

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

Senate Bill Would Eliminate Non-Therapeutic Use of Antibiotics in Animal Feed

A bipartisan group of senators has introduced a bill ([S. 1211](#)) aimed at phasing out routine use of antibiotics in food-producing animals. Spearheaded by U.S. Senator Dianne Feinstein (D-Calif.), the Preservation of Antibiotics for Medical Treatment Act (PAMTA) is identical to a House bill (H.R. 965) introduced earlier this year by U.S. Representative Louise Slaughter (D-N.Y.), who has championed such legislation since 2007.

PAMTA "addresses the rampant overuse of antibiotics in agriculture that creates drug-resistant bacteria, an increasing threat to human beings," Feinstein noted in a press release. The legislation would also (i) "require new applications for animal antibiotics to demonstrate (that) the use of the antibiotic will not endanger public health" and (ii) "not restrict the use of antibiotics to treat sick livestock or to treat pets." The bill's provisions would limit agricultural use of seven types of antibiotics identified by the Food and Drug Administration as "critically important in human medicine to ensure that antibiotic-resistance is not inadvertently accelerated," Feinstein said.

"The effectiveness of antibiotics for humans is jeopardized when they are used to fatten healthy pigs or speed the growth of chickens," she said. "This is a basic food safety initiative that would phase out the misuse of these drugs so that food in supermarkets across America will not spread strains of drug-resistant bacteria." See *Press Release of U.S. Senator Dianne Feinstein*, June 17, 2011.

HHS Inspector General Critical of FDA Recall System for Imported Food

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (IG) has issued a June 21, 2011, [report](#) criticizing the Food and Drug Administration's (FDA's) imported food recall guidance as "not adequate to ensure the safety of the nation's food supply because it was not enforceable." According to the audit, which covered the period from July 1, 2007, through June 30, 2008, "FDA oversaw 40 Class I recalls of imported food products

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contaminated with pathogens and other harmful substances that can cause serious illnesses." After reviewing 17 of those recalls, the IG concluded that firms (i) "did not promptly initiate recalls," (ii) did not submit viable recall strategies, (iii) "did not issue accurate and complete recall communications to their consignees," and (iv) "did not submit timely and complete recall status reports."

The report also faults FDA for the inconsistent application of its own monitoring procedures, including the agency's failure to conduct firm inspections and complete audit checks, promptly issue notification letters to consignees, and verify the proper disposal of recalled products. The report urges FDA to comply with its own guidance in the future, as well as consider the audit when implementing new strategies under the Food Safety Modernization Act (FSMA), which gives the agency mandatory recall authority.

Meanwhile, FDA has since unveiled "a new strategy to meet the challenges posed by rapidly rising imports" in a [special report](#) titled "Pathway to Global Product Safety and Quality." While praising expanded overseas inspection and cooperation programs as well as FDA's new powers under FSMA, the report warns that the agency "does not—nor will it—have the resources to adequately keep pace with the pressures of globalization." For example, notes the report, FSMA directs FDA "to inspect at least 600 foreign food facilities within the next year and double those inspections every year for the next five," a goal that will be impossible for the agency to meet "without a substantial increase in resources or a complete overhaul in the way it operates."

FDA is proposing transforming itself over the next decade "from a domestic agency operating in a globalized world to a truly global agency fully prepared for a regulatory environment in which product safety and quality know no borders." This transformation will evidently emphasize "an international operating model that relies on enhanced intelligence, information sharing, data-driven risk analytics, and the smart allocation of resources through partnerships." To achieve these results, FDA plans to (i) "assemble global coalitions of regulators dedicated to building and strengthening the product safety net around the world"; (ii) "develop a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets"; (iii) "expand its capabilities in intelligence gathering and use, with an increased focus on risk analytics and thoroughly modernized IT capabilities"; and (iv) "effectively allocate agency resources based on risk, leveraging the combined efforts of government, industry, and public- and private-sector third parties."

