

Food & Beverage

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Issue 22 • March 12, 2003

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LITIGATION UPDATE

Legislation, Regulations and Standards

U.S. Congress

[1] New Legislation Aims to Increase Safety of Meals in Schools

Citing gaps in the inspection, testing and preparation of food served to kids in public schools, Illinois Senator Richard Durbin (D) has introduced legislation (S. 506) to ensure the safety of meals served under the school lunch and breakfast programs. The programs provide low-cost or free meals to more than 27 million children each school day. The National School Act would (i) establish a federal advisory committee to provide state education food safety coordinators with information on school lunch suppliers, (ii) mandate more tests for *E. coli* and salmonella in ground uncooked meats donated by the U.S. Department of Agriculture and (iii) increase the number of state and local annual cafeteria inspections.

The bill has been referred to the Senate Committee on Agriculture, Nutrition and Forestry. Representative Jan Schakowsky (D-Ill.) is expected to sponsor companion legislation in the House of Representatives. See *The Chicago Tribune*, March 4, 2003.

U.S. Department of Agriculture (USDA)

[2] New Rules Established for Field-Testing Biopharm Crops; Lawsuit Threatened

USDA's Animal and Plant Health Inspection Service (APHIS) has established new rules that strengthen the permit conditions to field-test plants genetically engineered to produce pharmaceutical and industrial compounds. The rules, announced in the March 10, 2003, *Federal Register*, will apparently be applied to the 2003 growing season and address such issues as (i) increasing the number of field site inspections to ensure compliance with regulations and assigned permit conditions, (ii) separating by one mile experimental corn from corn raised for human consumption, and (iii) requiring dedicated equipment and storage facilities for the field test duration. APHIS also seeks comments on ways to improve the program, including permit confinement measures, procedures to verify compliance, and ways to enhance the transparency of the permitting system. Comments on these issues are due May 9, 2003.

Food industry representatives are reportedly supportive of USDA regulatory action in this area, but are calling for even stricter requirements. A coalition of 11 environmental and consumer organizations, however, has evidently filed a 60-day notice of intent to sue USDA, claiming the agency has violated the National Environmental Policy Act and the Endangered Species Act by failing to (i) conduct required environmental impact assessments and (ii) consult other federal agencies about "biopharm"



crop impacts on endangered species. The coalition, which includes Friends of the Earth, Greenpeace and the Center for Food Safety, has apparently indicated that suit will be filed if USDA does not impose a temporary ban on these crops by early May. USDA has reportedly announced that it would continue to allow farmers to plant the experimental crops. *See prnewswire.com*, March 6, 2003; *Reuters*, March 5 and 6, 2003; *Greenwire* and *BNA Daily Environment Report*, March 7, 2003.

In another development, agricultural and environmental groups filed a petition with USDA on March 11, 2003, seeking to halt Monsanto Co.'s plan to introduce genetically engineered herbicide-resistant wheat. *See Reuters*, March 11, 2002.

[3] AMS Takes Responsibility for Developing Regulations on Country-of-Origin Labeling

USDA's Food Safety and Inspection Service (FSIS) has announced that it is withdrawing its advance notice of proposed rulemaking (ANPR) on country-of-origin labeling for beef products. The action is being taken due to passage of a provision in the Farm Security and Rural Investment Act of 2002 that gives USDA's secretary authority through its Agricultural Marketing Service (AMS) to implement the act's labeling requirements by September 30, 2004. The FSIS announcement includes a brief review of comments it received in response to its ANPR, noting there was "minimal support" for mandatory requirements.

FSIS suggests that further comments on country-of-origin labeling be submitted to AMS in response to its October 11, 2002, *Federal Register* notice titled "Establishment of Guidelines for the Interim Voluntary Country of Origin Labeling of Beef, Lamb, Pork, Fish, Perishable Agricultural Commodities, and Peanuts Under the Authority of the Agricultural Marketing Act of 1946." The 2002 farm bill mandates that beef, lamb and pork retailers may designate the

covered meat commodity as having originated in the United States only if it is "exclusively born, raised, and slaughtered in the United States." *See Federal Register*, March 7, 2003.

Litigation

Acrylamide

[4] Agency Director Weighs in on Prop. 65 Interpretation

The director of California's Office of Environmental Health Hazard Assessment (OEHHA) has indicated to counsel for Burger King Corp. that acrylamide is not exempt from the warning requirements of the Safe Drinking Water and Toxic Enforcement Act (Prop. 65) as a naturally occurring chemical in food. According to OEHHA Director Joan Denton, "As you know, the regulation is quite explicit that this section applies to situations only to the extent that the chemical did not result from *any known human activity*. (Section 12501(a)(3), italics added.) By definition, cooking is a known human activity," and thus, including acrylamide in the exemption "would be incompatible with the existing regulation." Denton also reported that the agency will, within budgetary constraints, move forward with "all appropriate regulatory options," and was planning to seek relevant information through a public workshop and formal rulemaking procedures that could result in the establishment of an alternative risk level.

