

## FOOD & BEVERAGE LITIGATION UPDATE



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## LEGISLATION, REGULATIONS AND STANDARDS

### Senator Leahy Proposes Jail Time for Food Contaminators

Senator Patrick Leahy (D-Vt.) has introduced legislation that would give federal prosecutors the authority to seek prison sentences up to 10 years for those who "knowingly place contaminated food products into the nation's food supply." Explaining his reason for introducing the Food Safety Enhancement Act (S.3669), the senator referred to the *Salmonella* contamination of peanut products in 2008 involving the Peanut Corp. of America; the outbreak purportedly "left nine people dead and sickened hundreds more." According to a press statement, Leahy said, "The bill I introduce today would increase sentences for people who put profits above safety by knowingly contaminating the food supply. It makes such offenses felony violations and significantly increases the chances that those who commit them will face jail time, rather than a slap on the wrist, for their criminal conduct." See *Office of Senator Leahy Press Release*, July 29, 2010.

### FTC Chair Testifies About Aggressive Children's Privacy Agenda

During a recent Senate committee hearing on consumer privacy, Federal Trade Commission (FTC) Chair Jon Leibowitz described "aggressive" efforts the agency has undertaken to protect children's online privacy. He referred to actions taken over the past decade against Website operators that collected information from children without parental consent, as required by federal law. Among the companies that agreed to pay fines and change their practices were Hershey Foods Corp., Mrs. Fields Famous Brands, Inc. and American Pop Corn Co., which allegedly failed to comply with the law when engaging children in online games and birthday-related activities.

Leibowitz also noted that FTC plans to release a report later this year reflecting input from a number of stakeholder roundtables on privacy protection in an environment of new technologies and business models. According to Leibowitz, the commission is now conducting a comprehensive review of its parental notice rule "in light of changing technology, such as the increased use of mobile devices to access the Internet." The agency is also "assessing the privacy implications of online behavioral advertising" and "how best to protect and provide effective choice for the use of sensitive information, such as health, financial, children's, and location data."

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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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Senator Claire McCaskill (D-Mo.) reportedly commented during the July 27, 2010, hearing that she is "a little spooked out," by behavioral targeting, saying she feels like she is being "followed around."

Senate Commerce Committee Chair Jay Rockefeller (D-W.Va.) apparently echoed her concerns, stating, "We have a duty to ask whether . . . millions of Americans . . . fully understand and appreciate what information is being collected from them and whether or not they are empowered to stop certain practices from taking place." Leibowitz reportedly told committee members that the FTC is "gravitating to an opt-out of behavioral targeting [for multiple sites] through a single entity." While Leibowitz did not believe that online users would likely use an "opt-out" to the extent that consumers use the "do not call" registry, the availability of the choice is seen as reassuring. *See FTC Press Release and Advertising Age, July 27, 2010.*

### APHIS Announces Biennial Review and Reorganization of Select Agent and Toxin List

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has issued a [notice](#) of proposed rulemaking under the Agricultural Bioterrorism Protection Act of 2002, soliciting feedback on the list of select agents and toxins that could pose "a severe threat to animal or plant health, or to animal or plant products." APHIS has requested suggestions regarding (i) "any addition or reduction of the animal or plant pathogens currently on the list of select agents," and (ii) potential reorganization of the list "based on the relative potential of each select agent or toxin to be misused to adversely affect human, plant or animal health." According to APHIS, "Such tiering of the list could allow for the application of different security measures for those selected agents or toxins which post a higher risk to animal or plant health if they were to be stolen or otherwise misused."