"FDA regulated imports have quadrupled since 2000," FDA Commissioner Margaret Hamburg said in a June 20, 2011, news release. "The FDA and our global regulatory partners recognize this new reality and realize we must work proactively and collaboratively to address the challenges we face. The

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FDA must further collaborate and leverage in order to close the gap between our import levels and our regulatory resources. This report is an important step in ensuring we are able to fulfill our critical public health mission."

Advocacy Group Urges OIRA to Allow BPA Listing Under TSCA

Scholars with the Center for Progressive Reform have written a [letter](#) to Office of Information and Regulatory Affairs (OIRA) Administrator Cass Sunstein asking that OIRA conclude its review of the proposed listing of bisphenol A (BPA) under the Toxic Substances Control Act (TSCA). Stating that the review has been "delayed far longer than Executive Order guidelines allow," the June 20, 2011, letter was apparently prompted by an earlier U.S. Chamber of Commerce letter that urged OIRA to suspend the Environmental Protection Agency's (EPA's) consideration and initiation of all TSCA listings.

The center scholars note that the listing, which includes "chemicals of concern," informs the public about EPA's current thinking about these chemicals and could lead to a notice of proposed rulemaking (NPRM) that would invite public comment. According to the letter, the Chamber pays "lip service" to such transparency, but "its goal is to head off issuance of an NPRM." The scholars claim, "The Chamber is attempting to squelch, rather than advance, debate on these important issues. If the Chamber believes that EPA's science is flawed, it should make those arguments in a formal public comment process. The Chamber's current tactic serves only to generate more work for both OIRA and EPA while obfuscating and delaying the important health and safety information on which EPA seeks public input."

According to the letter, BPA "is used in the manufacture of many consumer products and has been shown to be a reproductive and developmental toxicant." The scholars observe that a TSCA listing requires less evidence than a rulemaking and takes issue with the Chamber's contention that EPA lacks the legal authority to list or consider listing chemicals in the absence of the more rigorous evidentiary support required for a rule. The Chamber was apparently concerned about a TSCA listing forming the basis for potential tort actions or advocacy group litigation, to which concern the scholars respond, "[P]lacement on the chemicals of concern list provides potential litigants with no additional statutory grounds for relief. Rather, such placement indicates to both the public and industry that EPA believes these particular chemicals warrant further study and investigation because of their potential effects."

IOM Issues Report on Early Childhood Obesity

The Institute of Medicine (IOM) has released a June 23, 2011, [report](#) titled *Early Childhood Obesity Prevention Policies* that recommends "evidence-based strategies... to promote healthy weights in children from birth to age 5." According to IOM, "almost 10 percent of infants and toddlers carry excess

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weight for their length, and slightly more than 20 percent of children between the ages of two and five already are overweight or obese.” IOM urges health care professionals to measure weight and length or height at every routine pediatric visit “in a standardized way, using the most current growth charts from the World Health Organization and the Centers for Disease Control and Prevention,” as well as determine which patients are at the highest risk of obesity based on their rate of weight gain, parents’ weight status and whether their “growth measurements [are] at or above the 85th percentile curves.”

IOM also advises parents and caretakers to encourage healthier behaviors “associated with a reduced risk of excessive weight gain over time in younger children,” such as increasing physical activity and sleep duration, and limiting screen time. In addition, the report cautioned that caretakers “should pay careful attention to how they feed children,” noting that “children’s food preferences can develop as early as infancy.” It further recommends that meals provided by child care facilities reflect “the meal patterns in the federal Child and Adult Care Food Program to ensure that children have access to healthy foods and age-appropriate portions.”

“Currently, the national government dietary recommendations—known as the *Dietary Guidelines for Americans*—do not include recommendations for children under the age of two,” concludes the IOM report. “Such guidelines are necessary for setting nutrition recommendations for public and federal programs, and therefore, the committee recommends that the Departments of Agriculture and Health and Human Services (HHS) establish dietary guidelines for children from birth to age two.” See *IOM Report Brief*, June 23, 2011.

