

Food & Beverage

LITIGATION UPDATE

Issue 76 • April 14, 2004

Table of Contents

Legislation, Regulations and Standards

- [1] TTB Issues Calorie and Carbohydrate Claims-Related Ruling for Alcohol Labeling and Advertising 1
- [2] FDA Reopens Comment Periods on Bioterrorism Rules; Announces Availability of Joint Plan with CBP 1
- [3] FDA Warns That Mexican Candy May Contain Lead 2
- [4] NTP to Evaluate Potential Toxicities of Genistein and Soy Formula 2
- [5] U.K. Food Agency Launches Consultation on Draft Strategic Plan 2
- [6] Ontario Government Expected to Levy “Fat Tax” on Inexpensive Meals 3

Other Developments

- [7] Californians Believe Childhood Obesity Is Fastest Growing Health Risk, Attribute Kids’ Food Choices in Part to Advertising 3

Media Coverage

- [8] “Lawyers Shift Focus from Big Tobacco to Big Food,” Kate Zernike, *The New York Times*, April 9, 2004 3

Scientific/Technical Items

- [9] German Study Finds Favorable Cardiovascular Risk Factor Profiles Among Drinkers 4
- [10] British Journal Discusses Moderate Drinking 4

Shook,
Hardy &
Bacon L.L.P.™

www.shb.com

Food & Beverage

LITIGATION UPDATE

Legislation, Regulations and Standards

Alcohol and Tobacco Tax and Trade Bureau (TTB)

[1] TTB Issues Calorie and Carbohydrate Claims-Related Ruling for Alcohol Labeling and Advertising

TTB has issued interim [rules](#) for the use of terms such as “low carbohydrate,” deciding that the statement can only be used in the labeling and advertising of wine, distilled spirits and malt beverages if such beverages contain no more than 7 grams of carbohydrates per serving. “We are looking to discourage what we see as current trends in advertising implying physical properties and health benefits obtained through consumption of alcohol that’s lower in carbohydrates,” a TTB spokesperson was quoted as saying. Under the interim policy, products not meeting the low-carb standard can be labeled and advertised as “reduced carbohydrate” or as having “lower carbohydrates,” if the labeling and advertising provides a comparison to the normal brand’s number of carbohydrates. According to TTB, the agency will in the near future issue a procedure “that sets forth the requirements for the testing of the calorie, carbohydrate, protein and fat content of wines, distilled spirits, and malt beverages. This procedure will also address tolerance ranges with regard to labeled statements of calorie, carbohydrate, protein and fat content.” See *TTB Ruling*, April 7, 2004; *The Wall Street Journal*, April 9, 2004.

Food and Drug Administration (FDA)

[2] FDA Reopens Comment Periods on Bioterrorism Rules; Announces Availability of Joint Plan with CBP

FDA has reopened for 30 days the public comment periods for interim final rules (IFRs) implementing two sections in Title III of the Public Health Security and Bioterrorism Preparedness Response Act of 2002. To ensure that those commenting on the interim regulations have had the benefit of FDA’s outreach and educational efforts, the agency now seeks (i) comment, on a limited set of issues, about the IFR which required domestic and foreign facilities that manufacture/process, pack or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003, and (ii) comment regarding the IFR requiring the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. Comments must be submitted by May 14, 2004. See *Federal Register*, April 14, 2004.

In a related development, FDA and Customs and Border Protection (CBP) have announced the availability of a plan titled “[Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes](#).” The *Federal Register* notice indicates that the plan “describes the process by which FDA and CBP intend to increase integration and examine whether we could amend the timeframe requirements in FDA’s prior notice interim final rule (IFR) to have the same advanced notice timeframes for arrivals by land via road or



rail, or arrival via air that are currently in CBP's advance electronic information rule." See *Federal Register*, April 14, 2004.

