

Food & Beverage

LITIGATION UPDATE

Issue 92 • August 25, 2004

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Legislation, Regulations and Standards

National Institutes of Health (NIH)

[1] NIH Issues Final Research Strategy for Obesity

“The challenges of today’s obesity epidemic are daunting,” according to the final version of a [strategic plan for obesity research](#) issued yesterday by NIH Director Elias Zerhouni. “We are especially concerned about the serious problems we see emerging in overweight children,” Zerhouni said. “Many of these are problems that we used to see only in adults.” The plan calls for coordination of efforts across the NIH, specifically advocating research concerning (i) behavioral and environmental approaches to modify lifestyles, (ii) the connection between obesity and type 2 diabetes, cardiovascular disease and certain cancers, (iii) medical approaches to prevent or treat obesity, and (iv) the risk of obesity among special populations, e.g., women, children, ethnic minorities. *See NIH Press Release, August 24, 2004.*

Food and Drug Administration (FDA)

[2] FDA Issues Bioterrorism-Related Guidance

FDA has issued a [contingency plan](#) for alternative ways of submitting the requisite prior notice of imported food during outages affecting FDA and Customs and Border Protection (CBP) program systems. Prior notice to FDA of all food imported or offered for import into the United States is mandated under section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and its implementing regulations. The contingency plan offers seven potential system downtime scenarios that could affect transmission, confirmation and processing of prior notice submissions, suggesting submission options for each identified scenario.

The agency has also issued a revised [compliance guide](#) titled *Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*. Aimed at FDA and CBP staff, the guide details typical prior notice violations and the appropriate regulatory action to address them. *See Federal Register, August 16, 2004.*



U.S. Department of Agriculture (USDA)

[3] **Biotechnology Committee to Discuss Traceability and Labeling Issues; G.E. Crop Confinement Topic of APHIS Workshop**

USDA's Advisory Committee on Biotechnology and 21st Century Agriculture will hold a [public meeting](#) on September 13-14, 2004, in Washington, D.C. The meeting's agenda includes discussion of the group's draft report on biotechnology impacts as well as domestic and international traceability and labeling regulations for biotechnology-derived products. The 18-member committee was established in 2003 and is charged with evaluating the long-term effects of biotechnology on the U.S. food and agriculture system. Members of the group include representatives of the biotechnology and food industries, farming interests, and environmental organizations. *See Federal Register*, August 19, 2004.

Meanwhile, USDA's Animal and Plant Health Inspection Service is holding a [three-day workshop](#) on September 13-15 in Riverdale, Md., to discuss ways of effectively confining transgenic plants and their progeny during field testing. The event will focus primarily on plant-made pharmaceuticals and plant-made industrials such as corn, barley, rice, safflower, and tobacco. Participation in the first two days of the workshop will be limited to panels of scientific experts; summaries of those panel discussions will be provided to the public on September 15. *See Federal Register*, August 23, 2004.

European Food Safety Authority (EFSA)

[4] **Risk of BSE in the United States Is Likely, Says European Food Safety Watchdog**

The European Union's independent food safety agency has issued a [risk assessment](#) that raises the risk of the presence of BSE in the United States from "unlikely" to "likely but not confirmed or confirmed at a lower level." Based on data from the period 1980 to 2003, the scientific report is one of 13 requested by the European Commission targeting the geographical bovine spongiform encephalopathy risk (GBR) in various countries. According to the report, "EFSA concludes that the current GBR level of USA is III, *i.e., it is likely but not confirmed*, that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent. As long as there are no significant changes in rendering or feeding, the stability remains extremely/very unstable. Thus, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent persistently increases." *See EFSA Press Release*, August 20, 2004.

Denmark

[5] **Danish Authorities Ban Fortified Kellogg's Products**

Claiming the amounts of added iron, calcium, vitamin B6, and folic acid could be "harmful to general health or food safety," the Danish Veterinary and Food Administration (DVFA) has rejected an



application from Nordisk Kellogg's A/S to sell 18 fortified breakfast products. The agency based its decision on a risk assessment produced by the Danish Institute for Food and Veterinary Research; the document's maximum levels for added vitamins and minerals were determined using the "upper safe limits" for such additives set by the European Commission's Scientific Committee on Food and the European Food Safety Authority. Kellogg's reportedly plans to challenge the decision given that the same fortified products are sold legally in other European Union member states. *See DVFA News Release*, August 11, 2004; *BBC News*, August 12, 2004.

