Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards Department of Health and Human Services (HHS)

[1] HHS Secretary Announces New Strategy to Combat Obesity

Late last week, HHS Secretary Tommy Thompson issued a Food and Drug Administration report containing recommendations "centered on the scientific fact that weight control is primarily a function of caloric balance." "Counting calories is critical for people to achieve and maintain a healthy weight," Thompson said. "This new report highlights FDA's overall strategy for getting consumers accurate, helpful information that allows them to make wise food choices at home, at supermarkets and in restaurants. Recommendations in the report include (i) issuing a proposed rule on ways of providing "more prominence to calories" on food labels, e.g., increasing the font size of that information, (ii) considering enforcement action against products that misrepresent serving sizes, and (iii) encouraging the restaurant industry to implement a voluntary "point-of-sale nutrition information campaign. See HHS Press Release, March 12, 2004.

[2] Dietary Guidelines Advisory Committee to Hold Third Meeting

The Dietary Guidelines Advisory Committee will hold its third meeting on March 30-31, 2004, in Washington, D.C. Public comments relevant to the group's review of the guidelines will be accepted throughout its deliberations. The 13-member federal panel is charged with preparing by 2005 the revised *Dietary Guidelines for Americans*, a report whose findings will affect, among other things, proposed changes to the Food Guide Pyramid. *See Federal Register*, March 10, 2004.

U.S. Department of Agriculture (USDA)

[3] USDA to Beef Up BSE Surveillance Efforts

USDA Secretary Ann Veneman announced this week that the agency will spend some \$70 million to enhance surveillance efforts for bovine spongiform encephalopathy (BSE). With an expected launch by June 1, 2004, the new program will allow the testing of 268,000 animals, which will include a sampling of "apparently normal, aged animals." *See USDA News Release*, March 15, 2004.

In a related development, USDA has reopened the comment period for its proposed rule amending regulations that would add Canada to a category of regions whose animals and animal products present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products. Comments on the proposal must be submitted by April 7, 2004. *See Federal Register*, March 8, 2004.

U.S. Congress

[4] House Easily Passes Obesity-Litigation Legislation

Voting 276-139, the U.S. House of Representatives last week approved a bill (H.R. 339) that would pro-



tect lawful manufacturers and sellers of food products from liability in new and pending obesity-related lawsuits. As passed, the bill adopts the definition of food at **21 U.S.C. § 321(f)** of the federal Food, Drug, and Cosmetic Act, which states that the "term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."

The legislation's outlook in the Senate this election year is uncertain. Senator Mitch McConnell (R-Ky.) introduced the Senate's companion bill (S. 1428) during July 2003, and it is now pending in the Senate Judiciary Committee. Similar legislation became law in Louisiana last year and is now pending in at least 22 state legislatures.

[5] Senate Passes Food Allergen and Animal Drug Legislation

Last week the Senate passed twofold legislation (S. 741) combining the Food Allergen Labeling and Consumer Protection Act of 2003 and the Minor Use and Minor Species Animal Health Act of 2003. With respect to food, the bill establishes labeling requirements for allergenic substances in various products. "Major food allergens" under the Act include milk, eggs, certain fish, Crustacea, tree nuts, wheat, peanuts, and soybeans. Other provisions require the secretary of the Department of Health and Human Services to (i) produce a report detailing the unintentional contamination of various food products with major food allergens and (ii) conduct inspections of food manufacturing facilities to ensure compliance with labeling rules. Similar legislation (H.R. 3684) introduced by Representative Nita Lowey (D-N.Y.) is pending in the House. See News Release from Office of Senator Judd Gregg, March 9, 2004.

United Kingdom

[6] British Government Issues Alcohol Harm Reduction Strategy for England

On Monday, the Prime Minister's Strategy Unit issued a public policy report calling for specific measures to address the incidence of alcohol misuse, the various consequences of which are estimated to cost Britain some £20 million annually through medical costs, lost productivity in the workplace and crime. Among other things, the report addresses implementing educational campaigns to change attitudes toward irresponsible drinking and instigating measures to improve early identification and treatment of alcohol-related problems. With respect to the alcohol industry, the report urges manufacturers not to develop products that might appeal to underage drinkers and ensure that advertising does not promote irresponsible or excessive consumption. See Strategy Unit News Release, March 15, 2004.

[7] FSA to Take Action Regarding Children's Diets

After lengthy evidence gathering and public consultation, Britain's Food Standards Agency (FSA) has reportedly adopted specific proposals to address the nation's incidence of childhood obesity. "Children are bombarded with messages that promote food high in fat, salt and sugar," FSA Chair Sir John Krebs was quoted as saying. "The evidence shows that these messages do influence children. Eating too much of these foods is storing up health problems for their future," he said. The agency's action plan includes (i) working with industry to reduce levels of fat, sugar and salt in processed foods marketed to kids and revising labeling rules to reflect same, (ii) encouraging schools to offer healthier foods and (iii) having the Advertising Standards Authority review current regulations pertaining to



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food advertising to children. *See FSA Press Release*, March 11, 2004.

