

# Food & Beverage

## LITIGATION UPDATE

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## LITIGATION UPDATE

### Legislation, Regulations and Standards

#### Food and Drug Administration (FDA)

##### [1] Bioterrorism High on Agenda in FDA's Strategic Action Plan

Stating that “we need a strong and effective FDA more than ever,” FDA Commissioner Mark McClellan, M.D., Ph.D., recently unveiled the agency’s [five-part strategic action plan](#). The agency will apparently focus on (i) efficient, science-based risk management, (ii) patient and consumer safety, (iii) better informed consumers, (iv) counter-terrorism, and (v) a strong FDA. The plan specifically addresses food-borne diseases, obesity and nutrition-related illness, and bioterrorism, with objectives established for each issue.

Regarding bioterrorism, FDA notes that its “regulatory authority and responsibility cuts across critical elements in any counterterrorism plan.” According to the agency, imported foods could “introduce deadly diseases into the country,” while FDA-regulated products “would play a central role in countering the effects of terrorism if another attack takes place.” Among the bioterrorism-related objectives is implementing “a comprehensive food security strategy to ensure the safety of foods regulated by FDA.”

##### [2] Food Advisory Committee Holds Latex-Allergy Meeting

The Additives and Ingredients Subcommittee of FDA’s Food Advisory Committee began a [three-day meeting](#) in Washington, D.C. on August 26, 2003, to gather information about purported allergic reactions to food prepared by food handlers wearing natural rubber latex gloves. According to the meeting notice, FDA has received reports from those allegedly sensitive to natural rubber latex who claim they have experienced allergic reactions after eating food they believe was prepared by food handlers wearing such gloves. The subcommittee also plans to use the meeting to provide advice and recommendations to FDA about the issue.

##### [3] FDA Small Entity Compliance Guide Explains *Trans*-Fat Rule

FDA has issued a [compliance guide](#) aimed at small entities to explain the agency’s new regulation requiring manufacturers to list *trans*-fatty acid content on the Nutrition Facts Panel of conventional foods and some dietary supplements by January 1, 2006. *Trans* fats are produced during partial hydrogenation of vegetable oils and have been linked to an increased risk of cardiovascular disease.

#### Environmental Protection Agency (EPA)

##### [4] EPA Issues Food Consumption Data

Using the U.S. Department of Agriculture’s Continuing Survey of Food Intakes by Individuals (CSFII), EPA’s National Center for Environmental



Assessment has issued a [CSFII Analysis of Food Intake Distributions](#) as part of the agency's update of its *Exposure Factors Handbook*. Among other things the analysis provides distributions of food consumption by individuals for dairy products, meats and aggregated categories such as total grains.

## Ireland

### [5] Irish Health Minister Considers Imposing "Fat Tax"

Irish Health Minister Michael Martin has been quoted as saying he is "very tentatively" evaluating the possibility of taxing high-fat foods as a way of combating Ireland's expanding waistline. A news source indicates that 60 percent of Irish citizens are either overweight or obese. *See Reuters*, August 26, 2003.

## State/Local Initiatives

### [6] California Assembly Approves Bill Targeting Children's Soft-Drink Consumption

The California Assembly has approved proposed legislation ([S.B. 677](#)) that would prohibit the sale of soft drinks to children in public elementary schools and restrict the sale of such products to junior high students. Existing state law calls for a ban on soft-drink sales at elementary and middle schools by January 1, 2004, but that prohibition will reportedly not take effect unless more state funds are allocated to nutrition programs. Among findings in the California Childhood Obesity Prevention Act are that "Each additional daily serving of sugar-sweetened soda increases a child's risk for obesity by 60 percent" and "Soft drinks now comprise the leading source of added sugar in a child's diet." *See Associated Press*, August 21, 2003.

## Litigation

### Acrylamide

#### [7] Court Expected to Stay Acrylamide-Warnings Action Against Fast-Food Companies

According to a news source, a California Superior Court judge is expected to sign an order staying a Proposition 65 enforcement action filed against McDonald's Corp. and Burger King Corp. Plaintiff Council for Education and Research on Toxics seeks warnings that the fast-food chains' fries contain acrylamide, a substance known to the state to cause cancer. The stay will apparently remain in effect until the state's Office of Environmental Health Hazard Assessment (OEHHA) completes its acrylamide review and advances relevant regulatory proposals. Further details about OEHHA's proposed acrylamide work plan appear in issue 42 of this Update, August 6, 2003. Plaintiff's counsel has reportedly indicated that an appeal will be taken from a stay order and has charged the court with "making a political decision like everyone else" in exempting the fast-food companies from Prop. 65 requirements while the case remains in limbo. *See Inside Cal/EPA*, August 22, 2003.

## Legal Literature

#### [8] Lawrence Shulruff, "Label the Dangers of Fat," *The National Law Journal*, August 18-25, 2003

Complaining that schools seem to have become "a vegetable- and fruit-free zone," this article calls for Food and Drug Administration regulations under an amended Nutrition Labeling and Education Act of 1990 that would require fast-food chains and

snack-food companies to place health warnings on their products or menus. Looking to the tobacco and alcohol beverage warnings as a paradigm, the article suggests, for example, that “a bag of barbecue potato chips may warn its nibblers that obesity is closely linked to type-2 diabetes. A sack of cheese puffs may caution that overweight children grow into overweight adults.” The article concludes by observing that warnings may not “solve the nation’s obesity problem overnight,” but could get the attention of parents, physicians and educators and “could lead to a change in attitudes and eating habits. When it comes to planning students’ lunch menus, it may even bring wayward schools back to their senses.”

