

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

[1] Pressure Mounts for Genetically Engineered Food Regulation; “Frankenfoods” Resisted by Trading Partners

Senator Richard Durbin (D-Ill.) has introduced a bill (S. 3095) that would amend the federal Food, Drug, and Cosmetic Act to “require premarket consultation and approval with respect to genetically engineered foods.” The Genetically Engineered Foods Act, which has been referred to the Committee on Agriculture, Nutrition, and Forestry, defines genetic engineering as “a transformation event,” i.e., one that involves “the introduction into an organism of genetic material that has been manipulated in vitro,” “to derive food from a plant or animal or to produce an animal.” Any producer of a genetically engineered food would be required to obtain FDA approval before introducing such food into interstate commerce. Such approval would require a determination that the food is (i) safe, (ii) safe under specified conditions of use, or (iii) not safe because the food “contains genes that confer antibiotic resistance,” “contains an allergen,” or “presents 1 or more other safety concerns.” An environmental assessment would be required with respect to the genetic engineering of animals. The Center for Science in the Public Interest apparently supports the legislation. See *CSPI Newsroom*, October 11, 2002.

Meanwhile, food industry representatives have reportedly met with the FDA, urging the agency to

finalize draft guidance on voluntary labeling and a proposed regulation that would require food developers to notify the FDA about their intent to market a food or animal feed developed through biotechnology. Critics do not believe the guidance and rule are adequate, said a news source. The pressure for some regulation is growing as some 70 percent of products on grocery store shelves contain genetically engineered ingredients and, according to some studies, genetically engineered crops are saving U.S. farmers millions of dollars by decreasing the need for pesticides and herbicides. See *Inside Washington Publishers*, October 18, 2002; *sfgate.com*, October 21, 2002.

On another front, a biotechnology trade organization is apparently adopting a voluntary moratorium on planting certain types of crops in major food-producing areas. According to a news source, such crops involve plants with altered genes that can be used to produce medically useful proteins that may be unacceptable for general food use or could contaminate food crops on nearby farms. The policy is reportedly designed to prevent a repeat of the recent StarLink corn debacle that resulted in a genetically engineered corn intended only for animal feed spreading to corn used in food for human consumption. See *washingtonpost.com*, October 21, 2002.

Internationally, there is significant resistance to biotech foods. Press reports have indicated that Asian importers are resisting genetically modified wheat, while the European Union (EU) has failed to lift its four-year old moratorium on approving new genetically modified organisms. A sticking point for agriculture ministers is apparently whether to



allow an unintentional presence of up to 1 percent of biotech material in a food product before requiring a warning label. The United States is reportedly considering a World Trade Organization challenge to the ban, which has cost corn growers alone some \$200 million annually in lost exports. An EU directive, however, came into effect on October 18 that would apparently allow biotech companies to apply for approval of their products. Member states do not intend to give any such products approval, said a news source, until further labeling and traceability rules are in place. U.S. Trade Representative Richard Mills was quoted as saying, "it remains unclear whether [the directive] will lead to any real change." See *Reuters Company News*, October 9, 2002; *Greenwire*, October 15, 2002; and *just-food.com*, October 18, 2002.

[2] Comments Sought on Draft Codex Guideline for Foods with Recombinant DNA Microorganisms

The U.S. delegate to the Codex Alimentarius task force on foods derived from biotechnology is soliciting comments on a draft guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms. The guideline, which is at step 6 of the eight-step Codex process, would affect products such as yogurt, cheese, fermented sausages, natto, kimchi, bread, beer, and wine. Specific attention is being drawn to paragraph 44 of the text that contains alternative proposals on the treatment of the annex on allergenicity. The comments, which will be incorporated into the U.S. government submission, are due by November 1, 2002. They should be submitted to Dr. H. Michael Wehr at Office of Constituent Operations, U.S. Food and Drug Administration, Room 1B-065, HFS 550, 5100 Paint Branch Parkway, College Park, MD, 20740; fax: (310) 436- 2618, or e-mail: Mwehr@cfsan.fda.gov.

Litigation

[3] Public Interest Groups Seek Peer Review Panel to Oversee Accreditation of Organic Certifiers

The Center for Food Safety and several other public interest groups have filed a petition with the U.S. Department of Agriculture (USDA) calling on the agency to convene a peer-review panel under the Organic Food Production Act that would assist the secretary in accrediting those entities seeking to become certifying agents. According to the October 16, 2002, petition, appropriate certification of organic farms is the key to USDA's new organic labeling program. More information about that program appears in issue 2 of this Update, October 16, 2002.

Petitioners are concerned that if the accreditation of certifying agents is not overseen by a panel formed under the Federal Advisory Committee Act and subject to public scrutiny, the integrity of the "organic" label will be threatened. They claim that one company has already tried to pressure the agency into relaxing the 100 percent organic feed requirement for organic chicken production. While the agency refused to accede to the request, the company's certifying agent has been accredited, purportedly raising "serious questions as to how thoroughly USDA scrutinized the ... application and whether the processes of accreditation review and decision making are rigorous enough to prevent acceptance of new certifying agents intent on manipulating the stringency of existing organic standards."

