Food & Beverage

LITIGATION UPDATE

Issue 53 • October 15, 2003

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Legislation, Regulations and Standards Food and Drug Administration (FDA)

[1] Interim Bioterrorism Rules Require Facility Registration and Import Notification

To secure the nation's food supply from deliberate contamination, the FDA has issued interim final regulations that will require domestic and foreign companies to register their facilities by December 12, 2003, and **provide notice** hours before imported goods reach U.S. ports of entry. The FDA's reporting process will be integrated with that of the U.S. Customs Service; thus, companies required to comply will be able to submit the majority of their notices to both agencies via the same electronic process. Industry officials are apparently supporting the rules, after their concerns with earlier drafts were addressed by more scaled-back provisions, although some are viewing potential implementation costs warily. See The Wall Street Journal and Star Tribune, October 10, 2003.

FDA has also released a food safety and food terrorism <u>risk assessment</u> which estimates that one in four Americans will develop a foodborne illness each year from inadvertent food contamination. While FDA apparently conducted more detailed, classified risk assessments as to the U.S. food supply's vulnerability to a terrorist act, this assessment only goes so far as to say that a search of al Qaeda caves and safe houses in Afghanistan after the September 11 attacks turned up many translated U.S. agricultural documents. "A significant part of the group's training manual," states the risk assessment, "is reportedly devoted to agricultural terrorism – specifically, the destruction of crops, livestock, and food processing operations." The document discusses incidents of unintentional and intentional food contamination in a number of countries that affected thousands of people at a high cost and concludes, "There is a high likelihood, over the course of a year, that a significant number of people will be affected by an act of food terrorism or by an incident of unintentional food contamination that results in serious foodborne illness."

In a related development, Margaret Glavin, a food safety policy expert, has been appointed FDA's new Assistant Commissioner for Counterterrorism. She most recently served as the U.S. Department of Agriculture's Acting Administrator of the Food Safety and Inspection Service. *See FDA News*, October 10, 2003.

U.S. Congress

[2] Victor Schwartz to Testify at Senate Subcommittee Hearing

Shook Hardy & Bacon partner <u>Victor Schwartz</u> is scheduled to testify before the Administrative Oversight and the Courts Subcommittee of the Senate Judiciary Committee in an October 16, 2003, hearing titled "Common Sense Consumption: Super-Sizing Versus Personal Responsibility." The hearing will focus on legislation <u>(S. 1428)</u> aimed at protecting lawful food and non-alcoholic beverage manufacturers and sellers from liability in new or continuing weight-related lawsuits. Schwartz opposes the



concept of "regulation through litigation" and will urge the committee to amend S. 1428 by adding a provision to prevent discovery abuses in regard to claims based only on foods that allegedly cause obesity. Similar legislation (H.R. 339) was introduced by Representative Ric Keller (R. Fla.) earlier in 2003.

[3] Connecticut Lawmaker to Introduce Nutritional Disclosure Legislation

Representative Rosa DeLauro is reportedly seeking co-sponsors for a bill that would require chain restaurants with 20 or more locations nationwide to provide information about the nutritional content of their foods and beverages. "People need to have [nutritional] information readily available to them when they are ordering, not buried in brochures or on Web sites," the Connecticut Democrat was quoted as saying. The Restaurant Information Act of 2003 would apparently resemble recent legislation in several states by requiring restaurants to post on menu boards or print in menus next to each item information about (i) calorie content, (ii) saturated and *trans*-fat content, (iii) carbohydrate content, and (iv) sodium content. The National Restaurant Association reportedly opposes DeLauro's proposal, citing the impracticality of standardized nutritional labels given the number of menu items customized for each patron. "If a restaurant put a little extra helping on a meal, and didn't disclose that on the menu, it would have misbranded the item, and trial lawyers would start swooping in to sue," Steve Anderson, president and CEO of the trade group said. See The Washington Times, October 10, 2003.

Codex Alimentarius Commission

[4] Meetings Scheduled for Public Input on Codex Activities

The U.S. Department of Agriculture (USDA) and the Food and Drug Administration will be sponsoring two meetings in preparation for a meeting of the Codex Committee on Food Import and Export Inspection and Certification Systems to be held in Brisbane, Australia, December 1-5, 2003. The first preparatory meeting will be held on October 22 to review and receive comments to develop draft U.S. positions. The second meeting, at which the draft U.S. positions will be reviewed, has been scheduled for November 12. *See Federal Register*, October 8, 2003.

Changes to Codex procedures will be addressed in Paris, France, November 17-21, during the 19th (Extraordinary) Session of the Codex Committee on General Principles. The USDA will conduct a public meeting to receive comments on the agenda on October 23. Further information about these meetings can be obtained at <u>www.fsis.usda.gov/OA/codex/</u> <u>new.htm</u>.

Great Britain

[5] British Agency Issues Obesity Report, Calls for Parental and Food Industry Action

Rising rates of childhood obesity in Britain should be addressed through family-based programs that address diet, exercise and lifestyle counseling, according to a new Health Development Agency (HDA) report titled *The Management of Obesity and Overweight: An Analysis of Diet, Physical Activity and Behavioral Approaches.* "The good news is that the evidence shows parents can successfully treat their child's obesity by actively changing the whole family's approach to diet and physical activity and



by avoiding couch potato lifestyles," HDA Chair Dame Yve Buckland said. "The myriad of childfocused food advertising is a real challenge, but parents can fight back – it's them at the checkout, not their children." The HDA report describes effective approaches to obesity and overweight management in both children and adults, citing annual National Health Service costs attendant to obesity of some £2.6 billion. Minister for Public Health Melanie Johnson was quoted as saying the report "once again highlights how crucial prevention is and how simple the message is that by helping people maintain a healthy diet and an active lifestyle, we can stop them from gaining weight in the first place.... We also want to see much more progress from industry to reduce added levels of salt, fat and sugar in processed foods." See BBC News and HDA News Release, October 10, 2003.

