

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Food Advisory Committee to Convene in December

The FDA committee responsible for advising the agency on regulatory issues related to food has scheduled a public [meeting](#) for December 10-11, 2003, in Washington, D.C. A *Federal Register* notice indicates that the Food Advisory Committee will address recommendations on methyl mercury in fish and shellfish as well as review reports of the Dietary Supplements, Additives and Ingredients, Food Biotechnology, Contaminants and Natural Toxicants, and Infant Formula subcommittees. Written submissions regarding issues pending before the committee must be received by November 26. See *Federal Register*, November 18, 2003.

U.S. Congress

[2] House Legislation Would Create Biotechnology Taskforce

Representative Nick Smith (R-Mich.) recently introduced a bill ([H.R. 3472](#)) that would establish a federal interagency taskforce “to promote the benefits, safety, and potential uses of agricultural biotechnology to improve human and animal nutrition, increase crop productivity, and improve agricultural sustainability while ensuring the safety of food and

the environment.” The primary objective of the group would be implementing educational efforts to domestic and foreign stakeholders with regard to the safety and potential of biotechnology-derived agricultural products. The proposal has been referred to the Committee on Agriculture.

Canada

[3] Canadian Agency Launches Investigation into Sports Supplements

In response to an unreleased internal report about the safety of energy bars, sports drinks and weight-loss preparations, the Canadian Food Inspection Agency is reportedly investigating industry practices by testing such products for label verification and compliance with government regulations. According to the report, “the presence in many of these products of non-permitted substances with pharmacological activity, excessive levels of vitamins and minerals and undeclared food allergens put the health of Canadians at risk.” A news source indicates that the agency is also concerned with many of the products’ unsubstantiated claims of health and performance benefits. An agency spokesperson was quoted as saying the investigation would likely take a year to complete. See *The Globe and Mail*, November 17, 2003.



Great Britain

[4] **Government Vows Action Absent Industry Progress on Sodium Content of Processed Foods**

Public Health Minister Melanie Johnson has issued a warning to the food industry promising government-mandated labeling of high-salt foods if manufacturers fail to reduce the levels of sodium in such products by February 2004. "If we don't see progress, then action on food labeling could be the answer," she said. "I want to see openness and honesty and healthier options, which in turn will open people's eyes to the risks of a high-salt diet." *See 10 Downing Street Press Release, November 10, 2003.*

European Union (EU)

[5] **Proposed Regulation Would Harmonize Divergent Rules Pertaining to Addition of Various Substances to Food**

Citing a desire to ensure consumer protection and facilitate circulation of products among member states, the European Commission has proposed a [new regulation](#) that would harmonize rules concerning food manufacturers' voluntary fortification of foods with vitamins, minerals and other certain other substances, e.g., herbal extracts. The proposal mandates (i) establishment of a list of approved substances that can be added to food, (ii) criteria for minimum and maximum levels of such substances and (iii) clear labeling requirements to allow consumers to evaluate products' nutritional quality.

Litigation

Artificial Growth Hormones

[6] **Lawsuit over Dairy Product Labeling Headed for Trial in January 2004**

January 5, 2004, appears to be the date currently set for trial of a lawsuit in which Monsanto Co. accuses a Maine dairy of using product labels and advertising that disparage the use of artificial growth hormones in dairy cows. The trial's location will be the federal district court in Boston. Defendant Oakhurst Dairy Inc. tried to move the case to its home state of Maine, but the judge handling the case denied the request. *See Portland Press Herald, November 18, 2003.*

Oakhurst's milk cartons include the statement "Our Farmer's Pledge: No Artificial Growth Hormones." Monsanto, which manufactures the growth hormone Posilac, claims that the "Farmer's Pledge" slogan conveys the message that milk from cows not treated with artificial growth hormones is safer or of higher quality than milk from treated cows. Such a message is misleading, deceptive and unsupported by scientific evidence, Monsanto alleges. Oakhurst claims that its labels simply state a basic fact that their customers say is important to them.

Legal Literature

[7] **Louis Bechtle, "Obesity and Related Health Claims: An Emerging Trend in Food Industry Litigation?" *Andrews Class Action Litigation Reporter, November 2003***

The current issue of a class-action periodical features a Q&A with a former federal judge who foresees challenges for plaintiffs who blame the food industry for obesity and related diseases.



