

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] Public Health Group Takes Attack on Dairy Industry's Weight Loss Campaign to FDA

“Given the tremendous public saturation of the weight loss promotion, a stop is urgently needed to any further dissemination of fraudulent health claims regarding the purported weight and fat loss benefits of dairy products,” charges a [citizen petition](#) to FDA from the health advocacy group Physicians Committee for Responsible Medicine (PCRM). PCRM contends that dairy advertisers’ assertion that eating three servings of dairy products daily will cause weight loss and fat loss constitutes a false and misleading claim under the Federal Food, Drug, and Cosmetic Act. Parties named in the petition include The Dannon Co., Inc., General Mills, Inc., and McNeil Nutritionals, LLC.

“The vast majority of scientific studies show that milk either causes weight gain or else has no effect at all on weight or body fat,” PCRM Senior Nutrition Scientist Amy Lanou said. “Nonfat milk is 55 percent sugar, while whole milk is nearly 50 percent fat, as a percentage of calories. Neither one is a formula for weight loss.”

PCRM contends industry assertions that consumption of dairy products will cause weight loss and fat loss are “health claims” that FDA has not approved. The advocacy group is therefore urging FDA to (i) declare dairy products labeled with weight-loss claims as misbranded; (ii) initiate a voluntary recall, court-ordered injunction or seizure of such products; and (iii) require corrective advertising and labeling. PCRM made similar accusations against the dairy industry in a petition to the Federal Trade Commission in April 2005. *See PCRM News Release*, June 9, 2005.

[2] FDA Issues Final Regulations for Arsenic in Bottled Water Products

FDA has finalized bottled water quality standard regulations that lower the existing allowable level for arsenic from 50 parts per billion (ppb) to 10 ppb, or 0.05 mg/L to 0.0010 mg/L, to maintain compatibility with the U.S. Environmental Protection Agency’s quality standards for public drinking-water as mandated under Section 410 of the Federal Food, Drug and Cosmetic Act. The [regulations](#) take effect as of January 23, 2006. Among other things, the new standards require manufacturers to (i) monitor finished bottled water products for arsenic at least once a year under the current good manufacturing practice (CGMP) regulations for bottled water and (ii) periodically test source water for arsenic unless the companies meet specific criteria for source water monitoring exemptions under the CGMP regulations. *See Federal Register*, June 9, 2005.



U.S. Congress

[3] House Lawmakers Reject Appropriations Amendment to Fund Mandatory COOL Program, Approve Measure That Bans Poultry Treated with Certain Antibiotics in the School Lunch Program

The U.S. House of Representatives last week approved a \$100.3 billion agriculture appropriations bill ([H.R. 2744](#)), after rejecting a floor amendment from Representative Dennis Rehberg (R-Mont.) which would have struck language that withheld funds for implementation of country-of-origin labeling (COOL) for meat or meat products. COOL advocate Representative Stephanie Herseth, (D-S.D.), was quoted as saying that “large meatpackers have rallied to kill this program because they don’t want American consumers to discover how much meat in the grocery case is actually imported,” while opponents of the program such as Representative Henry Bonzilla (R-Texas) claimed mandatory labeling would cost industry an additional \$1 billion and pose potential liability for retailers. According to news reports, the COOL program enjoys more support in the Senate, which is expected to take up the agricultural spending bill by the end of June.

The House approved Ohio lawmaker Sherrod Brown’s (D) appropriations package amendment that prohibits schools participating in the federal school lunch program from purchasing poultry treated with the fluoroquinolone class of antibiotics. Brown recently reintroduced the Preservation of Antibiotics for Medical Treatment Act of 2005 (H.R. 2562), legislation that directs the Food and Drug Administration to withdraw approval for the non-therapeutic use of antibiotics in food-producing animals. *See Associated Press and CQ Today*, June 8, 2005; *Western Livestock Journal*, June 13, 2005.