[8] California EPA Circulates "Final Work Plan" on Acrylamide

Cal/EPA will (i) consider revising its no-significant-risk level for acrylamide exposure and (ii) begin developing "a regulation on the form and content of warnings for acrylamide in food where a warning is required, according to a <u>work plan</u> that the agency's Office of Environmental Health Hazard Assessment (OEHHA) circulated March 12, 2004. Designated as a "Final Work Plan," it replaces a draft plan the agency submitted for public comment last summer. *See* issue 42 of this Update, August 6, 2003.

Acrylamide forms as a byproduct of high-temperature cooking processes in many high-carbohydrate foods and is reported to cause cancer in laboratory animals. Acrylamide has been listed as a carcinogen since 1990 under California's toxic-warnings regime, known as Proposition 65. The current no-significant-risk level for acrylamide – 0.2 micrograms per day – remains in effect while OEHHA implements its plan. Plaintiffs' counsel and advocacy groups contend that acrylamide levels in fries and other fast food fare exceed 0.2 micrograms.

OEHHA estimates that it will complete its work on the no-significant-risk level by spring 2005. A proposed warning for acrylamide in food might be released as early as summer 2004, with completion of the ensuing regulatory process in summer 2005.

Litigation

Negligence

[9] Southwest Missouri Jury Awards \$20 Million in Case Involving Worker's Exposure to Microwave Popcorn Flavoring

A jury in Jasper County, Missouri, has awarded \$18 million in compensatory damages to a former popcorn plant worker who claimed exposure to the butter flavoring used to manufacture microwave popcorn resulted in the development of his irreversible lung disease (bronchiolitis obliterans). Defendants, the New York-based International Flavors & Fragrance and its subsidiary Bush Boake Allen Inc., were also ordered to pay plaintiff Eric People's wife \$2 million for loss of consortium. Peoples, 32, alleged the companies knew that the butter flavoring was hazardous and failed to warn the Jasper plant employees about the dangers associated with the product or provide adequate safety instructions.

The lawsuit is reportedly the first of 30 such cases filed against the flavoring manufacturers by former workers at the Gilster-Mary Lee plant in Jasper. The National Institute of Occupational Safety and Health has purportedly linked bronchiolitis obliterans to vapors emitted by diacetyl, a chemical constituent of the butter flavoring. An attorney for defendant Bush Boake Allen was quoted as saying, however, that "The science continues to evolve. It has never been determined conclusively that diacetyl is the agent to blame. More studies are needed." *See St. Louis Today.com*, March 15, 2004; *The Joplin Globe* and *Associated Press*, March 16, 2004.



Advertising

[10] EU Judge Opines That French Alcohol Ad Ban Is Justified on Health Grounds

According to a European Court of Justice (ECJ) advocate general, a French ban on television advertising of alcoholic beverages during sporting events "breaches EU internal market laws but can be justified on health grounds." The European Commission (EC) apparently challenged the France's 'Loi Evin' legislation in 2001, claiming the law "contravened free market principles behind the EU's single market." Similarly, spirits manufacturer Bacardi challenged article 8 of the French 'Code de debits de boissons' from 1991, "which bans direct or indirect televised advertising of alcohol at sporting occasions aimed at French viewers." Both the EC and Bacardi have asked the EU courts to rule that the 'Loi Evin' infringes EU law by restricting the free movement of services. The advocate general's opinion is non-legally binding, however, it is evidently a strong indicator as to how the full ECJ will eventually decide the matter. See EU Politixplus.com and justdrinks.com, March 12, 2004.

Media Coverage

[11] Jacob Sullum, "Fast Food Damnation: Why Worry About Stupid Lawsuits?," *Reason Online*, March 5, 2004

A *Reason* columnist suggests that "the strongest rationale" for passage of obesity-litigation legislation is to ensure the master settlement agreement between state attorneys general and tobacco companies doesn't become a template for food companies. "The agreement that settled the state tobacco lawsuits in effect imposed a nationwide tax and nationwide regulations, including advertising restrictions that would have been unconstitutional if imposed by statute, without approval from Congress or any state legislature," Sullum writes. "A similar arrangement with food companies ... likewise would usurp the authority of state and federal legislators."

Sullum also describes what he calls a contradiction in statements by activist John Banzhaf concerning the scope of obesity litigation to date. Though Banhaf once bragged that food companies are running scared from obesity litigation, he now says that obesity-litigation legislation "is surely premature, because there has been only one obesity lawsuit, and it was dismissed by a federal judge," Sullum reports.

Scientific/Technical Items

Alcoholic Beverages

[12] Prenatal Alcohol Exposure Purportedly Linked to Peripheral Nerve Conduction Abnormalities in Children

A recent study in the Journal of Pediatrics examined the potential effects of prenatal alcohol exposure on the peripheral nervous system of infants and children. (M. Avaria, et al., "Peripheral Nerve Conduction Abnormalities in Children Exposed to Alcohol In Utero," J Pediatr 144: 338-343, 2004). The study compared the electrical properties in peripheral nerves in infants and children of heavy-drinking mothers with infants and children of nondrinkers. The results showed that alcohol-exposed children exhibited significant reductions in both peripheral nerve-conduction velocities and amplitude - effects that were discernible in infants and persistent in newborns at age 1. Women who reportedly stopped drinking in the second or third trimesters did not have significantly better outcomes regarding nerve conduction than those who drank throughout their pregnancy.





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 mcowing@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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