

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Issues Recordkeeping Regulations Under the Bioterrorism Act to Further Improve Food Security

FDA on Monday announced final regulations requiring “persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records” that identify “the immediate previous source of all food received, as well as, the immediate subsequent recipient of all food released.” The agency has scheduled [seven informational meetings](#) about compliance with the new rules in early 2005; most companies must comply within 12 months of the date the regulations are published in the *Federal Register*.

Outgoing HHS Secretary Tommy Thompson was quoted as saying that “publication of this record-keeping rule represents a milestone in U.S. food safety and security. There is more work to do yet, but our nation is now more prepared than ever before to protect the public against threats to the food supply.” Those remarks are more optimistic than sentiments Thompson expressed during a December 3, 2004, press conference announcing his resignation when he said he worried “every single night” about the possibility of terrorist attacks on

the nation’s food supply. “For the life of me, I cannot understand why the terrorists have not attacked our food supply because it is so easy to do.”

The recordkeeping regulations implement the last of four food-related provisions of the Public Health Security and Bioterrorism Preparedness Response Act of 2002. Previously implemented rules (i) require registration of foreign and domestic food facilities, (ii) establish procedures for the administrative detention of food that FDA believes could pose serious adverse health effects, and (iii) require prior notice of food products imported or offered for import to the United States. See *FDA News Release* and *The Wall Street Journal*, December 6, 2004

[2] FDA Proposes Lowering Standard for Arsenic in Bottled Water Products

FDA has proposed amending its [bottled water quality standard regulations](#) by lowering the existing allowable level for arsenic from 50 parts per billion (ppb) to 10 ppb, or 0.05 mg/L to 0.010 mg/L, to maintain compatibility with the U.S. Environmental Protection Agency’s quality standards for public drinking-water as mandated under Section 410 of the Federal Food, Drug and Cosmetic Act. The proposal would require bottled water manufacturers to periodically test source water for arsenic unless the companies met specific criteria for source water monitoring exemptions under current good manufacturing practice regulations. Those same regulations also require manufacturers to test finished bottled water products for arsenic at least once annually. See *Federal Register*, December 2, 2004.



U.S. Department of Agriculture (USDA)

[3] FSIS Extends Comment Period on *Listeria* Rule, Issues Attendant Report

The Food Safety and Inspection Service (FSIS) has extended the public comment period on the interim final rule titled “Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products” until January 31, 2005. In conjunction with extension of the comment period, the agency has issued a [report](#) that includes a discussion of the effectiveness of the interim rule and recommendations for future USDA action. The 28-member FSIS assessment team that authored the report found that the incidence of *Listeria monocytogenes* in ready-to-eat (RTE) meat and poultry products has generally been reduced because manufacturers have implemented various preventive measures such as adding antimicrobial ingredients to their products to inhibit growth of the pathogen. The assessment group’s recommendations for continued improvements in the safety of RTE products are directed at inspector training, product sampling, retail food handling, and better communication with small businesses. See *Federal Register*, December 2, 2004.

Canada

[4] Proposed Legislation Would Bolster Canadian Food Inspection Agency’s Bioterrorism-Related Activities

The minister of Agriculture and Agri-Food recently introduced legislation ([Bill C-27](#)) in Canada’s House of Commons that aims to increase the safety and security of the food supply by consolidating and modernizing provisions of the 10 different acts that currently provide the legislative base for

the Canadian Food Inspection Agency’s (CFIA’s) inspection, enforcement and compliance activities. Among other things, the CFIA Enforcement Act would give CFIA the authority to (i) hold products while awaiting test results, (ii) order the removal of imported food products that fail to meet the agency’s legislative and regulatory requirements, and (iii) develop food safety protocols based on Hazard Analysis Critical Control Points. The proposed law would grant CFIA and the Canada Border Services Agency joint authority to (i) halt imports of food, feed, seed, and fertilizer at the border, (ii) license importers, and (iii) establish recordkeeping systems to track the origin and destination of food products. See *CFIA News Release*, November 26, 2004.

