Food & Beverage

LITIGATION UPDATE

Issue 105 • December 1, 2004

Table of Contents

Legislat	cion, Regulations and Standards
[1]	CDC Admits to Overstating Number of Deaths Attributable to Obesity
[2]	Lawmakers Reject Attempt to Repeal Country-of- Origin Labeling
[3]	Missouri Senator Introduces National Food and Agricultural Science Act
[4]	FDA Survey Indicates Widespread Perchlorate Contamination of Lettuce and Milk
[5]	FDA Reopens Comment Period on Food Labeling Regulations
[6]	Canadian Lawmakers Call for Action to Reduce Trans Fats in Foods
[7]	German Law Would Impose Financial Liability for GM Crop Contamination
Litigati	on
[8] Scientif	Federal Court Rejects Lawsuit over Salt-Study Data3
[9]	Diabetics More Likely to Be Overweight or Obese, Says CDC



Food & Beverage

LITIGATION UPDATE

Legislation, Regulations and Standards

Department of Health and Human Services (HHS)

[1] CDC Admits to Overstating Number of Deaths Attributable to Obesity

The Centers for Disease Control and Prevention (CDC) has reportedly acknowledged mathematical flaws in its controversial spring 2004 study that blamed poor diet and physical inactivity for 400,000 preventable adult deaths in 2000. ("Actual Causes of Death in the United States, 2000," *The Journal of the American Medical Association* 291: 1238-1245, 2004). Using mortality data from 2000, the study also attributed some 435,000 preventable deaths to tobacco use and 85,000 preventable deaths to alcohol consumption.

Despite errors in the study, CDC Director Julie Gerberding was quoted as saying that obesity remains a leading cause of death. "This paper in and of itself is a very minor contributor to our knowledge of obesity," she said. Upon completion of an internal review of the study's statistical methodology, CDC is expected to submit a revised estimate of the number of deaths attributable to poor diet and physical inactivity to *JAMA* for publication. The Government

Accountability Office may also conduct its own review of the study's findings. *See The Wall Street Journal*, November 23, 2004; *The New York Times*, November 24, 2004.

U.S. Congress

[2] Lawmakers Reject Attempt to Repeal Country-of-Origin Labeling

Senate and House appropriators reportedly rejected an amendment that would have eliminated mandatory country-of-origin labeling (COOL) when recently finalizing the \$388.4 billion FY2005 omnibus spending bill. The consumer advocacy group Public Citizen called the lawmakers' decision "a big win for domestic farmers who benefit from COOL because it allows them to distinguish their products in the supermarket" and a "big win for consumers who have the right to know where their food comes from." The appropriations bill awaits final approval from President George Bush. *See The South Carolina Times and Democrat*, November 21, 2004; *Public Citizen.org*, November 23, 2004.

[3] Missouri Senator Introduces National Food and Agricultural Science Act

Senator Christopher Bond (R-Mo.) has introduced legislation (<u>S. 3009</u>) that would establish a Division of Food and Agricultural Science within the National Science Foundation (NSF) and fund various projects at agricultural research facilities.





Goals of the new NSF division would include (i) developing foods that improve health and combat obesity, (ii) increasing the competitiveness of U.S. agriculture in the world marketplace, and (iii) improving "food safety and food security by protecting plants and animals in the United States from insects, diseases, and the threat of bioterrorism." Oversight of the division would be provided by a director and a Standing Council of Advisors composed of 12 independent scientists and 12 stakeholders. The proposal has been forwarded to the Committee on Agriculture, Nutrition and Forestry.

Food and Drug Administration (FDA)

[4] FDA Survey Indicates Widespread Perchlorate Contamination of Lettuce and Milk

FDA has posted a new set of exploratory data on the incidence of perchlorate contamination in various foods that indicate 90 percent of 128 lettuce samples and 97 percent of 104 milk samples gathered from across the nation were contaminated by the rocket-fuel constituent. The agency speculates that the chemical contaminates food through the use of contaminated irrigation water, processing water and source waters for bottling. Findings of a National Academy of Sciences study expected in January 2005 will likely affect the establishment of standards for permissible levels of perchlorate contamination in food. Current federal standards for drinkingwater allow perchlorate contamination at levels no higher than 1 part per billion (ppb). FDA's new data found levels of the chemical as high as

11.9 ppb in lettuce and 5.76 ppb in pasteurized and raw milk samples obtained from retail outlets and a Maryland research facility. *See The Sacramento Bee* and *Greenwire*, November 30, 2004.

[5] FDA Reopens Comment Period on Food Labeling Regulations

FDA has **reopened** for 60 days the comment period on a 1995 proposed rule titled "Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims." More specifically, the agency seeks public comment on the "proposed amendments to permit unqualified health claims on certain foods that do not contain 10 percent or more of one of certain required nutrients, the proposed amendments to provide criteria that FDA would consider in determining whether to grant an exemption from disqualifying nutrient levels related to unqualified health claims of certain nutrients, and the proposed amendments to retain the word 'may' or 'might' in unqualified health claims." FDA also seeks information on the use of unlisted synonyms – i.e., terms not defined by regulation – and abbreviated health claims. Comments are due by January 18, 2005. See Federal Register, November 18, 2004.

