

## FOOD & BEVERAGE LITIGATION UPDATE



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### LEGISLATION, REGULATIONS AND STANDARDS

#### Industry Responds to FDA Finding on Bisphenol A

The American Council on Science and Health (ACSH) has responded to the Food and Drug Administration's (FDA's) recent [review](#) of bisphenol A in food contact applications, praising regulators for stopping short of a ban on the ubiquitous chemical but criticizing their concern for "hypothetical and non-existent health risks." FDA has stated that it now shares the National Toxicology Program's outlook on "the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children," and is considering a more aggressive oversight approach. To this end, the agency may seek new authority to govern BPA and its different formulations through the Food Contact Notification Program created in 2000. This regulatory framework not only requires manufacturers to provide detailed analysis on substance applications, but allows FDA to "quickly protect the public by revoking the use through a notice in the *Federal Register*." Noting that BPA was first approved for use as a food additive more than 40 years ago, the agency apparently "believes that the more modern framework is more robust and appropriate for oversight of BPA than the current one." See *Law360*, January 15, 2010; *The New York Times* and *The Washington Post*, January 16, 2010; *Greenwire*, January 18, 2010.

ACSH, however, has questioned the need for such measures. "BPA has been among the most well-studied substances known to man, and repeated evaluation by respected scientific bodies worldwide has without fail deemed BPA safe as typically used," stated an ACSH spokesperson in a January 15, 2010, press release, which added that "since BPA became commonplace in the lining of canned goods, food-borne illness from canned foods—including botulism—has virtually disappeared."

The American Chemistry Council (ACC) and Grocery Manufacturers Association (GMA) have seconded BPA's longstanding and extensive safety record. GMA agreed with FDA and the Department of Health and Human Services that there is currently "no need for consumers to change their consumption habits," welcoming further studies as adding to the "robust catalogue" of BPA research. In addition, ACC registered disappointment that "some of the recommendations are likely to worry consumers and are not well-founded." See *ACC and GMA Press Releases*, January 15, 2010.

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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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Meanwhile, *Inside EPA* has reported that FDA's review might "clear the way for EPA's [the Environmental Protection Agency's] own chemical action plan for the substance, which is currently undergoing review at the White House Office of Management & Budget (OMB)." The draft action plan apparently "lists an array of actions the agency plans to take under its existing authority to limit risks posed by the chemical." As an EPA spokesperson told the media source, the plan is slated for release in early 2010.

The FDA's assessment has also reverberated overseas, with the European Food Safety Authority (EFSA) reportedly pledging to reexamine the issue with the U.S. agency to determine any implications for its own position. Moreover, the UK Food Standards Agency (FSA) purportedly stated that it does not anticipate any immediate policy changes as the result of FDA's findings. "The situation in the UK hasn't changed," an FSA spokesperson told one reporter. "Working closely with [EFSA] and the [European Commission], we recently looked into the potential risks of bisphenol A and found that exposure of UK consumers to from all sources [sic], including all food contact materials, is well below levels considered harmful." See *FoodProduction-Daily.com*, January 18, 2010.

### Petition Seeks Withdrawal of FDA Approval for rBGH

Scientists and others objecting to the use of recombinant bovine growth hormone (rBGH) to stimulate milk production in dairy cows have reportedly resubmitted a [petition](#) to the Food and Drug Administration (FDA) challenging the new animal drug application approval for an rBGH drug. FDA apparently failed to respond to the original petition, filed in 2007. The petition also requests that dairy products made from cows treated with rBGH be labeled with a health-hazard warning.

The petitioners include Samuel Epstein, chair of the Cancer Prevention Coalition; Ronnie Cummins, national director, Organic Consumers Association; Arpad Pusztai, a consultant biologist from Scotland; and Jeffrey Smith, executive director, Institute for Responsible Technology. They claim that rBGH milk poses major cancer and other risks to the U.S. population and that the drug has toxic effects on cows. See *World-Wire.com*, January 15, 2010.

### DeLauro Urges Independent Review of USDA Inspection Practices

U.S. Representative Rosa DeLauro (D-Calif.) has called for an independent review of the U.S. Department of Agriculture's (USDA's) meat and poultry inspection system, citing the recent recall of approximately 864,000 pounds of beef possibly contaminated with *E. coli*. Issued by a Montebello, Calif.-based meat packing company, the recall involved ground beef products identified by USDA's Food Safety and Inspection Service (FSIS) during a recent food safety assessment. In addition, FSIS reportedly flagged some 2008 products based on the establishment's records.

According to DeLauro, an independent board would "support and advise USDA, ensure that the inspection process is rigorous and scientifically robust, and recommend changes to any practices that are insufficiently protecting our food supply." She further opined that this latest incident, which involved products produced

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almost two years ago, "is a glaring indication that the current inspection system for meat and poultry is inherently flawed and not sufficient to protect the public health." See *Meatingplace.com*, January 18, 2010; *DeLauro Press Release*, January 19, 2010.

