

## FOOD & BEVERAGE LITIGATION UPDATE

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## LEGISLATION, REGULATIONS AND STANDARDS

### FDA Report Focuses on Improved Retail Food Safety

The U.S. Food and Drug Administration (FDA) has released a 10-year [tracking report](#) that calls for increased focus on food safety practices in retail food establishments.

A companion [2009 retail food report](#) highlights the need for certified food protection managers to help achieve higher food-safety compliance levels.

The 1998-2008 tracking report, which studied more than 800 retail food establishments in 1998, 2003 and 2008, focused on five key risk factors: (i) food from unsafe sources, (ii) poor personal hygiene, (iii) inadequate cooking, (iv) improper holding of food (time and temperature), and (v) contaminated food surfaces and equipment. According to an FDA press release, "continued improvements are needed across the board" regarding personal hygiene, holding of food and food surfaces and equipment.

The 2009 report found that the presence of a certified food protection manager in full-service restaurants, delicatessens, seafood markets, and produce markets was correlated with "statistically significant higher compliance levels with food safety practices and behaviors" than facilities without one. According to FDA Deputy Commissioner for Foods Michael Taylor, the agency has also encouraged state, local and tribal regulatory agencies to adopt the FDA Model Food Code that recommends standards for management, personnel, food operations, equipment, and facilities to enhance retail food safety. "The key to food safety is prevention at every step from farm to table," Taylor said. "Food retail managers, like growers or processors, have a responsibility to reduce the risk of foodborne illness." See *FDA News Release*, October 22, 2010.

### EPA Science Advisors Issue Revised Report on Arsenic Assessment

The Environmental Protection Agency's (EPA's) Science Advisory Board has scheduled a [public teleconference](#) on November 22, 2010, to conduct a

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quality review of a draft board report that analyzes EPA's February 2010 toxicological review of inorganic arsenic.

The board forwarded its review comments to EPA Administrator Lisa Jackson on October 25. Among other matters, the draft comments note that EPA has only partially responded to its 2007 suggestions about factoring background dietary intake of inorganic arsenic into its "assessment of lung and bladder cancer risk associated with exposures to arsenic in drinking water." In this regard, the board recommends that EPA make "more transparent the scientific basis of the exposure assumptions used" and enhance "the rigor and transparency of the sensitivity analysis."

EPA's review, which apparently proposes a 17-fold increase in cancer potency from oral exposure to inorganic arsenic, has been developed under the Integrated Risk Information System (IRIS), and the agency is accordingly considering making the federal arsenic standards for drinking water more stringent. A number of congressional representatives and industry interests have written to the administrator to express their concerns. Republican lawmakers have, in fact, called on the agency to "suspend further work on the IRIS assessment of inorganic arsenic," contending that the agency must consider ongoing research and thoroughly evaluate all existing scientific data. They assert that small drinking water systems are still struggling to comply with standards developed under the Clinton administration.

Industry interests claim that "many aberrations from generally accepted public processes and procedures" have marked the development of the IRIS assessment. They contend that opportunity for public participation has been limited and that the Science Advisory Board work group participating in the project has not been provided whatever public comment was submitted. They also believe that comments by outside scientists have been ignored. Of most concern is that the agency appears to be rushing to judgment given the costs that apparently will be involved to reducing arsenic concentrations in drinking water and soil. *See InsideEPA.com, October 27, 2010.*

### Overseas FDA Food Safety Offices Topic of New GAO Report

The Government Accountability Office (GAO) has just released a [report](#) that discusses how the Food and Drug Administration's (FDA's) new overseas food safety offices are functioning and offers recommendations for enhancing strategic planning and developing a workforce plan "to help recruit and retain overseas staff." Titled "Oversees Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed," the report was prepared for the House Committee on Oversight and Government Reform.

