Food & Beverage

LITIGATION UPDATE

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Table of Contents

Legislation, Regulations and Standards

[1] CSPI Urges FDA to Limit Acrylamide in Food....1
[2] Reporting Requirements Under Bioterrorism Act to Be Streamlined....1
[3] Obesity Emerging as Top Health Threat in the United States....1
[4] Agency Publishes Interim Final Rule to Control *Listeria Monocytogenes* in Ready-to-Eat Meat and Poultry Products....2
[5] New Biotechnology Committee to Hold First Meeting....2
[6] New Legislation Seeks Improvements in Meat and Poultry....2
Product Safety....2
[7] Scotland's Chief Medical Officer Calls for Soft Drink Ban in Schools....2

Other Developments

[8] CSPI Targets Misleading Food Labeling Claims; Concerns Raised About Baby Formula Marketing....3

Scientific/Technical Items

[9] Periodontal Disease Linked to Obesity....3
[10] Antioxidants May Reduce Certain Effects of Alcoholism....4
[11] FAO/WHO Call for Data on Acrylamide....4

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Legislation, Regulations and Standards

U.S. Food and Drug Administration

[1] CSPI Urges FDA to Limit Acrylamide in Food

In a formal **petition** submitted June 4, 2003, an advocacy group asks FDA to require food manufacturers to limit acrylamide in their products. The petitioner, the Center for Science in the Public Interest (CSPI), alleges that current acrylamide levels "could lead to both thousands of human cancers each year and somewhat less-quantifiable risk of neurologic illnesses."

For most foods, the limits requested by CSPI would be set by food class (e.g., potato chips, fries, coffee) and would equal the median acrylamide level now found in the foods in that class. For "infant formulas and other foods intended for babies," however, "FDA should set particularly protective limits," CSPI recommends.

CSPI's petition calls for a much more aggressive approach than FDA's **Draft Action Plan for Acrylamide in Food**, first circulated in September 2002 and updated in February 2003. The plan states that FDA intends to develop methods for acrylamide analysis, research mechanisms of acrylamide, assess the current dietary exposure of U.S. consumers to acrylamide, gather information about the toxicology of acrylamide, assess the potential risk of acrylamide exposure, and evaluate options for reducing potential risk.

Acrylamide became a public health issue in 2002 when Swedish researchers reported that the substance forms when certain foods are fried, baked or roasted at high temperatures. Recent articles disagree on acrylamide's health effects.

[2] Reporting Requirements Under Bioterrorism Act to Be Streamlined

FDA and the Bureau of Customs and Border Protection (CBP) have announced that the prior-notice requirements established under the Bioterrorism Act for food importers will be implemented in a manner that will allow importers to notify both agencies using an integrated process. Apparently, importers will be able to fulfill FDA requirements with CBP's Automated Commercial System, which importers currently use to meet Customs requirements. FDA is reviewing comments submitted on its notice rule and expects to publish a final rule in early October 2003; the Bioterrorism Act requires prior notice for imported food shipments beginning December 12. Further details about FDA's proposed rule appear in issue 16 of this Update, February 5, 2003. *See FDA News*, May 27, 2003.

Centers for Disease Control and Prevention

[3] Obesity Emerging as Top Health Threat in the United States

CDC Director Julie Gerberding, M.D., was quoted during a June 4, 2003, address in California as saying that obesity and the general lack of physical activity in America must become a priority for the nation's health care system. "We just recalculated the actual

causes of death in the U.S., and we did see that obesity moved up very close to tobacco and is almost the number one health threat," she said.

Meanwhile, CDC is hosting a conference titled **"The Public's Health and the Law in the 21st Century"** on June 16-18 in Atlanta, Georgia. The event will include a session targeting school-based policies on nutrition and physical activity as well as the official launch of the Public Health Law Association.

U.S. Department of Agriculture (USDA)

[4] Agency Publishes Interim Final Rule to Control *Listeria Monocytogenes* in Ready-to-Eat Meat and Poultry Products

USDA's Food Safety and Inspection Service (FSIS) has announced an interim final rule that will strengthen controls for *Listeria monocytogenes* in establishments that produce certain ready-to-eat (RTE) meat and poultry products. The rule, developed after notice-and-comment procedures undertaken since February 2001, amends 9 C.F.R. Part 430 by adding definitions and introducing revised testing protocols and recommendations for control measures. RTE producers will be required to develop written programs to control *Listeria* and to verify their effectiveness through testing. Testing data must be shared with FSIS, and all establishments are encouraged to employ additional and more effective control measures by subjecting those adopting the most effective controls, i.e., employing both a post-lethality treatment and a growth inhibitor for *Listeria* on RTE products, to fewer inspections. The rule will be effective 120 days after its June 6, 2003, publication, and FSIS will accept comments for 18 months to review and evaluate the effectiveness of these approaches. *See Federal Register*, June 6, 2003.

[5] New Biotechnology Committee to Hold First Meeting

The newly formed Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) will hold its first **public meeting** on June 16-17, 2003, in Washington, D.C. Charged with evaluating the long-term impacts of biotechnology on the U.S. food and agriculture system, the 18-member committee is composed of members representing such groups as the biotechnology industry, food manufacturers, farmers, and environmental organizations. *See Federal Register*, June 2, 2003.

U.S. Congress

[6] New Legislation Seeks Improvements in Meat and Poultry Product Safety

A bill introduced by Senator Charles Schumer (D-N.Y.) on June 5, 2003, would amend the federal Meat Inspection Act and the Poultry Products Inspection Act to improve the safety of meat and poultry products. Provisions of the **Meat and Poultry Products Traceability and Safety Act of 2003** would require the secretary of the Department of Agriculture to establish a traceability system for all stages of production, processing and distribution of meat and poultry products. The bill has been referred to the Committee on Agriculture, Nutrition and Forestry.