LITIGATION

FSIS Finds Unapproved Drugs in Veal, Seeks Permanent Injunction Against Producer

Alleging that tissue samples from Virtue Calves veal sold for slaughter since 1995 have contained illegal drug residues, the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) has sued the producer and its owners in a California federal court seeking an order to stop the defendants from selling food containing an unsafe new animal drug, deemed adulterated under federal law. *United States v. Virtue*, No. 11-902 (U.S. Dist. Ct., E.D. Cal., Sacramento Div., filed June 22, 2011).

According to the complaint, FSIS identified in defendants’ veal calves desfur-roylceftiofur, gentamicin, neomycin, penicillin, tetracycline, sulfadiazine, and sulfamethoxazole. While the latter two drugs have never been approved for use on any animals, the remaining drugs have no legal tolerances approved for use in calves, according to FSIS. The agency contends, “Defendants have a long history of illegal drug residues in the edible tissues of the veal calves

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they sell for use as human food.” The defendants were purportedly warned repeatedly in writing about their failure to comply with the law and about poor record-keeping practices. Despite these warnings, “defendants persist in introducing adulterated food into interstate commerce.” The complaint also alleges that defendant John Virtue stated that he was unwilling to correct the illegal practices thus creating “a cognizable danger of recurrent violation and an intolerable risk to the public health.”

The government seeks permanent injunctive relief and the costs of investigation and suit. Specifically, FSIS seeks to enjoin the defendants “from directly or indirectly violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, any article of food consisting of animals and their edible tissues that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) or 342(a)(4).” FSIS also seeks an order that the defendants “cease introducing or delivering for introduction into interstate commerce any article of food within the meaning of 21 U.S.C. § 321(f), consisting of animals and their edible tissues, unless and until defendants bring their operations into compliance with the law to the satisfaction of FDA.”

Class Action Alleges Inflated Prices for Home-Delivered Groceries

A Pennsylvania resident has sued Safeway, Inc. on behalf of a putative nationwide class of consumers who placed online orders for the home delivery of groceries and were allegedly charged about 10 percent more for each item in addition to a delivery fee. *Rodman v. Safeway, Inc.*, No. 11-03003 (U.S. Dist. Ct., N.D. Cal., filed June 17, 2011). According to the complaint, Safeway assures consumers that they will pay the same prices for home-delivered goods that they would pay in the store. An “FAQ” section of Safeway’s Website allegedly states “You will be charged the prices charged in the store on the day your order is picked and delivered.”

Believing that the prices charged for his initial online order were high, the plaintiff apparently compared the prices for his second order with in-store prices and found that prices for 10 of 14 items included the “secret” add-on cost. Alleging breach of contract, violations of California’s Consumers Legal Remedies Act, false and misleading advertising, and unlawful business acts and practices, the plaintiff seeks an injunction to stop the grocery from continuing to engage in the alleged unlawful practices; restitution and disgorgement; an accounting, statutory, general, special, and exemplary damages; attorney’s fees; costs; and interest. The plaintiff alleges damages exceeding \$5 million.

Suit Alleges Burrito Salt and Calorie Counts Were Misrepresented

A woman who claims she consumed Ramona’s burritos believing they were low in calories and sodium, has filed a putative class action alleging that the company mislabeled its products and that the burritos were much higher

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in calories and sodium than individual labels in and before 2006 and bulk labels indicated. *Solomon v. Ramona's Mex. Food Prods., Inc.*, No. BC463914 (Cal. Super. Ct., Los Angeles County, Cent. Dist., filed June 17, 2011).