According to the report, an FDA presence in foreign countries has improved the agency's ability to build relationships with stakeholders abroad, to inspect foreign facilities and provide limited food safety training to overseas

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counterparts. Still, with only 42 total staff covering China, Europe, India, Latin America, and the Middle East, resources are apparently stretched and FDA has had some challenges with staffing. Foreign language capabilities and the domestic reintegration of staff serving abroad have apparently posed some staffing obstacles.

### EC Opens Public Consultation on Nanomaterial Definition

The European Commission (EC) has [solicited](#) feedback on its proposed definition of the term “nanomaterial.” In response to a European Parliament request, the EC’s [draft recommendation](#) recognizes the need for a definition “at the global level, to serve as a basis also for EU regulation and implementing measures and instruments.”

The proposal defines a nanomaterial as that material which meets at least one of the following criteria: (i) it consists of particles with one or more external dimensions in the size range of 1 nanometer to 100 nanometers for more than 1 percent of their size distribution; (ii) it has internal or surface structures in one or more dimensions in the size range of 1 nanometer to 100 nanometers; or (iii) it has a specific surface area by volume greater than 60 square meters by per cubic centimeter, excluding materials consisting of particles with a size smaller than 1 nanometer. Comments may be electronically submitted to the EC by November 19, 2010.

### Washington State AG Continues Campaign to Ban Alcoholic Energy Drinks

Washington State Attorney General Robert McKenna has issued an October 25, 2010, [letter](#) to Food and Drug Administration (FDA) Commissioner Margaret Hamburg, alleging that a recent incident involving alcoholic energy drinks (AEDs) sent nine college students to emergency rooms with alcohol poisoning. According to the letter, “Once at the hospital, medical staff found the blood-alcohol levels of the impacted students ranged from .123 percent (legally drunk) to .35 percent—a lethal level of alcohol poisoning... The investigation concludes that the students—all under 21 years old—combined AEDs with other kinds of alcohol.”

Citing the October 8 [police report](#), McKenna has claimed that the affected students were drinking an AED manufactured by Phusion Projects, LLC, known as “Four Loko,” which contains 12 percent alcohol and “high doses of caffeine and sugar.” Moreover, the letter continues, “The frightening incident... is hardly unique. In fact, AEDs are sweeping college campuses... Twenty-three students at New Jersey’s Ramapo College were hospitalized in September after a drinking binge. Some, if not all, had consumed Four Loko.”

McKenna has apparently drawn attention to the incident as part of his effort to outlaw AEDs. In September 2009, he joined with 18 state attorneys

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general in urging FDA to review the safety of caffeinated alcoholic beverages. McKenna has also committed to pursuing a state ban if the agency does not act soon. "I want to reiterate my belief that AEDs do not comport with FDA guidelines and present a serious threat to public health and safety," he concludes in the letter, which requests an update on FDA's investigation. See *McKenna News Release*, October 25, 2010.

In response to the allegations Phusion Projects has cautioned against blaming one particular product, noting that Four Loko "is mentioned only twice in the 44-page police report," while "hard liquor, vodka, rum or other alcohol is mentioned at least 19 times; beer is mentioned at least 3 times; and illegal drugs or roofies are mentioned at least 14 times." As one company spokesperson was quoted as saying, "Alcohol misuse and abuse and under-age drinking are issues the industry faces and all of us would like to address. The singling out or banning of one product or category is not going to solve that. Consumer education is what's going to do it." See *Phusion Projects Press Release* and *The New York Times*, October 26, 2010.

### Baltimore Officials Issue Citation for Repeat *Trans* Fat Ban Violations

The Baltimore City Health Department has reportedly issued its first environmental citation for repeat violations of the city's *trans* fat ban. According to an October 25, 2010, press release, the department fined Healthy Choice \$100 after inspectors twice found the Lexington Market food vendor using "a margarine product with *trans* fat levels in excess of 0.5 grams per serving."

