Food & Beverage

LITIGATION UPDATE

Issue 152 • November 30, 2005

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Issues Guidance for Industry on Recordkeeping Rules and Records Access Under Bioterrorism Act

FDA has updated guidance regarding implementation of Bioterrorism Act provisions that require the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Those covered by the regulation must comply by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business.

Other guidance issued this week clarifies circumstances under which the agency can access and copy records under the Bioterrorism Act. The document also describes how FDA intends to exercise its authority to inspect records under sections 414 (a) and 704(a) of the Federal Food, Drug, and Cosmetic Act. *See Federal Register*, November 22 and 30, 2005.

U.S. Department of Agriculture (USDA)

[2] USDA Proposes Making China Eligible to Export Processed Poultry Products; Approves Chile's Eligibility to Export Meat

The agriculture department's Food Safety and Inspection Service (FSIS) has proposed amendments to poultry inspection regulations that would allow the People's Republic of China to export processed poultry and poultry products to the United States. According to FSIS, China's poultry processing system includes requirements that match provisions of the Poultry Products Inspection Act and its implementing regulations. Any Chinese poultry exports would be subject to reinspection at U.S. ports of entry. FSIS is accepting comments on the proposal until January 23, 2006.

Meanwhile, FSIS has completed a review of Chile's meat slaughter and processing inspection system and issued a final rule adding that nation to the list of approved countries eligible to export meat and meat products. FSIS inspectors will reinspect any such products at U.S. ports of entry. *See Federal Register*, November 21 and 23, 2005.

Switzerland

[3] Switzerland Approves Five-Year Ban on GMOs

About 56 percent of Swiss voters this past Sunday voted in favor of a five-year moratorium on the propagation of genetically modified plants and



animals. "The vote reflects the view across the E.U., not just Switzerland," an advocate of the ban was quoted as saying. "The public doesn't want to eat genetically modified food," the Friends of the Earth spokesperson said. Biotech proponents reportedly predict the GM ban could negatively affect the Swiss economy and damage the nation's prominence as a scientific research center. Switzerland is not a member of the European Union, which has been hesitant to embrace GMOs, but lifted a moratorium on certain GM crops in 2004. See Reuters, November 27, 2005; The International Herald Tribune, November 28, 2005.

Litigation Clean Water Act

[4] EPA Reaches \$1 Million Settlement with California Soft Drink Bottler

The Seven-Up/RC Bottling Co. of Southern California has reportedly agreed to pay more than \$1 million in criminal and civil fines for industrial stormwater and wastewater violations at soft drink bottling plants in Vernon and Buena Park, California. The company will also plead guilty to 12 misdemeanor violations of the Clean Water Act (CWA). According to the U.S. Environmental Protection Agency, the plants discharged acidic pollutants into a local sewer system and failed to follow CWA stormwater discharge permit requirements. See EPA Press Release, November 10, 2005.

Other Developments

[5] Australian Physicians Call for Ban on Food Advertising to Children

Citing statistics indicating that more than one-half of Australian youth will be overweight by 2025 unless all affected stakeholders address the issue, the Australian Medical Association this week issued a position statement calling for "an immediate ban on all forms of food advertising to children, including sports sponsorship and the use of promotional toys." The medical group also recommends that the federal government (i) mandate "userfriendly" food product labeling, (ii) fund healthy nutrition campaigns and (iii) monitor the health claims on functional foods. See Australian Medical Association News Release, November 28, 2005.

[6] Harvard Agribusiness Seminar to Examine Global Food System

Anticipating and capitalizing on emerging opportunities in global agribusiness will be the focus of a Harvard Business School seminar on January 8-11, 2006, in Boston, Massachusetts. Specific topics at the 2006 Agribusiness Seminar will include (i) opportunities for multi-national retailers in China; (ii) trade laws; (iii) food safety regulations; (iv) the logistics of processing plants, supply sources and value chains; and (v) biosafety issues related to genetically modified products. More information about the event is available here.



[7] New Public Citizen Group Targets Food and Water Issues

Public Citizen, the nonprofit founded by Ralph Nader in 1971 "to protect health, safety and democracy," has reportedly launched a group called **Food and Water Watch**. The new consumer advocacy organization's reported mission: "protecting our food and water from increased corporate control, factory farming and privatization." *See Public Citizen News Release*, November 15, 2005.

Scientific/Technical Items Respiratory Disease

[8] Chronic Lung Disease Purportedly Linked to Meaty, Salty, Starchy Diet

A diet rich in meat, sodium and refined starches likely increases the risk of developing chronic respiratory symptoms, according to study funded in part by the National Institute of Environmental Health Sciences (NIEHS). (L. Butler, et al., "Prospective Study of Dietary Patterns and Persistent Cough with Phlegm Among Chinese Singaporeans," American Journal of Respiratory and Critical Care Medicine, November 15, 2005). Researchers found that ethnic Chinese adults living in Singapore who consumed a traditional diet consisting of pork, chicken, noodles, and preserved foods were 40 percent more likely to develop chronic respiratory symptoms than individuals who primarily consumed vegetables, fruit and soy foods. "We know that cigarette smoking can be a specific cause of COPD [chronic obstructive pulmonary disease], but now we're learning that

avoiding certain foods may help reduce chronic respiratory symptoms both in smokers and non-smokers," NIEHS Director David Schwartz, M.D., was quoted as saying. The research team noted that the typical "Western" diet consumed by many Americans – red and processed meats, sweets, and refined grains – shares many similarities with the Chinese "meat-dim sum" diet.

Cancer

[9] Obesity Linked to Cancer Mortality in High-Income Countries

Researchers from the United States and Australia have assessed worldwide cancer mortality trends in association with nine modifiable behavioral and environmental risk factors. (G. Danaei, et al., "Causes of Cancer in the World: Comparative Risk Assessment of Nine Behavioural and Environmental Risk Factors," The Lancet 366: 1784-93, November 19, 2005). The research team computed attributable risk fractions for various factors purportedly related to site-specific cancer mortality. Of the estimated 7 million deaths from cancer worldwide in 2001, smoking, alcohol use, and low fruit and vegetable intake were the leading risk factors for cancer mortality. Smoking, alcohol use and overweight/obesity were the primary causes of cancer mortality in high-income countries.



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Food & Beverage Litigation Update is distributed by
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