Backed by the National Academies, the Executive Order 13486 Working Group and the National Science Advisory Board for Biosecurity, APHIS has asked respondents in favor of a tiered list "what criteria should be used to designate high risk select agents or toxins." The agency notes that a reorganized list could reflect (i) "the relative ease with which a particular select agent or toxin might be disseminated or transmitted from one animal to another or into the environment"; (ii) "the potential for high animal or plant mortality rates"; (iii) "the potential for a major animal or plant health impact"; (iv) "select agents or toxins whose misuse might result in public panic or other social or economic disruption"; or (v) "select agents or toxins whose use might require Federal, State, and/or local officials to take special action in planning for major animal or plant health disasters." APHIS will accept public comments until August 30, 2010. *See Federal Register, July 29, 2010.*

### FDA Issues Terms for Voluntary Compliance with Menu Labeling Regulations

The Food and Drug Administration (FDA) has issued a [notice](#) specifying the terms and conditions for voluntary compliance with section 4205 of the Affordable Care Act of 2010, which established nutritional labeling requirements for chain restaurants with more than 20 locations and vending machine operators with more than 20 machines. Other retailers not covered by section 4205 can elect to become subject to the federal law by registering biannually with FDA.

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Restaurants and similar establishments that voluntarily opt in “will no longer be subject to State or local nutritional labeling requirements unless those requirements are identical to Federal requirements,” according to the agency. Vending machine operators are already covered by state and local regulations identical to federal requirements, although Congress has “expressly provided” that they may still undertake voluntary registration. The agency will accept comments until October 21, 2010. *See Federal Register*, July 23, 2010.

### FDA Proposes Information Collection on Pet Event Tracking Network

The Food and Drug Administration (FDA) has [solicited](#) feedback on a proposed information collection related to the Pet Event Tracking Network (PETNet). PETNet would allow state and federal regulators “to quickly and effectively exchange information about outbreaks of illness in companion animals associated with pet food.” FDA has envisioned the voluntary system as a “secure, Internet-based network” that would provide a platform for members to receive and create alerts about pet food incidents. According to the agency, “The information will be used to help State and Federal regulators determine how best to use inspectional and other resources to either prevent or quickly limit the adverse events caused by adulterated pet food.”

FDA has anticipated that each participating state would report via PETNet approximately 10 times per year. “[G]iven that the form only has 11 items and most are drop down fields, 20 minutes is a sufficient amount of time to complete the form,” states FDA, which has requested comments by September 27, 2010. *See Federal Register*, July 27, 2010.

## LITIGATION

### Procedural Missteps Doom Trade Association Challenge to EPA Rule Ending Domestic Pesticide Tolerances

The D.C. Circuit Court of Appeals has upheld, in part, the Environmental Protection Agency’s (EPA’s) denial of objections filed to its final rule revoking all residues of the pesticide carbofuran permitted on or in raw and processed foods. [Nat’l Corn Growers Ass’n v. EPA, No. 09-1284 \(D.C. Cir., decided July 23, 2010\)](#). EPA revoked the carbofuran “tolerances” after notice-and-comment rulemaking because it determined that aggregate dietary exposure to residues of carbofuran is “not safe” and because exposure to the chemical in drinking water exceeded “the level of concern with respect to both children and adults.” This action effectively banned its use on both domestic and imported food for human consumption.

The U.S. company that makes the pesticide and several trade organizations filed objections to the revocation and a hearing request, which EPA denied. While the objectors had participated in the rulemaking proceeding, they attempted to either introduce new evidence during the objection phase or simply recycled arguments submitted during the comment phase as to the revocation of domestic tolerances. According to the court, the agency was justified in refusing to consider the new evidence and the recycled arguments. The court also refused to substitute its judgment on the “highly technical and factual matters” raised by the petitioners.

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As to EPA's decision to also revoke all carbofuran tolerances for imported foods, despite acknowledging that this exposure alone is safe, the court vacated this part of the final rule because EPA claimed that petitioners had failed to make a timely request that import tolerances be left in effect. The petitioners had apparently made this request twice. According to the court, "EPA's decision to revoke these tolerances was arbitrary and capricious."