Concerns about obesity and an inner ear disorder exacerbated by high-sodium intake allegedly led the plaintiff to purchase and consume one to two burritos daily beginning in 2006. At that time, single and multiple packages purportedly indicated that each burrito contained 170 calories and 270 mg sodium. Individual burritos were allegedly re-labeled in 2010 to 340 calories and 580 mg sodium, while the bulk packaging continued to carry the lower values. According to the complaint, "Plaintiff is informed and believes each BURRITO always actually contained 340 calories and 580 mg sodium despite Defendant's advertising and mislabeling that it contained half that amount."

Seeking to certify a class of California consumers, the plaintiff alleges violation of the Consumers Legal Remedies Act, fraudulent and deceptive practices, unlawful and unfair practices, false advertising, breach of implied and express warranties, and unjust enrichment. She seeks general and special damages, restitution, disgorgement, injunctive relief, attorney's fees, and costs.

Farm Workers Allege Hostile Work Environment Created to Certify Farm for Foreign Workers

African-Americans who briefly worked at a North Carolina farm in 2010 allege that they were subjected to a hostile work environment and discriminatory job conditions so the employer could obtain certification under a Department of Labor (DOL) program that allows farmers to hire seasonal foreign workers when U.S. workers are not available and hiring foreign workers will not adversely affect the wages and working conditions of similarly employed U.S. workers. *Fulford v. Alligator River Farms, LLC*, No. 11-00103 (U.S. Dist. Ct., E.D.N.C., E. Div., filed June 20, 2011). The Equal Employment Opportunity Commission allegedly issued the plaintiffs a letter of determination relating to their claims.

According to the complaint, DOL certification requires that employers undertake specified efforts to recruit U.S. workers after the need for the services of foreign workers (referred to as H-2A workers) arises. Among other matters, the employer must submit a job, or clearance, order to the local state employment agency. The order must include job-related information including wages, working conditions, and productivity standards, and that the employer can request, but not require, workers to work on federal holidays and the Sabbath.

The plaintiffs allege that the defendant hired 56 H-2A workers from Mexico in 2009 and intended to rehire these workers in 2010. The plaintiffs allegedly began working for the defendant March 25, 2010, under the DOL certification procedures. They allege that they were assigned to plant broccoli but not

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provided with tools to do the job. They were allegedly subject to exhortation, correction, derogatory remarks, orders to speed up, and a daily changing standard of production. They also allege that the clearance order included an hourly wage specification but that they were left with the impression by supervisors that they would be paid on a piece rate. They purportedly worked on one side of the field while Mexican workers were on the other side of the field, and different, more favorable working conditions were allegedly accorded to the Mexican workers. All of the plaintiffs except one were either terminated by March 28 for failure to meet production requirements or quit "to avoid the humiliation of being 'cut.'" The final plaintiff was asked to work on a Sunday and terminated when he reported to work after going to church.

Alleging violations of their rights under the Migrant and Seasonal Agricultural Worker Protection Act (AWPA) and violations of their civil rights under Title VII, the plaintiffs seek declaratory and injunctive relief, as well as statutory damages of \$500 per person for each of the AWPA violations, compensation for non-pecuniary losses, punitive damages, costs, expenses, and interest.

Juicy Juice® Health Claims Class Action Appealed to Ninth Circuit

Plaintiffs alleging that they were misled by the purportedly unsubstantiated claims Nestlé USA Inc. made about its Juicy Juice® Brain Development and Immunity products have filed an appeal to the Ninth Circuit Court of Appeals from a district court order dismissing their consolidated class action. *Chavez/Bonsignore v. Nestlé USA, Inc.*, No. 09-9192 (U.S. Dist. Ct., C.D. Cal., W. Div., notice of appeal filed June 22, 2011). The lower court apparently gave the plaintiffs two opportunities to state a cognizable claim under California's unfair competition and false advertising laws before dismissing the action in May 2011. According to the court, the plaintiffs' second amended complaint "as with previous versions of the plaintiffs' pleading in this action, is that it lumps together distinct products and multiple factual allegations without giving the reader a clear sense of which allegations support which specific claims." See *Law360*, June 23, 2011.

