

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Announces Voluntary Food Retail Standards

The FDA has invited comments on a draft document, *Voluntary National Retail Food Regulatory Program Standards* (Program Standards), aimed at creating national uniformity among retail food regulators. In the interest of preventing foodborne illness, the Program Standards not only identify “best management practices,” but “define nine essential elements of an effective regulatory program for retail food establishments.” These elements include: (i) “regulatory foundation”; (ii) “inspection program based on HACCP principles”; (iii) “foodborne illness and food security preparedness and response”; (iv) “compliance and enforcement”; and (v) “industry and community relations.” Agencies enrolled in the program must also complete a self-assessment, conduct a “baseline survey of the regulated industry,” and obtain an external audit within three years. Existing records may be used to document compliance with the Program Standards.

Written or electronic comments must be submitted by January 16, 2007. See *Federal Register*, November 14, 2006.

U.S. Department of Agriculture (USDA)

[2] Agricultural Research Service Seeks Nominations for Biotechnology Advisory Committee

The Agricultural Research Service is seeking nominations for “qualified persons” to serve on the Secretary’s Advisory Committee on Biotechnology and 21st Century Agriculture (AC21). AC21 is responsible for (i) assessing the “long-term impacts of biotechnology” on the U.S. food supply, and (ii) advising USDA on “pressing individual issues, identified by the Office of the Secretary, related to the application of biotechnology in agriculture.” Nominees should have “recognized expertise” in a scientific field or policy issue that pertains to biotechnology or its multifarious uses. If selected by the agriculture secretary, AC21 members can serve up to six consecutive years. Nominations must be faxed or postmarked on or before December 11, 2006.

In other AC21 news, the group is slated to meet on December 13-14. Including representatives of other government agencies, the meeting will address “coexistence issues on the development and use of new crops derived through modern



biotechnology.” Those wishing to make oral presentations should submit a request at least three business days before the meeting.

See *Federal Register*, November 9, 2006.

Center for the Evaluation of Risks to Human Reproduction (CERHR)

[3] CERHR Invites Public Comments on Genistein Brief

CERHR has requested public comments on a National Toxicology Program (NTP) [draft brief](#) assessing the reproductive and developmental risks associated with genistein and soy formula. In the brief, NTP concluded that there is “insufficient evidence” to determine whether genistein, a phytoestrogen found in soybeans, has an adverse effect on humans. Animal studies suggested, however, that adults and pregnant women do not consume enough genistein to cause concern. According to NTP, it is also unlikely that genistein poses a threat for infants on a soy formula diet. Written comments should be received by December 8, 2006.

See *Federal Register*, November 8, 2006.

Legal Literature

[4] Stuart Smith & Drew Kershen, “Agricultural Biotechnology: Legal Liability Regimes from Comparative and International Perspectives,” *Global Jurist Advances* (2006)

This article discusses legal mechanisms in several countries that could provide recovery for damages allegedly caused by genetically modified crops. The authors compare legal, administrative and

criminal systems in the United States, Canada, Denmark, and Germany, and then discuss ongoing international negotiations with respect to liability and redress under the Cartagena Protocol on Biosafety. They contend that the inclusion of “traditional damage within an international liability and redress regime will require a harmonization of domestic laws that is highly unlikely to occur,” and thus, that “these countries are unlikely to agree to a consensus for an international liability and redress regime.” The article concludes by explaining how agreements to include “speculative claims – related to long-term biological diversity, environmental, or human health damage” in an international liability and redress regime will either not become operational or, if adopted, will run counter to the U.N.’s goal of eradicating extreme poverty and environmental sustainability.

Other Developments

[5] Defense Lawyers Gather in Chicago to Address Food Liability Issues

During a recent food liability seminar in Chicago, Illinois, Shook, Hardy & Bacon Partner [Madeleine McDonough](#) provided a comprehensive food law update that focused on legislative, regulatory and litigation developments over the past year. Sponsored by DRI, an international organization of defense trial lawyers and corporate counsel, the seminar also featured presentations on food-borne illness claims, state and federal food labeling requirements, product recalls, and assessing the value of food and beverage cases. According to McDonough, future trends will likely involve a continuing emphasis on youth marketing issues and obesity, “factory farming,” water scarcity, nanotechnology, and global climate change. She



stressed that the most successful litigation prevention and preparation strategies include (i) the adoption of best practices in production, labeling and marketing, (ii) the creation of effective crisis management plans, (iii) the development of comprehensive electronic discovery and document retention plans, (iv) the use of contracts to allocate risks, and (v) the ongoing monitoring of and participation in regulatory and legislative initiatives.

[6] **Public Policy Conferees Consider Obesity-Related Issues**

The Association for Public Policy Analysis and Management held a conference November 2-4, 2006 in Madison, Wisconsin, that focused on tax and spend issues and included a session on the ways federal initiatives can affect obesity. In a presentation titled, "Tobacco Control as a Model for Trimming the Obesity Problem," University of Baltimore Economics Professor David Levy, Ph.D., asserted that the most important lesson learned from tobacco control is "the need for multiple policies coordinated as part of a comprehensive strategy." Among the policies Levy expects to be effective in the obesity arena are educational programs, marketing limits, greater access to treatment, and economic incentives such as taxes, subsidies and insurance. Abstracts and papers are available at www.appam.org.