Other Developments

[5] CSPI Asks Federal Trade Commission to Take Action Against National Geographic Society for Allegedly Misleading Potential Subscribers to Kids’ Magazine

Advertising-free copies of *National Geographic Kids* used in direct mail solicitations aimed at potential subscribers “mislead reasonable consumers into believing that its monthly issues are similarly free of advertising,” according to a [complaint](#) the Center for Science in the Public Interest (CSPI) filed with the Federal Trade Commission on December 1, 2004. The consumer advocacy organization claims a typical issue of the magazine is “jam-packed with advertisements” that “significantly impact children’s health by encouraging junk food consumption and a sedentary lifestyle, which have been shown to lead to childhood obesity and early onset of ‘Type 2’ diabetes in some children.” Such ads allegedly include those for



candy, sugary cereal, snack foods, pizza, fast food, DVDs, television shows, and video games. CSPI is asking the Federal Trade Commission to (i) stop the National Geographic Society from distributing advertising-free samples of the magazine as long as regular issues contain ads, (ii) prohibit dissemination of the mailing and (iii) require the National Geographic Society to offer refunds to current subscribers. *See CSPI News Release*, December 1, 2004.

[6] **Pew Report Targets State, Federal Roles in Oversight of Genetically Modified Crops**

A new [report](#) from the Pew Initiative on Food and Biotechnology concludes that many state governments lack the appropriate legal authority, personnel and financial resources to oversee the myriad issues generated by the cultivation of genetically modified crops. “The diverse levels of preparedness of states reflected in this report suggests that the federal-state partnership needs to be reviewed and strengthened to ensure that states have the resources they need to be full partners with federal regulators and to enable them to respond to unique local concerns,” co-author Michael Taylor said. Topics addressed in the report include the effect of Confidential Business Information on states’ ability to evaluate field trial safety and states’ authority to oversee certain GM crops that produce pesticidal substances.

Meanwhile, a recent Pew survey of consumer attitudes about GM foods reportedly revealed that opposition to “introducing GM foods into the U.S. food supply” has declined from 58 percent in 2001 to 47 percent in 2004. *See Pew Initiative on Food and Biotechnology News Releases*, November 24 and December 2, 2004.

Media Coverage

[7] **Kathleen McGowan, “Pay Attention to This,” *Psychology Today*, November/December 2004**

“Like addicts, overeaters may be compensating for a sluggish dopamine system by turning to the one thing that gets their neurons pumping. It’s a mark of changing times – and more sophisticated science – that the head of the National Institute on Drug Abuse is thinking about doughnuts as well as heroin,” according to this article about Nora Volkow, the new director of the National Institute on Drug Abuse. Dopamine is a brain chemical involved in generating the feelings of motivation and pleasure; drugs like heroin or nicotine allegedly stimulate its release. Volkow’s brain imaging research has shown that drug addicts have fewer dopamine D2 receptors, and similar brain imaging studies have reportedly shown that overweight individuals have fewer dopamine receptors than people of normal weight. “With fewer receptors,” according to the author, “the dopamine system is desensitized, and the now-understimulated addict needs more and more of the drug to feel anything at all.”

Scientific/Technical Items

Cardiovascular Disease

[8] **Obesity’s Effect on Cardiovascular Health of American Youth Unclear, Say CDC Researchers**

Researchers from the Centers for Disease Control and Prevention (CDC) reported this week that the effects of obesity on American youths’ cardiovascular



health remain unclear. (Earl Ford, et al., "Trends and Risk Factors for Cardiovascular Disease Among Children and Adolescents in the United States," *Pediatrics* 114(6): 1534-1544, December 2004). The study compared data from two national surveys conducted in 1988-1994 and 1999-2000 and found that the waist circumferences of both boys and girls aged 2 to 17 increased by nearly 1 inch over the study period. Average blood pressure readings increased by more than two points in the 8-to-17 age group, according to the researchers. Cholesterol levels, however, remained virtually unchanged over

the study period, and blood levels of triglycerides and glucose, a marker for diabetes risk, declined slightly over the two-survey period.

An American Heart Association representative was quoted as saying the study should not give parents "a false sense of security" because cardiovascular risk factors can show up long after obesity develops. Stephen Daniels, M.D., also said it is possible that the averages reported in the CDC study do not single out groups of obese youngsters who are at higher risk. *See Health Day Reporter*, December 6, 2004.



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