Canada

[6] Canadian Lawmakers Call for Action to Reduce *Trans* Fats in Foods

By a vote of 193 to 73, Canada's House of Commons has approved a motion from the minority New Democratic Party that calls on the government to (i) establish a multi-stakeholder



task force charged with developing strategies to reduce *trans* fats in Canadian foods to the lowest levels possible and (ii) develop attendant regulations limiting the *trans* fat content of all food products sold in Canada. "Legislating *trans* fats out of food is safer for families than weak voluntary guidelines and confusing labels," New Democratic Party Leader Jack Layton was quoted as saying. "Families have a right to safe food, and industry should have an obligation to make it safer. When a drug is unsafe, it's not subject to a voluntary ban or a label, and there's no reason families' food should be treated differently," Layton said. *See New Democratic Party Press Release*, November 11, 2004; *Reuters*, November 23, 2004.

Trans fats are contained in partially hydrogenated oils and are commonly found in cookies, crackers and margarine. Their consumption has allegedly been linked to high cholesterol, heart disease and diabetes. In June 2003, the Danish government adopted restrictions that limit *trans* fats in domestic and foreign manufactured fats and oils to 2 percent.

Germany

[7] German Law Would Impose Financial Liability for GM Crop Contamination

The lower house of Germany's Parliament last Friday reportedly approved a proposal that would make producers of genetically modified crops liable for contamination of conventional crops. Among other things, the proposed law would establish a registry of GM crop locations and allow "a farmer who has sustained damage ... to decide which neighbor to claim compensation from." A spokesperson for a federation of north German

biotech companies was quoted as saying the measure "will have catastrophic consequences" and "set the use of biotechnology in agriculture back years." The Bundesrat, the upper house of Parliament, is expected to take action on the measure by the end of 2004. See New Scientist.com, November 26, 2004.

Litigation

Information Quality Act

[8] Federal Court Rejects Lawsuit over Salt-Study Data

A federal judge in Virginia has rejected an effort to compel the federal government to release data from a study of blood pressure and dietary salt. *Salt Institute v. Thompson*, No. 04-359 (E.D. Va.) (dismissed November 15, 2004). In 2002, the government used the study to back up its recommendation that consumers restrict sodium intake by limiting salt consumption.

The lawsuit stemmed from the government's denial of a petition filed under the Information Quality Act by the same two industry groups that filed the lawsuit, Salt Institute and the U.S. Chamber of Commerce. Plaintiffs claimed that the National Heart Lung and Blood Institute "wrongfully withheld important and readily available scientific information from the public and interested researchers, inappropriately used incomplete and potentially unsound scientific data, and disseminated inaccurate influential health risk information in violation of controlling legal standards and good scientific practice."





U.S. District Judge Gerald Bruce said he did not have jurisdiction to consider the merits of plaintiffs' complaint. "An agency's decision to deny a party's information quality complaint is not reviewable by this court," he held. "There is nothing in the [Information Quality Act] that provides a right of action in a court of law for alleged violations of its provisions.....[T]he language of the [Act] reflects Congress' intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts." Judge Lee also ruled that plaintiffs lacked standing to sue.

The Information Quality Act, enacted in December 2000, requires federal agencies and the White House Office of Management and Budget to establish data quality guidelines that include a mechanism to request corrections to data that allegedly fail to meet the Act's requirements.

Scientific/Technical Items Obesity

[9] Diabetics More Likely to Be Overweight or Obese, Says CDC

A Centers for Disease Control and Prevention (CDC) <u>analysis</u> of two large databases on health and nutrition among American adults reports that most adults with diagnosed diabetes are overweight

or obese. ("Prevalence of Overweight and Obesity Among Adults with Diagnosed Diabetes – United States, 1988-1994 and 1999-2002," MMWR 53(45): 1066-1068, November 19, 2004). The analysis found that during 1999-2002, the prevlence of overweight or obesity among diagnosed diabetics was 85.2 percent, while the prevalence for obesity alone was 54.8 percent. Trends for overweight or obesity did not differ significantly among male and female diabetics, but diabetic women ages 20-64 had a significantly higher prevalence of obesity compared to women age 65 or older. According to the analysis, obesity in diabetics is associated with poorer control of blood glucose levels, blood pressure and cholesterol, which places individuals at a higher risk of developing cardiovascular disease.



Food & Beverage

LITIGATION UPDATE

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.



Geneva, Switzerland

Houston, Texas

Kansas City, Missouri

London, United Kingdom

Miami, Florida

Orange County, California

Overland Park, Kansas

San Francisco, California

Tampa, Florida

Washington, D.C.

