

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

U.S. Congress

[1] Leahy-Snowe Legislation Would Repeal Rider Undermining Organic Standards

Senator Patrick Leahy (D-Vt.) and Senator Olympia Snowe (R-Maine) have introduced bipartisan legislation (S. 457) that would repeal a last-minute provision added to the Omnibus Appropriations Bill allowing producers to label dairy and meat products as “organic” even though the products do not meet U.S. Department of Agriculture criteria for such designation. The rider was included in the bill to benefit a Georgia poultry operation which objected to the organic standards’ requirement that animals be fed organically grown feed. Companion legislation to the Organic Restoration Act has been introduced in the House of Representatives by Representative Sam Farr (D-Calif.) and Representative Ron Kind (D-Wis.). See *The New York Times*, February 27, 2003; *Office of Senator Patrick Leahy Press Release*, February 28, 2003.

Alcohol and Tobacco Tax and Trade Bureau (TTB)

[2] TTB Issues Final Rule for Health Claims Related to Alcoholic Beverages

TTB has issued final regulations that limit health-related statements appearing on alcoholic beverage

labeling or in advertising for such products. Under the final rule, labels and advertisements cannot contain any health-related statement, including specific health claims, that are untrue in any particular or tend to create a misleading impression. A health claim will be considered misleading unless “it is truthful and adequately substantiated by scientific or medical evidence; sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and outlines the categories of individuals for whom any alcohol consumption poses risks.”

“Directional” statements – those directing consumers in a neutral manner to a third party for more information – will be considered misleading unless accompanied by a disclaimer. TTB will evidently evaluate specific health claims in consultation with the Food and Drug Administration (FDA). If FDA decides that a specific health claim is a drug claim failing to comply with the Food, Drug and Cosmetic Act, TTB will not approve the label. See *Federal Register*, March 3, 2003.

Environmental Protection Agency (EPA)

[3] Cancer Risk Assessment Guidance Acknowledges Children’s Susceptibility

EPA has released for public comment its revised cancer risk assessment guidelines and supplemental guidance regarding children. The supplemental guidance, issued as a “non-binding statement of policy,” multiplies the cancer potency factor of



known carcinogenic substances for children 2 and younger by a factor of 10 and for 2- to 15-year-olds by a factor of 3. Comments on the guidelines must be submitted before May 1, 2003. While industry has apparently opposed special provisions for children, environmentalists support the move. A Washington, D.C.-based research and advocacy organization reportedly urged parents to protect their children by washing raw foods, buying organic foods and washing the hands of children who have played on wooden playground equipment treated with arsenic. According to a news source, if approved, the new guidelines are expected to affect the ways government officials make some of their earliest decisions in the rulemaking process. Food safety is apparently among the policy issues that will be affected. The guidelines and other related material can be accessed at www.epa.gov. See *Federal Register, Inside EPA* and *The Orlando Sentinel*, March 3, 2003; *Greenwire*, March 4, 2003.

Food and Drug Administration (FDA)

[4] Public Input Sought on Vitamin D₃ and “Healthy” Food Labeling Regulations

In recent *Federal Register* notices, FDA announced that (i) written objections and requests for hearing could be submitted on its rule about “the safe use of vitamin D₃ as a nutrient supplement in calcium-fortified fruit juices and juice drinks,” and (ii) comments could be submitted on regulations about “sodium levels for foods that use the nutrient content claim ‘healthy.’” The vitamin D₃ rule, which limits the supplement to 100 international units in juice beverages intended for anyone other than infants, took effect February 27, 2003. Responding to a petition filed by the Minute Maid Co., FDA determined that “there is a reasonable certainty that no harm will result from the use of vitamin D₃ as a nutrient supple-

ment at the levels specified in calcium-fortified fruit juices and juice drinks, excluding fruit juices and juice drinks specially formulated or processed for infants.” Objections and requests for hearing must be submitted by March 31, 2003. See *Federal Register*, February 27, 2003.

Regarding the sodium levels in foods claimed to be “healthy,” FDA is proposing to amend 21 C.F.R. § 101.65 “to permit the previously-established, second-tier [more stringent] sodium level to take effect for ‘healthy’ individual foods and to retain the first-tier sodium level for ‘healthy’ meal and main dish products.” The second-tier level is 360 mg. or less per serving; the first-tier level is 600 mg. or less per serving. According to the notice, FDA retained the first-tier level for meals and main dishes “because implementing the second-tier sodium level could result in the substantial elimination of meal and main dish products bearing the claim ‘healthy’ from the marketplace.” Comments are due by May 6, 2003. See *Federal Register*, February 20, 2003.

World Health Organization (WHO)

[5] WHO Report Sets Strict Limitations on Sugar and Salt Consumption for Healthy Diets

Proclaiming that “Nutrition is coming to the fore as a major modifiable determinant of chronic disease, with scientific evidence increasingly supporting the view that alterations in diet have strong effects, both positive and negative, on health throughout life,” a new technical report from WHO and the Food and Agriculture Organization of the United Nations has stimulated debate in the food and beverage industry. The report calls for strict limitations on added sugar, saturated fats and salt in healthy diets and blames processed “energy-dense” foods and a lack of exercise for “the growing



epidemic of chronic disease afflicting both developed and developing countries.”