### Dietary Guidelines Advisory Committee to Meet, Comments Solicited

The U.S. Department of Agriculture and Department of Health and Human Services have published a [notice](#) announcing the fifth meeting of the Dietary Guidelines Advisory Committee. Scheduled for February 9, 2010, the meeting will be conducted as an online Webinar and is expected to consist of discussions about (i) nutrient adequacy, (ii) energy balance and weight management, (iii) carbohydrates and protein, (iv) sodium, potassium and water, (v) fatty acids and cholesterol, (vi) ethanol, and (vii) food safety.

Written comments may be submitted and must be received no later than February 3 for the committee's consideration before the meeting. Comments may also be submitted at any time "throughout the Committee deliberation process." To participate in the online program, pre-registration is required. Webinar capacity is limited, and a waiting list will be maintained if necessary. See *Federal Register*, January 22, 2010.

### Preliminary Steps Taken to Nullify EPA Endocrine Disruptor Screening Program

After the Congressional Research Service (CRS) questioned the validity of agency regulations that had not been submitted as required by law to Congress and the Government Accountability Office (GAO), the Center for Regulatory Effectiveness [wrote](#) to House and Senate leaders asking Congress to advise the Environmental Protection Agency (EPA) that its endocrine disruptor screening program "is not in effect" until the required notice is provided. More information about the CRS report appears in issue 332 of this Update.

According to a news source, EPA's program, mandated under the Food Quality Protection Act, was designed to identify pesticides that might cause adverse effects on human health and the environment. The center, a business-backed think tank, cited the CRS report in making its case to nullify the program. An EPA spokesperson reportedly responded that its action describing the agency's endocrine disruptor policies and procedures and announcing the list of chemicals to receive testing orders was not a regulation under the Congressional Review Act (CRA) and thus did not require submission to Congress and the GAO. A center board member apparently disputed that contention, claiming that the law broadly defines "rule" to include any "agency statement . . . designed to implement, interpret, or prescribe law or policy."

Of the few courts that have reportedly considered whether federal regulations can be nullified for agency failure to comply with the CRA, most have determined that the law expressly bars judicial review, despite any legislative history to the contrary. Still, at least one federal district court has concluded that the judicial bar was "ambiguous" and declined to dismiss a challenge to agency action on this basis.

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According to the court, the CRA “has no enforcement mechanism, and to read it to preclude a court from reviewing whether an agency rule is in effect . . . would render the statute ineffectual.” See *U.S. Law Week*, January 19, 2010.

### OSHA Seeks Public Input on Workplace Health and Safety Issues; Meeting Scheduled

The Occupational Safety and Health Administration (OSHA) has published a [notice](#) scheduling a public meeting February 10, 2010, in Washington, D.C., to consider a range of issues relating to workplace safety. According to the notice, OSHA will also establish a public docket as part of this initiative, which is “in keeping” with a presidential memorandum and Office of Management and Budget directive to give the public more opportunities to participate in regulatory decisions and developments.

Among other matters, the agency seeks input on “the most important emerging or unaddressed health and safety issues in the workplace,” what the agency can do to “enhance the voice of workers in the workplace,” whether OSHA needs to take additional measures to improve its compliance assistance efforts for the benefit of small businesses, and how the agency can better “reach high risk employees and employers with training, education and outreach.” Those planning to attend the meeting must register by February 3, and written comments must be submitted by March 30.

### Panel Urges Obesity Screenings, Comprehensive Weight-Management for Kids

The U.S. Preventive Services Task Force (USPSTF) has issued a [recommendation statement](#) advising clinicians to screen children ages 6 and older for obesity and to refer them for intensive counseling and behavior treatment if warranted. USPSTF bases its guidance “on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.” In an update to its 2005 guidelines for screening children and adolescents, USPSTF reportedly claims that treating obese kids can help them lose weight only if rigorous diet, activity and behavior counseling are involved.

According to its latest study, the expert panel found “adequate evidence that multicomponent, moderate- to high-intensity behavioral interventions” for obese children can “effectively yield short-term (up to 12 months) improvements in weight status.” As USPSTF Chair Ned Calonge told a news source, the group realizes that most pediatricians are not equipped to offer the necessary treatment and that it may be hard to find or afford. He said the recommendations showcase scientific evidence about program efficacy and “not whether or not those services are currently available.” See *Pediatrics*, January 18, 2010; *Associated Press*, January 19, 2010.

