

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] Agency Schedules Outreach Meetings on Bioterrorism Rules

FDA will be conducting a series of meetings around the country in November 2003 “to provide an overview of the new FDA rules and the U.S. Customs and Border Protection processing procedures for implementing” those sections of the Bioterrorism Act of 2002 involving food facility registration and prior notice of imported food shipments. FDA is hoping to reach (i) U.S. owners, operators or agents in charge of domestic food facilities that manufacture, process, pack, or hold food under FDA’s jurisdiction for human or animal consumption, and (ii) persons who import or offer for import in the United States food under FDA’s jurisdiction. A registration form and schedule can be obtained [here](#). See *Federal Register*, October 28, 2003.

[2] FDA Issues Guidance on Antimicrobial Veterinary Drugs

Concerns about antibiotic resistance in humans have apparently led the FDA to issue [guidance](#) for industry on evaluating the safety of antimicrobial drugs given to livestock to prevent illness and encourage rapid growth. While the guidance is not mandatory, it outlines a three-part evaluation process, the answers to which will factor into FDA’s consideration of new drug applications. The process

involves (i) a “release assessment” to determine the probability that the use of an antimicrobial drug will result in the development of resistant bacteria in an animal, (ii) an “exposure assessment” to estimate the likelihood that if such bacteria did develop, people would ingest them, and (iii) a “consequence assessment” to evaluate whether humans will be harmed if they are exposed to such bacteria. FDA also plans to use the guidance to review drugs already in use; critics contend such review could take a half-century to complete. See *CBSNews.com*, October 23, 2003.

Meanwhile, FDA has also issued [draft guidance](#) on a general approach to establish an acceptable daily intake for veterinary drug residues in human food. Titled “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing,” the guidance was developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products, which is working to harmonize requirements for the approval of such products among the European Union, Japan and the United States. Comments must be submitted by November 24, 2003. See *Federal Register*, October 23, 2003.

U.S. Congress

[3] House Lawmaker Introduces Concurrent Resolution on Obesity

Representative Robert Andrews (D-N.J.) recently introduced a concurrent resolution ([H. Con. Res. 303](#)) to express the sense of Congress with respect



to obesity-related issues. More specifically, the concurrent resolution advocates (i) establishment of a National Obesity Awareness Month, (ii) recognition of various stakeholders in promoting obesity awareness and (iii) federal responsibility for raising awareness of obesity's attendant medical effects and increasing funding for research, prevention and treatment efforts.

Russia

[4] Russian Government to Mandate GM Labeling

The Russian government is reportedly considering amendments to its federal consumer protection rights law that would require disclosure of genetically modified (GM) ingredients on food product labels; the amended law would also apparently mandate disclosure of all additives. *See justfood.com*, October 23, 2003.

Meanwhile in Britain, the operator of more than 1,600 convenience and grocery stores has decided to prohibit the sale of GM products in its retail outlets and ban the growing of GM foods on its farms. The chief executive of the Co-operative Group was quoted as saying the decision followed a survey of patrons which found (i) 55 percent of patrons would not knowingly buy food containing GM ingredients and (ii) 78 percent of patrons were opposed to the growing of GM crops in Great Britain. *See BNA Daily Environment Report*, October 24, 2003.

State/Local Initiatives

[5] California Carcinogen Committee Makes Acrylamide Recommendations

California's Proposition 65 Carcinogen Identification Committee (CIC) has reportedly recommended

that the Office of Environmental Health Hazard Assessment (OEHHA) conduct a broad public warning campaign for acrylamide in foods, while also loosening the existing exposure limit that could exempt many foods from future Proposition 65 (Prop. 65) enforcement actions. The CIC evidently believes that industry-financed public outreach is preferable to individual warning label requirements, with some CIC members apparently suspecting that the public no longer pays attention to food-product labels. According to a news source, OEHHA is not expected to develop a new no-significant-risk level for acrylamide in foods until well into 2004, a timetable that could affect pending acrylamide-related litigation against fast-food restaurants, which litigation has been stayed briefly to allow OEHHA to move forward with its acrylamide work plan. The dispute over acrylamide is said to mark a "watershed moment" in Prop. 65 enforcement because state officials have never encountered a chemical present in many foods at significant levels that is included on the state's list of substances known to cause cancer. *See Inside EPA*, October 24, 2003.

[6] Maine Backs Off Bottled Water Labeling Law

According to a news source, Maine has agreed to settle litigation brought by the Grocery Manufacturers of America (GMA) challenging the state's new requirement that bottled water labels "identify the name and geographic location of the body of water, well or public water supply from which the water was obtained." The state will not enforce the law, which was to have taken effect September 1, 2003, unless federal law changes or the Food and Drug Administration decides that the measure does not conflict with federal statutes or otherwise exempts the state from federal requirements. GMA had claimed that federal law bars states from setting

their own bottled water identification standards. See *Maine Today.com*, October 28, 2003.