"Businesses can make it easier for people to live healthier lives by simply replacing the use of partially hydrogenated vegetable oil with a healthier alternative," Baltimore's health commissioner was quoted as saying. "While we are pleased with the high rates of compliance we've seen since the ban took effect, we will continue to sanction businesses that repeatedly fail to comply." See *City of Baltimore Health Department Press Release*, October 25, 2010.

## LITIGATION

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### *Pelman v. McDonald's Corp.*: No Class Certification for Obese Teens

A judge from the U.S. Court of International Trade, sitting by designation in a New York federal district court, has determined that the obesity-related claims filed in 2002 against McDonald's Corp. cannot be pursued as a class action. *Pelman v. McDonald's Corp.*, No. 02-7821 (U.S. Dist. Ct., S.D.N.Y., decided October 27, 2010). Essentially, the court found that individual causation issues predominated over common ones and that, as to any common issues, the plaintiffs had failed to show that the putative class was sufficiently numerous for the court to certify an issues class. A spokesperson reportedly indicated

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that the company was pleased with the decision, stating, “As we have maintained throughout these proceedings, it is unfair to blame McDonald’s for this complex social problem.”

Teenagers alleging obesity-related health problems claimed that they were misled by the fast food chain’s deceptive advertising into believing that the food could be consumed daily without any adverse health effects. They also claimed that the company (i) failed to disclose that some product ingredients and processing were “substantially less healthy than were represented to Plaintiffs,” and (ii) represented that it would provide nutritional brochures and information materials that were not adequately available at its restaurants. According to the court, these three claims, which alleged identical injuries—financial costs, false beliefs and obesity-related conditions—actually present a single cause of action under New York’s General Business Law (GBL).

The court determined that the only viable injuries that could be claimed under the GBL “are those related to the development of certain medical conditions.” Because all of the proposed experts “essentially agree that the presence of such causal connection, if any depends heavily on a range of factors unique to each individual,” i.e., in terms of “the extent of each plaintiff’s consumption and energy expenditure,” the claims fail the predominance test for class certification. The court elaborated, “because factual questions with regard to, at the very least, the nutritional composition of food products consumed by each plaintiff from sources other than Defendant’s facilities, as well as the level of regular physical activity engaged in by each plaintiff, predominate in the inquiry with respect to an essential element of Plaintiffs’ cause of action, this case is not appropriate for adjudication on a class-wide basis.”

Also requiring individualized proof, according to the court, was whether each plaintiff ate McDonald’s food because he or she “believed it to be healthier than it was in fact.” In this regard, the court agreed with McDonald’s, which pointed out “[a] person’s choice to eat at McDonald’s and what foods (and how much) he eats may depend on taste, past experience, habit, convenience, location, peer choices, other non-nutritional advertising, and cost, although [b]eliefs about nutrition may influence a person’s decision in some cases, [it will] not always [be the case].”

The plaintiffs also asked the court to certify an issue class “for a determination of Defendant’s liability for its deceptive conduct on consumers under [GBL] § 349.” While the court agreed that the affirmative product representations and the “omission of material information regarding the actual nutritional composition of Defendant’s products” could be evaluated on the basis of objective standards and thus fulfilled commonality, typicality, predominance, adequacy of representation, and superiority class action requirements, the court refused to certify the issues due to insufficient evidence of numerosity. The court

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stated, "Plaintiffs have not presented the court with any specific evidence that there are any other persons who had not yet reached the age of twenty-one as of August 2002, were exposed to McDonald's nutritional marketing scheme in New York during the years from 1985 until 2002, ate regularly at McDonald's, and subsequently developed the same medical conditions as Plaintiffs." The court also found that the plaintiffs had not submitted sufficient evidence from which these facts could reasonably be inferred. Thus, the court denied the motion for certification of an issue class.

