

Food & Beverage

LITIGATION UPDATE

Issue 12 • January 8, 2003

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LITIGATION UPDATE

Legislation, Regulations and Standards

U.S. Food and Drug Administration (FDA)

[1] CSPI Report Critical of FDA Policies on Genetically Engineered Foods

The Center for Science in the Public Interest (CSPI) has released a study, *Holes in the Biotech Safety Net*, that finds FDA's "current voluntary notification process is not up to the task of ensuring the safety of future GE [genetically engineered] crops." CSPI recommends that (i) FDA be given the authority "for mandatory review and safety approval of GE crops, including the authority to require any data it deems necessary to conduct a thorough food-safety assessment"; and that FDA (ii) "develop detailed safety standards and testing guidelines," (ii) "require developers to submit not summaries of data, but complete details about their testing methods, the actual data from safety tests, and statistical analyses of those data," (iii) "establish an approval process which is transparent and provides the public with an opportunity to comment on submissions," (iv) "perform and make available to the public detailed assessments of commercialized GE crops," and (v) "reassess the safety of commercialized GE crops if new safety concerns are recognized or new tests become available."

The report, based on 14 pre-market review applications obtained under the Freedom of Information Act and involving GE crops such as corn, tomatoes and squash, claims that current procedures have led to the submission of insufficient and erroneous data

that raise questions about the safety and nutrition of genetically engineered crops. According to CSPI, "biotech companies weren't always performing the right tests to look for potentially dangerous compounds, including allergens, and ... there was a great deal of unevenness among different developers' submissions." Lacking relevant legal authority, FDA apparently does not mandate specific tests, thus analysis of some known toxins and allergens was omitted from some applications. The report can be accessed at www.cspinet.org.

[2] Agency Issues Health Claims Guidance, Food Labeling Regulations Compliance Date

FDA has announced the availability of a document titled *Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements* (<http://www.cfsan.fda.gov/~dms/hclmgui2.html>). The guidance evidently updates the agency's approach to implementing the D.C. Circuit Court of Appeals decision in *Pearson v. Shalala* (164 F.3d 650 (D.C. Cir. 1999)), a case in which plaintiffs challenged FDA's general health claims regulations for dietary supplements and the agency's decision not to allow health claims for four specific substance/disease relationships. According to a *Federal Register* notice, the agency believes "this guidance will assist food manufacturers and distributors in formulating truthful and nonmisleading messages about the health benefits of their products." To meet the criteria for a qualified health claim, petitioners will now have to "demonstrate, based on a fair review by scientific experts of the totality of publicly



available scientific information, that the 'weight of the scientific evidence' supports the proposed claim." Food manufacturers are reportedly pleased with FDA's new ruling, while Consumer Federation of America Chair Howard Metzenbaum was quoted as saying, "This change lowers the bar for making food health claims and sends the food industry down the path of confusing and misleading claims that has characterized dietary supplements in recent years." See *Federal Register*, December 20, 2002; *The New York Times*, January 1, 2003.

Meanwhile, FDA has established January 1, 2006, as the uniform compliance date for food labeling regulations issued between January 1, 2003, and December 31, 2004. Comments on the action are due by March 17, 2003. See *Federal Register*, December 31, 2002.

U.S. Centers for Disease Control and Prevention (CDC)

[3] Alcoholic Beverage Labeling on Conference Call Agenda

The National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect is scheduled to convene a public conference call from 1 to 4 p.m. EST on January 23, 2003. A *Federal Register* notice indicates that items on the agenda include discussion of activities proposed by the Center for Science in the Public Interest regarding labeling on alcoholic beverages by the Bureau of Alcohol, Tobacco and Firearms, and a draft letter to the surgeon general requesting reissue of the federal advisory against drinking during pregnancy. To be connected to the conference call, dial (800) 713-1971 and enter code 908417. See *Federal Register*, January 6, 2003.

U.S. Department of Agriculture (USDA)

[4] Coalition Seeks Moratorium on Planting Bioengineered Crops

A coalition of health, consumer and environmental groups has filed a citizen petition with USDA seeking a moratorium on the use and planting of food crops as genetically engineered pharmaceutical-producing plant varieties (GEPPVs). The Genetically Engineered Food Alert, a Washington, D.C.-based coalition of seven non-profits including Friends of the Earth and state Public Interest Research Groups, claims that contamination of food crops has become a serious concern and seeks in addition to a moratorium (i) new GEPPV regulations, (ii) programmatic environmental impact statements for GEPPVs, (iii) changes in policies and regulations on confidential business information and the Freedom of Information Act, and (iv) the creation of a publicly available field-test-violations database. The petition can be found on the coalition's Web site at www.gefoodalert.org. Other groups are also apparently questioning government policies about agricultural biotechnology; they include the National Food Processors Association, the Center for Science in the Public Interest and the Grocery Manufacturers of America. See *USA Today*, December 17, 2002; and *BNA Daily Environment Report*, December 18, 2002.