State/Local Initiatives

[6] California Legislature Calls on Federal Trade Commission to Implement Nutritional Standards for Foods and Beverages Marketed to Children

Citing young children's inability "to comprehend the persuasive intent and biased nature of advertising" and obesity-attributable medical costs of some \$7.7 billion to the state in 2003, the California Legislature has approved a joint resolution ([SJR 29](#)) that calls on federal officials and food and beverage manufacturers to take various actions with respect to products marketed or advertised to children. Sponsored by Senator Sheila Kuehl (D-Los Angeles County), the measure asks Congress and the president to require the Federal Trade Commission to (i) implement nutritional standards "for foods and beverages that are acceptable to advertise or market to children, including foods and beverages that make a positive contribution to children's diets and health by being moderate in portion size, calories, saturated fat, *trans* fat, refined sugars, and sodium, and provide key nutrients," and (ii) prohibit

advertising and marketing of products failing to meet those standards through venues in which children make up a large part of the audience. The legislature also wants food companies and media outlets to comply with a voluntary code of practice for responsible advertising to kids.

Legal Literature

[7] "Obesity Liability: A Super-Sized Problem or a Small Fry in the Inevitable Development of Product Liability?" Samuel Romero (student author), 7 *Chapman Law Review* 239 (2004)

"As product liability law presently stands," this law-review comment states, "the fast-food industry will most likely not be held liable for influencing the public's eating behavior.... Yet one is left with the unsettling feeling that obesity is not strictly a personal choice. It is undisputed that the food industry markets to children to influence both their behavior and, through them, their parents' behavior." The student author's belief is that "the food industry should not be exempted from liability" by legislation.

The article discusses potential causes of action against food companies, including misrepresentation, warranty, defective design, failure to warn, generic negligence, and negligent marketing. Actions against food companies "fit[] neatly" into a theory of negligent marketing, the author argues. "Under this theory, plaintiffs would claim that the risk of childhood obesity is affirmatively enhanced by the marketing and advertising campaigns of the fast-food industry. Additionally, plaintiffs would claim that fast-food companies target children and induce them to eat dangerous foods. This conduct is foreseeable and intentionally increases the risk children will become obese."



Scientific/Technical Items

Cancer

[8] Obesity Linked to Development of Nine Types of Cancer

“There’s no question about it...obesity has the ability to reverse the gains we have made on cancer,” says Eugenia Calle, the lead author of an epidemiological review in the oncology journal *Nature Reviews Cancer* 4: 579-591, 2004, (Calle and Kaaks). The review indicates that obesity can lead to cancers of the colon, breast, uterus, kidney, esophagus, pancreas, gall bladder, liver, and stomach. Studies indicate that an overweight woman has twice the risk of developing endometrial cancer, or cancer of the uterine lining, as a lean woman. If obese, a woman’s risk for developing those cancers increases as much as 3.5 to five times as that of the lean individual. In addition, obese individuals reportedly have up to three times the risk of kidney cancer and a certain type of esophageal cancer as individuals of normal weight. Overweight and obese men, according to the review, are 50 percent more likely than lean men to develop colon cancer. Fat is also linked to breast cancer in post-menopausal women, increasing the risk of that disease by 30 percent in overweight individuals and by 50 percent among obese individuals.

Precise mechanisms for the connection between excess weight and malignant tumors have yet to be determined. Theories suggest, however, that fat cells release free fatty acids and proteins that encourage inflammation and cause the body to produce more insulin. Insulin, in turn, can spur cell proliferation that can lead to malignant tumors. Fat cells also produce estrogen, and recent studies have found higher than usual estrogen levels in breast cancers among post-menopausal women and in cases of uterine cancers.

Cardiovascular Disease

[9] Age and Obesity Blamed for Growing Trends in Adult Hypertension

Nearly 65 million adults in the United States (one in three) have high blood pressure, according to research published online this week in the journal *Hypertension*. (Larry Fields, et al., “The Burden of Adult Hypertension in the United States 1999 to 2000. A Rising Tide.”) The number of adults with hypertension increased by nearly 30 percent from 1994 to 2000. Data for the study were derived from U.S. Census figures and the 1999-2000 National Health & Nutrition Examination Survey (NHANES III). The study does not offer explanations for the rise in hypertension, but various press reports have quoted blood pressure experts who attribute the increase to an aging population and growing rates of obesity. See *Associated Press*, August 24, 2004.



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