[7] **Advertising and Food Industries Address Marketing to Children**

The Children's Advertising Review Unit (CARU), which monitors child-related industries, has made significant changes to its guidelines and procedures. Under the new rules, ads geared toward children younger than 12 cannot include subtle editorial content, and commercial content in "so-called

advergimes" must be clearly demarcated as such. CARU also gained power to challenge any promotional material it views as "unfair," in addition to enforcing specific violations.

In a separate development, 10 food companies representing two-thirds of the industry have released the "Children's Food and Beverage Advertising Initiative." The commitment, which will be monitored by The Council of Better Business Bureaus, stipulates that each party must allocate one-half of its marketing budget to promoting healthy choices to children. The companies also agreed to pull all food and drink advertising from elementary schools.

While policy makers have reportedly lauded the move to self-regulate, some advocacy groups have called the plan a regression. "If a 'healthy lifestyle message' means that Ronald McDonald is peddling a bike while peddling junk food, that message still does more harm than good," said one critic from the Center for Science in the Public Interest. *See Advertising Age* and *Reuters*, November 14, 2006; *Food Navigator USA*, November 15, 2006.

[8] **"Nano Ink" Identifies Damaged Food Packaging**

Designed using nanotechnology, a new "intelligent ink" can reportedly tell consumers if food packaging has been penetrated by oxygen. The ink, which changes color from blue to white under ultraviolet light, will remain white in an oxygen-free environment but reverts to blue when air is present. "Our technology has the potential to eliminate food poisoning due to poor packaging or tampering," said the University of Strathclyde researcher, Andrew Mills, who designed the ink. "The labels will also reassure customers that the food they are feeding



their families is as fresh and safe as it left the factory.” See *Food Production Daily Europe*, November 14, 2006.

[9] China Facing Obesity Epidemic, Government Warns

Sixty million Chinese are overweight and 160 million have high blood pressure, a Chinese official recently told a global health forum. Chinese authorities have attributed the weight gain, at least in part, to “excessive” consumption of meat and oil at the expense of rice, milk and beans. School children, young adults and middle-age individuals are the most likely to be affected as the population experiences increased income levels and decreased physical activities in the country’s major cities. See *AP-Food Technology*, November 9, 2006.

Media Coverage

[10] Election Fall-Out Includes Speculation over Tort Reform Legislation

Among the spate of articles published since Democratic victories changed political control of the U.S. Congress and some state legislatures is a comprehensive review appearing online at *law.com*. With everything from judicial appointments to asbestos litigation problems on Democratic agendas, it is expected by some that there will be “at least a cooling of tort reform fervor.” Yet, common ground can apparently be found on such legislative proposals as “cheeseburger” bills, i.e., those measures that would restrict obesity-related lawsuits against fast-food companies. And the U.S. Chamber

of Commerce is apparently holding out hope that mass medical screening abuses and securities litigation will also attract bipartisan attention. In any event, House Judiciary Committee staffers do not expect that divisive social issues will crowd that body’s crowded agenda as they have over the past 12 years. See *The National Law Journal*, November 14, 2006.

Scientific/Technical Items

[11] Red Meat Linked to Breast Cancer Risk, Study Claims

Women who consume 1.5 servings of red meat per day might double their risk of contracting estrogen and progesterone receptor-positive breast cancer. Eunyoung Cho, et al., “Red Meat Intake and Risk of Breast Cancer Among Premenopausal Women,” *Archives of Internal Medicine*, November 13, 2006. The study, which apparently sampled 90,659 women over 12 years, also concluded that eating processed meat more than three times per week made women more likely than once-a-month consumers to develop breast cancer. “Several biological mechanisms may explain the positive association between red meat intake and hormone receptor-positive breast cancer risk,” Cho and her team wrote in their report, which speculated that alleged carcinogens in cooked meat and growth hormones might also be confounding risk factors. See *BBC News*, November 14, 2006; *The Daily Telegraph*, November 15, 2006.



[12] Risk of Pancreatic Cancer Allegedly Linked to Soft Drink Consumption

A diet high in added sugar and soft drinks could increase a person's risk of developing pancreatic cancer. Susanna Larsson, et al., "Consumption of sugar and sugar-sweetened foods and the risk of pancreatic cancer in a prospective study," *The American Journal of Clinical Nutrition*, November 2006. "Evidence is mounting that abnormal glucose metabolism and hyperinsulinemia may be involved in the development of pancreatic cancer," the researchers claimed. "Conditions such as diabetes mellitus, a high body mass index (BMI, in kg/m²), and physical inactivity, all hallmarks of insulin resistance, have been directly related to the risk of this malignancy." Following more than 70,000 men and women for an average of 7.2 years, the study reported that those who drank five or more soft drinks daily had nearly double the risk of pancreatic cancer. See *MedPage Today*, November 9, 2006.



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