

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

U.S. Department of Agriculture (USDA)

[1] Murano Addresses Food Safety Issues at Chicago Event

USDA Under Secretary for Food Safety Elsa Murano has been quoted as saying that even though irradiation is the single most effective tool in killing food-borne pathogens, the cost of installing irradiation equipment prevents its widespread use. Murano made the remarks in a keynote speech during the [First World Congress on Food Irradiation](#) held May 5-7, 2003, in Chicago. During her speech, Murano also reportedly said the USDA's Food Safety and Inspection Service intends to encourage (i) a farm-to-table strategy for pathogen control, (ii) food-safety standards based on HACCP (Hazard Analysis and Critical Control Point) principles, (iii) improved risk analysis, and (iv) a streamlined regulatory approval process to garner use of validated decontamination technology. *See Reuters and MeatAMI.com*, May 5, 2003.

U.S. Food and Drug Administration (FDA)

[2] FDA Extends Comment Period for Salt Rule

FDA has extended to July 5, 2003, the comment period for a proposed rule regarding sodium levels in foods claimed to be "healthy." The agency proposes to amend 21 C.F.R. § 101.65 "to permit the previously-established, second-tier [more stringent]

sodium level to take effect for 'healthy' individual foods and to retain the first-tier sodium level for 'healthy' meal and main dish products." The second-tier level is 360 mg. or less per serving; the first-tier level is 600 mg. or less per serving. According to the *Federal Register* notice, FDA retained the first-tier level for meals and main dishes "because implementing the second-tier sodium level could result in the substantial elimination of meal and main dish products bearing the claim 'healthy' from the marketplace." *See Federal Register*, May 6, 2003.

Denmark

[3] Denmark Restricts *Trans* Fatty Acids in Foods

The Danish government has reportedly adopted restrictions that will limit the *trans* fatty acids in domestic and foreign manufactured fats and oils to 2 percent beginning June 1, 2003. The new regulations follow years of research by the Danish Nutrition Council, which has concluded "The information that has now been documented about the harmful effects of *trans* fatty acids means that Denmark finds it necessary to introduce regulations of the content of *trans* fatty acids in our foods." The health risks linked to *trans* fatty acid consumption are cardiovascular diseases, an impact on fetal weight and the development of Type 2 diabetes. As of December 31, the restrictions will extend to oils and fats in processed foods. The Danish government is apparently hoping that similar legislation will be adopted in the European Union. *See FoodNavigator.com*, April 28, 2003.



Litigation

[4] Beverage Maker Sued in Three States for Fraudulent Claims

Plaintiffs in three states have reportedly filed suit against herbal iced tea maker Arizona, alleging that its "Arizona Rx" product-line claims of enhanced memory, reduced stress and improved health are fraudulent. According to the plaintiffs, the levels of gingko biloba, panax ginseng, echinacea, and other substances in the Arizona Rx teas are too small to be beneficial. A Center for Science in the Public Interest (CSPI) spokesperson noted that some of the Rx products are high in calories, and it is unclear whether any dose of these herbs would justify the health claims. Houston trial attorney Martin Siegel, who represents the plaintiffs in class action suits filed in New York, Illinois and California, apparently seeks relief under state fraud, false advertising and deceptive trade practices laws. The U.S. Food and Drug Administration (FDA) evidently warned Arizona about the products in 2000, but took no further action against the company. A CSPI spokesperson was quoted as saying, "If the FDA is unwilling or unable to crack down on this kind of quackery, consumers are perfectly justified in hauling a company like Arizona into court." See *CSPI Newsroom*, April 29, 2003.

Legal Literature

[5] Katherine Van Tassel, "Adding Biotech Foods to the Tort System," *Western Massachusetts Law Tribune*, April 2003

Contending that liability under the tort system for injury allegedly caused by genetically modified (GM) foods should be assessed under a risk-benefit analysis, this article suggests that the Restatement (Third) of Torts: Products Liability (1998) errs in

retaining the consumer expectations test for cases involving food products, including those with GM ingredients. According to the article, the latter test was retained on the basis of two misconceptions, i.e. (i) "food processors do not follow design specifications so there is nothing to test the end product against to determine if there is a manufacturing defect," and (ii) "while 'consumer expectations are not adequate to supply a standard for defect in other contexts, assessments of what consumers have a right to expect in various commercial food preparations are sufficiently well informed . . . based on culturally defined, widely shared standards that food products ought to meet.'"

The article notes that GM foods clearly have "a design like any other manufactured product," and that consumers are not generally aware that more than 60 percent of all packaged foods in the United States contain GM ingredients. Under a risk-benefit analysis, jurors would have to balance GM food benefits such as decreasing pesticide and herbicide usage, increased crop yields, and positive impacts on world hunger with the likelihood and severity of illness caused by GM food consumption, including evidence of increases in food allergies, antibiotic resistance or negative impact on the environment. The article concludes "In this fashion, juries can weigh the benefits of a GM food product against its risks in a reasoned fashion to weed out those which are not beneficial to society."