Titled *Diet, Nutrition and the Prevention of Chronic Diseases*, the March 3, 2003, final draft report establishes as dietary intake goals (i) less than 10 percent “free sugars,” defined as “all monosaccharides and disaccharides added to foods by the manufacturer, cook or consumer, plus sugar naturally present in honey, syrups and fruit juices”; (ii) less than 5 grams per day of salt; (iii) fruit and vegetable consumption equal to or greater than 400 grams per day; and (iv) a protein, fat and carbohydrate balance of 10-15 percent, 15-30 percent and 55-75 percent, respectively.

The report, which can be obtained from WHO’s Web site at www.who.int, also discusses the role of sedentary lifestyles in the development of obesity and links obesity to chronic disabling diseases and premature death. According to the report, “in 2001, chronic diseases contributed approximately 59% of the 56.5 million total reported deaths in the world and 46% of the global burden of disease.” While organizations such as the U.S. National Soft Drink Association and the Grocery Manufacturers of America criticized the report, claiming “a thorough review of scientific literature on the subject of obesity shows there is no association between sugar consumption and obesity,” consumer-oriented groups claimed the report was watered down due to “heavy pressure from the food industry and the U.S. government.” According to the president of the International Association of Consumer Food Organizations, this purported pressure “forced the WHO to drop key public policy recommendations such as restricting food advertising to children and taxing unhealthy junk foods that had appeared in earlier draft versions of the report.”

The report was prepared by an international team of scientists; its recommendations will apparently be used as the basis for talks with health authorities

in the near future. Food industry officials will apparently be consulted in May. See *CSPI Newsroom*, February 27, 2003; *Associated Press, Food Ingredients First* and *WHO Press Release*, March 3, 2003.

Meanwhile, the United Kingdom’s Institute of Food Science and Technology has updated its information statement on salt, indicating that “healthy adults can maintain a sodium balance with intakes of 10-20 mmol (230-460 mg) / day, equivalent to 0.57-1.15 g salt / day.” The statement calls for further reductions in salt content of manufactured or prepared foods, adequate food labeling and appropriate medical advice to avoid excessive intakes.

Litigation

Web Privacy

[6] **FTC Reaches Settlement with Hershey Foods and Mrs. Fields for Children’s Privacy Violations**

Without admitting any wrongdoing, Hershey Foods Corp. and Mrs. Fields Original Cookies Inc., have agreed to pay \$185,000 to settle charges that they collected personal information online from children without their parents’ consent. The Federal Trade Commission (FTC) had brought the charges under the Children’s Online Privacy Protection Act, alleging that Hershey did not ensure parents actually completed consent forms when their children were responding to sweepstakes offers and that Mrs. Fields collected information without parental consent by encouraging children ages 12 and younger to sign up for free birthday treats. The settlement also requires the food companies to delete customer lists derived through their Web sites, permit the FTC to monitor their future activities and post privacy notices on any online site directed to children.



The complaints, settlement agreements and information about the relevant statutory and regulatory provisions can be accessed at www.ftc.gov. The director of the FTC's Bureau of Consumer Protection was quoted as saying, "These settlements offer food for thought for anyone who operates a Web site that caters to kids." See *FTC News Release* and *Reuters*, February 27, 2003.

Other Developments

[7] **Coca-Cola Grant to Pediatric Dentistry Group Generates Controversy**

An unrestricted grant of about \$1 million from the Coca-Cola Foundation to the American Academy of Pediatric Dentistry (AAPD) Foundation has reportedly left some observers with "the implication that there is something shady going on. It just doesn't look right, and I don't like the association with any commercial product like that casting a shadow on our industry," Michael Biermann, D.D.S., an American Dental Association board member, was quoted as saying. Consumption of soft drinks has reportedly been linked to cavities and obesity in children.

An academy press release indicates that the grant will "support important clinical, basic and behavioral research, which will be conducted by independent investigators. This affiliation will also create public and professional educational programs, based on science, that promote improved dental health for children."

Center for Science in the Public Interest (CSPI) Executive Director Michael Jacobson reportedly asserts that the grant "will make the AAPD a captive of Coca-Cola, making it extremely unlikely that the AAPD will take positions antagonistic to the company, like opposing soft drink machines in schools, or supporting labeling of the added-sugar content

of foods." See *AAPD Press Release*, March 3, 2003; *The New York Times* and *CSPI Newsroom*, March 4, 2003.

Scientific/Technical Items

Alcoholic Beverages

[8] **Study Looks at Liquor Consumption of Underage and Adult Excessive Drinkers**

Underage drinkers and adult excessive drinkers are responsible for approximately 50 percent of all liquor consumed annually in the United States, according to survey data published recently in *The Journal of the American Medical Association*. "Alcohol Consumption and Expenditures for Underage Drinking and Adult Excessive Drinking," S.E. Foster, et al., *JAMA* 289(8): 989-995, 2003. National Center on Addiction and Substance Abuse researchers evidently combined data from three different national surveys in an attempt to apportion total alcohol consumed and consumer expenditures on alcohol among underage (12-to 20-year-olds) and adult excessive drinkers – those consuming more than two drinks per day. They determined that underage drinkers consumed 19.7 percent of the liquor drunk in the United States in 1999, accounting for \$22.5 billion (19.4 percent) of the \$116.2 billion spent on alcoholic beverages that year. Adult excessive drinkers accounted for 30.4 percent of the liquor consumed, accounting for \$34.4 billion or 29.6 percent of the 1999 total expenditure for such beverages. To discourage underage drinking, the researchers call for higher liquor taxes, anti-drinking publicity campaigns and tougher penalties for those who sell liquor to minors.



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Food & Beverage Litigation Update is distributed by Dale Walker 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 dwalker@shb.com or mboyd@shb.com. 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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