

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

Democrats Wrangle over Fate of Food Safety Bill

Representative John Dingell (D-Mich.) recently sent a public [letter](#) to Senator Dianne Feinstein (D-Calif.), blaming her pursuit of a bisphenol A (BPA) ban for stalling the Food Safety Modernization Act ([S. 510](#)). Feinstein has apparently sought to include “controversial language” in the bill that would prohibit BPA in food and beverage packaging. According to Dingell, “recent press accounts” have suggested that Feinstein’s stance has endangered the fate of the legislation, which would grant the Food and Drug Administration (FDA) new authority to monitor the national food supply and enforce regulations.

Other food safety advocates such as Safe Table Our Priority have reportedly joined Dingell in asking Feinstein to drop her agenda. Although Dingell noted the ongoing disagreement over BPA’s safety, he nevertheless urged his fellow lawmaker to negotiate with industry interests. “It would be calamitous if a bill to protect American consumers from unsafe food cannot become law this year because of controversy over a single point,” wrote Dingell, who authored a similar measure that passed the House in July 2009.

Meanwhile, Feinstein has publicly responded to Dingell by vowing to craft a workable compromise or introduce an amendment on the Senate floor. “I believe that we need legislation to protect consumers, especially babies and toddlers, from harmful chemicals,” she was quoted as saying. “BPA is a chemical widely used in the production of certain plastics and has been linked to negative health problems, including brain and behavioral disorders, cancer, diabetes, heart disease and obesity. The Food Safety Bill is the logical place for this legislation, but special interests are fighting to obstruct any legislation to ban BPA from consumer products.” See *Law360.com* and *The Washington Post*, July 20, 2010.

Business Leaders Take Aim at Food and Beverage Policies Posing Impediment to Growth

In response to an Office of Management and Budget (OMB) request, the Business Roundtable and The Business Council have prepared a [report](#) with a list of laws and regulations that the nation’s business leaders reportedly believe “have a dampening

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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.

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effect on economic growth and job creation." Among the business groups' concerns are proposals that would affect how the food and beverage sectors conduct business. Titled "Policy Burdens Inhibiting Economic Growth," the report cited Food and Drug Administration food labeling policies, proposals to increase beverage taxes, pending changes to food safety laws, proposed nutrition standards, and youth marketing initiatives as areas of particular concern.

OMB Watch, an organization dedicated to "equitable regulatory and budgetary processes," questioned the timing of the White House invitation, claiming that recent economic and environmental catastrophes were due to lax regulation and not "because government has been too zealous." Acknowledging that OMB may have initiated the dialogue as a "political calculus—a bone thrown to cranky executives upset with the Obama administration's efforts to cure some of America's ills, in order to get Big Business off Obama's back," the watchdog warned that efforts to pursue the Business Roundtable's suggestions would "risk tearing major holes in the public safety net," and send "a signal to the American public that government is not on their side." See *OMB Watch*, July 16, 2010.

APHIS Seeks Participants in Biotech Quality Management System Program

The Animal and Plant Health Inspection Service (APHIS) has issued a [notice](#) requesting voluntary participation in a program designed to improve compliance with regulations pertaining to the importation, interstate movement and environmental release of genetically engineered (GE) organisms. APHIS conducted a pilot Biotechnology Quality Management System (BQMS) Program in 2009 and has since refined its draft audit standard and procedures and program training sessions.

The program is intended to help all regulated entities, including universities, small businesses and large companies, to develop "sound management practices through the creation and implementation of a customized biotechnology quality management system." Participants will be expected to attend several training sessions, develop a BQMS within their organization, establish procedures addressing the movement and field testing of regulated GE organisms, participate in evaluations, and submit to a third-party verification audit. Letters of interest may be submitted at any time, but APHIS encourages submission as soon as possible because training sessions will be scheduled for summer and fall 2010. See *Federal Register*, July 19, 2010.

FDA Solicits Feedback on Information Collection Related to Environmental Assessments

The Food and Drug Administration (FDA) has [called](#) for comments on a proposed information collection included in a guidance document titled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition [CFSAN]." Under the National Environmental Policy Act of 1969, FDA must consider the environmental impact of its actions, including those related to food contact substance notifications; exemption requests for food additives; and petitions for GRAS affirmation, food additives and food colorings, food labeling, health claims, and nutrient content claims.

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FDA has since, however, amended its rulemaking to exclude certain classes of actions “that do not individually or cumulatively have a significant effect on the human environment.” Instead of routinely requiring information about the production of FDA-regulated articles, FDA has eliminated the previously required environmental assessment (EA) and provided guidance “to help industry submit a claim of categorical exclusion or an EA” to CFSAN. This guidance addresses the following questions: (i) “What types of industry-initiated actions are subject to a claim of categorical exclusion?”; (ii) “what must a claim of categorical exclusion include by regulation?”; (iii) “what is an EA?”; (iv) “when is an EA required by regulation and what format should be used?”; (v) “what are extraordinary circumstances?”; and (vi) “what suggestions does CFSAN have for preparing an EA?”