[7] Florida Governor Establishes Obesity Task Force

Florida Governor Jeb Bush (R) recently signed an executive order creating a 14-member task force to address the state's rising rates of overweight and obesity. "Diseases related to overweight and obesity cost everyone in Florida tens of billions of dollars annually," Florida Department of Health Secretary John Agwunobi was quoted as saying. Among other things, the advisory group is charged with (i) providing recommendations on ways of promoting the overweight and obesity issue as a "major public health problem" with serious economic implications for the state, (ii) identifying evidence-based strategies to promote healthy lifestyles and (iii) submitting a report with its findings and recommendations to the governor by February 14, 2004. See *Florida Department of Agriculture and Consumer Services Press Release*, October 15, 2003.

Other Developments

[8] Hudson Institute Challenges Yogurt Producer's Marketing Claims

A think tank that promotes free trade and "technological innovations in agriculture" has [called on](#) Stonyfield Farms to "put their money where their marketing mouths are and offer valid proof of their latest health claims." According to the Hudson Institute's Center for Global Food Issues (CGFI), the organic yogurt maker, which is owned by Danone, is linking its products to child health issues, i.e., "suggesting organic yogurt in vending machines can help reduce childhood obesity." CGFI, whose motto appears to be "Milk is Milk," also accuses Stonyfield

of falsely implying that its organic products are healthier than those with hormones and pesticides, noting that Food and Drug Administration marketing guidelines state that "no-hormones" claims are false because all dairy products naturally contain hormones. Stonyfield claims that it pays farmers not to treat cows with the synthetic bovine growth hormone rBGH.

According to a Stonyfield [press release](#), Rhode Island students will be the first in the nation to have "an innovative healthy, vending machine" with "organic yogurt, string cheese, dried fruit, soy nuts, and pita chips among other low-fat and low-sugar products." The vending pilot, subsidized by Stonyfield, was developed in partnership with a local nutrition education organization, a food distributor, school administration, and students "to help improve student nutrition." Stonyfield's president and CEO was apparently motivated to launch his healthy vending project by the current obesity epidemic among youth.

[9] USDA Boards Promote Food Consumption; Pork Check-off Program Deemed Unconstitutional

Critics of food-industry marketing practices have reportedly expressed concern about the support that is being provided for fatty-food promotion by boards appointed and overseen by the U.S. Department of Agriculture (USDA). For example, the National Dairy Promotion and Research Board apparently provided consumer research and "menu development expertise" to Pizza Hut when that company created "Stuffed Crust Pizza," and "The Insider," its "cheesiest" products. According to the board's chair, ensuring the use of a lot of cheese in these products resulted in Pizza Hut moving 100 million pounds of cheese in one year.



At least one member of Congress believes that USDA's mission conflicts with its role in revising the food guide pyramid. Senator Peter Fitzgerald's (R-Ill.) proposal to put the Department of Health and Human Services in charge of dietary advice has been criticized by the director of USDA's Center for Nutrition Policy and Promotion which is rewriting the dietary guidelines. Director Eric Hentges, who previously worked for the meat industry, reportedly said that USDA's mission is not to trumpet U.S. farm products, but to provide "a safe, affordable, nutritious food supply."

According to a press report, nutritionist Marion Nestle, who has been critical of food-industry influence on government nutrition programs, calls USDA-picked boards that oversee industry check-off programs, which are used for generic promotion and ads, "federally sanctioned and administered public relations enterprises to benefit certain food commodities." Small producers also generally oppose the mandatory check-off programs which, they claim, benefit their larger competitors, and have had some success challenging the programs on First Amendment grounds in court. Recently, a 6th Circuit Court of Appeals [panel](#) found the USDA's pork check-off program unconstitutional. It is unknown whether USDA will appeal the latest decision. *See Chicago Tribune and Associated Press, October 23, 2003.*

ers at the Feeding Infants & Toddlers Study (FITS), commissioned by the makers of Gerber baby food, report finding that not only are infants and toddlers ingesting too many calories, they are eating foods high in fat, sugar and salt, and low in nutritional value. In an overview of the FITS study presented at the recent annual meeting of the American Dietetic Association (ADA), these researchers presented data showing that 1- and 2-year-olds consume on average 270 excess calories per day, a surplus of almost 30 percent. Children as young as 7 months were shown to be getting surpluses of 20 percent. They further reported that up to one-third of children ages 2 and younger consume no fruits and vegetables in a given day and that those children who do eat vegetables are most likely to eat french fries. At age 1 year, more than 60 percent of the children studied had dessert or candy at least once per day and 16 percent ate a salty snack. By 19 months, these numbers rose to 70 percent and 27 percent, respectively. At 15 months, 30 to 40 percent of the children studied were having a sugary fruit drink each day while 10 percent had a soft drink. "If kids are having soft drinks at such an early age, it's going to be very, very challenging to introduce other types of foods for them later," a child nutritionist at the ADA meeting was quoted as saying. *See Associated Press, October 27, 2003.*

Scientific/Technical Items

Nutrition

[10] Children's Dietary Habits Established at Early Age

A new study concludes that children as young as 1 and 2 years old are setting bad eating habits that could plague them into their adult years. Research-



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