

## FOOD & BEVERAGE LITIGATION UPDATE

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## LEGISLATION, REGULATIONS AND STANDARDS

### White House Child Obesity Task Force Issues Action Plan

While the president’s Task Force on Childhood Obesity released its [action plan](#) with 70 specific recommendations to significant praise and fanfare this week, nutrition professor and author Marion Nestle questioned whether the ideas will actually work given their reliance on voluntary collaboration and participation. She said in her blog, “Voluntary, as evidence demonstrates, does not work for the food industry. Much leadership will be needed to make this plan work. But these recommendations should give advocates plenty of inspiration to continue working on these issues.”

First lady Michelle Obama joined several task force members when the report was issued and said, “For the first time, the nation will have goals, benchmarks, and measureable outcomes that will help us tackle the childhood obesity epidemic one child, one family, and one community at a time. We want to marshal every resource—public and private sector, mayors and governors, parents and educators, business owners and health care providers, coaches and athletes—to ensure that we are providing each and every child the happy, healthy future they deserve.”

The report focuses on four priority areas: “empowering parents and caregivers”; “providing healthy food in schools”; “improving access to healthy, affordable foods”; and “increasing physical activity.” Among its specific recommendations are developing standard nutrition labels for food packages, limiting the licensing of popular entertainment characters to healthy food and beverage products and restricting all forms of marketing to children, either voluntarily or through consideration of federal regulation.

According to a U.S. Department of Agriculture (USDA) press statement, federal agencies will take a number of actions within the next year to implement the report’s recommendations. For example, Health and Human Services will issue new guidance for physical activity and nutrition standards in child care settings, get calorie counts on menus and develop clear “front of pack” food labels; USDA will update the Dietary Guidelines and Food Pyramid and work with Congress to pass a child nutrition reauthorization bill that will improve food in schools; and FTC will continue monitoring the marketing of food to children and will follow up its 2008 report on industry practices.

The president and CEO of the Grocery Manufacturers Association reportedly issued a statement in response to the report, saying, “We agree that everyone has a role to play, including industry. We embrace our responsibility.” Pamela Bailey also apparently

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said the industry would continue to make healthier products and mentioned a coalition established in October 2009 that encourages a balance of energy intake and physical activity to reduce obesity.

The International Dairy Foods Association reportedly approved the task force's "integrated approach" to the issue and said the dairy industry is committed to playing its part to ensure the health of U.S. children. The Center for Science in the Public Interest released a statement that called the recommendations "bold, yet achievable," and urged Congress to pass pending legislation that "would provide a historic increase in school lunch funding, get junk food out of vending machines, and help schools implement stronger nutrition and physical activity wellness policies."

The Center for Consumer Freedom said that parts of the report were "certainly worthwhile, like its efforts to tackle 'food deserts' and promote physical activity." Still, the organization criticized its threat of agency action on youth marketing or increased taxes on "bad" foods or soft drinks, calling such efforts "big government's overreach" and a strategy that will not work.

In a related development, Baltimore has reportedly named a sustainable food specialist as the city's food policy director. Holly Freishtat will apparently be charged with trying to combat poor eating habits in inner city neighborhoods by improving demand for and access to healthful food. She reportedly hopes to expand the number of farmers' markets that will take food stamps. When she had a similar position in the state of Washington, Freishtat reportedly established a curriculum to teach low-income grade school students about good nutrition through gardening and cooking and established programs to expand farmers' markets and home gardens. *See USDA News Release, Center for Consumer Freedom Press Release, CSPI Press Release, Associated Press and CBS News, May 11, 2010; The Baltimore Sun, FoodNavigator-USA.com, The Washington Post, May 12, 2010; FoodPolitics.com, May 13, 2010.*

### FSIS Sets New Performance Standards for *Salmonella* and *Campylobacter*

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has [issued](#) a new set of performance standards to reduce the incidence of *Salmonella* and *Campylobacter* bacteria in young chickens and turkeys.

The new standards hold poultry slaughterhouses more accountable by decreasing the number of samples allowed to test positive for the pathogens. After two years under the new standards, USDA predicts that 39,000 illnesses due to *Campylobacter* will be avoided each year as will 26,000 fewer illnesses attributable to *Salmonella*.

