Shook, Hardy & Bacon L.L.P.

ISSUE 389 | APRIL 8, 2011

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

National Menu and Vending Machine Labeling Laws Proposed

The Food and Drug Administration (FDA) has issued its proposed menu-labeling rule for chain restaurants and calorie-labeling rule for food in vending machines. According to Department of Health and Human Services Secretary Kathleen Sebelius, "These proposals will ensure that consumers have more information when they make their own food choices. Giving consumers clear nutritional information makes it easier for them to choose healthier options that can help fight obesity and make us all healthier." Comments on the proposals, which were mandated under the Affordable Care Act, must be submitted by June 6, 2011, for the menu-labeling rule and by July 5 for the vending machine rule.

Excluded from the menu-labeling rule are "[m]ovie theaters, airplanes, bowling alleys, and other establishments whose primary purpose is not to sell food," and FDA is requesting comments "on whether additional types of food establishments should or should not be covered by the new rule." The proposal would also not apply to restaurants that do not offer standardized menu items and are not part of a chain with 20 or more locations doing business under the same name. FDA has tentatively concluded that the requirements would not apply to the alcoholic beverages served in restaurants.

The nutrition information that would be required under the menu-labeling rule includes total calories; calories from fat; grams of total fat, saturated fat and *trans* fat; milligrams of cholesterol and sodium; and grams of total carbohydrates, sugars, dietary fiber, and protein. The restaurant or other food facility would have the option of choosing how to make the nutrition information available, including a counter card, sign, poster, handout, loose leaf binder, booklet, electronic device, or on a menu. Calories for self-serve foods, such as those in buffet lines, would also have to be disclosed. The proposal further establishes the methods for determining nutrient content and provides that failure to comply "will render food misbranded" under the Food, Drug, and Cosmetic Act. FDA also proposes that restaurant menus and

SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

menu boards include the statement, "A 2,000 calorie diet is used as the basis for general nutrition advice; however, individual calorie needs may vary."

The vending machine proposal would apply to vending machine operators who operate more than 20 vending machines that sell articles of food. It would not apply to machines that dispense food as part of a game, such as those allowing a variety of items, such as toys, coins or wrapped candies to be accessed by use of a large maneuverable claw arm. Also excluded are machines lacking a selection button and dispensing foods in bulk. FDA is "interested in comments demonstrating any unintended adverse effect resulting from the exclusion of vending machines without selection buttons from the calorie labeling requirements." Under the proposal, covered vending machine operators would be required to register with FDA every other year and would have to "provide a sign in close proximity to the article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article."

This calorie disclosure would not be required "[i]f the Nutrition Facts Panel of an article of food sold from a vending machine may be examined by a prospective purchaser before purchasing the article." The panel "must be in a size that permits the prospective purchasers to easily read the nutrition information while the food is in the vending machine." Vending machine operators may rely on the calorie information provided by the companies making the packaged foods they sell in their machines and will be given one year to comply once the rule goes into effect. *See FDA Press Release*, April 1, 2011.

Reactions to the proposal ranged from mixed praise on the part of the Center for Science in the Public Interest (CSPI) to skepticism by those questioning why movie theaters and alcoholic beverages served in restaurants are excluded. The president and chief executive of the National Restaurant Association reportedly indicated that the organization supports the menu-labeling proposal, so that "the same type of nutrition information [will be provided] to consumers in any part of the country." According to a news source, Representative Rosa DeLauro (D-Conn.), who authored the bill imposing the disclosure requirements, said that she would work to strengthen the rules so they apply to movie theaters and alcoholic beverages. Nutrition professor Marion Nestle was quoted as saying, "For people who are interested or curious, this will be staggering information. And they'll change their behavior. For others, it's not."

FDA estimates that one-third of all calories are consumed outside the home, and the U.S. Department of Agriculture (USDA) has determined that Americans spend 42 percent of their food budgets on meals and snacks outside the home. USDA has also found that Americans consume more calories, fat and cholesterol when they eat away from home. The debate over whether knowing how many calories are in the foods offered in many food facilities will affect consumer behavior reportedly continues. In those cities, counties

and states that have adopted menu-labeling laws, restaurant chains have apparently reformulated menu items or added lower-calorie choices. *See CSPI Press Release*, *The Washington Post,* and *The New York Times,* April 1, 2011; *The Wall Street Journal*, April 2, 2011; *Slate.com*, April 5, 2011.

