

Food & Beverage

LITIGATION UPDATE

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Table of Contents

Legislation, Regulations and Standards

- [1] Feral Pigs New Suspects in *E. Coli* Outbreak1
- [2] FDA Revises Guidance on Food Allergen Labeling1
- [3] Comments Sought for Codex Biotech Foods Meeting Agenda Items1
- [4] CDC Investigates Salmonella Outbreak in 18 States2
- [5] Exercise Guidelines Will Contribute to a “Culture of Wellness,” Say
Federal Officials2
- [6] *BMJ* Editorial Wonders if EC Alcohol Strategy Will Be Derailed2
- [7] NYC Chews over Proposal to List Calories on Fast Food Menus3

Other Developments

- [8] ACSH Issues *Trans* Fat Report, Claims Risks Are Exaggerated3
- [9] Alexandra Lewin, et al., “Food Industry Promises to Address Childhood
Obesity: Preliminary Evaluation,” *27 Journal of Public Health Policy* 327 (2006) .4
- [10] CSPI Claims New Study Supports Campaign to Reduce Salt in
Processed Foods4
- [11] IOTF Attributes Childhood Obesity to Historic Food Polices5
- [12] SpongeBob SquarePants and Dora the Explorer to Promote Fruits
and Vegetables5

Media Coverage

- [13] Energy Drinks Continue to Stir Controversy5
- [14] Michael Mason, “One for the Ages: A Prescription That May Extend Life,”
The New York Times, October 31, 20066

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LITIGATION UPDATE

Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] Feral Pigs New Suspects in *E. Coli* Outbreak

Health officials investigating *E. coli*-tainted spinach have reportedly identified the same strain of bacteria in wild pigs from the implicated area. Three weeks ago, FDA announced that a cattle ranch near Natural Selection Foods, LLC, where the outbreak allegedly originated, had tested positive for the *E. coli* strain, but could not specify how the cross-contamination occurred. A California Department of Health Services spokesperson apparently said the wild pigs are one “real clear vehicle,” although investigators continue to test water sources, soil and other wildlife for the deadly strain of *E. coli*. See *Associated Press*, October 26, 2006.

[2] FDA Revises Guidance on Food Allergen Labeling

The FDA has revised its “Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004.” The guidance apparently “represents the agency’s current thinking on issues related to FALCPA and food allergens generally.”

While the agency is accepting comments on the revisions, which are effective immediately, it “has determined that prior public participation is not feasible or appropriate.” See *Federal Register*, November 2, 2006.

Food Safety and Inspection Service (FSIS)

[3] Comments Sought for Codex Biotech Foods Meeting Agenda Items

FSIS has published a [notice](#) announcing a public meeting and soliciting comments on items that will be considered when the Codex Alimentarius Commission’s *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology meets in Japan in late November 2006. The USDA’s food safety undersecretary and FDA will sponsor the November 14 meeting in Washington, D.C., at which U.S. positions on Codex agenda items will be discussed. Among the agenda items are (i) a proposed draft guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals, (ii) a review of the work done by international organizations evaluating the safety and nutrition aspects of foods derived from biotechnology, and (iii) a discussion paper on sanitary surveillance after placing food derived from biotechnology on the market. See *Federal Register*, October 30, 2006.



U.S. Centers for Disease Control and Prevention (CDC)

[4] CDC Investigates Salmonella Outbreak in 18 States

CDC is investigating a salmonella outbreak believed to have sickened 172 people in 18 states. Health officials apparently told media outlets that *salmonella typhimurium*, a common strain of the disease, might have contaminated widely distributed produce, but stressed that the investigation is still in the early stages. No fatalities have been reported in connection with the outbreak. See *CDC Press Release, Forbes* and *The New York Times*, October 31, 2006.

U.S. Department of Health and Human Services (HHS)

[5] Exercise Guidelines Will Contribute to a “Culture of Wellness,” Say Federal Officials

HHS unveiled a [plan](#) last Thursday to develop physical activity guidelines as part of a larger effort to curb obesity-related disease. Slated for 2008, the Physical Activity Guidelines for Americans “will summarize the latest knowledge about activity and health, with depth and flexibility targeting specific population subgroups, such as seniors and children.” In discussing his intentions to meet with the food and beverage industry about the guidelines, HHS Secretary Mike Leavitt said he envisions a “culture of wellness,” which cannot be obtained through “regulations and penalties.” See *Associated Press*, October 26, 2006.

Meanwhile, the Institute of Medicine held the [Workshop on the Adequacy of Evidence for Physical Activity Guidelines](#) on October 23-24, 2006. Sponsored by HHS, the workshop asked participating scientists “whether there is a sufficient evidence base for HHS to proceed in a more systematic way to develop a comprehensive set of physical activity guidelines for Americans.” Speakers also addressed the evidence available for “population subgroups” such as pregnant women and persons with disabilities. The results of the workshop will be published in January 2007.