The petition further claims that USDA did not foresee a dramatic increase in the number of organic certifying agents at the time the organic labeling regulations were proposed. Applications have more than doubled since 2000, a situation that petitioners claim could lead to control of the certification

process by large agribusiness corporations at the expense of small organic farmers and farmer-based certifying organizations. USDA's National Organic Program Final Rule apparently calls for the establishment of a peer-review panel to (i) evaluate the program's adherence to accreditation procedures, (ii) review the program's accreditation decisions, and (iii) ensure that the accreditation process is in conformity with International Organization for Standardization (ISO) guidelines.

Other Developments

[4] Grocery Manufacturers of America Address Legal Issues at Conference

As this Update goes to press, the Grocery Manufacturers of America (GMA), a food industry trade organization, is conducting a legal conference in Washington, D.C., to discuss issues ranging from obesity-related and acrylamide litigation to corporate reforms after Enron, bioterrorism and regulatory developments in the areas of antitrust, advertising and marketing, and the Food and Drug Administration. Scheduled speakers included representatives of Kraft Foods North America, Inc.; Philip Morris Companies, Inc.; General Mills, Inc.; Frito-Lay, Inc.; The Coca-Cola Co., Inc.; and Gerber Products Co.

[5] Low-Income Mothers Spend Food Budgets on Fast Food

A study of low-income women in Louisiana has reportedly shown that they spend one-third to one-half of their food budgets on fast-food meals for themselves and their children. The study's findings, which were presented at the annual meeting of the American Dietetic Association, were apparently based on interviews with 30 women, some of whom spent up to 55 percent of their food money on fast food. According to researcher Dr. Carol O'Neil, diets

potentially high in fat may put these women and their families at risk of developing "heart disease, type 2 diabetes, stroke. All of the diseases that we think of as chronic, degenerative problems." The spending patterns were not apparently altered by participation in the U.S. Department of Agriculture's food-stamp program. The study also reportedly found that these women generally consumed only half a serving of fruit each day and did not consume enough milk or vegetables. See *Reuters Health*, October 22, 2002.

Media Coverage

[6] Paul Raeburn, Julie Forster, Dean Foust, and Diane Brady, "Why We're So Fat," *Business Week*, October 21, 2002

This article examines factors that could account for the growing number of overweight and obese Americans. Health experts apparently blame "an unhealthy environment that encourages overeating and discourages physical activity." That environment includes (i) inexpensive and oversized portions of unhealthy foods, (ii) aggressive food industry marketing, including hundreds of television advertisements broadcast during Saturday morning cartoon hours, (iii) soft-drink deals with school districts, and (iv) a significant drop in physical activity among both adults and children. According to the article, legislators, litigators and the food industry itself are beginning to address the challenge. Experts and industry analysts apparently assert that food choices are a matter of "personal responsibility," but note that public health campaigns focusing on changed behavior "have failed spectacularly." The article concludes by stating that the obesity epidemic can be solved by doing four simple things – eating less junk food, eating more fruits and vegetables, controlling portions, and exercising.



Scientific/Technical Items

Cardiovascular Disease

[7] WHO to Issue Report Calling for Reduced Salt and Fat Content in Processed Foods

A World Health Organization (WHO) report slated for release on October 30, 2002, will reportedly call on governments worldwide “to develop successful collaboration with the food industry to reduce salt and high fat in processed food” as a way of decreasing risk factors – e.g., high blood pressure, elevated cholesterol, obesity – that contribute to the development of cardiovascular disease. Titled *World Health Report 2002*, the document also evidently encourages governments to adopt other populationwide strategies that champion exercise and greater consumption of fruits and vegetables to complement drug interventions in combating cardiovascular risks. Report co-author Anthony Rodgers, of the University of Auckland, New Zealand, was quoted as saying that if processed food manufacturers reduced the salt content of their products, e.g., bread, cereal, soup, sausage, by as little as 5 percent per year, “people would gradually get to prefer less salty food” and their risk of developing cardiovascular disease would likely decrease as a consequence. See *WHO Press Release, Wall Street Journal*, October 18, 2002.

Acrylamide

[8] WHO and FAO Launch Acrylamide Web Site

The World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) have launched a new Web site to serve as a global resource and inventory of research

on health risks related to acrylamide in food. When fully developed, the WHO/FAO Acrylamide in Food Network will reportedly comprise (i) a database of those involved in acrylamide research, (ii) references for published research, and (iii) updates about the current status of research projects. All interested parties are invited to submit relevant information to the Web site. See *WHO/FAO Acrylamide in Food Network*, www.who.int/fsf/acrylamide/research.htm.

Genetically Engineered Foods

[9] NAS Studies “Unintended Effects” of Genetically Engineered Foods

The National Academy of Sciences (NAS) has formed a committee to summarize “science-based approaches to assessing (or predicting) unintended health effects of genetically engineered foods in order to assist in their evaluation prior to commercialization.” The 12-member group will evidently produce a report on the topic by August 2003 as well as a short report detailing the potential unintended health effects of foods derived from cloned animals. See *NAS Current Project Systems, Project I.D. No. BBXX-K-00-02-A*.

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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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