United Kingdom

[7] Scotland's Chief Medical Officer Calls for Soft Drink Ban in Schools

Soft drinks should be banned from schools because they "contribute to dental decay" and contain "hidden calories," according to Scotland's chief medical officer, Dr. Mac Armstrong. Armstrong made the recommendation in an **annual report** released June

5, 2003. The report asserts that nearly two-thirds of Scottish children ages 11 through 15 drink soda every day, while only half eat cooked vegetables daily.

The report also discusses "an increase in the number of children who are overweight. The proportion of Scottish 9- to 11-year-old boys who are overweight rose from 5.4 percent in 1984 to 12.7 percent in 1994 and of girls from 9.9 percent to 16.7 percent and the upward trend is continuing."

The British Soft Drinks Association stated that the ban Armstrong has proposed is unnecessary. "The soft drinks industry provides a very wide range of different products suitable for all ages and tastes, including fruit juices, bottled waters, and low sugar drinks," a spokesperson was quoted as saying. "Manufacturers and vending machine operators work in partnership with schools to provide the choice of drinks each school decides is best." *See just-drinks.com*, June 6, 2003.

Other Developments

[8] CSPI Targets Misleading Food Labeling Claims; Concerns Raised About Baby Formula Marketing

In its June 2003 newsletter, the Center for Science in the Public Interest (CSPI) focuses on the purportedly unsupported and misleading claims that appear on food and supplement packages without any government oversight. According to CSPI, current Food and Drug Administration (FDA) regulations give food manufacturers "carte blanche to claim that a food or supplement can affect the structure or function of the body, as long as they don't claim the food prevents or treats a specific disease." CSPI criticizes as scientifically suspect claims for fruit juices and cereal that link their ingredients to energy, healthy eyes, weight loss, and urinary-tract health. The organization also contends that the distinction between "structure/function" claims (which do not require FDA review and approval) and disease claims "can be comically minor." For example, "improves sexual performance" is considered to be a structure/function claim, while "helps restore sexual potency" is a disease claim requiring FDA approval.

Meanwhile, baby-formula manufacturers are reportedly adding fatty acids to their products and marketing them as a means to improve IQ and eyesight in infants. Critics are apparently concerned that aggressive product promotions will cost parents more for products that may not deliver such benefits. While the FDA apparently permitted manufacturers to add fatty acids following a five-year review, the agency found that studies on their purported health benefits had "mixed" results, and the American Academy of Pediatrics has not endorsed the claims because of alleged "unknown adverse effects." A major independent study on the issue is expected to be released in September 2003. *See CSPI Newsroom*, May 30, 2003; *The New York Times*, June 1, 2003.

Scientific/Technical Items

Obesity

[9] Periodontal Disease Linked to Obesity

New study results add gum disease to the growing number of chronic health conditions associated with obesity. S. Mohammad, et al., "Obesity and Periodontal Disease in Young, Middle-Aged, and Older Adults," *Journal of Periodontology* 74(5): 610-615, 2003. To evaluate the relationship between body weight and periodontal disease, Case Western Reserve University researchers analyzed national survey data on more than 13,000 adults, comparing gum disease rates by body weight, waist

circumference and age. In the youngest population studied, those ages 18 to 34, overall and abdominal obesity were associated with an increased prevalence of periodontal disease. Obese young adults were at an almost two-fold increased risk. This increased risk did not, however, extend into older adults. While the researchers explain that it is too early to know why this risk was only seen in young adults, they caution that obesity should not be discounted as a potential risk factor for gum disease, particularly because gum disease is known to exacerbate other chronic conditions (i.e., diabetes).

Alcoholic Beverages

[10] Antioxidants May Reduce Certain Effects of Alcoholism

Newly published research by Cornell University scientists contends that antioxidant intake may avert alcohol damage to the brain. D.G. Herrera, et al., "Selective Impairment of Hippocampal Neurogenesis by Chronic Alcoholism: Protective Effects of an Antioxidant," *Proceedings of the National Academy of Sciences* published online before print June 5, 2003. Using a rat model, Daniel Herrera and colleagues discovered that while alcoholism damages part of the brain used in memory and learning, antioxidant supplements prevent such damage. The researchers fed two groups of rats either a regular diet or one containing moderate doses of alcohol. A select number of rats in each group were also given ebselen, a synthetic antioxidant. After six weeks, those rats given moderate doses of alcohol had a more than 65 percent reduction in the number of new neurons and a nearly three-fold increase in cell death in the dentate gyrus, a region of the brain involved in memory and learning. Those rats receiving both alcohol and the ebselen supplement exhibited neither a reduction in new cells nor an increase in cell death. Indeed, they showed the same brain characteristics as those receiving no alcohol. Given these results, Herrera and colleagues suggest that alcohol abuse has the potential to kill newly formed brain cells and that oxidation is the likely mechanism by which it happens.

Acrylamide

[11] FAO/WHO Call for Data on Acrylamide

The Food & Agriculture Organization/World Health Organization Acrylamide in Food Network is soliciting representative data on levels of acrylamide in food and the total diet "which is both reliable and comparable at the international level." All data submitted will be provided to the Joint FAO/WHO Expert Committee on Food Additives for use in its safety evaluation of acrylamide in food. More information is available at **http://www.acrylamide-food.org/call_for_data.htm**.

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LITIGATION UPDATE

Food & Beverage Litigation Update is distributed by Dale Walker 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 dwalker@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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