Media Coverage

[6] Michael Pollan, "The Futures of Food," *The New York Times*, May 4, 2003

This article, part of a special food section in the Sunday Magazine section of *The New York Times*, discusses changing perceptions about the foods of



tomorrow. Starting with images from "The Jetsons" where food was created as a pill in the laboratory, the article explores the counterculture's emphasis on natural foods in the 1960s and 70s and more recent trends toward the consumption of organics, traditional plant and animal species, and locally grown produce purchased directly from the farm.

According to the article, the food industry is embracing "nutraceuticals" and "functional foods," which have been supplemented with the healthful components of other foods and beverages to confer health benefits beyond those of ordinary foods. As the author observes, "The growth of the American food industry will always bump up against a troublesome biological fact: try as we might, each of us can eat only about 1,500 pounds of food in a year. ... Unless agribusiness is content to limit its growth to the single-digit growth rate of the American population – something Wall Street would never abide – it needs to figure out ways to make us each spend more each year for the same three quarters of a ton of chow. The best way to do this has always been by 'adding value' to cheap raw materials." The article concludes by suggesting that breaking down the chemical parts of foods and adding them to others may not work, noting "We didn't evolve, after all, to eat phytochemical extracts or flavor fractions or mycoproteins grown on substrates of glucose."

Other Developments

[7] Iowa Senator Calls for WTO Case Against European Union

Senator Charles Grassley (R-Iowa) has reportedly called on U.S. trade officials to bring a case against the European Union (EU) before the World Trade Organization (WTO) challenging the EU moratorium on importing genetically modified (GM) foods.

The moratorium has been said to cost U.S. farmers hundreds of millions of dollars annually. The Bush administration decided to put off such action when it was trying to secure European support at the United Nations for its military action in Iraq. Grassley states in his letter, "Saddam Hussein's regime has now been deposed. Accordingly, I see no reason for putting off a WTO challenge." EU officials are currently considering rules that would require labeling and tracing of all GM products, a move criticized by U.S. agricultural interests concerned about "new, unscientific barriers to processed food products" and agricultural commodities. Meanwhile, Canadian researchers have reportedly developed a system that would prevent GM crops from crossbreeding. The system involves breeding "seed lethality" and seed lethality suppression genes in GM plants. See *Greenwire*, April 30, 2003; *euractiv.com*, May 2, 2003; and *Associated Press*, May 5, 2003.

Scientific/Technical Items

Obesity

[8] New Research Links Obesity to Incidence of Birth Defects

Overweight and obese women face significantly increased risks of having infants with birth defects, according to a study published this week in the journal *Pediatrics*. "Maternal Obesity and Risk for Birth Defects," M.L. Watkins, et al., *Pediatrics* 111(5): 1152-1158, 2003. Centers for Disease Control and Prevention researchers purport to have not only confirmed a previously established association between prepregnancy maternal obesity and spina bifida, but also to have established new associations between maternal obesity and heart defects, multiple anomalies and omphalocele, a disorder in which



the intestines or other abdominal organs protrude through the navel. Among the women studied, those who were obese were twice as likely to have an infant with spina bifida or heart defects and more than three times as likely to have an infant with multiple anomalies or omphalocele when compared to women of normal weight. Further, those who were merely overweight almost doubled their risk of having an infant with heart defects or multiple birth defects. The researchers speculate that nutritional deficits in overweight and obese women may account for these abnormalities.

[9] New York Study Indicates That Preschool-Age Children Are Increasingly Obese

New research shows that even toddlers are showing signs of obesity and the precursors of obesity-related disorders. "Obese Children Referred to the Pediatric Endocrinologist: Characteristics and Outcome," N. Shaw, et al., Abstract 803, Presented at the Pediatric Academic Societies' Annual Meeting, Seattle, Washington, May 3-6, 2003. State University of New York at Buffalo researchers examined the records of 385 children referred to pediatric endocrinologists for obesity treatment, finding that the onset of obesity is common in preschool-age children and that referral for treatment is often delayed. They also found abnormally high insulin levels, which can lead to diabetes, in children as young as age 3. On follow-up, the researchers discovered that dietary and exercise education provided by endocrinologists was ineffective in abating the progression of obesity. After two years, the children were, on average, even more overweight. The authors stress the need for obesity interventions that focus not only on children, but on parents and school systems because they shape childhood diets.

[10] Cato Institute Scholar Challenges Cancer Society Research

Steven Milloy, who publishes *JunkScience.com* and serves as an adjunct scholar for the Cato Institute, has challenged research that recently linked obesity to cancer. Further details about the study appear in issue 29 of this Update, April 30, 2003. According to Milloy, the American Cancer Society based its findings on data collected in 1982 by 70,000 untrained volunteers who interviewed two million friends and family about their health and lifestyle characteristics. Milloy states "None of the health and lifestyle data were verified for accuracy. The researchers really didn't know what or how much the study subjects ate, smoked, drank or exercised, for example. Not even the study subjects' height and weight were verified." Apparently, information on family history of cancer was ignored, and Milloy reports that the alleged increased risk was 9 percent for those who are moderately overweight, significantly lower than the 100 percent increased risk that the cancer society itself recommends as a minimum when looking for associations due to data quality problems with lower risk estimates. Milloy concludes, "Using the poor quality data, the researchers could do no better than to produce weak – that is, dubious – statistical associations between increased body weight and cancer incidence."



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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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