FDA Launches Recall Search Engine

The Food and Drug Administration (FDA) has launched a new "consumer-friendly" **Web portal** detailing the latest recalls, market withdrawals and safety alerts for food and other products regulated by FDA. According to an April 4, 2011, press release, the new searchable database organizes all recall information since 2009 "by date, product brand name, product description, reason for the recall, and the recalling firm." It also provides a link to news releases about each recall, as well as a **photograph** of the products in question.

Designed with input from stakeholder groups such as the Center for Science in the Public Interest, Food Marketing Institute, Grocery Manufacturers Association, and Pew Health Group, the Web portal answers to Food Safety Modernization Act (FSMA) requirements that FDA implement "a consumer-friendly recall search engine within 90 days after the law went into effect." Under FSMA, the agency must also indicate whether it offered the opportunity for a voluntary recall or ordered a mandatory one, in which case FDA must also specify whether the event is ongoing or completed.

"The new search page not only provides consumers with an easy-to-read table of information on products they are searching for, it also represents the delivery of one of the first major actions called for under the Food Safety Modernization Act," said FDA Deputy Commissioner for Foods Mike Taylor, who has also asked users and stakeholders for their continuing input. "We encourage people to check out our new recalls search page for themselves, and use it whenever they have a question about a recall."

Agencies Seek Data on *Listeria* in Ready-to-Eat Foods

The Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) have **announced** that they are seeking comments and scientific data to update a risk assessment on the relationship between foodborne *Listeria* in selected ready-to-eat (RTE) foods and human health. According to the agencies, the effort is designed to evaluate reduction or prevention strategies of *Listeria* exposure to RTE foods, such as "the impact of changing refrigerated time and temperature storage prior to consumption."

The agencies specifically request comments or data on areas including (i) *Listeria* "contamination in different RTE foods sampled at retail or in the processing plant," (ii) *Listeria* "survival and growth dynamics in RTE foods," (iii) "the relationship between the dose of *Listeria monocytogenes* ingested with

food and the frequency of *Listeria*," (iv) "current food consumption practices in the United States" relating to RTE foods, and (v) storage times and temperatures that may affect *Listeria* growth during food transport and storage in consumers' homes. Comments are requested by July 6, 2011. *See Federal Register,* April 7, 2011.

FSIS to Hold Meat and Poultry Pending Test Results

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **proposed** a procedural change that would allow inspectors to keep meat and poultry products from commerce "until FSIS test results for harmful substances are received." FSIS currently recommends that processors and official import establishments hold sampled products pending test results, but has evidently concluded that this voluntary measure has allowed adulterated shipments to enter the market. "Therefore, FSIS is announcing its tentative determination not to apply the mark of inspection until negative results are available and received for any testing for adulterants," stated the agency, which will accept comments on the proposal for 90 days after publication in the *Federal Register.*

FSIS has argued that a mandatory "test and hold" requirement will "substantially reduce serious recalls for meat and poultry." Along with the agency's new and revised performance standards to reduce *Salmonella* and *Campylobacter* incidence in young chickens and turkeys, the new policy aims to comply with the directives of President Barack Obama's (D) Food Safety Working Group, which has asked federal agencies to prioritize foodborne illness prevention, strengthen surveillance and enforcement, and improve response and recovery in the event of recall. In addition, as Under Secretary Elisabeth Hagen noted, "testing and holding at U.S. points-of-entry… will strengthen safety efforts focused on imported food—offering an additional safeguard to American consumers." *See FSIS Press Release,* April 5, 2011.

The measure has already drawn public support from the American Meat Institute (AMI), which in 2008 submitted a petition for industry-wide "test and hold" rules reflecting "the voluntary practices of AMI's members." According to AMI President J. Patrick Boyle, "this policy will prevent needless recalls, further ensure food safety and maintain consumer confidence." *See AMI Press Release,* April 5, 2011.

Codex Meetings Slated to Discuss Food Labeling, Fresh Fruits and Vegetables

The Office of the Under Secretary for Food Safety, the U.S. Department of Agriculture and the Food and Drug Administration have **announced** an April 25, 2011, public meeting in College Park, Maryland, to provide information and receive public comments on draft U.S. positions to be discussed at the 39th session of the Codex Committee on Food Labeling (CCFL) on May 9-13

in Quebec City, Canada. CCFL is responsible for such things as "studying problems associated with the advertisement of food with particular reference to claims and misleading descriptions for drafting provisions on labeling applicable to all foods."