Although Center for Science in the Public Interest (CSPI) Food Safety Director Caroline Smith DeWaal generally welcomed the standards, she lamented the fact that "USDA still lacks authority to enforce these standards by closing failing plants. For consumers to fully realize the benefits of the improved standards, Congress should reinstate USDA's authority to enforce its performance standards."

In a related move, FSIS has issued the third edition of a [compliance guide](#) for poultry slaughter that includes recommendations for controlling *Salmonella* and *Campylobacter*.

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FSIS will accept comments on the performance standards and compliance guide until July 13, 2010. *See USDA Press Release and CSPI Website, May 10, 2010; Federal Register, May 14, 2010.*

### FDA Issues Industry Guidance on Boil-Water Advisories

The Food and Drug Administration (FDA) has issued industry [guidance](#) to advise food manufacturers on appropriate protocol for dealing with a boil-water advisory. The guidance is also “intended to assist food manufacturers in evaluating food that already was produced with water subject to the advisory.”

According to FDA, once a [boil-water advisory](#) has been issued, food manufacturers “should stop using the water subject to the advisory until the water again meets the applicable Federal and State drinking water quality standards.”

The guidance offers assistance to affected manufacturers in evaluating water used in heated foods, ice, bottled water, ready-to-eat foods, and water used for cleaning and hand-washing. The agency issued the guidance in response to the recent boil-water advisory that affected some two million residents of metropolitan Boston. Comments are requested at any time. *See Federal Register, May 13, 2010.*

### European Union Allows Madeira to Remain Free of GMOs

The European Union has reportedly allowed Madeira, an autonomous region of Portugal located 500 kilometers from the African coast, to prohibit the use of genetically modified organisms (GMOs) on the archipelago. According to *The New York Times*, the European Commission “quietly” let the deadline pass for opposing the GMO ban, which Portuguese officials claimed was necessary to preserve Madeira’s rare subtropical laurel forests, known as laurisilva. “[T]he case of Madeira represents a significant landmark, because it is the first time the commission... has permitted a country to impose such a sweeping and definitive rejection of the technology,” states the May 9, 2010, article.

In issuing its decision, the European Commission apparently circumvented the European Food Safety Authority and signaled “the unofficial beginning of a new—and potentially highly contentious—policy that would give European nations and regions far greater freedom to decide when to ban such crops.” This policy seeks to grease the wheels of the GMO approval process by permitting countries and regions more latitude to set their own agricultural agendas. As EU Commissioner for Health and Consumer Affairs John Dalli was quoted as saying, the priority was to get experts, companies and activists to “understand and accept a process that they will not try to second-guess or try to attack once a decision not to their liking is taken.”

## LITIGATION

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### Federal Appeals Court Sends Obesity Disability Litigation Back to Trial Court

The Second Circuit Court of Appeals has returned to a federal district court litigation alleging that a karate instructor was fired because he was obese in violation of a New York City law that forbids disability-based workplace discrimination. [Spiegel v.](#)

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[\*Schulmann, No. 06-5914 \(2d Cir., decided May 6, 2010\)\*](#). According to the appeals court, no cases have yet addressed whether the city law applies to the obese, and the lower court was directed to consider whether the plaintiff had made a *prima facie* case of discrimination under that law.

The plaintiff, who claimed his roommate was fired from a similar position after the plaintiff notified the defendant that he intended to file an employment discrimination charge, also alleged unlawful retaliation under the Americans with Disabilities Act (ADA). Affirming the lower court's dismissal of this claim, the appeals court found that the ADA does not permit an individual to be held liable for retaliation. As to the plaintiff's claim of unlawful discrimination under a state law prohibiting disability-based workplace discrimination, the court cited case law holding that weight-based discrimination requires evidence that a plaintiff is incapable of meeting the employer's weight requirements due to a cognizable medical condition. Because the plaintiff's physician diagnosed him with hypogonadism without linking the condition to his weight, the court found no competent medical evidence confirming the connection.

While the appeals court remanded the case for consideration of the remaining city law-based claim, it also allowed the district court to decide whether to "exercise supplemental jurisdiction over this claim" or to dismiss the claim without prejudice to its re-filing in state court for this area of the law to be further developed in the state courts.