Denying plaintiffs' request for additional class discovery, the court ordered the parties to consult and submit a revised scheduling order by November 29. News sources were unable to discuss the case with the plaintiffs' lead counsel; the case has already been appealed twice to the Second Circuit Court of Appeals. Under Federal Rule of Civil Procedure 23(f), the plaintiffs have 14 days to ask an appeals court to consider whether it will permit an appeal from the ruling. *See Bloomberg*, October 27, 2010.

### Challenge to California's Referendum Procedure Presented in *Amicus* Brief

According to a news source, an appellate lawyer in California has submitted an *amicus* brief to the Ninth Circuit Court of Appeals, claiming that the state's ballot initiative process, adopted 99 years ago, was improperly voted into law. He has asked the court to certify the question to the California Supreme Court. This issue arose in a case involving the validity of Proposition 8, a voter-approved ballot measure that banned same-sex marriage. A federal district court ruled that Proposition 8 violates the U.S. Constitution.

If the process that led to the adoption of Proposition 8 is ultimately overturned, it could call into question the validity of Proposition 65, which has required manufacturers and retailers to warn consumers if their products contain chemicals known to the state to cause cancer or reproductive harm. The state has been considering in recent months how to effectively apply the law to the food industry.

This is reportedly the first legal challenge ever mounted to California's initiative process. The *amicus* brief apparently argues that the legislature enacted the initiative process as "Senate Amendment 22" in 1911, but it should instead have approved the measure as a "revision" to the state constitution, thus requiring a supermajority vote in the House and Senate as well as a constitutional convention. *See Law.com*, October 28, 2010.

### Putative Class Alleges Breyers "All Natural" Ice Cream Contains Non-Natural Cocoa

A California resident has filed a putative class action against the company that owns the Breyers ice cream brand, alleging violations of consumer protection



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laws because its 23 chocolate-flavored products are labeled “All Natural” but also contain cocoa processed with alkali. *Denmon-Clark v. Conopco, Inc.*, No. 10-7898 (U.S. Dist. Ct., C.D. Cal., E. Div., filed October 20, 2010).

According to the complaint, “Breyers Ice Cream products containing alkalinized cocoa are processed with potassium carbonate which is a recognized synthetic substance.” While acknowledging that the Food and Drug Administration (FDA) does not directly regulate the use of the term “natural,” the plaintiff alleges that the agency has a policy that defines “the outer boundaries of the use of that term” and clarifies that “a product is not natural if it contains color, artificial flavors, or synthetic substances.”

The plaintiff alleges that FDA requires products made with an “alkalization” process to include the statement “Processed with alkali.” Breyers’ Website includes this information on its product ingredient lists. She also alleges that she purchased Breyers All Natural Chocolate Ice Cream about four times each year and believed that the product was “all natural and relied on this representation in making the purchase.” The plaintiff does not allege any personal injury from consuming the product.

Seeking to certify a statewide class of all consumers who purchased Breyers Ice Cream in the state since October 2006, the named plaintiff alleges unlawful, unfair and fraudulent business practices; false advertising and unjust enrichment. Alleging damages in excess of \$5 million, she requests restitution or Breyers’ profits from the transactions, an order enjoining misleading advertisements, attorney’s fees, costs, interest, and “an order requiring an accounting for, and imposition of a constructive trust upon, all monies received by Breyers as a result of the unfair, misleading, fraudulent and unlawful conduct alleged herein.”

### Public Interest Group Seeks White House Documents on Scientific Integrity Policies

Public Employees for Environmental Responsibility (PEER) has filed a complaint in federal court under the Freedom of Information Act (FOIA), seeking documents from the White House Office of Science and Technology Policy (OSTP) related to the development of policies to protect scientific integrity in federal agencies, such as the U.S. Department of Agriculture and the Food and Drug Administration. [\*PEER v. OSTP, No. n/a \(U.S. Dist. Ct., D.D.C., filed October 19, 2010\)\*](#).

According to the complaint, President Barack Obama (D) issued an executive order in March 2009, requiring the development of such rules by July. They have not yet been promulgated. OSTP Director John Holdren reportedly wrote online in June 2010 that the “process has been more laborious

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and time-consuming than expected,” and that an interagency panel has developed draft recommendations for OSTP and Office of Management and Budget review.

