Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Environmental Protection Agency (EPA)

[1] EPA's Updated Cancer Risk Assessment Guidance Acknowledges Children's Susceptibility

EPA this week issued its long-awaited final Guidelines for Carcinogen Risk Assessment and Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens to assist government officials in assessing possible cancer risks from exposures to environmental pollutants. "The agency's new cancer guidelines represent an opportunity to bring our best understanding of how chemicals might lead to cancer and provide our best information for regulatory decisionmaking," an EPA spokesperson was quoted as saying. Under guidelines that EPA issued in 1986, cancer risks to children were considered to be no greater than those of similarly exposed adults; the new supplemental guidance, however, multiplies the cancer potency factor of known carcinogenic substances for children ages 2 and younger by a factor of 10 and for 2 - to 15-year-olds, by a factor of 3. Food safety is among the policy issues likely to be affected by the revised guidance. The guidelines and attendant materials are available here.

Codex Alimentarius Commission

[2] U.S. Codex Delegates Schedule Public Meeting to Discuss Draft Positions on Various Food Labeling Proposals

The U.S. Department of Agriculture and the Food and Drug Administration have scheduled an April 26, 2005, **public meeting** in Washington, D.C., to discuss U.S. draft positions to be presented at the 33rd Session of the Codex Committee on Food Labeling on May 9-13 in Kota Kinabalu, Malaysia. Issues to be considered at the April 26 meeting include (i) labeling provisions of draft commodity standards, (ii) proposed labeling for foods derived from certain techniques of genetic modification, (iii) country-of-origin labeling, and (iv) a discussion paper on advertising. *See Federal Register*, March 15, 2005.

State/Local Initiatives

[3] California/EPA to Unveil Acrylamide Proposals in Early April 2005

Cal/EPA's Office of Environmental Health Hazard Assessment will propose regulatory options for acrylamide in foods under Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act) on April 8, 2005. The antitoxics law requires businesses to warn the public about exposure to chemicals "known to the state to cause cancer or reproductive toxicity." Acrylamide was listed as a carcinogen under Prop. 65 in 1990, and the current nosignificant-risk-level of 0.2 micrograms per day was based on occupational exposures unrelated to food consumption. In recent years, however, food scientists have discovered that the chemical also forms as a byproduct of high-temperature cooking processes in many high-carbohydrate foods.

In a related development, news of Cal/EPA's forthcoming acrylamide proposals has prompted a California state court to extend the stay in a pending Prop. 65 enforcement action against McDonald's Corp. and Burger King Corp. *Council for Education and Research on Toxics v. McDonald's Corp. et al.*, No. BC280980 (Superior Court of Los Angeles County) (filed 9/5/02). The plaintiff, Council for Education and Research on Toxics, seeks penalties for defendants' alleged failure to warn that their french fries contain acrylamide. A status conference in the case has been set for April 20. *See Inside Cal/EPA*, March 25, 2005.

Litigation Deceptive Trade Practices

[4] California Woman Files Putative Class Action Alleging Low-Sugar Cereals Mislead Consumers

Cereal makers are representing that they "offer a nutritional advantage over ... full-sugar breakfast cereal products, when in fact, the removed sugar is replaced by other carbohydrates, thus offering no significant nutritional advantage," according to a purported class action lawsuit filed last week in California state court. *Hardee v. Del Mission Liquor*, *et al.*, No. GIC844745 (Superior Court of San Diego County) (filed 3/24/05). (complaint not available online) Plaintiff Jennifer Hardee, whom a press report describes as "a Navy wife and homemaker with two young daughters who eat cereal," purports to represent all California consumers who have bought reduced-sugar varieties of General Mills' Cocoa Puffs and Trix, Kellogg's Frosted Flakes, and Post's Fruity Pebbles, believing that the products were healthier than their full-sugar counterparts. She reportedly seeks reimbursement for the costs of the low-sugar cereals and other damages. Named defendants in the lawsuit include Del Mission Liquor, a liquor and grocery retailer in San Diego that sells reduced-sugar children's cereals; General Mills Inc.; Kellogg Co.; and Kraft Foods. *See The Wall Street Journal and Associated Press*, March 28, 2005.