### Federal Court Dismisses "I Can't Believe It's Not Butter" Case

A federal district court in California has dismissed claims against the company that makes the product "I Can't Believe It's Not Butter," finding that, while not preempted under federal labeling law, the complaint failed to allege facts "plausibly suggestive" of a claim entitling the plaintiff to relief under the U.S. Supreme Court's recently adopted *Twombly/Iqbal* pleading standard. *Rosen v. Unilever U.S., Inc.*, No. 09-02563 (U.S. Dist. Ct., N.D. Cal., decided May 3, 2010). The plaintiff alleged that the company violated state consumer protection laws by advertising its product as nutritious when, in fact, it contains partially hydrogenated oil, "an artificial, man-made substance that has no nutritional value and is known to cause a number of health problems."

The defendant sought to dismiss the claims as expressly preempted under the Nutritional Labeling and Education Act, contending that use of the phrase "0g Trans Fat" on product labels complies with Food and Drug Administration regulations where a product contains less than 0.5 grams of *trans* fat per serving. The court disagreed, finding that the plaintiff was not directing his allegations at the phrase, but was, instead, alleging that the company deceptively promoted its product as nutritious, healthy to consume, better than similar products, and "Made with a Blend of Nutritious Oil." Because these statements are not regulated under federal law, claims based on them could not be preempted.

The defendant also challenged the plaintiff's complaint for failure to plead "enough facts to state a claim for relief that is plausible on its face." *Bell Atl. Corp. v. Twombly* 550 U.S. 544 (2007). Citing *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), the court also

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observed that a claim is plausible on its face “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” The court set forth *Iqbal*’s two-pronged analysis, that is, a court first discounts allegations that are little more than “threadbare recitals of the elements of a cause of action, supported by mere conclusory statements,” and then examines the remaining allegations to determine whether they “state a plausible claim for relief.”

The court reduced the plaintiff’s claims to a syllogism: “For the representation ‘blend of nutritious oils’ to be true, all constituent oils must be nutritious. One of the constituent oils in the product [partially hydrogenated oil] is not nutritious. Therefore the product representation is false.” The court found the major premise (“all constituent oils must be nutritious in order for the blend to be nutritious”) to be “merely a conclusion.” Because the plaintiff did not allege any facts specific to what a “blend” must contain to be “nutritious,” the court found the conclusion unsupported by any facts. The court also found the minor premise (“partially hydrogenated oil is not nutritious”) a mere conclusion lacking factual support, noting that federal regulations define *trans* fat as a nutrient.

Applying the second *Iqbal* prong, the court examined the relationship between the premise that partially hydrogenated oil is not a nutrient and the allegedly false representations and found “an implausible legal theory.” According to the court, the plaintiff committed three logical fallacies—the fallacy of begging the question, the fallacy of composition and the fallacy of division—and, thus, the complaint was rendered implausible on its face. The court dismissed the claims with prejudice.

### ***E. Coli* Plaintiff Settles with Cargill**

A woman featured in a 2009 *New York Times* article that was part of a Pulitzer-prize winning series on food safety has reportedly settled her claims against Cargill, Inc., which allegedly produced the *E. coli*-contaminated hamburger that left her paralyzed with neurological problems and kidney damage. Represented by plaintiffs’ attorney William Marler, Stephanie Smith is a former dance instructor now confined to a wheelchair. Marler claimed that her medical bills have already totaled more than \$2 million and that she will require additional rehabilitation and multiple transplants. The terms of the settlement, which must be approved by a court, are apparently confidential. Marler was quoted as saying, “Stephanie’s tragedy has taken on a life of its own, and hopefully it will continue to focus people on why food safety is important.” Cargill reportedly said in a joint statement that it “deeply regrets” her injuries and has invested in excess of \$1 billion in meat science research and new food safety technologies. See *Associated Press*, May 12, 2010.

### **Hearings Begin on Fraud Allegations in Litigation over Pesticides Used on Nicaraguan Banana Plantations**

A California trial court has reportedly begun hearing evidence to determine if a 2007 \$2.3 million jury award to Nicaraguan banana plantation workers who claimed they were sterilized by exposure to pesticides was based on fraud. Defendant Dole Food Co. convinced the court in 2009 to dismiss two similar pending cases on the

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basis of testimony, by witnesses whose identities were kept secret due to purported threats of violence in Nicaragua, that the plaintiffs' lawyers recruited bogus plaintiffs, coached them and used spurious lab tests to support their claims of sterility. An appeals court ordered the plaintiffs who had won awards in the earlier case to prove that their allegations were not fraudulent.