Agenda items include (i) "recommendations on the declaration of sodium (salt)"; (ii) "mandatory nutrition labeling"; (iii) "labeling of foods and food ingredients obtained through certain techniques of genetic modification/ genetic engineering"; and (iv) "modified standardized common names." *See Federal Register,* April 1, 2011.

In a related matter, a public meeting was held April 5 in Washington, D.C., to provide information and receive public comments on draft U.S. positions to be discussed at the 16th session of the Codex Committee on Fresh Fruits and Vegetables (**CCFFV**), meeting on May 2-6 in Mexico City, Mexico. CCFFV is responsible for "elaborating worldwide standards and codes of practice as may be appropriate for fresh fruits and vegetables."

Agenda items included (i) "possible extension of territorial application of the Codex Standard for Fresh Fungus Chanterelle"; (ii) draft standards for avocado, tree tomatoes, chili peppers, pomegranate; and (iii) "quality tolerances at import and export control points." *See Federal Register,* April 1, 2011.

European Parliament Fails to Block Infant Formula Health Claim

The European Parliament's Environment, Public Health and Food Safety Committee has reportedly failed to block approval for an infant formula manufacturer's claim that adding the fatty acid docosahexaenoic acid (DHA) to baby food "contributes to the normal visual development of infants up to 12 months of age." Although the application to include the health claim had already received favorable opinions from the European Food Safety Authority and European Commission, the committee MEPs last month **voted** against authorization, arguing "that there is no scientific consensus on the effect that DHA-fortified formula have on infants, that more research is needed on the possible effects, both beneficial and harmful, of DHA supplements, and that the health claim could be misleading." But this resolution did not gain enough support in the April 4-7, 2011, plenary session of Parliament, which ultimately approved the DHA health claim by a margin of eight votes.

Meanwhile, *The Telegraph* has reported public "anger" at the outcome, citing concerns raised by the World Health Organization (WHO), Royal College of Pediatrics and Child Health, and other health groups about synthetic DHA, as opposed to the version that naturally occurs in breast milk. According to the April 6 news article, WHO has found no solid evidence "to be able to say that adding DHA to infant formula will have important clinical benefits." The organization has also warned that "general promotion of these products may induce mothers to use infant formula in the first six months of life and/or stop continued breast feeding after this period."

EFSA Confirms Food Irradiation Safety

The European Food Safety Authority (EFSA) has **issued** an April 6, 2011, statement on food irradiation that summarizes the 2010 scientific opinions adopted by the Panel on Biological Hazards and the Panel on Food Contact Materials, Enzymes, Flavorings and Processing Aids, which together assessed the procedure's efficacy and safety. Using the latest available evidence, these panels have evidently concluded "that there are no microbiological risks for the consumer linked to the use of food irradiation," and "that most of the substances formed in food by irradiation are also formed during other types of food processing, with levels comparable to those arising, for instance, from the heat treatment of foods."

According to EFSA, "only a very limited quantity of food consumed in Europe is irradiated," a practice considered part of "an integrated food safety management program… that includes good agricultural, manufacturing and hygienic practices." Still, panel experts have recommended that "decisions on foods which can be irradiated and on the doses used should not be based only on predefined food categories, as is currently the case, but also on factors such as: the bacteria concerned, the level of bacterial reduction required, whether the food is fresh, frozen, dried, or on the food's fat or protein content." They have also warned that decisions about irradiation should also account for "the diversity of food products nowadays available to consumers such as ready-to-eat foods." *See EFSA News Story,* April 6, 2011.

French Food Agency to Broaden Aspartame Study

The French Agency for Food, Environmental and Occupational Health and Safety (ANSES) has reportedly reassessed the nutritional benefits and risks of intense sweeteners, confirming that two new studies "provide no sufficient scientific basis for a toxicological re-evaluation of aspartame." ANSES apparently dismissed the first study concerning the effects of aspartame on mice because of methodological deficiencies, while finding the second one insufficient to establish a cause and effect relationship between aspartame and preterm delivery.

The agency concluded, however, that it shares "the desire of the European Food Safety Authority to study the toxicological risks inherent in sweeteners." It thus noted that it intends to "broaden" its aspartame research, as well as initiate "a working group to assess the nutritional benefits and risks of intense sweeteners and the need to draw up recommendations for any vulnerable population groups—including pregnant women—identified in the course of its work." *See ANSES Press Release,* March 15, 2011.