Consumers Abandon Suits Alleging Misleading Deli Meat Labeling

A federal court in Florida has dismissed without prejudice two putative class actions against Kraft Foods alleging that the packaging for its Oscar Mayer® deli meat products misleads consumers about their actual fat content. *McDougal v. Kraft Foods, Inc.*, No. 11-61202; *Rogel v. Kraft Foods, Inc.*, No. 11-61281 (U.S. Dist. Ct., S.D. Fla., decided June 23, 2011). The plaintiffs filed voluntary dismissal notices in the cases, one of which is discussed in [Issue 396](#) of this *Update*. A company spokesperson reportedly indicated when the *McDougal* complaint was filed that the allegations were unfounded. See *Law360*, June 23, 2011.

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Final Court Approval Given to *Trans* Fat Class Settlement

A federal court in California has approved a non-monetary settlement of a class action alleging that Unilever U.S., Inc.'s health-related claims for margarine products containing *trans* fats were false and misleading. *Rosen/Red v. Unilever U.S., Inc.*, Nos. 09-02563, 10-00387 (U.S. Dist. Ct., N.D. Cal, San Francisco Div., decided June 21, 2011). Additional information about the settlement appears in [Issue 398](#) of this *Update*. Unilever denied any wrongdoing but agreed to reformulate its stick and spread products to remove partially hydrogenated vegetable oils. A number of excluded, individual claims against the company will not be affected by the settlement.

Insurers Claim No Duty to Defend Four Loko Lawsuits

Insurance companies with policies covering Phusion Projects, Inc., which makes the caffeinated alcohol beverage Four Loko®, have filed a summary judgment motion in their declaratory judgment action against the company, claiming that a policy exclusion unambiguously frees them from defending or indemnifying the beverage maker. *The Netherlands Ins. Co. v. Phusion Projects, Inc.*, No. 11-1253 (U.S. Dist. Ct., N.D. Ill., E. Div., filed June 22, 2011). The companies contend that their commercial general liability and commercial umbrella policies have liquor liability exclusions that apply to actions pending in Florida, Illinois and New Jersey alleging that "Four Loko caused a particularly dangerous kind of intoxication" and seeking monetary damages for deaths and injuries. Details about a similar insurance coverage lawsuit involving other insurers appear in [Issue 396](#) of this *Update*.

OTHER DEVELOPMENTS

Food Nutrition Labeling and Youth Marketing Continue to Generate Comment

Calling for the food industry to put voluntary nutrition labeling initiatives on hold, Kelly Brownell, director of Yale University's Rudd Center for Food Policy and Childhood Obesity, has co-authored an opinion piece about front-of-package nutrition labeling in *The New England Journal of Medicine*. Among other matters, the article recommends that industry leaders await an Institute of Medicine report with nutrition labeling recommendations due for release this fall.

Brownell suggests that the nutrition keys system under development by the industry may confuse consumers by "including so many symbols" and allowing companies the discretion to change the nutrients listed. According to the article, "The most notable deficiency of the industry system is its lack of a science-based, easily understood way to show consumers whether foods have a high, medium, or low amount of a particular nutrient." Brownell

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contends that the traffic-light system used in Great Britain is much clearer. *See NEJM*, June 23, 2011.

In a related development, National Public Radio recently included a segment on its "Morning Edition" program about the government's proposal to reduce the amount of "junk food" advertising to which children are exposed. The program focused on whether the proposed guidelines should include teens or simply focus on children younger than 12. Briefly mentioned were new methods of advertising by means of social media, such as cell phone messages and online games, of which teens are "heavy consumers." Reporter Yuki Noguchi noted that the Interagency Working Group, comprising the Federal Trade Commission, Food and Drug Administration, U.S. Department of Agriculture, and the Centers for Disease Control, seeks comments on the proposal by July 14, 2011. *See NPR*, June 22, 2011.