According to a news source, Dole presented evidence showing that the plaintiffs could not recall details about plantations where they had purportedly been employed, could not answer questions about the chemical's smell or were apparently sterile before they began to work on a banana farm. The plaintiffs are reportedly represented by a new lawyer who has claimed that Dole obtained testimony about an alleged fraud by giving witnesses cash and treating them lavishly; the company contends that the expenses were approved by the court and agreed to by plaintiffs' former lawyers. Their current lawyer also argued that Dole had all of the evidence about the alleged fraud before trial. The court will continue hearing evidence in June 2010. *See The Los Angeles Times*, May 12, 2010.

### OTHER DEVELOPMENTS

#### IOM Report Questions Health Claims Based on Biomarkers

The Institute of Medicine (IOM) this week published a consensus report titled *Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease*, which urges the Food and Drug Administration (FDA) to apply "the same degree of scientific rigor for evaluating biomarker use across regulatory areas, including drugs, medical devices, biologics, foods, and dietary supplements." IOM describes biomarkers, such as blood cholesterol levels, as "biological yardsticks" used to predict health effects when it is difficult to measure the actual incidence of disease or death. According to a May 12, 2010, press release, "FDA has been hampered in its ability to assess the proliferation of health claims being made by food and supplement manufacturers in part because it lacks a process broadly accepted across the regulatory, food, and medical communities to evaluate biomarkers as valid and appropriate measurements to substitute for clinical outcomes."

Commissioned by FDA, the report proposes a three-part framework for "consistently and rigorously [assessing] the selection and use of biomarkers across the food, device and drug areas." This framework apparently entails (i) "validating that a biomarker can be accurately measured"; (ii) "ensuring that it is associated with the clinical outcome of concern"; and (iii) "confirming that it is appropriate for the proposed use." The report also evaluates several common biomarkers, including blood levels of cholesterol and beta-carotene as indicators of cardiovascular health.

IOM has since called on Congress to give FDA "the authority to conduct studies on how well consumers understand food and supplements health claims and require manufacturers to make changes if needed to promote greater clarity." In particular, the institute notes that consumers may not realize when health claims for food ingredients are not based on actual health outcomes. As the report concludes, "[T]here is neither rationale nor scientific grounds for basing regulatory decisions on different levels of scientific evidence for different substances—science is science." *See Reuters*, May 12, 2010.



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Meanwhile, the Center for Science in the Public Interest (CSPI) has welcomed the findings as a basis for establishing a regulatory framework for dietary health claims. “We support the IOM conclusion that when foods or dietary supplements claim to provide drug-like benefits, they should be held to rigorous scientific standards,” stated CSPI Legal Affairs Director Bruce Silverglade. “Right now, FDA policies are riddled with loopholes that let companies make phony promises on weak scientific evidence.” See *CSPI Press Release*, May 12, 2010.

### Advocacy Organization Report Calls for Protection of Young Agricultural Workers

Human Rights Watch has issued a [report](#) titled “Fields of Peril: Child Labor in US Agriculture” that describes the working conditions facing the nation’s youngest field laborers and calls for changes to federal employment and environmental laws to provide them with greater protections. According to the report, child farmworkers as young as age 12 often work for 10 or more hours per day, five to seven days a week. Some begin working part-time at ages 6 or 7.

Many of the labor law protections for other youth workers apparently do not apply to agricultural workers, and Human Rights Watch reportedly found that many children earn far less than minimum wage, particularly when they are paid for production rather than by the hour and when their employers charge them for tools, gloves and drinking water. They also have higher rates of dropping out of school and experience higher numbers of fatalities than children working other jobs.

Secretary of Labor Hilda Solis reportedly commended the report and said that her department has put illegal child labor on its priority list. “We simply cannot—and this administration will not—stand by while youngsters working on farms are robbed of their childhood,” she said. According to Solis, the agency has added more than 250 field investigators to its staff and planned to add more. The Environmental Protection Agency, also criticized in the report, apparently responded by saying “Many of the concerns mentioned in the Human Rights Watch report are sound.” The agency said it expects to propose amendments to federal worker protection standards by 2012 to better protect children.