According to a news source, counsel for the group that brought a Prop. 65 enforcement action against Burger King and others for failure to warn about acrylamide in their food products believes OEHHA's pronouncement on the issue significantly boosts his case. Raphael Metzger was quoted as saying, "I

view the decision as very favorable to the case in that in California neither of the so-called defenses that McDonald's and Burger King are asserting are in fact exemptions from liability. Unless they can obtain an alternate no-significant-risk level orders of magnitude greater than the published risk level [0.2 micrograms per day], they have no defense." He reportedly added, "If there are other feasible means of processing the product, so that it is not so chock-full of acrylamide – I don't know if an alternative can be established." Burger King counsel has apparently called for swift OEHHA action, claiming the issue "has important implications for millions of Californians, and we now have lawsuits pending in two different courts, against a total of six companies. There will be more. This is not an issue which should be decided by private litigants. It's an issue that should be decided by the agency charged with implementing Prop. 65." See *Inside EPA*, March 7, 2003.

Other Developments

[5] Consumer Groups File Comments with FDA Opposing Food Irradiation

Asserting that chemical byproducts in irradiated ground beef and other foods may increase the risk of colon cancer and DNA damage in those who eat them, two consumer groups have reportedly filed comments with the U.S. Food and Drug Administration (FDA) urging the agency to deny five pending requests to irradiate certain foods, including ready-to-eat meat and poultry products. Public Citizen and the Center for Food Safety reportedly based their contentions on recent European Union-funded studies which concluded and confirmed previous findings that specific chemicals found only in irradiated foods, i.e., 2-alkylcyclobutanones (2 ACBs), cause DNA damage in human cells and promote

tumor development in rat colons. "If any other food additive had as much science about health risks stacked up against it, the claims that it is safe would be laughed at," a Center for Food Safety spokesperson was quoted as saying.

The consumer groups apparently want FDA to (i) delay approval of irradiation for more foods until further peer-reviewed research is conducted on 2-ACBs and other toxicity risks, (ii) analyze 2-ACB levels and potential risks related to foods the agency has already approved or is considering for irradiation, and (iii) hold public meetings to discuss the alleged health effects of irradiation. See *Public Citizen News Release*, February 26, 2003.

Media Coverage

[6] Mary Eberstadt, "The Child-Fat Problem," *Policy Review*, February/March 2003

Claiming that "there would appear to be an obvious relationship" between "absentee parents" and "overstuffed children," this article explores recent scientific studies showing associations between mothers working and the unhealthy dietary and exercise habits of their children. The article asserts that the epidemic of overweight and obesity among children in the United States and other industrialized nations can be explained by the rising incidence of mothers working outside the home. According to the article, unsupervised children eat more, spend more time in front of the television set and are less apt to play outdoors. The children of working mothers are also apparently less likely to be breast-fed, another purported risk factor for obesity. The article further suggests that the loss of a domestic life in which mothers are with their children around the clock could have led to the use of food by both mothers and their children to "compensate for other



things that are being missed." The article appears in a publication of the Hoover Institute, a conservative think tank in Washington, D.C.

Scientific/Technical Items

Obesity

[7] IOM Report Links Obesity to Risk of Cancer

A report issued March 10, 2003, by the National Academy of Science's Institute of Medicine (IOM) asserts that "smoking, unhealthy diet, obesity, sedentary lifestyles, and failure to get screened all contribute to the excess burden of cancer" in the United States. <http://search.nap.edu/books/0309082544/html/> In *Fulfilling the Potential of Cancer Prevention and Early Detection*, members of the National Cancer Policy Board make 12 recommendations for increasing the effects of evidence-based cancer prevention and early detection interventions. With regard to obesity, they recommend that the U.S. Department of Health and Human Services develop a national strategy to address "the epidemic of obesity, unhealthy diet and physical inactivity in America, which are all significant risk factors for cancer and other diseases." Interventions the board members cite as ways to reduce cancer risk include (i) youth policies targeting the availability of healthy lunches and physical education requirements in schools and (ii) environmental policies related to zoning and land use that affect opportunities for exercise.

[8] Researchers Blame Sedentary Lifestyle and Fast Food for Obesity and Diabetes

Eating fast food and watching television combine to increase the risk of obesity and diabetes, according to research presented recently during the

American Heart Association's 43rd Annual Conference on Cardiovascular Disease Epidemiology and Prevention in Miami. "Fast Food Meal Frequency and the Incidence of Obesity and Abnormal Glucose Homeostasis in Young Black and White Adults: The CARDIA Study," M.A. Pereira, et al., *Circulation* 107: e7001, 2003. Harvard Medical School's Mark Pereira and colleagues followed more than 5,000 young adults for 15 years, monitoring dietary and lifestyle factors and assessing obesity and abnormal glucose levels. After adjusting for demographic factors, smoking, alcohol use, and physical activity, the researchers concluded that the frequency of fast food consumption was directly associated with the risk of developing obesity and abnormal glucose metabolism in Caucasians but not in African-Americans. Pereira et al. asserted that those in the Caucasian cohort who ate fast food more than two times per week more than doubled their risk of diabetes and increased their risk of obesity by approximately 80 percent. The researchers further concluded that Caucasian subjects who watched at least three hours of television per week in addition to frequently eating fast food were almost three times as likely to be obese or diabetic. While unable to explain the exact mechanism by which such lifestyle factors may increase the risk of obesity or diabetes, the researchers contend that fast food consumption influences overall dietary quality.

Acrylamide

[9] EU Launches Acrylamide Database

A new European Union (EU) initiative provides online access to a database of international research efforts related to the presence of the chemical acrylamide in food. http://europa.eu.int/comm/food/fs/sfp/fcr/acrylamide/acryl_database_en.html. See EU Press Release, March 10, 2003.

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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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