## Other Developments

### [9] Experts Warn of Worldwide Diabetes Epidemic

According to a report released by diabetes experts convening in Paris, the disease is expected to affect more than 300 million people worldwide in the next 20 years at a cost that could rise to \$396 billion annually. Comparing the epidemic to the AIDS pandemic and blaming rapid culture and social changes, health experts called for food companies to produce healthier foods and for governments to set up prevention campaigns. Adult onset diabetes, which is linked to obesity, can apparently lead to blindness, kidney failure, heart disease, disability, and death. See *Reuters*, August 25, 2003.

### [10] Journals Criticized for Lack of Conflict-of-Interest Policies

Alleging that the publications “aren’t reliably disclosing their authors’ financial ties to drug and biotechnology companies,” a group of 30 scientists and the Center for Science in the Public Interest are

encouraging the journals *Science* and *Nature* to adopt conflict-of-interest policies. In an [August 21, 2003, letter](#) to the editor of *Science*, the group charges, for example, that a February 2003 article on obesity and the environment authored by James Hill failed to disclose Hill’s financial ties to various drug manufacturers and his appointment to McDonald’s Global Advisory Council on Healthy Lifestyles. According to the letter, “... scientific research is increasingly harnessed to entrepreneurialism in biotechnology, pharmaceuticals, and other fields. As a result, it is increasingly important to identify authors or quoted scientists who have management or advisory roles in companies by those affiliations and not simply by their academic appointments.” See *CSPI News Release*, August 21, 2003.

## Media Coverage

### [11] News Stories About Obesity Proliferate

From New York City to Los Angeles, media coverage of obesity-related issues is accelerating. The latest issue of *Business Week* notes that law professor and food-industry critic John Banzhaf has turned his sights to the use of adult nutrition guidelines on children’s food labels, calling them “deliberate misrepresentation.” A Kraft product is highlighted as an example. Meanwhile, articles appearing in the media on the east and west coasts address the issues from the perspective of (i) recent scientific research on portion sizes and (ii) the political debates that pit those who blame the industry and advertising and those who think personal responsibility is to blame for America’s expanding waistlines. See *Los Angeles Daily News*, August 24, 2003; *The New York Times*, August 25, 2003; and *Business Week*, September 1, 2003.



## Scientific/Technical Items

### Alcohol

#### [12] Genes Might Play a Role in Alcohol Consumption

Researchers have identified a genetic variation that they believe predisposes young people to harmful drinking habits. A.I. Herman, et al., "Serotonin Transporter Promoter Polymorphism and Differences in Alcohol Consumption Behaviour in a College Student Population," *Alcohol and Alcoholism* 38(5): 446-449, 2003. The George Washington University team examined more than 200 college students, assessing drinking frequency and patterns and analyzing each student's genetic structure. They found that those students with a particular variant of the serotonin transporter gene (5-HTTLPR) were more likely to binge drink, more often drank to become inebriated and consumed more alcohol per occasion than students without the genotype.

Individuals inherit two copies of the 5-HTTLPR gene, one from each parent. Two normal variations are generally labeled long or short. Among the students followed in this study, those with two copies of short 5-HTTLPR appeared most at risk for maladaptive consumption. The research team suggests that taken together with other research, their findings indicate that "genetically mediated differences in serotonergic response play an important role in mediating patterns of alcohol intake." They note that individuals with the homozygous short 5-HTTLPR are also known to be at higher risk for anxiety and that this condition may mediate the relationship between 5-HTTLPR and alcohol consumption.

#### [13] Constituent of Grapes Linked to Longer Life

Researchers have discovered that resveratrol, a compound commonly found in grapes and red wine, may prolong life, at least in yeast cells. K.T. Howitz, et al., "Small Molecule Activators of Sirtuins Extend *Saccharomyces Cerevisiae* Lifespan," *Nature* online 24 August 2003; doi:10.1038/nature01960. The scientific team, composed of investigators from Harvard Medical School and BIOMOL Research Laboratories in Pennsylvania, was able to show that certain small molecular compounds, including resveratrol, extend the lifespan of yeast cells by as much as 70 percent.

Resveratrol is believed to mimic the effects of severe calorie restriction, long known to slow the pace of aging and increase maximum lifespan in a variety of organisms, ranging from yeasts to laboratory animals. Both resveratrol and calorie reduction stimulate proteins in the sirtuin family, increasing DNA stability and promoting cell survival.

According to Harvard's David Sinclair, resveratrol is more common in grapes grown in harsh environments. Similarly, other protective molecules identified also came from plants grown under stressful conditions. Sinclair speculates that plants make these molecules as part of their own defense response and that individuals who ingest such plants "can pick up on these clues."

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## LITIGATION UPDATE

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](mailto:dwalker@shb.com) or [mboyd@shb.com](mailto: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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