EWG Issues Updated Guide to Pesticides in Produce

The Environmental Working Group (EWG) has [released](#) its "2011 Shopper's Guide to Pesticides in Produce" updating "pesticide loads" on 53 conventional fruits and vegetables. EWG analysts reportedly reviewed U.S. Department of Agriculture and Food and Drug Administration data from 2000 to 2009 that detailed the amounts and types of pesticides found on sampled produce, most of which was washed and peeled before testing.

Providing "Dirty Dozen" and "Clean 15" lists, the guide replaces celery with apples as the worst offender, with pesticides found on 98 percent of more than 700 apples tested. Cilantro was tested for the first time since EWG started tracking data in 1995, with 33 unapproved pesticides showing up on 44 percent of samples—"the highest percentage of unapproved pesticides recorded on any item" since tracking began, according to EWG.

EWG claims that consumers who eat five fruits and vegetables daily from its clean list can lower their pesticide intake by 92 percent. "Pesticides are toxic," said Sonya Lunder, an EWG senior analyst. "They are designed to kill things and most are not good for you. The question is, how bad are they?" *See EWG Press Release*, June 13, 2011.

CEO Reports Conflicts of Interest Among EFSA Food-Additive Experts

The Corporate European Observatory (CEO) has published a [report](#) accusing European Food Safety Authority (EFSA) food-additive experts of concealing conflicts of interest and industry ties. CEO claims that 11 out of 20 experts on EFSA's Panel on Food Additives and Nutrient Sources in Food (ANS) "have a conflict of interest, as defined by the Organization for Economic Cooperation and Development," which states that such conflicts arise when an individual or corporation "is in position to exploit his or their own professional or official capacity in some way for personal or corporate benefit," whether or not

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an unethical or improper act results. The report also alleges that four ANS members have “failed to declare active collaborations with the food-industry funded think-tank and lobby group, the International Life Sciences Institute (ILSI).”

In particular, CEO faults EFSA for failing to adopt a “red list” similar to the one used by the European Medicines Agency that bars consultants with specific industry ties from serving as experts. The group also criticizes EFSA’s expert nomination process for favoring those with food company connections, and argues that the ANS panel’s reliance on unpublished, industry-sponsored studies has undermined public confidence in its recommendations. “Stricter rules on conflicts of interest and fundamental changes in the way EFSA opinions are shaped are urgently needed. . . . New, efficient EFSA rules on conflicts of interest should outlaw any consultancy and advisory work, paid or unpaid, not only for individual companies, but also for industry associations and think tanks predominately funded by the food industry,” the report concludes.

In a related development, a June 21, 2011, *ABA News* report also examines the purported influence of food interests on the science of nutrition, citing several U.S. researchers critical of industry-funded studies and projects. The article follows the career of David Allison, director of the University of Alabama at Birmingham’s National Obesity Research Center, who was forced to resign as incoming president of the Obesity Society after receiving payment from the New York Restaurant Association to file an affidavit in its case against New York City’s menu-labeling laws. It also notes that large institutions, such as the Children’s Hospital of Philadelphia and American Association of Family Physicians, have received funds from soft drink companies.

“Critics say Allison is part of a concerted effort by big food to co-opt scientists not only by funding their research but by offering them lucrative speaking and consulting deals, in an effort to confuse U.S. families about the health effects of popular food products,” the article claims. “Such tactics, critics say, are similar to those once used by Big Tobacco.”

CHW Article Focuses on “Astroturf” Food Advocacy

Corporations and Health Watch (CHW) has published a June 22, 2011, article claiming that food and beverage companies frequently deploy a public relations strategy known as “astroturfing” to disguise “corporate-driven” propaganda as “bottom-up, grassroots community activism.” Titled “Corporations, the Public’s Health and Astroturf,” the article specifically warns consumers against “cloaked Websites” that “intentionally disguise authorship in order to put forward a political agenda,” as well as against front groups funded and organized by industry interests. In particular, CHW singles out Americans Against Food Taxes as a group that advertises itself as “a coalition of concerned citizens” who oppose the soda tax, but which is purportedly

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funded by the American Beverage Association and includes as members “the world’s largest food and soft drink manufacturers.”