[3] FDA Warns That Mexican Candy May Contain Lead

Late last week, FDA issued a public [statement](#) warning that particular chili-flavored Mexican candy products sold in the United States are likely to contain elevated amounts of lead. The candy at issue includes lollipops coated with chili powder and others coated with mixtures of salt, lemon flavoring and chili powder. The agency also warned that tamarind, another popular Mexican candy often sold in glazed ceramic packaging, can become contaminated when lead leaches from the glaze into the candy. According to FDA, chili powder becomes contaminated with lead during the manufacturing process. See *FDA Statement*, April 9, 2004.

In late March 2004, FDA issued a [letter](#) to manufacturers, importers and distributors of imported candy announcing the agency's intention to establish more stringent guidance for considering regulatory action against candy products that contain lead levels exceeding 0.1 parts per million, an amount equivalent to the Food Chemicals Codex specification for lead in sucrose, the primary ingredient in candy.

National Toxicology Program (NTP)

[4] NTP to Evaluate Potential Toxicities of Genistein and Soy Formula

NTP's Center for the Evaluation of Risks to Human Reproduction is [requesting](#) public comment on genistein and soy formula as well as soliciting nominations of scientists to serve on an expert panel to evaluate the compounds for their potential reproductive and developmental toxicities. Accord-

ing to NTP, genistein is a phytoestrogen naturally contained in some legumes, e.g., soybeans, and in products derived from animals that consumed genistein-containing feed. It is found in various foods, over-the-counter dietary supplements and the soy formula sometimes given to infants as a supplement or replacement for maternal breast milk or cow's milk. NTP particularly invites input concerning relevant studies, planned studies, human exposure, use patterns, and environmental occurrence. See *Federal Register*, April 13, 2004.

United Kingdom (UK)

[5] U.K. Food Agency Launches Consultation on Draft Strategic Plan

Reducing food borne illness, helping reduce diet-related disease and making it easier for consumers to make informed choices by mandating improved nutrition disclosure on labeling, are general goals outlined in the Food Standards Agency's (FSA's) draft [Strategic Plan 2005-2010](#). FSA's specific aims include (i) working with industry to reduce by 50 percent the incidence of U.K. chickens that test positive for *Campylobacter*, (ii) developing a rapid live test for transmissible spongiform encephalopathies, (iii) establishing "targets for the salt content of the 10 food categories contributing most salt to the diet," (iv) working with industry "to achieve changes in the way food is promoted to children to redress the imbalance between less healthy foods and healthier alternatives," and (v) developing guidance on the minimization of pesticide residues in food. The agency is soliciting public comment on the draft document until June 25, 2004.



Canada

[6] Ontario Government Expected to Levy “Fat Tax” on Inexpensive Meals

Claiming that the number of obese Canadian children has tripled since 1981, Ontario Health Minister George Smitherman announced late last week the Liberal government’s intention to levy an 8 percent sales tax on meals costing CAN\$4 or less; such meals are currently exempt from the tax. According to news reports, Smitherman also said the sale of “unhealthy” fast foods in schools will soon be prohibited. “There’s lots and lots of places where you can access french fries in our society,” he was quoted as saying. “I think it would be better if school wasn’t one of them.” A spokesperson for the Ontario Restaurant Hotel and Motel Association estimated that the new tax will cost industry CAN\$214 million and endanger jobs. See *The Globe and Mail*, *The Toronto Star*, April 9, 2004.

Other Developments

[7] Californians Believe Childhood Obesity Is Fastest Growing Health Risk, Attribute Kids’ Food Choices in Part to Advertising

A recent [survey](#) of more than 1,000 California adults reportedly revealed that 92 percent of them “believe the problem of childhood obesity is serious, and eight in ten think the problem has worsened.” Funded by the California Endowment, a private health foundation, the survey found that most California residents “opt for a community approach to resolve the [obesity] crisis, such as improvements to school health environments and fast food restaurant nutrition labeling, rather than leaving it solely to children and their families.” Specific areas in which Californians seek policymaker action include (i) enforcement of “current school requirements to

teach students about nutrition and physical activity in the classroom and requiring physical education throughout high school” and (ii) “requiring fast food and chain restaurants to post nutritional information on their menus and creating a public advertising campaign to raise awareness about the influence that food and beverage ads have on the food choices of children.”