### **Bayer AG Seeks to Overturn \$1.5 Million Jury Award in GM Rice Case**

Contending that conventional farmers' claims for damages from the contamination of U.S. rice crops with a genetically modified (GM) variant are preempted by federal law, Bayer AG has filed an appeal to the Eighth Circuit Court of Appeals from an adverse jury verdict rendered in bellwether cases that are part of multidistrict litigation involving thousands of farmers. *In re Genetically Modified Rice Litig.*, MDL No. 1811 (U.S. Dist. Ct., E.D. Mo., E. Div., appeal filed July 28, 2010). Bayer AG indicates in its notice of appeal that the case "presents a number of substantial issues, including some of first impression in this Circuit."

Other than preemption, the issues Bayer AG apparently intends to raise include (i) whether the trial court misinterpreted U.S. Department of Agriculture regulations; (ii) whether the Economic Loss Rule bars plaintiffs' claims; (iii) whether the trial court properly exercised jurisdiction over Bayer AG, "a German holding company"; and (iv) whether the trial court's evidentiary rulings and jury instructions were in error.

The \$1.5 million verdict at issue in the appeal was rendered in favor of two Arkansas farmers and a Mississippi farming company. The awards were apparently based on the number of acres planted and how the contamination affected each farmer. When the contamination became known in 2006, a number of countries immediately imposed restrictions on U.S. rice exports, which caused a dramatic drop in the demand and price for all U.S. long-grain rice. A plaintiffs' attorney was quoted as saying, "The EU is by and large gone as a market for American long-grain rice farmers. They're not importing anywhere near what they were, and that's been the biggest and longest lasting effect from the contamination." See *Product Liability Law* 360, July 29, 2010.

### **GM Maize Prohibited by Court Order in Brazil**

A judge from the Curitiba Environment Court in Brazil has reportedly prohibited Bayer from marketing Liberty Link maize, a crop genetically modified (GM) to be herbicide-resistant, anywhere in the country. According to a news source, the court took the action due to the absence of any plan to monitor the crop post-release or any studies about the potential effects of the technology on regional biomes, i.e., distinct ecological communities of plants and animals.

If Bayer fails to immediately suspend the marketing, planting, transportation, import, or disposal of its GM maize, the company will apparently be fined R\$50,000 per day. The ruling came in a class-action lawsuit filed by several Brazilian non-governmental organizations, including AS-PTA and Terra de Direitos.

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The court also annulled the government's approval of the crop's commercial release and ordered the National Biosafety Technical Commission, which is responsible for approving the release of GM crops in Brazil, to ensure access to GM release procedures and the public dissemination of all non-secret information. See *GMWatch.org*, July 28, 2010; *LEISA's Farm Blog*, July 29, 2010.

### OTHER DEVELOPMENTS

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#### American Farm Bureau Censures EU for GM Crop Moratorium

The American Farm Bureau Federation (AFB) has issued a policy [statement](#) urging the Office of the U.S. Trade Representative (USTR) to "initiate a retaliation process" against the European Union over its de facto moratorium on genetically modified (GM) crops. Despite a 2006 World Trade Organization ruling that found fault with EU approval procedures for GM crops, the bloc has allegedly failed to implement "a timely and predictable regulatory process," resulting in "substantial damage" to U.S. agriculture. Although AFB initially agreed to suspend formal action in favor of normalizing trade, the industry group has since reversed that decision. According to AFB, "If the EU does not immediately begin to make timely, science-based regulatory decisions on pending and future applications, soybean exports also are at serious risk." See *AFB Press Release*, July 26, 2010.

Meanwhile, the European Commission (EC) recently approved six GM corn varieties via "the usual and standard" authorization procedure, which cleared the crops for importation, processing, and food and feed uses, but not for cultivation. In a July 28, 2010, statement, the commission noted that all submissions, including a renewal for insect-resistant Bt11 maize, received "a positive safety assessment from the European Food Safety Authority." Made in the absence of a member state consensus, the EC authorizations are reportedly valid for 10 years, "and any products produced from this GM maize will be subject to the EU's strict labeling and traceability rules."