European Commission (EC)

[6] *BMJ* Editorial Wonders if EC Alcohol Strategy Will Be Derailed

According to an editorial appearing in the *British Medical Journal*, the EC is poised to adopt a modest alcohol strategy to address the “adverse health consequences of alcohol” that may be derailed by “a massive and highly effective” campaign by the alcohol industry. The strategy, not yet in the public domain, is expected to address (i) “protection of young people and unborn children,” (ii) “reduction of deaths from alcohol related traffic accidents,” (iii) “reduction of alcohol related harm among adults, especially as it affects their work,” (iv) “increasing awareness of the impact of harmful consumption,” and (v) “creation of a better evidence base for future policies on alcohol in Europe.”

While the strategy is also expected to “foresee[] several actions at the European level” such as the regulation of cross-border advertising, *BMJ* commentator Martin McKee notes that a report produced for a brewers trade organization by the



Weinberg Group argues “there is no need for Europe wide action.” The group, characterized by McKee as “an American company previously involved in the tobacco industry’s campaign to undermine evidence on the harmful effects of passive smoking,” apparently concludes in its report that “there is not enough evidence to substantiate a link between alcohol advertising and consumption.” See *British Medical Journal*, October 28, 2006.

State/Local Initiatives

[7] NYC Chews over Proposal to List Calories on Fast Food Menus

The New York City Board of Health is apparently considering whether fast food restaurants should be required to list calories on menus and menu boards. To be voted on this December, the [proposal](#) is the second half of a widely publicized health initiative that would also prohibit restaurants from serving foods containing trans fats. Under the new scheme, restaurants with “standardized” menus would be compelled to display calorie counts “in a size and typeface at least as large as the price or name of the menu item.” The rule would apply only to restaurants that have made nutritional information available to the public.

Industry representatives have reportedly said the measure punishes restaurants for providing health information to customers. Some chains specializing in customized orders, such as Starbucks, have also argued that calorie counts will be unreliable when one ingredient is substituted for another. In a written statement to the Board of Health, the president of the National Council for Chain Restaurants said, “Restaurants should be encouraged in their

health education efforts, not dissuaded from such effort by misplaced regulatory policies.” See *The New York Times*, October 30 and November 1, 2006.

Other Developments

[8] ACSH Issues *Trans* Fat Report, Claims Risks Are Exaggerated

The American Council on Science and Health (ACSH) has issued a [report](#) titled “*Trans* Fatty Acids and Heart Disease,” which contends that health risks from *trans* fats have been exaggerated.

The report details what is known about how *trans* fats affect blood cholesterol levels and how that translates into elevated risks for coronary “events.” Researchers have apparently estimated that up to 200,000 such events could be averted each year if *trans* fats were virtually eliminated from the American diet. The report’s author criticizes the epidemiological studies that have led to these alarming statistics as well as the media reports that have allegedly overblown their significance and the legislative and regulatory initiatives that have been launched in response to the scare.

According to the report, many food products cannot be reformulated to remove trans fats without turning to other, potentially more damaging substances to yield an acceptable product. Stating that trans fats “are not poison; they are simply one of several dietary factors that affect blood lipid levels, and blood lipid levels are only one of several major factors that influence the risk of heart disease,” the report recommends that emphasizing an array of diet and lifestyle goals that address all of the major risk factors for heart disease will be of greater benefit to public health.



In related developments, when KFC announced with some fanfare that it would be switching to *trans-fat-free* cooking oil, the Center for Science in the Public Interest (CSPI) reportedly withdrew from the class action filed against the fast food chain in June 2006. CSPI Executive Director Michael Jacobsen was quoted as saying that “Colonel Sanders deserves a bucket full of praise.” The lawsuit, however, has not been dismissed altogether as the trial lawyers who filed the putative class claims are continuing the action, according to a CSPI press release, which cautions that “if KFC breaks its promise, as McDonald’s did several years ago, CSPI says it will take Colonel Sanders back to court.”

Despite KFC’s pledge, New York City’s Board of Health is apparently moving forward with plans to ban the substance from city restaurants in December with an 18-month phase-in period; during a board hearing on October 30, 2006, dozens testified in favor of the ban. Recent news reports about the issue have detailed the issues food manufacturers and processors face when attempting to switch to alternatives that are less likely to cause heart disease. For example, biscuit shortening has been difficult to replace. Other fast food restaurants are reportedly still testing oil substitutes to cook their fries and chicken products. *See The Wall Street Journal* and *Advertising Age*, October 30, 2006; *The New York Times*, October 30 and 31, 2006.

