

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Office of Management and Budget (OMB)

[1] OMB Director Advocates New Dietary Guidelines

In a May 27, 2003, "prompt" [letter](#) to the Departments of Agriculture and Health and Human Services, OMB Director John Graham recommends that the agencies update the nation's *Dietary Guidelines* and *Food Guide Pyramid* to reflect new evidence about the purported benefits of omega-3 fatty acids and purported risks of *trans*-fatty acids in the diet. "Health researchers have found that Americans can significantly reduce the risk of heart disease with a modest change in their diets," Graham said. "The government should make this life-saving information as widely available as possible." Foods high in omega-3 fatty acids (e.g., fish, flaxseed) have been linked to a reduced risk of heart disease, while those high in *trans*-fatty acids (e.g., baked goods, margarine) have been linked to an increased risk of cardiovascular ailments. An agriculture department spokesperson was quoted as saying that revised versions of the food guidelines are scheduled for issue in 2005, but that "it's too soon to tell whether they'll include any of the OMB's recommendations." See *OMB News Release*, May 28, 2003; *cnn.com*, May 29, 2003.

Food and Drug Administration (FDA)

[2] Biotech Stakeholders Fail to Agree on Mechanisms to Protect Health and Environment

Interest groups that have been meeting for two years under the auspices of the Pew Initiative on Food and Biotechnology have apparently been unable to agree on a legislative/regulatory mechanism to protect public health and the environment with respect to agricultural biotechnology products. The 18-member stakeholder forum, comprising representatives of the biotechnology industry, environmental and consumer advocacy organizations, farming and ranching interests, food processing and marketing companies, and academia, did agree on the basic elements of a regulatory system, i.e., transparency, public participation and adequate regulatory-enforcement resources and authority. But the group was unable to achieve consensus on the details. According to a news source, the group was moving toward legislation that would give FDA authority to ensure the safety of bioengineered foods, but Monsanto would not agree to the legislative recommendation. Currently, biotech companies may, but need not, notify the FDA of their intent to market a biotech food and supply studies demonstrating product safety. The forum's final report can be accessed at <http://pewagbiotech.org/>. See *BNA Daily Environment Report*, June 3, 2003.



U.S. Department of Agriculture (USDA)

[3] USDA to Offer Irradiated Meat to Public Schools

As of January 2004, public schools across the nation will be able to order irradiated ground beef through the National School Lunch Program. The federal initiative feeds about 28 million low-income children every day. Irradiation is a Food and Drug Administration-approved process used to prevent food borne illness by exposing products to gamma rays to kill bacteria. School districts will be able to choose between irradiated and non-irradiated beef, and USDA will provide educational materials for distribution to students and parents. The consumer group Public Citizen strongly opposes the availability of irradiated meat through the program. A Public Citizen representative was quoted as saying "This horrendous decision benefits the meat industry at the expense of society's most vulnerable citizens – our children. Approving irradiated meat for school cafeterias nationwide means the USDA is willing to put our children's health at risk to help cover up the meat industry's sanitation failures." See *USDA News Release*, Associated Press and *Public Citizen News Release*, May 29, 2003.

Alcohol and Tobacco Tax and Trade Bureau (TTB)

[4] TTB Extends Comment Deadline on "Alcopop" Regulation

TTB has announced that it will extend the comment deadline on a proposal that would change product labels, taxes and advertising on many "malt alternative drinks" (otherwise known as alcopops). Details about the [proposed regulations, Notice No. 4](#) appear in issue 24 of this Update, March 26,

2003. Responding to a request from the E. & J. Gallo Winery, TTB has decided to accept public comments for an additional 120 days, or until October 21, 2003. See *Federal Register*, June 2, 2003.

Litigation

[5] Public Health Advocates Issue Agenda for Obesity Conference

The Boston-based Public Health Advocacy Institute has issued a [tentative agenda](#) for the organization's First Annual Conference on Legal Approaches to the Obesity Epidemic. Slated for June 20-22, 2003, at the Northeastern University School of Law, the event's aim is bringing together "public health advocates, experts, academics, and attorneys to examine the nature of the obesity epidemic and its dire implications for public health, and explore how the use of law – regulation, legislation and litigation – may contribute to ending the epidemic."

Sessions on June 21 will include a keynote address by *Food Politics* author Marion Nestle and panel discussions targeting "obesity and the current food environment," "litigation approaches to changing the food environment," and "lessons from past and current litigation." Panel participants will include Kelly Brownell, Ph.D., of Yale University's Center for Eating and Weight Disorders; Michael Jacobson, Ph.D., of Center for Science in the Public Interest; John Banzhaf, J.D., of George Washington University Law School; and Philip James, chair of the International Obesity Task Force.

Attendance at the June 22 legal strategy workshop is limited to those willing to sign an affidavit swearing (i) "not to appear as an expert witness or work as a consultant or in any other capacity for or in the food industry before December 31, 2006," and (ii) that "I, and any firm/organization for which I am



working, am not currently retained by, and hereby commit myself and my firm/organization not to take as a client, any defendant in a food industry case before December 31, 2006."