Arizona Governor Proposes Medicaid Fee for Smokers, Obese

Arizona Governor Jan Brewer (R) has reportedly proposed levying a $50 annual fee on smokers, the chronically ill or obese who receive aid from the state's financially strapped Medicaid program. Effective October 1, 2011, if approved by the Arizona Legislature, the plan would apply to childless adults who "need to work with their primary care physician to develop a care plan."

According to news sources, the measure is part of a wider plan to help the state save $510 million. "If you want to smoke, go for it," a spokesperson for Arizona's Medicaid program was quoted as saying. "But understand you're going to have to contribute something for the cost of the care of your smoking."

State Senator Kyrsten Sinema (D-Phoenix) asserted that she would vote against the measure because it would unfairly penalize the obese. "If someone is obese because they're severely disabled or can't exercise, we shouldn't be punishing them," she said. "I mean, it's not their fault." *See CNNMoney, The Wall Street Journal,* April 1, 2011.

New York City to Consider Ban of Toy Giveaways in Restaurant Meals

New York City Council Member Leroy Comrie (D) has introduced a **bill** (Int. No. 530) that would ban toy giveaways in restaurant meals deemed high in calories, sodium and fat. Amending the city's administrative code "in relation to setting nutrition standards for distributing incentive items aimed at children," the bill mirrors a similar San Francisco measure set to go into effect in December 2011.

Comrie's proposal would require establishments that offer toys with meals to make sure the food contains less than 500 calories, 600 milligrams of sodium and 35 percent of calories from fat. A half cup of fruit or vegetables and one serving of a whole-grain product must be included in the meal. Violators would be subject to fines ranging from $200 to $2,500.

"While I recognize that ensuring children have access to, and eat more, nutritious meals is ultimately the responsibility of their caretakers, the City Council can empower parents by making it harder for the fast food industry to target children with predatory marketing techniques," Comrie was quoted as saying. *See Reuters*, April 5, 2011.

LITIGATION

Court Sets Hearing on Fees in Native American Discrimination Suit Against USDA

A federal court in the District of Columbia has reportedly scheduled an April 26, 2011, hearing to determine whether attorneys representing Native American farmers and ranchers in the settlement of claims alleging discrimination against the U.S. Department of Agriculture (USDA) should receive $60.8 million in fees. *Keepseagle v. Vilsack*, No. 99-03119 (U.S. Dist. Ct., D.D.C., preliminary settlement approval filed November 1, 2010). The sum represents 8 percent of the $760 million settlement; Department of Justice attorneys oppose the request and will file supporting papers in the next week. *See The Blog of LegalTimes*, April 5, 2011.

LEGAL LITERATURE

Litigation and Obesity Symposium Transcripts Available

Public interest lawyers and industry representatives debated the merits of using litigation to address obesity at a December 2010 symposium hosted by George Mason University, and edited transcripts have recently been made available in the *Journal of Law, Economics & Policy*. Among the speakers was John Banzhaf whose law students at George Washington University have long focused on "public interest litigation," including lawsuits and regulatory initiatives against the interests of cigarette manufacturers.

Banzhaf claims that a reporter's question in 2002 about using litigation as a weapon in other arenas, such as concerns over obesity, led to the "modern fat litigation movement." He contends that litigation and the courts are a legitimate tool to effect policy change, arguing that until corporations and their customers are forced to pay the full costs of their products, changes will not be made. Banzhaf also discussed the 10 lawsuits or threats of litigation that convinced food companies to reformulate their products in recent years; most involved charges that the companies failed to accurately disclose information about their products on food labels. He also claimed a victory in Brazil, involving an order against McDonald's to pay a former manager $17,500 for the 65 pounds he gained while in the company's employ.

During a panel discussion, industry attorneys and a former Federal Trade Commission (FTC) policy planning office director argued that litigation will not affect the incidence of obesity. They stated, among other matters, that the court system "is not a satisfactory vehicle for creating public policy," tobacco litigation is an inapt model for obesity-related litigation, and advertising does not cause obesity. They also discussed how personal responsibility plays a large role in whether people eat too much and exercise too little. The former

FTC director discussed research the agency had conducted indicating that children actually watch less commercial television today than they did in the past and are exposed to fewer food commercials.