In a related development, the U.S. Department of Agriculture (USDA), National Dairy Council and National Football League (NFL) have launched a “Fuel Up to Play 60” campaign aimed at fighting childhood obesity by encouraging better food choices and 60 minutes of physical activity each day. According to a January 15, 2010, USDA press release, “this unprecedented partnership will help educate our youth about steps they can and should take to lead healthy lives.” Dairy farmers have reportedly

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committed \$250 million over the next five years to the program, which “taps the power of the NFL and its teams, players and physical activity programming to add recognition and value for students.” More than 60 percent of the nation’s 96,000 private and public schools have enrolled in the program.

Meanwhile, first lady Michelle Obama reportedly told the U.S. Conference of Mayors that she plans to launch a major initiative in February to combat childhood obesity because “the statistics never fail to take my breath away.” The initiative will apparently include a partnership among federal government, local officials, and nonprofit and business leaders to provide more nutritious foods in schools, more opportunities for kids to be physically active and better community access to affordable, healthful food. *See USA Today*, January 20, 2010.

### OEHHA Extends Comment Deadline on Latest Prop. 65 Food Warning Proposal

California EPA’s Office of Environmental Health Hazard Assessment (OEHHA) has extended the comment period for its food warning regulations until March 1, 2010. The latest proposal is to establish a pilot program that would impose Proposition 65 (Prop. 65) warning obligations on food manufacturers and retailers to inform consumers about the presence of food ingredients known to the state to cause cancer or reproductive harm. Additional information about the pilot program appears in issue 331 of this Update. The program, which would expire in four to five years, would allow the agency to test its assumptions about levels of participation and coverage. *See News from OEHHA*, January 21, 2010.

### New Jersey Requires Chain Restaurants to Post Calorie Counts

New Jersey Governor Jon Corzine (D) has reportedly signed a [bill](#) (S. 2905/A. 4236) that requires major restaurant chains doing business in the state to fully disclose calorie information on menu items. Franchises with more than 20 locations nationally must post calorie counts next to each item on the menu, as well as on drive-through and indoor menu boards.

“One of the best ways to improve our health and well being is to deal directly with obesity and proper eating,” Corzine said. “This legislation is a clear step in that direction, as it will allow New Jerseyans to know the calorie content of the food they are eating at these establishments.” *See NewJerseyNewsroom.com*, January 18, 2010.

### New York Governor Proposes Soda Tax to Help Balance Budget

New York Governor David Paterson (D) has [released](#) a 2010-11 executive budget proposal that calls for “a new excise tax of approximately one penny per ounce on sugared beverages linked to obesity (\$465 million).” According to the proposal, which claims that obesity-related disease costs the state’s health care system \$7.6 billion annually, the so-called soda tax “will discourage consumption of those unhealthy products and improve long-term health outcomes.” The legislature has until April 1, 2010, to enact a budget for the upcoming fiscal year.

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Past efforts to institute a levy on sugar-sweetened beverages have met with opposition. “[Paterson] has proposed a soda tax before, then caved, after orchestrated industry protests across the state,” noted a January 19 *New York Times* editorial that urged the governor to “resist and keep the tax.” In addition, the Center for Science in the Public Interest (CSPI) has praised the initiative, deeming it a “courageous yet common-sense move” to dissuade consumers from purchasing “a totally unnecessary and worthless product.” See *CSPI Press Release*, January 19, 2009.

### LITIGATION

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#### U.S. Supreme Court Agrees to Consider GM Alfalfa Seed Appeal

The U.S. Supreme Court has agreed to hear an appeal from a Ninth Circuit Court of Appeals decision enjoining the sale and planting of genetically modified (GM) alfalfa seed until the government completes an environmental impact statement (EIS) for the crop’s proposed delisting. *Monsanto Co. v. Geertson Seed Farms*, No. 09-475 (U.S., certiorari granted January 15, 2010) (Breyer, J., not participating). The parties’ briefs must be filed in February and March 2010.

The questions before the Court are (i) “Did the Ninth Circuit err in holding that NEPA [National Environmental Policy Act] plaintiffs are specially exempt from the requirement of showing a likelihood of irreparable harm to obtain an injunction?”; (ii) “Did the Ninth Circuit err in holding that a district court may enter an injunction sought to remedy a NEPA violation without conducting an evidentiary hearing sought by a party to resolve genuinely disputed facts directly relevant to the appropriate scope of the requested injunction?”; and (iii) “Did the Ninth Circuit err when it affirmed a nationwide injunction entered prior to this Court’s decision in *Winter v. NRDC*, 77 U.S.L.W. 4001 (U.S. 2008), which sought to remedy a NEPA violation based on only a remote possibility of reparable harm?”

According to a news source, the Obama administration opposed Monsanto’s petition because the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS) could complete the EIS and moot the issues in the case by deregulating GM alfalfa before the Court can hear and decide the appeal. Still, the administration apparently disagreed with the Ninth Circuit’s ruling. More information about the case can be found in issues 274 and 309 of this Update. Details about the APHIS EIS, which is currently undergoing public review, can be found in issue 333 of this Update.