Genetically Modified Foods

[6] Egypt Withdraws Support From U.S.-Led Action Before WTO; GM Issues Continue to Generate Controversy

Egypt's European Union (EU) ambassador has reportedly informed the European Consumers' Organization that the country has withdrawn its support for the World Trade Organization (WTO) action brought by the United States challenging the EU's moratorium on the import of genetically modified (GM) products. Further details about the U.S. action appear in issue 31 of this Update, May 14, 2003. An EU official was quoted as saying the withdrawal "is pretty embarrassing for this 'coalition of the willing,'" and that the United States was forced to "put the group [of complainants] together in a total haste – so really it's no wonder the whole thing is now falling apart."

In other developments, Britain is apparently entering a poorly publicized debate over GM crops that will allow the public to comment on the divisive issue. A decision on whether to grow the crops in the United Kingdom has reportedly been on hold for four years while large-scale trials are carried out to see if the powerful weedkiller used on the GM crops causes further harm to wildlife. The trials are expected to conclude in July 2003 when the last test field of GM oilseed rape is harvested. According to a wildlife advisory group, pesticides have destroyed 40 percent of Britain's farmland birds since the early 1960s.

Meanwhile, EU commissioners have reportedly rejected a proposal that would have required liability legislation to protect organic and conventional farmers from GM crops. According to the EU's agriculture commissioner, buffer zones and crop rotation should protect non-GM crops, and thus, a liability regime would be unnecessary. Tests in the United States, however, have revealed that traces of GM grains are repeatedly found in wheat supplies even before biotech wheat has been planted. The contamination apparently comes from GM soybeans and corn particles that have been mixed in with wheat supplies. See *just-food.com* and *Reuters*, May 29, 2003; BNA *Daily Environment Report* and *news.independent.co.uk*, June 2, 2003.

Other Developments

[7] Experts Convene in Finland to Discuss Obesity Causes and Effects

During the 12th European Congress on Obesity held May 29 – June 1, 2003, in Helsinki, Finland, some 1,500 doctors, nutritionists, researchers, and geneticists gathered to discuss the latest trends and research. As in the United States, obesity prevalence has apparently risen dramatically in Europe in recent years. The World Health Organization estimates that 10 to 20 percent of men and 10 to 25 percent of women in Europe are obese, with childhood obesity up 20 percent in the late 1990s. Dr. Ian Campbell, who chairs the United Kingdom's National Obesity Forum and believes that the obese face significant obstacles in losing weight, was quoted as saying that "Inherited susceptibilities, environmental influences, other diseases, and pressure from food manufacturers, food markets, advertisers, and the media interact to influence weight gain – or loss." Campbell apparently recommends the use of medication to assist patients on weight-reduction programs.



Other conference speakers reported that (i) health-care professionals with special training in obesity management were no more successful than those without training at helping patients lose weight, primarily due to patient-consultation time constraints; (ii) education programs that encourage people to get more exercise and make healthy food choices will only be effective if accompanied by changes in urban planning, food marketing and portion sizes; (iii) some 70 genes may be involved in obesity and could explain why some individuals gain weight more easily than others; and (iv) no European country is providing a satisfactory level of care for the obese, who have few specialists to consult and may not be able to afford weight-reducing drugs. The European Association for the Study of Obesity is reportedly developing guidelines on obesity management in adults for medical personnel to enhance the quality of obesity care. *See Reuters*, May 29, 30 and 31, 2003; *FoodNavigator.com*, May 30, 2003; *cnn.com*, June 2, 2003; *www.telegraph.co.uk*, and *www.docguide.com*, June 3, 2003.

Scientific/Technical Items

Weight Loss

[8] Two Studies Target Long-Term Effect of Low-Carbohydrate Diets

Low-carbohydrate, high-fat diets have apparently gained a measure of credibility with the release of two new studies which indicate that such diets may be associated with decreases in cardiovascular risk. The studies are among the first long-term controlled clinical trials to compare low carbohydrate diets, like that of Robert Atkins, M.D., with low-fat diets. They showed that in addition to some minimally improved weight loss, adherence to low-carbohy-

drate diets yielded lower triglycerides and higher high-density lipoprotein (HDL) cholesterol concentrations, both of which are believed to help prevent atherosclerosis, the buildup of plaque in the arteries.

In the first study, investigators assigned 132 obese subjects to either a carbohydrate restricted or a calorie and fat restricted diet. F.F. Samaha, et al., "A Low-Carbohydrate as Compared with a Low-Fat Diet in Severe Obesity," *The New England Journal of Medicine* 348: 2074-2081, 2003. Among the 79 subjects who completed the six-month study, those who followed the low-carbohydrate diet lost more weight, exhibited lower triglyceride levels and showed improved insulin sensitivity.

In the second study, researchers conducted a one-year trial, examining 63 obese subjects randomly assigned to either the Atkins or a conventional diet. G.D. Foster, et al., "A Randomized Trial of a Low-Carbohydrate Diet for Obesity," *The New England Journal of Medicine* 348: 2082-2090, 2003. While also losing a significant number of subjects during the study, ending with only 26, the researchers were able to demonstrate that those people who stuck with the Atkins diet showed lower triglyceride concentrations and higher HDL cholesterol. They further found that although the Atkins diet initially produced greater weight loss, no significant difference remained after one year. Both sets of researchers urge caution in interpreting their results, suggesting that longer and larger studies are needed before the safety and efficacy of low-carbohydrate diets can truly be judged.



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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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