Litigation

Genetically Modified Organisms (GMOs)

[4] German Court Orders Monsanto to Release Results of Controversial GM Corn Study

A court in Cologne, Germany, last week ordered Monsanto to give the environmental group Greenpeace access to a study whose results reportedly indicate that rats fed a strain of biotech corn developed by Monsanto had smaller kidneys and elevated levels of white blood cells and lymphocytes compared to rats that were fed non-GM corn. The European Commission is currently evaluating whether to approve the corn, MON 863, for human consumption. The St. Louis, Mo.-based biotech company tried to block public dissemination of the study, asserting it contained “confidential business information which could be of commercial use to our competitors and exploited by others for commercial advantage,” but Greenpeace argued that the study’s results should be made public under a European Union law granting access to risk assessments for GM plants. *See Greenpeace Press Release*, June 10, 2005; *The (London) Independent*, June 12, 2005.

Other Developments

[5] British Advertising Authority Rules Against Atkins Diet Claim

Britain’s independent Advertising Standards Authority (ASA) has upheld a complaint about Atkins Diet advertisements that described the low-carbohydrate approach to weight loss as a way to “enjoy a healthier lifestyle” and therefore asked Atkins Nutritionals Inc. to discontinue the claim. Atkins



apparently supplied ASA with 44 studies to support the claim, but ASA decided the short-term nature and limited scope of the studies failed to support it. ASA also noted that the Atkins regime conflicts with the U.K. government recommendation for starchy foods to make up one-third of most adults' diets. See *ASA News Release*, June 1, 2005.

Media Coverage

[6] **“Striking Back at the Food Police,” Melanie Warner, *The New York Times*, June 12, 2005**

This article focuses on activities of the industry-backed Center for Consumer Freedom in the obesity debate and the group's director, Rick Berman, whom the author says “in some ways ... has become the face of the food industry as it tries to beat back regulations and discourage consumer lawsuits.” Berman takes aim at government obesity statistics and “food police” organizations such as the Center for Science in the Public Interest (CSPI), claiming CSPI Director Michael Jacobson has a “messiah complex” and that food companies’ attempts to “appease” obesity concerns by reformulating products will likely be unsuccessful because CSPI and other advocacy groups will continue to “go after all the unhealthy ones you still make.” Boston physician David Ludwig, M.D., an outspoken critic of the soft drink industry, is quoted as saying that the Center for Consumer Freedom makes “a lot of noise, but nobody in academia takes their arguments seriously. They stand for food industry freedom, not consumer freedom.”

Scientific/Technical Items

Dairy

[7] **Harvard Researchers Purportedly Link Milk Consumption to Weight Gain in Children**

Children who consume three or more servings of milk daily are more likely to gain weight, according to recent research published in this month's *Archives of Pediatrics & Adolescent Medicine* (C. Berkey, et al., “Milk, Dairy Fat, Dietary Calcium, and Weight Gain,” *Arch Pediatr Adolesc Med* 159: 543-550, 2005). Harvard researchers examined the relationship between milk intake in children ages 9 to 14 over a one-year period as part of a nationwide study of 13,000 youth. Children who drank more than three 8 oz.-servings of milk a day experienced significantly greater gains in body mass than children who drank less milk on a daily basis. The association held regardless of the type of milk consumed (whole, low-fat or skim) and appeared to be independent of calcium intake, growth or physical activity.

Lead researcher Catherine Berkey was quoted as saying that she expected milk consumption to have had some weight benefit for kids, “so I was surprised when it [the study] turned out the way it did. ... The studies are all over the place, but the dairy industry tells children and adults, ‘Drink more milk and you will lose weight.’ I think that’s misleading,” she said. A spokesperson for the National Dairy Council disputed Berkey’s contention by saying the council’s campaign promoting milk as a weight-loss aid is aimed at adults as part of a reduced-calorie diet. See *The Washington Post*, June 6, 2005.



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