Codex Alimentarius Commission

[5] U.S. Delegate to Biotechnology Task Group Calls for Members

The Codex Ad-Hoc Intergovernmental Task Force on Foods Derived from Biotechnology will be meeting in Yokohama, Japan, March 11-14, 2003. U.S. delegate L. Robert Lake has issued a call to those interested in being a U.S. delegation member to

submit a request and supporting statement no later than January 22, 2003. The agenda for the task force meeting can be obtained at www.codexalimentarius.net. One item on the agenda will be consideration of the *Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms*. In further Codex developments, the Food Safety and Inspection Service (FSIS) recently announced it was conducting a January 8 meeting in College Park, Maryland, to prepare for the Orlando, Florida, meeting of the Codex Committee on Food Hygiene, January 27 – February 1. A number of Codex standards and codes relating to fish, poultry, milk, and eggs will apparently be considered by the committee. See *Federal Register*, December 23, 2002.

Litigation

Poultry

- [6] *Physicians Committee for Responsible Medicine v. Tyson Foods, Inc.*, No. CGC-02-415864 (Superior Court of California, San Francisco County) (filed December 18, 2002)

Claiming that advertisements for Tyson Foods, Inc., chickens are misleading and deceptive, a Washington, D.C.-based nonprofit health and research group has filed a lawsuit against the poultry producer in California seeking an end to such advertisements and a requirement that Tyson place health warnings on its products. The complaint filed by the Physicians Committee for Responsible Medicine (PCRM) alleges that (i) defendant's "heart-healthy" advertisements for chicken are misleading due to the relatively high cholesterol content in some chicken parts; and (ii) defendant's assertions about its "all natural" products are likewise misleading due to the way the chickens are bred and raised in

a "factory farm" environment that requires hefty antibiotic doses to maintain health. According to the complaint, the extensive use of antibiotics in chickens has led to the development of antibiotic-resistant bacterial infections of humans. Citing a recent *Consumer Reports* study showing that more than one-half of Tyson chickens contain harmful bacteria, PCRM challenges Tyson's advertising claims on its Web site in an ad campaign titled "Natural Born Killers?" The site can be accessed at www.pcrm.org. See *prnewswire.com*, December 18, 2002; *CBS MarketWatch*, December 19, 2002.

Legal Literature

- [7] Franklin Crawford, "Fit for its Ordinary Purpose? Tobacco, Fast Food, and the Implied Warranty of Merchantability," 63 *Ohio St. L.J.* 1165 (2002)

This article comprehensively explores the Uniform Commercial Code's (UCC) warranty of merchantability as applied in cases against cigarette manufacturers and suggests that however the courts ultimately decide to use the theory in such litigation will affect emerging fast-food lawsuits. According to the article, expansive interpretations of merchantability to include latent harmful product effects will make the UCC synonymous with and subsumed by tort law, "such that it loses its basic character as a simple promise that the seller's goods will work." Noting that activists are beginning to "vilify the fast food industry," the article observes that unless courts limit the warranty of merchantability, they will have to find "that a variety of these unpopular products [such as high fat, sugar and calorie foods, alcoholic beverages and firearms] are unmerchantable."



Other Developments

[8] Health Policy Group Issues Report on Alcohol Ads and Youth

Georgetown University's Center on Alcohol Marketing and Youth (CAMY) has issued a report which concludes that nearly 25 percent of alcohol advertising on television during 2001 was more likely to be seen by 12- to 20-year-olds than by adults. Titled *Television: Alcohol's Vast Adland* (<http://camy.org/research/tv1202/>), the report also contends that the "alcohol industry's voluntary guidelines for ad placements on television are so lax that they allow the substantial exposure of youth to alcoholic beverage advertising, including advertising on programs with disproportionate numbers of young people in the viewing audience." The average American youth evidently saw 245 alcohol commercials in 2001, "but the 30% of youth who were most likely to see alcohol advertising on TV saw at least 780 ads." According to the report, youth saw more ads for beer than for juice, gum, chips, tennis shoes, or jeans. CAMY has reportedly submitted the report to the Federal Trade Commission, requesting a review of alcohol companies' marketing practices. See *CAMY Press Release*, December 17, 2002; *The New York Times*, December 18, 2002.

Scientific/Technical Items

Alcoholic Beverages

[9] Researchers Address Link Between Alcohol Consumption and Lung Cancer Risk

People who consume one to two alcoholic drinks per day are not at any greater risk of developing lung cancer than nondrinkers, according to an article

published recently in the *Journal of the National Cancer Institute* (94(24): 1877-1882, 2002). Boston University School of Medicine's Luc Djousse, M.D., and colleagues followed two groups, the famed Framingham Study cohort and the Framingham Offspring cohort, examining health and survey data from both. Among the more than 9,000 participants, they discovered 269 cases of lung cancer. These cases were matched by age, gender and smoking history with participants who were not diagnosed with lung cancer. Drinking habits were compared, and the researchers concluded that light to moderate alcohol consumption was not a factor in the cancers. They did, however, find evidence suggesting that those offspring who drank more than two drinks a day were at an increased risk of developing lung cancer. The numbers were too small in this subcategory to draw any definitive conclusions.

Upcoming Meetings

[10] NFPA Conference to Address Food Product Liability Issues

Sessions during the National Food Processors Association's (NFPA's) upcoming Food Claims and Litigation Conference will reportedly address strategies to defend emotional distress claims, the admissibility of consumer complaint data history, and food allergens. Speakers at the event will include in-house counsel from Kraft, Nestle and the Campbell Soup Co. The conference will be held February 11-13, 2003, at the Sheraton Wild Pass Resort and Spa in Phoenix, Arizona. More details are available at www.nfpa-food.org.

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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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