Media Coverage

[8] “Lawyers Shift Focus from Big Tobacco to Big Food,” Kate Zernike, *The New York Times*, April 9, 2004

Obesity litigation is no laughing matter, this article asserts. “A well-honed army of familiar lawyers who waged war against the tobacco companies and won mega million-dollar settlements is preparing for a new wave of food fights Lawyers on both sides see broad potential for litigation, including challenges to the ways children are wooed toward sugar and fatty foods, deceptive labeling and misleading advertisements.”

Citing sources from both the plaintiffs’ and defense bars, the article suggests that new cases will focus on consumer-protection laws and are likely to involve children. And at least one source highlights the role that company documents may play in obesity cases. “Communications they thought were internal can be used in ways no one expected,” a defense lawyer is quoted as saying. “Lawyers worry in particular about what is in marketing plans, where marketers are prone to speaking about goals like ‘owning’ the preschool or teenage market, or strategizing about how to display sugary food so children can easily persuade their parents to buy it,” the article states.

Scientific/Technical Items

Alcoholic Beverages

[9] German Study Finds Favorable Cardiovascular Risk Factor Profiles Among Drinkers

A study of 4,700 German women and men reports favorable cardiovascular risk factor profiles for alcohol drinkers from both sexes. (M. Burger, et al., "Alcohol Consumption and Its Relation to Cardiovascular Risk Factors in Germany," *European Journal of Clinical Nutrition* 58: 605-614, 2004.) The researchers assessed blood levels of total cholesterol and HDL cholesterol, fibrinogen (a substance that acts to increase the coagulability of the blood), and homocysteine, an independent risk factor for occlusive vascular disease. The data indicate that the most favorable cardiovascular risk factor profiles occurred in women who were deemed "moderate" drinkers; for men, the most favorable levels were observed in the higher alcohol consumption groups. Beer drinking had pronounced effects on homocysteine levels in both women and men. Beer consumption was inversely associated with homocysteine levels, with the lowest levels of homocysteine in men from higher beer consumption categories. The authors speculate that the apparent homocysteine-lowering effect from beer consumption might be attributable to its content of B-vitamins, particularly folate, but that further research is needed.

[10] British Journal Discusses Moderate Drinking

A news feature in the British journal *Nature* (H. Pearson, "The Demon Drink," *Nature* 428: 598-600, April 2004) questions whether public health officials can promote the message of moderation in alcohol consumption, even if epidemiologic studies indicate that alcohol consumption reduces the risk of heart attack. The feature observes that a recent World Health Organization (WHO) report concluded that "the harm caused by alcohol nearly equals that from smoking," and that "small amounts of alcohol increase the risk of injury and boost the chances of developing about sixty diseases, including several cancers, liver cirrhosis and neuropsychological disorders." According to the author, these risks, when added to the adverse social consequences of drinking, more than offset any reported cardiovascular gains from alcohol consumption. The feature article also discusses a recent working group report from Britain's Academy of Medical Sciences on the need to curb heavy drinking in Britain and a resolution before the WHO's World Health Assembly that proposes making action on alcohol a priority for for the organization. The British Academy's working group concluded that the most forceful measures to curb alcohol consumption include raising the minimum legal drinking age, cutting the number of liquor retailers, increasing taxes, and restricting both advertising and the hours during which drinks can be sold.



Food & Beverage

LITIGATION UPDATE

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 mcowing@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.

Shook,
Hardy &
Bacon L.L.P.™

Geneva, Switzerland

Houston, Texas

Kansas City, Missouri

London, United Kingdom

Miami, Florida

New Orleans, Louisiana

Orange County, California

Overland Park, Kansas

San Francisco, California

Tampa, Florida

Washington, D.C.