The executive director of the Center for Food Safety, which initiated the litigation on behalf of a coalition of non-profits and farmers, was quoted as saying in response to the U.S. Supreme Court’s decision to grant review, “Although we believe a further hearing is unnecessary, we are confident we will again prevail, as the lower courts have already three times determined. We hope that this grand stage will further inform the public, policymakers and the media about the significant risks of genetically engineered crops and the vital need to protect farmers and the environment.” Idaho-based alfalfa farmer Phil Geertson reportedly said about the certiorari grant, “We trust the Supreme Court will uphold farmers’ right to choose their crop of



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choice and protect us from the constant fear of contamination from GE crops." See *Center for Food Safety News Release*, January 15, 2010; *STLtoday.com*, January 16, 2010.

### Federal Court Remands Consumer Protection Claims Filed Against Cereal Maker

A federal court in the District of Columbia has remanded to the D.C. Superior Court a lawsuit brought by the National Consumers League (NCL) against General Mills alleging that the company falsely misrepresents that Cheerios® "has drug-quality properties that would reduce total and 'bad' cholesterol levels when eaten." *Nat'l Consumers League v. General Mills, Inc.*, No. 09-01881 (U.S. Dist. Ct., D.C., decided January 15, 2010). The cereal maker removed the case to federal court claiming that it was removable either as a class action under the Class Action Fairness Act (CAFA) or under the court's diversity jurisdiction.

The NCL disclaimed Article III standing because it did not sustain any injury in fact, but was instead bringing the suit under the "private attorney general" provision of the D.C. Consumer Protection Procedures Act. This provision allows a person to bring an action on behalf of the general public to seek relief "from the use by any person of a trade practice in violation of the law." Because NCL did not itself sustain any harm, the court agreed that it lacked standing to pursue litigation in the federal court. The court also determined that even if NCL had Article III standing, the court lacked subject matter jurisdiction because the case was not a class action and, as a private attorney general suit, fell squarely within a CAFA exception. The court further concluded that the claims did not reach the monetary threshold required for diversity jurisdiction.

### MDL Court Issues Ruling on Motion for Reconsideration in Bisphenol A Litigation

A federal multidistrict litigation (MDL) court in Missouri has issued an order and opinion disposing of defendants' motion that it reconsider its prior rulings refusing to dismiss some of the bisphenol A-related claims in the case on the basis of federal preemption and primary jurisdiction. *In re: Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, MDL No. 1967 (U.S. Dist. Ct., W.D. Mo., W. Div., decided January 19, 2010). Details about the court's prior ruling appear in issue 327 of this Update. The court also denied defendants' motion to certify the issues for immediate interlocutory appeal.

In its opinion, the court clarifies its holding allowing plaintiffs to proceed with their unjust enrichment claims, acknowledging that its prior holding may not have been clear. "The Court did not intend to suggest that all Plaintiffs automatically and necessarily have a valid claim for unjust enrichment. . . . [T]he Court cannot conclude that no purchaser can assert a claim for unjust enrichment. Ultimately, differences in individual circumstances and the content of state laws make it impossible for the Court to hold that *all* consumers either have or do not have a cause of action as a matter of law."

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## OTHER DEVELOPMENTS

### HSUS Buys Shares of Burger Chains

The Humane Society of the United States (HSUS) has reportedly purchased stock in Jack in the Box Inc. and Steak n' Shake Co. in an effort to persuade each restaurant chain "to implement the types of basic animal welfare changes many of its competitors have made." The activist group has criticized both companies for allegedly using "eggs from caged hens, pork from crated pigs, and poultry from producers that use a particularly cruel but standard method of slaughter." HSUS has purportedly employed similar tactics to influence other establishments, in addition to supporting legislation in Michigan and California that phases out "extreme confinement of certain farm animals." One HSUS spokesperson also stated that these production methods are at odds with "public opposition to farm animal abuse," opining that Jack in the Box's "history with food safety" should make "improving conditions on the factory farm... a top priority." See *HSUS Press Release*, January 14, 2010; *Meatingplace.com*, January 18, 2010.

### HFCS Removed from Chocolate Milk in San Francisco School District

The San Francisco Unified School District has reportedly announced plans to stop serving non-fat chocolate milk made with high-fructose corn syrup (HFCS) and replace it with formulations using sucrose or regular white sugar. Selling nearly 12,000 cartons of nonfat chocolate milk daily, the district agreed to the change after parents complained about the HFCS content. Its supplier, Berkley Farms, plans to start shipping the reformulated chocolate milk next month, although company officials have noted that the substitution will offer the same caloric and sugar content as the old formula and will not make a difference nutritionally. See *San Francisco Chronicle*, January 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.