Plaintiffs' primary hurdle is causation, according to Bechtle. "This element is extremely difficult to prove because of the variety of causes over varying time segments that can lead genetically diverse plaintiffs to become overweight and develop related health problems. As a result, plaintiffs may be more successful in enjoining defendants from engaging in certain practices, such as deceptive advertising and production practices, rather than in recovering dollar damages." As for the prospect of obtaining class certification in obesity cases, Bechtle says the task would be "arduous," with plaintiffs' most significant challenges centering on the requirements of commonality, predominance and typicality.

Plaintiffs' best chance for success may be to argue that a food constituent presents "dangers unknown to the public, undermining the consumer's ability to make safe dietary choices," Bechtle says. "As nutritional research continues and new legal strategies emerge, we can expect many developments in food industry litigation. The prospect of liability could increase, for example, if it is ever proven that a fast-food company intentionally prepared its foods to make them addictive."

Bechtle, former chief judge emeritus of the Eastern District of Pennsylvania, spent seven years on the Judicial Panel on Multidistrict Litigation. He now practices with a Philadelphia law firm that typically represents defendants in complex civil litigation.

Other Developments

[8] Coca-Cola Issues Voluntary Guidelines for Sales to Schoolchildren

Carbonated drinks should be available only in vending machines in middle schools and high schools, and should not be sold at all in elementary schools during the school day, according to

[voluntary guidelines](#) that Coca-Cola Co. issued November 17, 2003. The company further recommends that school districts (i) place timers on vending machines to constrain hours of operation and (ii) offer juices, waters and other non-carbonated drinks wherever soft drinks are sold. Similar guidelines are already in place in some districts.

A Coca-Cola press release says the guidelines "are designed to help school decision-makers respond to concerns about commercialism and nutrition while maintaining their ability to raise critical resources for their schools." News articles report that national education groups have endorsed the guidelines, while some advocacy groups and local school officials have criticized them. "This is a good start from Coke but the ultimate goal would be to get rid of carbonated beverages and provide more nutritious products," one school board member was quoted as saying. *See Associated Press*, November 14, 2003; *The Wall Street Journal* and *Coca-Cola Press Release*, November 17, 2003.

[9] Australia Estimates Lives Both Lost and Prolonged by Alcohol Use

A [new report](#) by Australia's National Drug Research Institute describes patterns of alcohol use and contrasts the number of deaths attributed to alcohol misuse with the lives prolonged "due to the assumed protective effects of alcohol against cardiovascular disease." Titled *Australian Alcohol Indicators, 1990-2001*, the report was issued November 17, 2003, by the health ministry.

"While per capita alcohol consumption has been relatively stable since 1993, there have been recent fluctuations in drinking patterns among younger Australians with teenage girls aged 14 to 17 greatly increasing their consumption and men aged 18 to 24 decreasing their consumption," the report states.



The report estimates that 31,113 Australians died “from risky and high risk alcohol use” in the decade ending 2001, and that 75 percent of those deaths were among men. “The leading causes of death,” according to the report, “were alcoholic liver cirrhosis (6,825), road crash injury (5,489), cancer (2,874), and suicide (2,495). More people died from the acute (16,756) than long term or chronic effects of alcohol (14,377), reflecting the more common pattern of drinking to intoxication.”

On the other end of the spectrum, the report estimates that “low risk alcohol use ... prevented at least 6,000 premature deaths per year during this period, mostly among elderly Australians.” The authors suggest that “many more deaths would have been prevented if all Australians drank within the [health ministry’s] guidelines for low risk drinking.”

Scientific/Technical Items

Obesity

[10] **Obesity and HRT Linked to Increase in Size of Breast Tumors**

A new analysis prepared by the American Cancer Society has revealed a small but significant increase in the number of unusually large tumors in women newly diagnosed with breast cancer during the 1990s. A. Ghafoor, et al., “Trends in Breast Cancer by Race and Ethnicity,” *CA: A Cancer Journal for Clinicians* 53: 342-355, 2003. Using national surveillance data, researchers were able to show the incidence of tumors larger than 5 centimeters increased by slightly more than 2 percent annually between 1992 and 2000 among white women (similar results were not found among other racial and ethnic groups). While the researchers made no effort to link increases in tumor size to any particular risk factor when conducting their study, they speculate that both obesity and hormone replacement therapy after menopause might be partially responsible. Both affect the production of estrogen, increased levels of which can fuel tumor growth. Tumor size is of particular concern because it is an indicator of cancer stage. Larger tumors are generally more advanced and more likely to have metastasized.



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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 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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