Legal Literature

[6] Charles Moellenberg, Jr., "Regulation by Litigation and the Limits of Government Power," Washington Legal Foundation Critical Legal Issues, Working Paper Series No. 119, October 2003

In this **working paper** prepared for the Washington Legal Foundation, attorney Charles Moellenberg criticizes the way in which state and local governments are attempting to stretch the limits on the scope of liability for public nuisance. Public-nuisance law has not historically been used to regulate product sales, and the well-established rules regarding products liability and negligence "do not lend themselves to wide-scale regulatory schemes or cost recoveries by government officials," according to Moellenberg. Nevertheless, governments have attempted to expand the scope of public-nuisance law to bring suits against manufacturers of cigarettes, guns and lead paint. Moellenberg warns that if these types of lawsuits are allowed, it is only a matter of time before other lawful, non-defective products are targeted – e.g., alcohol, high-fat foods and sports utility vehicles.

Other Developments

[7] Liverpool Brewery to Place Drinking Advice on Labels

A British brewery will reportedly begin placing cautionary messages on one of its products in November 2003. According to a news source, Cains Brewery's 2008 Celebration Ale will carry the message "Alcohol advice: Robert Cain supports responsible drinking. Excessive drinking can cause harm. Observe the daily guidelines for sensible drinking. Do not drink and drive." A picture illustrating how many units of alcohol the bottle contains will also appear on the labels. A company spokesperson was quoted as saying, "it's important that the whole industry takes positive action instead of just talking about the issue," i.e., "the heavy drinking culture which is causing health problems in the U.K." *See BBC News*, October 9, 2003.

Media Coverage

[8] Michael Pollan, "The (Agri)Cultural Contradictions of Obesity," *The New York Times,* October 12, 2003

According to this article, governmental policies that changed in the 1970s to support agricultural overproduction are as much to blame for the current "obesity epidemic" as fast-food super-sizing, foods laced with *trans* fats and sugars, and aggressive food marketing to children. The author discusses the waves of corn overproduction that resulted in a 19th century alcohol epidemic and today is argu-



ably responsible for "the most serious public-health problem facing the country." Some researchers are apparently predicting "that today's children will be the first generation of Americans whose life expectancy will actually be shorter than that of their parents. The culprit, they say, is the health problems associated with obesity."

The article points to agricultural policies developed during the Nixon administration to deal with soaring commodity prices that created "cheap corn," characterized as "the building block of the 'fast-food nation'" which is transformed into the high-fructose corn syrup in giant-sized soft drinks and inexpensive beef and chicken products. The article concludes by suggesting that the country will only be able to address its excess calorie problem by dealing with "the mountain of cheap grain that makes the Happy Meal and the Double Stuff Oreo such 'bargains.'"

[9] Kim Severson, "Make It a Super-Size, Then Call Your Lawyer," San Francisco Chronicle, October 12, 2003

"The people who cook your dinner," begins this article, "are starting to get nervous. Really nervous." Discussing recent legislative initiatives in California and Congress as well as lawsuits intended to regulate the food industry, this article focuses on the debate over who is responsible for expanding waistlines in the United States. Those, like John Banzhaf and Marion Nestle, who point the finger at the food industry, are quoted along with restaurateurs who claim that consumer choice drives the industry. And, as the article observes, many restaurant chains are responding to the controversy by offering healthoriented menu selections.

Scientific/Technical Items Obesity

[10] New Analysis Deems 4 Million American Adults Severely Obese

The number of severely obese American adults has quadrupled since the 1980s, according to new findings in the Archives of Internal Medicine. R. Sturm, "Increases in Clinically Severe Obesity in the United States, 1986-2000," Archives of Internal Medicine 163(18): 2146-2148, 2003. Using rates identified in this study, approximately 4 million adults can be classified as extremely obese, putting them at a disproportionately high risk of obesity-related health problems. To arrive at these estimates, Roland Sturm, an economist at the RAND Corp., examined data from the Centers for Disease Control and Prevention Behavioral Risk Factor Surveillance System from 1986 to 2000, calculating body mass index (BMI) and categorizing levels of obesity. He found that the number of extremely obese adults grew almost twice as fast as the number of those less severely obese during that time frame. More specifically, the number of individuals classified as severely obese (about 100 pounds overweight, with a BMI of 40) increased from 1 in 200 to 1 in 50, while the number of those most severely obese (about 150 pounds overweight), increased by five times, from 1 in 2000 to 1 in 400. By contrast, the number of those exhibiting moderate obesity, with a BMI between 30 and 40, merely doubled, from 1 in 10 to 1 in 5. The rapid increases in severe and most severe obesity challenge the long-held belief that the clinically obese are a fixed portion of the population and are not affected by changes in eating habits and patterns in physical activity. Sturm suggests that as the number of obese individuals shifts gradually higher, the extreme categories may actually grow the fastest.



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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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