A bill introduced in Congress in 2009 with 87 co-sponsors would eliminate discrepancies in child labor laws that exempt agricultural workers, except for those working on family farms, and collect better data on the number of child laborers and their work-related injuries. The proposed legislation is reportedly opposed by the American Farm Bureau; a spokesperson was quoted as saying, “We think it’s going too far to resolve a problem that’s very isolated. At what point do you take away the opportunity for rural youth to get gainful work experience?” See *The Associated Press*, May 6, 2010.

### Pew Report Urges Integration of Pathogen Data

The Pew Charitable Trusts’ Produce Safety Project (PSP) at Georgetown University has issued a [report](#) that calls for a “unified, cross-agency” approach to tracking foodborne pathogens in humans, animals, food, and feed.

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Titled *Building the Foundations of a Modern Food Safety System*, the report charges the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and U.S. Department of Agriculture (USDA) with summarizing “surveillance data on human foodborne illnesses—including outbreaks and sporadic cases—and on pathogen contamination in domestic and imported animals, food and feed.”

PSP apparently based its recommendations on “extensive research and interviews” with food safety authorities in Denmark, The Netherlands, and the United Kingdom, according to a May 10, 2010, press release. The group has urged U.S. regulators to learn from steps taken by these countries to reform their food safety data collection and analysis since the 1990s.

In addition, the report provides specific recommendations for data collection and research, including (i) “revamping farm-to-table surveillance”; (ii) “developing cross-agency strategies for priority settings and attributing the burden of specific foods to overall foodborne illness”; (iii) “better coordination of food safety research”; (iv) “increasing the role of regulatory in research program entities”; (v) “ensuring transparency and public participation”; (vi) “expanding traceability requirements along food chain”; and (vii) “standardizing record-keeping and creating incentives or requirements for electronic information tracking.”

“We also believe there is an advantage to be gained by the creation of an independent federal institute for food safety risk analysis,” stated one co-author. “It would be comprised of the majority of scientists and analysts currently within FDA, CDC and USDA food safety groups and tasked with supporting a risk-based food system through integrated research, data collection and analysis. That is the model from European countries with strong-food-safety systems.”

### AWI Demands Labeling Changes for Perdue® Chickens

The Animal Welfare Institute (AWI) has apparently launched a campaign “to publicly expose Perdue for using misleading labeling claims to manipulate consumers who are trying to make humane choices in the market place.” In a [letter](#) to Perdue Farms, Inc., AWI directs the company to cease advertising some of its chicken products as “Humanely Raised” or “Raised Cage Free” because these terms do not reflect “any meaningful improvement upon conventional husbandry.”

According to the letter, such claims exploit the average consumer’s unfamiliarity with industry practices by implying “the chickens are raised under conditions that exceed the norm.” See *AWI Press Release*, May 12, 2010.

Meanwhile, Perdue has reportedly defended the labels as responsive to consumer requests for additional education. “Consumers told us they regard the USDA Process Verified Program as being the most credible available today,” one Perdue representative was quoted as saying. “We therefore developed several USDA Process Verified programs, including Humanely Raised and Raised Cage Free to respond to consumers’ desire for more information.” See *Meatingplace.com*, May 12, 2010.



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### MEDIA COVERAGE

#### Marion Nestle Co-Authors Book on Pet Food Industry

New York University Professor Marion Nestle has announced the publication of *Feed Your Pet Right*, an extension of *What to Eat* that traces the evolution of commercial pet foods and recommends alternative diets. According to a May 10, 2010, *Food Politics* blog post, even those people without pets should pay attention to this \$18 billion industry because “[p]ets eat the same food we do, just different parts... The safety issues are identical.”

Written with Cornell University Professor Emeritus Malden Nesheim, the book turns a critical eye on the five major companies that produce pet food. The authors apparently explain “how pet foods are and are not regulated, how pet food companies influence government oversight and veterinary training and research, and how ethical considerations affect pet food research and product development.” In addition, they make recommendations for pet food owners, industry, government regulators, and veterinarians.

Nestle also notes the similarities between pet and human food marketing, citing non-standard labeling and a dearth of comparative studies as sources of consumer confusion. As she told *Time* magazine in a May 11 promotional interview, “In the book we recommend that pet-food labels be changed to resemble human-food labels so that they’re easier to understand.” She admitted, however, that her research “found no evidence that complete and balanced pet food is harmful to pets, except where mistakes have been made in the course of production.”

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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.

