Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Government Accountability Office (GAO)

[1] GAO Report Faults FDA's Oversight of Animal Feed Testing Program; Harkin Calls for Evaluation of USDA National Animal Identification Plan

FDA's animal feed testing program fails to ensure industry compliance with agency guidelines designed to prevent the spread of bovine spongiform encephalopathy (BSE), says a new GAO <u>report</u>. "Keeping ruminant byproducts out of cattle feed is the most important firewall against BSE getting into or spreading among U.S. cattle," Senator Tom Harkin (D-Iowa), who requested the GAO investigation, said in calling on FDA to immediately remedy the alleged problems with the testing program.

In its report, GAO asserts that (i) FDA's failure to set appropriate time limits for laboratories and district offices to analyze and review feed samples results in cattle consuming feed that contains banned protein products; and (ii) FDA managers' failure to establish effective oversight controls has led to noncompliance with the program.

Meanwhile, Senator Harkin yesterday asked GAO to evaluate the agriculture department's strategy for implementing a national animal identification system. The ranking Democratic member of the Committee on Agriculture, Nutrition and Forestry, claims that USDA has "no clear plan for moving forward with a workable system" and wants the agency to justify giving private entities responsibility for animal-tracking data. *See Press Releases of Senator Tom Harkin*, November 9 and 15, 2005.

Food and Drug Administration (FDA)

[2] FDA Limits Health Claims on Tomato Products

Responding to petitions from a dietary supplements manufacturer and food companies, the FDA last week rejected a proposal to allow lycopene alone (as a supplement or food ingredient) to include claims asserting that the carotenoid may reduce the risk of various cancers, but approved four heavily qualified claims for potential health benefits related to tomato-based foods.

With respect to the Lycopene Health Claim Coalition's request for a claim linking tomato lycopene to a reduced risk of developing prostate cancer, FDA authorized the following statement for product labels: "Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting the claim." The coalition includes H.J. Heinz Co. and the Morningstar Co. (owned by Kellogg). In response to a petition from American Longevity, Inc., FDA concluded there is "very limited credible evidence" linking lycopene alone or tomato intake to various cancers, but authorized qualified claims linking tomato consumption to a reduced risk of gastric, ovarian and pancreatic cancer. *See*

FDA Letters of Partial Denial, November 8, 2005; *Associated Press*, November 10, 2005.

[3] FDA Issues Revised Guidance for Enforcement of Bioterrorism Regulations Requiring Prior Notice of Imported Food

FDA has updated the <u>compliance policy guide</u> for FDA and Customs and Border Protection (CBP) staff charged with enforcing Bioterrorism Act provisions that require domestic and foreign companies to register their facilities and provide notice to FDA and CBP hours before imported food shipments reach U.S. ports of entry. Revisions to the policy guide pertain to routine shipments of food transshipped through the United States, arriving from and exiting to the same country, and the Harmonized Tariff Schedule code. *See Federal Register*, November 14, 2005.

State/Local Initiatives

[4] California County Rejects Ban on Transgenic Organisms

Voters in Sonoma County, California, last week defeated a hotly contested ballot initiative that would have imposed a 10-year moratorium on the cultivation, sale and distribution of most genetically modified (GM) foods, animals, fish, and crops. "We got out-barraged by the opposition's messages and out-lied by their ads," a spokesperson for GE-Free Sonoma County was quoted as saying. "We hoped the voters would see through the lies, and they didn't," he said. Supporters and opponents of Measure M reportedly spent a combined \$850,000 to publicize their positions on the proposal. To date, three California counties – Mendocino, Marin and Trinity – have approved ballot initiatives prohibiting GM organisms, while voters in Humboldt, Butte and San Luis Obispo counties have rejected similar ordinances. *See (Santa Rosa) Press Democrat*, November 8, 2005; *Associated Press*, November 9, 2005.

Other Developments

[5] Demanding a Code of Conduct, Entertainment Unions Decry Product Placement as "Stealth Advertising"

The East and West Coast affiliates of the Writers Guild of America and the Screen Actors Guild have denounced product integration in television shows and theatrical films, urging advertisers and the entertainment community to adopt guidelines to protect the public from undisclosed advertising. "The public has a right to be informed that they are viewing *de facto* subliminal advertising," a Writers Guild spokesperson was quoted as saying. "We're calling on the industry to engage in a dialogue to institute a code of conduct that will establish standards governing the use of commercial products in all television or film. Barring an industry agreement, we will take this issue to the FCC for federal intervention," Patric Verrone said.

In a **white paper** issued Monday, the groups recommend (i) full and clear disclosure of product integration at the beginning of TV programs, (ii) limited product placement in children's programming, (iii) creative rights for writers when incorporating products into program content, and

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(iv) extending any adopted code of conduct to cable TV, "where some of the most egregious abuse is found." *See The New York Times*, November 13, 2005; *WGA Press Release*, November 14, 2005.

Scientific/Technical Items Cardiovascular Disease

[6] Eating Out Allegedly Linked to Cardiovascular Problems in Youth

Children who frequently dine out may be at greater risk of developing cardiovascular disease than those who eat more meals at home, according to research presented this week at the American Heart Association's Scientific Sessions 2005 in Dallas, Texas. Wisconsin researchers examined risk factors for cardiovascular disease and diabetes in some 620 Wausau, Wisconsin, youth and found that those who often eat out exhibited significantly higher blood pressure and cholesterol levels, lower levels of the "good" cholesterol HDL, and lower insulin sensitivity. Youth who ate out more frequently also consumed more foods high in starch, sugar, sodium, fat, and cholesterol, and consumed nearly twice as many soft drinks as those who mostly had meals at home. "As a culture, we say we value physical activity and healthy eating, but in reality we're all about convenience and convenience foods because we have such busy schedules," lead author Karen Olson, executive director of Wausau's Cardiovascular Research and Education Foundation, said.

The study also indicated that kids who routinely dine out are significantly less active than their peers and tend to eat more fast food and junk food at home. "In a 21-meal week, eating out four times shouldn't create the high-sugar, high-sodium, highfat intake that we saw," Olson said. "We think it's not just the eating out, but they way these children are eating all the time, with lots of frozen pizzas and packaged macaroni and cheese on the days they eat at home." *See Reuters*, November 14, 2005.



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Food & Beverage Litigation Update is distributed by Mark Cowing 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 <u>mcowing@shb.com</u> or <u>mboyd@shb.com</u>. 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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