Other Developments

[5] Concerned Stakeholders to Convene in Kansas City for International Symposium on Agroterrorism

The potential for terrorist activity targeting crops, livestock and food processing systems will be the topic of a five-day symposium in Kansas City, Missouri, on May 2-6, 2005. Sponsored by the Federal Bureau of Investigation and the Executive Board of the Heart of America Joint Terrorism Task Force, the event will feature sessions focusing on (i) developing intelligence to identify vulnerabilities to agriculture, (ii) the weaponization of pathogens, (iii) industry's perspective on food security, (iv) detecting and reporting disease outbreaks, (v) livestock identification methods, and (vi) the role of law enforcement in responding to agroterrorist threats. Invited speakers include FBI Director Robert Mueller, USDA Secretary Mike Johanns and Senator Pat Roberts (R-Kan.). Registration information is available here.

[6] Outspoken Health Advocacy Group Calls for Mandatory Cattle Identification and Tracking System

A new report from Center for Science in the Public Interest champions a mandatory national animal identification and tracking program to prevent cattle contaminated with bovine spongiform encephalopathy (BSE) or hazardous bacteria from entering the U.S. food supply. "American ranchers' alleged health concern about young Canadian cows exposing American consumers to BSE is all sizzle and no steak – it has nothing to do with human health and everything to do with protecting their profits," CSPI Food Safety Director Caroline Smith DeWaal said. Among other things, CSPI recommends (i) requiring cattle to bear visible identification indicating the farm of origin and year of birth; (ii) prohibiting all high-risk cattle parts from animal feed and pet food; (iii) banning all spinal and neck bones from food production; and (iv) finalizing the ban on downer cattle in the food supply. See CSPI News Release, March 21, 2005.

[7] Rutgers Survey Finds Limited Public Awareness and Knowledge of Genetically Modified Foods

"Americans are largely unaware of GM foods, both of its presence in their lives and of its wide application in food production," according to a <u>survey</u> conducted by the Rutgers Food Policy Institute. Less than one-half of survey respondents (48%) knew that GM foods are available in supermarkets, and less than one-third of them (31%) believed they had ever eaten GM products. Other survey findings showed that participants want food labeling to clearly indicate pesticide use, GM status and country of origin. *See Associated Press*, March 24, 2005.

Scientific/Technical Items Prostate Cancer

[8] High Levels of Cholesterol Purportedly Speed Growth of Prostate Cancer

A new study conducted by researchers in Boston claims that high blood cholesterol levels aid the growth of prostate tumors at the molecular level by affecting chemical signaling patterns within tumor cells. (L. Zhuang, et al., "Cholesterol Targeting Alters Lipid Raft Composition and Cell Survival in Prostate Cancer Cells and Xenografts," Journal of Clinical Investigation doi:10.1172/JCI200519935.) Researchers injected human prostate cancer cells into experimental mice and observed tumor responses. Cholesterol reportedly accumulated in the outer membranes of tumor cells in the mice consuming high-cholesterol diets, thereby activating a chemical pathway that is key to cell survival and proliferation. According to the researchers, highcholesterol diets did not trigger new cancers in the mice, but six weeks after tumor cells were injected in the mice, the number of tumors more than doubled in mice on such diets, and "the tumors were markedly larger in size." Test tube studies indicated that cholesterol-lowering statin drugs reduced cholesterol in the cell membranes and inhibited activation of the cell-survival pathway, resulting in increased cell death and blocking tumor cell growth. Study co-author Michael Freeman was quoted as saying the findings "open up a new paradigm in thinking about how cancer might be controlled pharmacologically by manipulating cholesterol." See Boston Children's Hospital Press Release, March 17, 2005.

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Food & Beverage Litigation Update is distributed by 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, please contact us by e-mail at <u>mcowing@shb.com</u> or <u>mboyd@shb.com</u>. You can also reach us at 816-474-6550. We welcome any leads on new developments in this emerging area of litigation.



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