“In some ways, these sorts of propaganda efforts are not new,” opines the article, which likens astroturfing to legislative efforts led by the National Smokers Alliance in the 1990s. “This kind of sophistry, ‘it’s not Astroturf, it’s just organizing,’ is a common argument made by those trying to defend such tactics.”

MEDIA COVERAGE

Charles Siebert, “Food Ark,” *National Geographic Magazine*, July 2011

“[T]he movement to preserve heirloom varieties goes way beyond America’s renewed romance with tasty, locally grown food and countless varieties of tomatoes. It’s also a campaign to protect the world’s future food supply,” writes *National Geographic*’s Charles Siebert in this July 2011 article discussing the dangers of homogeneity when it comes to commercial agriculture and highlighting the work of modern seed banks. Estimating that “we have lost more than half of the world’s food varieties over the past century,” Siebert claims that lack of biodiversity has left the current crop of high-yield vegetables and grains increasingly susceptible to diseases such as Ug99, “a virulent and fast-mutating strain” of *Puccinia graminis*, or wheat stem rust.

“Roughly 90 percent of the world’s wheat is defenseless against Ug99,” writes Siebert, who warns that a significant humanitarian crisis is now inevitable, especially in countries introduced to industrialized agriculture during the green revolution. “Given the added challenges posed by climate change and constantly mutating diseases like Ug99, it is becoming ever more urgent to find ways to increase food yield without exacerbating the genetic anemia coursing through industrialized agriculture’s ostensible abundance. The world has become increasingly dependent upon technology-driven, one-size-fits-all solutions to its problems. Yet the best hope for securing food’s future may depend on our ability to preserve the locally cultivated foods of the past.”

SCIENTIFIC/TECHNICAL ITEMS

Critique of Study Linking Obesity to Social Networks Buried in Statistical Journal

In 2007, a study published in the *New England Journal of Medicine* generated widespread media coverage for its claims that obesity can be transmitted via social networks, such as friendship, familial relationship or marriage. Details about the study appear in [Issue 225](#) of this *Update*. The authors wrote additional papers on other personal characteristics, including smoking cessation,

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happiness and loneliness, concluding in each that a process of contagion or infection within the social network transmits the characteristics and that the transmission occurs up to three steps in the network, thus providing evidence of a “three degrees of influence” rule of social network contagion.”

A new study published in a lesser known journal, contends that the authors’ statistical analyses do not support their conclusions. [Russell Lyons, “The Spread of Evidence-Poor Medicine via Flawed Social-Network Analysis,” *Statistics, Politics, & Policy*, Vol. 2, Issue 1 \(2011\)](#). According to Russell Lyons, an Indiana University mathematician, the 2007 paper was based on insufficient attention to assumptions and misinterpretation of results not only by the authors, but also by its reviewers. He points to a corollary illustrated by this inadvertent misuse of statistics, i.e., “that top journals do not serve as rigorous judges of quality, due to lack of statistical competence.” Lyons concludes that “we need to improve our statistics education” and, given the difficulty he had getting his paper reviewed and published due to an apparent distaste for critiques, recommends the establishment of a journal specifically devoted to critiques.

At the core of Lyons’s critique is that the 2007 study authors analyzed associations “calculated from statistical models whose parameters are estimated by using the observational data.” They argued that the associations were not just associations, but measured causal effects, by ruling out the equally plausible possibilities, according to Lyons, that the associations were a result of “homophily (or selection), which is the fact that people tend to associate with others like themselves, and a shared environment (also called ‘confounding’ or ‘contextual influences’ by other researchers).” Lyons also points to a lack of statistical significance to the directional estimates in the papers and questionable assumptions made in the use of statistical models.

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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.

