated, in ecologically sensitive areas, or near schools or homes." See *Associated Press*, August 5, 2004; *Earthjustice Press Release*, August 6, 2004.

Media Coverage

[8] **"The War on Fat: Is the Size of Your Butt the Government's Business?"** Jacob Sullum, *Reason Online*, August/September 2004

Mixing two parts Andy Rooney with one part David Letterman, journalist Jacob Sullum uses this [essay](#) to challenge what he calls arguments "that the government must rescue consumers – especially children – from the environmental forces that make them fat, thereby rescuing taxpayers from the burden of obesity-related medical expenses." The article parodies psychologist Kelly Brownell, attorney John Banzhaf and other proponents of taxes on high-calorie foods, restrictions on food advertising, regulation of food makers, and litigation by obese consumers. Sullum's response: "The war on fat is the latest manifestation of a collectivist philosophy that says the government has a duty to protect 'public health' by discouraging behavior that might lead to disease or injury. It also reflects an

anti-capitalist perspective that views people as helpless automatons manipulated into consuming whatever big corporations choose to produce. The anti-fat crusaders want to manipulate us too, but for our own good. They seek to reshape us by reshaping the world."

Scientific/Technical Items

Cancer

[9] **Carbohydrate Intake Linked to Breast Cancer in Mexican Women**

Women in Mexico whose diets rely heavily on carbohydrates are twice as likely to get breast cancer as those with more balanced diets, according to a study funded by the Centers for Disease Control and Prevention, the Mexican Ministry of Health and the American Institute for Cancer Research. I. Romieu, et al., "Carbohydrates and the Risk of Breast Cancer Among Mexican Women," *Cancer Epidemiology, Biomarkers & Prevention* 13(8): 1283-1289, August 2004. In the case-control study of 1,866 Mexico City women ages 20 to 75, those who derived 57 or more percent of total energy intake from carbohydrates incurred a breast cancer risk that was 2.2 times higher than those whose diets included less starch and sugar. Sucrose and fructose demonstrated the strongest association for the disease in the study. Increased blood sugar levels trigger the release of insulin, thereby influencing the division of cells and possible carcinogenesis. Insulin and insulin-like growth factor have also been linked to higher levels of estrogen, a breast cancer risk factor in pre-menopausal women. Dietary fat consumption showed no significant association with breast cancer risk overall. Harvard University's



Walter Willet, a co-author of the study, was quoted as saying the research “raises important questions about high carbohydrate diets, particularly among populations or individuals prone to insulin resistance. However, one study is not enough to make major changes in diet, and more work on this topic is urgently needed.” See *American Association for Cancer Research Press Release*, August 6, 2004.

[10] No Strong Association Between Dairy Products and Breast Cancer, Say North Carolina Researchers

In reviewing the results of relevant cohort and case-control studies, two Duke University researchers have concluded that “the available epidemiologic evidence does not support a strong association between the consumption of milk or other dairy products and breast cancer risk.” P. Moorman and P. Terry, “Consumption of Dairy Products and the Risk of Breast Cancer: A Review of the Literature,” *American Journal of Clinical Nutrition* 80(1): 5-14. Dairy products have been suspected of increasing breast cancer risk because products like whole milk and various cheeses have relatively high levels of saturated fat. Milk products may also contain pesticides and various growth factors that have been shown to promote breast cancer cell growth under experimental conditions. The calcium and vitamin D content of dairy products, however, has been hypothesized to reduce breast cancer risk. Moorman’s and Terry’s review of the epidemiologic

literature indicated no consistent pattern of increased or decreased breast cancer risk with high consumption of dairy products overall or when broken down into high-fat and low-fat categories.

Cardiovascular Disease

[11] Heart Association Panel Advises Getting Antioxidants from Food, Not Supplements

An American Heart Association advisory panel has concluded that current research fails to justify the use of antioxidant supplements to prevent or treat cardiovascular disease. P. Kris-Etherton, et al., “Antioxidant Vitamin Supplements and Cardiovascular Disease,” *Circulation* 110: 637-641, August 3, 2004. The committee reviewed studies published between 1994 and 2002 on the effects of antioxidant supplements on cardiovascular disease, finding that most studies, including those involving vitamins E, C and beta-carotene, reported no effect on cardiovascular events. “While the research shows that antioxidant supplements have no benefit, the role oxidative stress plays in the development and progression of heart disease has yet to be clarified,” lead author Penny Kris-Etherton, Ph.D., was quoted as saying. “We still know too little about the oxidative mechanisms in humans and lack biochemical markers with which to evaluate antioxidants,” she said.



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Mark Cowing and Mary Boyd in the Kansas City office of SHB.
If you have questions about the Update or would like to receive back-up materials,
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