Stephen Gardner, who brings litigation on behalf of the Center for Science in the Public Interest against the industry, also participated in the panel discussion. He spent some time discussing the lawsuit recently filed against McDonald's Corp. in California to stop the company from selling its Happy Meals® with toys that Gardner contends "are there as an attempt to cut into parental responsibility, to cut into parental rights, by going around the parent, no matter how hard they try to prevent it, and marketing straight to the kids." Banzhaf provided a rebuttal to industry claims, saying "My simple answer is déjà vu: I've heard all of this over, and over, and over again. I heard it twenty years ago when we started suing tobacco companies." He stated that he will continue to litigate public health issues because "we have proven over, and over again, that this stuff works."

MEDIA COVERAGE

Food Marketing to Youth Discussed in Brussels

According to public health lawyer and activist Michele Simon, who recently attended a meeting in Brussels "to address the problem of cross-border marketing of unhealthy food to children," the same types of issues confronting public health advocates in the United States confront their counterparts in Europe. Regulatory standards are apparently under development, but Simon did not share the details because they are still in draft and the meeting was closed to the public.

She did, however, discuss a presentation by an industry representative who apparently outlined voluntary efforts that food and beverage companies have undertaken in Europe to decrease the number of TV ads children are exposed to. Simon questioned the effectiveness of these efforts and industry's transparency, noting that the messages companies are delivering to children in other ways, such as the Internet, are not apparently being tracked.

Simon also provided a summary of the Federal Trade Commission's update on "the stalled federal voluntary guidelines in process here." According to an agency representative, proposed voluntary guidelines should be issued in the next two to three months and will be followed by a 45-day comment period. The proposal will not apparently differ to a great extent from a draft published in December 2009, but is intended "to be feasible, something industry will adopt on a voluntary basis, and [will not] be dead on arrival."

Simon concludes, "I left Brussels with the impression that the food industry is engaging in the same charade all over the world: setting weak, self-serving, voluntary guidelines designed to ensure companies can keep right on marketing their unhealthy brands to children while mollifying regulators and distracting researchers with evaluating their useless pledges, commitments, and initiatives." *See Corporations and Health Watch*, March 23, 2011.

Meanwhile, the same online publication has made available reports prepared by the Berkeley Media Studies Group on marketing issues. They are "**The Soda and Fast-Food Industries Target their Marketing Towards Mothers of Color**," and "**Target Marketing Soda & Fast Food: Problems with Business as Usual**." The group contends that the industries "exploit cultural ties and values to create a demand for some of the unhealthiest foods and beverages that contribute to the obesity epidemic" and foster "structural racism" by perpetuating misleading stereotypes and "promoting high fat, sugary, salty foods to communities where the rates of childhood obesity are highest and growing the fastest." *See Corporations and Health Watch*, April 6, 2011.

SCIENTIFIC/TECHNICAL ITEMS

Rudd Center Study Compares Compulsive Eating with Substance Addiction

Yale University's Rudd Center for Food Policy and Obesity has published a **study** that reportedly compares addictive eating behavior in both obese and lean women to substance dependence. Ashley Gearhardt, et al., "Neural Correlates of Food Addiction," *Archives of General Psychiatry,* April 2011. According to an April 4, 2011, press release, researchers assessed the addictive eating behavior of 48 adolescent women ranging from lean to obese, then used "brain-imaging procedures" to examine (i) "how the brain responded to cues signaling the impending delivery of a highly palatable food (chocolate milkshake) versus cues signaling the impending delivery of a tasteless control solution," and (ii) how the brain responded "during the actual intake of the chocolate milkshake versus the tasteless solution."

The results apparently suggested that both lean and obese subjects "with higher food addiction scores showed different brain activity patterns than those with lower food addiction scores," exhibiting "greater activity in parts of the brain responsible for cravings and motivation to eat, but less activity in the regions responsible for inhibiting urges such as the desire to drink a milkshake." As lead author Ashley Gearhardt explained, these findings "support the theory that compulsive eating may be driven in part by an enhanced anticipation of food rewards and that addictive individuals are more likely to be physiologically, psychologically, and behaviorally reactive to triggers such as advertising."

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 389 | APRIL 8, 2011

The study authors have thus concluded that changes to the current food environment "may be critical to successful weight loss and prevention efforts." They particularly noted that "ubiquitous food advertising and the availability of inexpensive palatable food may make it extremely difficult to adhere to healthier food choices because the omnipresent food cues trigger the reward system," thereby limiting the effectiveness of "the current emphasis on personal responsibility as the anecdote [sic] to increasing obesity rates."

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

FOOD & BEVERAGE LITIGATION UPDATE

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.