[9] [Alexandra Lewin, et al., “Food Industry Promises to Address Childhood Obesity: Preliminary Evaluation,” 27 *Journal of Public Health Policy* 327 \(2006\)](#)

Marion Nestle has joined two other authors to explore whether food industry promises to address childhood obesity have resulted in effective action. Based on an analysis of recent initiatives undertaken

by McDonald’s Corp. and Kraft Foods, they contend “industry self-regulation does not adequately protect children from inappropriate marketing of unhealthful foods.” According to the article, while these companies have made minor ingredient and menu changes, their offerings continue to depart from healthy nutrition standards, and children remain exposed to product promotions tied to cartoon and movie characters, particularly through “advergaming” on the Internet. The authors note that ice cream sundaes, apple pies and double cheeseburgers cost less than a full salad at McDonald’s and that Kraft’s *Sensible Solutions*® products are only minimally more nutritious than comparable items. Claiming that food companies “cannot – and will not – stop making and marketing nutritionally questionable food products to children,” the article concludes by calling for “regulatory intervention.”

[10] CSPI Claims New Study Supports Campaign to Reduce Salt in Processed Foods

The Center for Science in the Public Interest (CSPI) has praised a new study on children’s salt consumption that allegedly “demonstrates that a modest reduction in salt intake causes immediate falls in blood pressure and, if continued, may well lessen the subsequent rise in blood pressure with age.” Feng J. He, et al, “Importance of Salt in Determining Blood Pressure in Children,” *Hypertension*, November 1, 2006. According to CSPI, processed foods and restaurants make it “virtually impossible” for children not to over-consume salt. Both CSPI and the American Medical Association have recently called on FDA to designate salt as a food additive. *See CSPI Press Release*, October 31, 2006.



[11] IOTF Attributes Childhood Obesity to Historic Food Policies

An International Obesity Task Force [report](#) claims that childhood obesity is partly caused by “historic food policies which have led to distorted food supplies and prices.”

Titled *Global strategies to prevent childhood obesity: Forming a societal plan that works*, the report presented at the McGill Integrative Health Challenge Think Tank last week also charges that “EU, US and Japanese distortions of the market through large-scale agriculture and trade subsidies contribute to ensure that less nutritious foods still pervade the world.” Advocating a societal solution, the report recommends, among other approaches, that governments (i) adopt WHO’s traffic light labeling scheme; (ii) ban marketing to children; (iii) stop subsidizing sugar and cheap fats in favor of fruit and vegetables; (iv) increase prices on fatty, sugary and salty foods; and (v) restrict access to fast food and soft drinks. See *Food Navigator USA.com*, October 27, 2006.

[12] SpongeBob SquarePants and Dora the Explorer to Promote Fruits and Vegetables

“Adding SpongeBob and Dora peaches, plums and nectarines to our successful assortment of Nickelodeon branded fruits and vegetables will make the produce aisle even more kid-friendly,” a spokesperson for Nickelodeon told the media last week. The licensed fruit will apparently appear next spring alongside kid-sized carrots, apples, pears, cherries and spinach, which Nickelodeon has already agreed to license under its brands. In 2005,

Nickelodeon’s health initiative, “Let’s Go Play,” joined The Alliance for a Healthier Generation to launch a media campaign aimed at preventing obesity.

Critics, however, have reportedly called SpongeBob produce nothing more than a “window dressing” on the marketing of junk food to children. “These companies are in the cross hairs of litigation and poor public relations,” said one consumer advocate. In January 2006, Nickelodeon’s parent company received a letter of intent to sue from the Center for Science in the Public Interest, which frequently targets companies that allegedly market to children. See *Food Navigator USA.com*, October 25, 2006; *USA Today*, July 18, 2006; and *Issue 156* of this Report.

Media Coverage

[13] Energy Drinks Continue to Stir Controversy

“It’s Starbucks for kids,” says blogger Dan Mayer in an article about the alleged dangers of energy drinks. “With the tons of caffeine that they put into these things, it gives you a little legal form of speed essentially.” *Associated Press* writer Carla Johnson covers the trend in an article titled “Caffeine-Stoked Energy Drinks Worry Docs,” which focuses on claims that allege “the drinks, laden with caffeine and sugar, can hook kids on an unhealthy jolt-and-crash cycle.” Doctors and nutritionists interviewed by Johnson said, in addition to a caffeine high, prolonged use may result in side-effects, such as heart palpitations, caused by the “megadoses” of vitamins found in many brands.



[14] Michael Mason, "One for the Ages: A Prescription That May Extend Life," *The New York Times*, October 31, 2006

"Many scientists regard the study of life extension, once just a reliable plotline in science fiction, as a national priority," writes *Times* reporter Michael Mason regarding claims that a calorie-restricted diet may increase human lifespan. Research undertaken at the Wisconsin National Primate Research Center reportedly showed that older rhesus monkeys who ate less were "the picture of monkey vitality," while others of the same age were becoming frail, wrinkled and diseased. Exploring the implications of this outcome, Mason states that "calorie-restricted diets have been shown in various animals to affect molecular pathways likely to be involved in the progression of Alzheimer's disease, diabetes, heart disease, Parkinson's disease and cancer."

Mason also quotes consumers who maintain that restricting calories has improved their overall health, though he later adds that federal scientists have linked "exceptional thinness" to an increased risk of death. Concluding that the scientific debate will not likely change American diets, he speculates that drugs "mimicking the effects of calorie restriction" might be the next anti-aging breakthrough.



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