The FDA notice of proposed information collection includes the estimated reporting burdens for likely respondents, which include businesses “engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.” The agency will accept comments until September 20, 2010. *See Federal Register*, July 21, 2010.

Diminished FSA to Retain Food Safety Mandate

The UK Department of Health (DH) has [announced](#) its intention to preserve the Food Standards Agency (FSA) as a non-ministerial authority responsible for food safety policy and enforcement. According to a July 20, 2010, press release, DH will take over England’s nutrition policies, including those related to (i) food labeling and health claims; (ii) dietetic food and food supplements; (iii) calorie information in catering establishments; and (iv) product reformulation to reduce salt, saturated fat, sugar, and portion sizes. DH will also conduct nutrition research and work with the Scientific Advisory Committee on Nutrition, while the Department for Environment, Food and Rural Affairs (Defra) will handle country-of-origin labeling, other types of non-food-safety labeling, and food composition policies used to characterize products such as honey, jam, chocolate, and ice cream.

On matters of food safety, however, advice from FSA experts “would be final.” The authority will also retain oversight of nutrition and labeling policy in Scotland, Wales and Northern Ireland. This restructuring will transfer approximately 70 policy posts to DH and 25 to Defra, although 2,000 staff will remain with FSA.

“Reorganizing in this way will contribute to the Government’s objective to improve efficiency, and is paramount to the key priority of improving the health of the nation by creating a public health service,” stated DH. “To achieve this coherence, some policy-based functions can be brought ‘in house’ to give a more coordinated approach on health and food issues.” *See Written Ministerial Statement*, July 20, 2010.

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IASO Urges Tougher Standards for Food Marketing to Children

The International Association for the Study of Obesity (IASO) has released a July 2010 [report](#) on the PolMark Project, a survey commissioned by the European Union to examine how member states regulate food and beverage marketing to children. According to IASO, “The researchers found that two-thirds of the 53 countries in the region now have official policies on the need to restrict the promotion of unhealthy food to children, a dramatic increase since a similar survey five years earlier. However, most countries are depending on self-regulation by industry and only a few have brought in specific statutory measures.”

The report apparently notes that 92 percent of key stakeholders interviewed in 11 countries “believed there was a link between advertising and child obesity.” In addition, (i) two-thirds “believed current controls on marketing to children were not strong enough”; (ii) more than 80 percent “thought that restrictions on advertising for certain types of programs would be acceptable”; and (iii) “[m]ost interviewees favored protecting children up to 12 years of age and just over half supported protection up to 16 years.” Health and consumer groups also purportedly expressed “frustration” that regulators seemed reluctant to “challenge commercial interests.”

IASO has urged the European Union to encourage international standards for food and beverage marketing. “This cannot be dealt with one country at a time—too much marketing creeps in through satellite TV, Internet, advertising embedded in video games, and sponsored international events,” stated IASO Research Director Tim Lobstein. “Now companies are moving away from TV advertising and towards child-oriented Internet sites, developing social networking and viral marketing, using product placement in films and games, direct mobile phone marketing and other means of reaching children without parents’ knowledge.” See *IASO Press Release*, July 2010.

LITIGATION

Cookware Manufacturer Settles Complaint Alleging Fraudulent Health-Related Advertising

According to a news source, a company that makes high-priced cookware and targets its sales to Spanish-speaking immigrants in the Los Angeles area has agreed to settle litigation accusing it of fraudulently claiming that its products could cure diseases ranging from cancer and Alzheimer’s to diabetes and heart disease. *California v. Rena Ware Int’l, Inc.*, No. BC437981 (Cal. Super. Ct., Los Angeles County, settlement reached July 1, 2010). California Attorney General Jerry Brown brought the lawsuit, alleging unfair competition and false advertising. Sales representatives reportedly told consumers that the cookware reduced high blood pressure by removing hormones from meat while it cooked. Under the agreement, the manufacturer will pay a total of \$625,000 to resolve the dispute and must ensure, by means of an independent monitor, that it will refrain from using either false information or high-pressure sales tactics. See *Mealey’s Personal Injury Report*, July 12, 2010.

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OTHER DEVELOPMENTS**Diversity Publication Takes on Obesity**

In a recent issue that celebrates the top diverse U.S. companies, including several food manufacturers and restaurant chains, *Diversity Inc.* calls out the food and beverage industry, in an investigative report, for marketing, public relations and lobbying tactics some believe have led to unhealthy eating habits and a national obesity epidemic. Titled "How the Food Industry Profits While Society Pays," the report describes the effects of an overweight and obese society on the U.S. health care system, while noting that hundreds of hospitals have fast-food restaurants on their premises. The report suggests that racial and social-justice issues are implicated in the obesity epidemic, citing statistics showing that African-American, Latino and inner-city communities are saturated with fast-food restaurants.