#### Conference to Examine Marketing Obesity Prevention

DTC Perspectives Inc. has [announced](#) the 2010 Marketing Disease Prevention in America (MDPA) Conference, which will discuss how health care marketing can effectively address obesity prevention. Slated for October 19-21 in Atlanta, Georgia, the conference is designed for advertisers, health and wellness marketers, media representatives, pharmaceutical marketers, public health advocates, and those in the food, beverage and weight loss industries.

MDPA will provide participants with information on the increasing prevalence of obesity; the latest legislative, regulatory and voluntary efforts to limit food and beverage marketing; consumer behaviors and attitudes toward healthy living; the role of retailers and manufacturers in preventing obesity; and the impact of new technologies on public health. Speakers will include David Kessler, former commissioner of the Food and Drug Administration, as well as representatives from the American Beverage Association, Centers for Disease Control and Prevention, National Action Against Obesity, and Trust for America's Health.

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**MEDIA COVERAGE**

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**Elizabeth Kolbert, "The Scales Fall: Is there any hope for our overfished oceans?,"  
*The New Yorker*, August 2, 2010**

In this literature review, *The New Yorker's* Elizabeth Kolbert recounts the decline of bluefin tuna and other aquatic species due to overfishing, technological advances and lukewarm governance by authorities like the International Commission for the Conservation of Atlantic Tunas (ICCAT). According to Kolbert, the world passed "the point of what might be called 'peak fish'" in the late 1980s, when the global catch topped out at 85 million tons. "For the past two decades, the global catch has been steadily declining," she warns. "It is estimated that the total take is dropping by around five hundred thousand tons a year."

Kolbert thus turns to several books on aquatic ecosystems and ocean sustainability to explain the confluence of cultural, historical and technological factors that have brought whole fisheries to the brink of extinction. To this end, she trawls such watery tomes as (i) *Saved by the Sea: A Love Story with Fish* (David Helvarg); (ii) *Managed Annihilation: An Unnatural History of the Newfoundland Cod Collapse* (Dean Bavington); (iii) *Four Fish: The Future of the Last Wild Food* (Paul Greenberg); (iv) *From Abundance to Scarcity* (Michael Weber); (v) *Five Easy Pieces: How Fishing Impacts Marine Ecosystems* (Daniel Pauly); and (vi) *The Unnatural History of the Sea* (Callum Roberts).

Kolbert concedes, however, that the plight of bluefin tuna has at least drawn international attention to "the sorry state of ocean life." She particularly notes new efforts to dedicate some waters as "marine protected areas" and to establish new regulatory mechanisms like "individual transferable quotas," which incentivize sustainability by granting fishermen a marketable stake in their catches. In addition, other ecologists have evidently proposed "smart aquaculture" solutions that do not use wild fish as feed sources. "Just when things seem bleakest," writes Kolbert, "hope—dolphinlike—swims into the picture."

**SCIENTIFIC/TECHNICAL ITEMS**

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**Researchers Find BPA in Cash Register Receipt Paper**

Two recently released studies have purportedly found high concentrations of bisphenol A (BPA) in the thermal paper used by many retailers to print cash register receipts. Researchers with the Warner Babcock Institute for Green Chemistry in Massachusetts tested 10 blank cash register receipts from Boston-area businesses and found some had BPA concentrations as high as 19 mg on a 12-inch long receipt. Ted Mendum, et al., "Concentration of bisphenol A in thermal paper," *Green Chemistry Letters and Reviews*, July 28, 2010. They suggest that businesses avoid any potential health risks by using BPA-free receipt paper.

The Environmental Working Group (EWG) also apparently studied BPA concentrations in cash register receipts, submitting 36 samples from fast food restaurants, large retailers, grocery stores, gas stations, and post offices to a lab for testing.

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According to EWG, 40 percent of the samples had high BPA levels, in some instances 250 to 1,000 times greater than levels found in canned foods, baby bottles and infant formula. EWG could not say what fraction of the BPA on cash register receipts might be absorbed through the skin, but it did say that its presence could be of concern to retail workers who handle hundreds of receipts each day. "Federal data analyzed by EWG shows that retail workers carry an average of 30 percent more BPA in their bodies than other adults."

EWG reports that retailers use thermal paper because the BPA and dye coatings allow them to print receipts without using ink. In addition to calling for retailers to switch to BPA-free alternatives, EWG advises consumers to avoid allowing infants and children to handle receipts, keep saved receipts in a separate envelope, wash hands thoroughly after handling receipts and before preparing and eating food, and refrain from recycling receipts and other thermal paper as BPA residues will "contaminate recycled paper." A coin rubbed on a receipt will reveal whether it is thermal paper because the heat of the friction will apparently discolor thermal but not conventional paper. See *Environmental Working Group Featured Article*, July 27, 2010.

### Obesity Eclipses Tobacco as No. 1 Public Health Priority

A recent editorial in *The New England Journal of Medicine* has warned that health care reform, rising medical costs and childhood obesity have overtaken tobacco as the top public health priorities, even though smoking "remains by far the most common cause of preventable death and disability in the United States." Titled "Don't Forget Tobacco," the opinion piece claims that federal, state and private efforts to reduce smoking "have seen their assets dwindle or their priorities change" as obesity comes to dominate the discourse. "Lack of insurance, childhood obesity and tobacco use are very different public health challenges, requiring different solutions. All three threaten the most vulnerable Americans," opine the authors. "By assuming that the tobacco war has been won, we risk consigning millions of Americans to premature death."

Meanwhile, a July 27, 2010, *New York Times* article fleshes out this trend, tracking the dollars diverted from anti-tobacco campaigns to address childhood obesity. According to the *Times*, the Obama administration has "awarded more funds to fight obesity than tobacco through two big new money sources for preventative health," the economic stimulus package and health care reform legislation. Totalling \$1.15 billion, this funding apparently sets aside \$200 million "for tobacco-use prevention, but much more to grapple with obesity."

Although the inequity has drawn criticism from anti-tobacco activists, it apparently mirrors state-level decisions to cut smoking cessation programs and redirect tobacco taxes into other public health efforts. Moreover, private foundations have followed suit, with the Robert Wood Johnson Foundation (RWJF) purportedly pledging to spend \$500 million in five years to tackle childhood obesity, a sum comparable to the \$700 million it spent taking on tobacco companies. "When we made the commitment to spend \$500 million in obesity, we made the commitment to see if we couldn't do for childhood obesity what we did in tobacco," RWJF Senior Vice Present James Marks was quoted as saying.

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### CMAJ Editorial Urges Energy Drink Regulation

"Caffeine-loaded energy drinks have now crossed the line from beverages to drugs delivered as tasty syrups," opines a July 26, 2010, *Canadian Medical Association Journal* editorial, which recommends "strict regulations" and warning labels comparable to those required for caffeine tablets. According to the authors, these sweetened beverages pose a unique health risk to adolescents, 73 percent of whom reported consuming at least 100 mg of caffeine per day, and college students who "often mix energy drinks with alcohol, a potentially hazardous combination because the high levels of caffeine can mask the perception—but not the consequences—of acute alcohol intoxication." Moreover, claims the editorial, these products "are often targeted toward children and youth through carefully designed advertising campaigns as well as sponsorship of events such as snowboarding and skateboarding competitions."

The editors thus call for "government-mandated restrictions on labeling, sales and marketing, or self-imposed industry standards with clear labeling accompanied by public education." They also back a moratorium on all energy drink advertising that targets youth. "Should our minister of health encounter obstacles because of an antiquated Food and Drug Act, she will have even greater cause to boost her energy toward drafting new legislation in this area," they conclude.

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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.