A report sidebar discusses the largest fast-food chains, noting the tens of thousands of restaurants that bear their logos around the world and the ways they market to children. "On a positive note," the report observes that these companies have made a commitment to diversity thus earning a place on the magazine's top diverse company rolls. Numerous references are made to recent films and books that have tried to draw attention to "Big Food" issues, and the report includes quotes from industry critics, such as Kelly Brownell, Michele Simon, David Kessler, and John Banzhaf, each of whom apparently claimed the food and beverage industry was following the tobacco industry's "playbook." Banzhaf, a law professor at George Washington University, reportedly said that fast-food companies do not tell consumers about the addictive properties of their products. "I think when a fast-food company deliberately doesn't tell you important information that both legally and morally they bear some responsibility. It is deception by omission," he was quoted as saying.

The report includes industry responses to the nation's obesity problem. McDonald's Corp. said that it creates jobs, pays taxes and contributes to the local communities where it does business. It also said, "To suggest that any single business or group of businesses is responsible for the obesity problem is at best inaccurate, and, at worst, irresponsible." Burger King Corp. pointed to the ways it is helping "promote nutrition education" to its customers "in a manner that will have a meaningful impact on their nutritional choices." Kraft Foods discussed how it is reformulating its products to reduce sodium, fat, added sugars, and calories, while increasing beneficial ingredients.

Concluding with a discussion of government initiatives to address nutrition and health, including Michelle Obama's "Let's Move" campaign, the report gives the final word to Philadelphia attorney Jonathan Scott Goldman. After referring to plaintiffs who sued McDonald's in 2002 for their obesity-related health problems, Goldman states, "individual citizens do not have anything approaching the influence over our elected government that the fast-food corporations can afford. The corporate special interests now control Washington, D.C., and the ordinary people are disorganized, disenfranchised and out of the political loop. While this is not how our government was meant to work, this is the current political reality." During law

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school, Goldman authored an article discussing how tobacco litigation theories would be used against the food industry; a summary of that 2003 article appears in [issue 82](#) of this Update. See *Diversity Inc.*, June 2010.

Catfish Farmers of America Warn Lawmakers of Import Risks

The Catfish Farmers of America (CFA) has reportedly released a commissioned [report](#) that evaluates the human health risks associated with catfish consumption. Presented to lawmakers and backed by Senate Agriculture Committee Chair Blanche Lincoln (D-Ark.), the report identifies several major hazards for aquaculture fish, including “pathogenic microorganisms, antimicrobial/drug residues, and environmental chemicals.” In particular, the findings cite regulatory surveillance testing that revealed illegal antibiotics, drugs and other chemicals in imported fish but not in the domestic aquaculture supply. “The use and resulting presence of these antibiotics can cause microorganisms to gradually become resistant to the antibiotics and their ability to treat human infections is thereby decreased,” states Exponent, Inc.’s Center for Chemical Regulation and Food Safety, which authored the report.

The report thus recommends that freshwater aquaculture “should have an inspection system that differs from other seafood systems,” with an emphasis on “prevention of contamination across the entire catfish production, processing, and distribution chain.” It specifically notes that the U.S. Department of Agriculture’s Food Safety and Inspection Service is better equipped than either the Food and Drug Administration or the National Oceanic and Atmospheric Administration (i) “to define performance standards for microbial hazards,” (ii) “to conduct baseline testing to determine the current presence of contaminants in the foods across an industry,” (iii) “to test production in individual facilities,” and (iv) “to evaluate each establishment’s progress toward achieving acceptable performance levels.” In addition, the report suggests that the non-governmental Global Food Safety Initiative would place further constraints on marketing products which cannot meet stringent safety standards.

Meanwhile, the National Fisheries Institute (NFI) has declared the report a manufactured food safety scare to eliminate foreign competition in the catfish market. According to a July 22, 2010, NFI press release, the contention that catfish is a “major contributor to antibiotic resistance in the U.S. is an absurd exaggeration.”

EU Snack Industry to Standardize Portion Sizes

The European Snacks Association (ESA) has apparently [vowed](#) to standardize product portion sizes, citing dietary recommendations and consumption patterns. In conjunction with an EU trade group representing food and beverage manufacturers, ESA has set a reference serving size that does not exceed 8 percent of the overall Guideline Daily Amount (GDA), or approximately 160 kcal. Thus, according to ESA, (i) “30g of snacks would provide 120-170 kcal, depending on the nature of the ingredients/preparation of the product”; and (ii) “30g of nuts would provide 170-200 kcal, depending on the nutritional differences between nuts and their preparation.” ESA has also promised to declare the number of portions per package so that consumers can adjust their dietary habits as needed.

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ESA has also issued guidelines for individually wrapped and sold products "weighing 50g or less that are designed to be eaten in a single occasion." For these items, "the nutrition information provided should be based on the actual product weight." Single-portion items that exceed this weight limit, including multi-serve packs, "should be labeled based on the reference serving size of 30g for snacks and nuts." ESA members have reportedly agreed to phase in these labeling provisions over the coming months, as well as launch new snack lines in 30g portions. See *ESA Position Statement*, July 2010; *FoodNavigator.com*, July 20, 2010. ■

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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.