Representatives from the latter two offices “have been honing a final set of recommendations” in the intervening months, said Holdren. PEER sought the panel’s recommendations, position papers and interagency communications under FOIA from OSTP, but claims that the White House has failed to respond and thus, has violated FOIA deadlines. The organization seeks an order requiring that the documents be disclosed.

PEER Executive Director reportedly said, “Why is the development of transparency policy cloaked in secrecy? The public should know which agencies oppose a presidential directive to stop politicizing science and why.” See *PEER News Release*, October 19, 2010.

### **Poultry-Import and COOL Disputes on WTO Calendar**

The United States has reportedly decided not to file an appeal from a World Trade Organization (WTO) ruling that its ban on Chinese poultry imports, imposed in 2004 upon fears of an avian flu outbreak, was illegal. According to a news source, this ends the trade dispute. While the legislative ban expired within five years, under current U.S. law, the U.S. Department of Agriculture cannot allow poultry imports unless the foreign country’s food safety procedures are deemed equivalent to those used in the United States. A 2009 appropriations bill included this provision despite lobbying by U.S. trade organizations against it. See *FoodNavigator-USA.com*, October 27, 2010.

Meanwhile, WTO has apparently decided to open to the public the second hearing on a complaint filed by Canada and Mexico, challenging the U.S. promulgation of country-of-origin labeling for cattle and hog imports. The parties reportedly requested an open hearing, which will take place December 1-2, 2010, in Geneva, Switzerland. See *meetingplace.com*, October 25, 2010.

### **Brazilian Court Orders McDonald’s to Compensate Former Manager for Weight Gain**

According to a news source, a Brazilian judge has ordered McDonald’s Corp. to pay one of its former franchise managers US\$17,500 because he gained 65 pounds over the 12 years he worked for the company. He reportedly claimed that he was required to sample all of the restaurant’s foods everyday to ensure their quality, and he consumed the free lunches that were offered to company employees. The 32-year-old man apparently convinced the court that he had to sample the food because McDonald’s hired people to make unannounced



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visits to its restaurants to guarantee that food, cleanliness and service standards were maintained. See *Product Liability Law 360*, October 28, 2010.

### OTHER DEVELOPMENTS

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#### Food and Beverage Industry Groups to Devise FOP Labeling System

The Grocery Manufacturers Association (GMA) and Food Marketing Institute (FMI) have [unveiled](#) plans to create a front-of-package (FOP) labeling system that aims to “inform consumers and combat obesity.” According to an October 27, 2010, joint press release, the FOP system will display “important information on calories and other nutrients to limit... in a fact-based, simple and easy-to-use format.” The two industry groups have also pledged to consult stakeholders as they work to finalize the system and “provide consumers with information on nutrients needed to build a ‘nutrient-dense’ diet and on ‘shortfall nutrients’ that are under-consumed in the diets of most Americans.”

The announcement followed the release of an Institute of Medicine report calling for FOP labels that highlight the nutrients of greatest concern to consumers—calories, saturated fats, *trans* fat, and sodium—as well as serving size. Co-sponsored by the Food and Drug Administration (FDA), the Phase 1 report examined and compared 20 different FOP rating systems as part of the agency’s push to implement uniform standards. “As details get worked through, our hope is that the industry will develop a label that aids in consumer understanding and helps parents and other shoppers easily identify and select products that contribute to a healthy diet,” one FDA spokesperson was quoted as saying. Additional details about the IOM report appear in Issue [368](#) of this *Update*. See *The New York Times*, October 27, 2010; *Bloomberg*, October 28, 2010.

Meanwhile, the Center for Science in the Public Interest (CSPI) has expressed reservations about the new initiative, claiming that a “credible system” must show a product’s calories, saturated fat, sodium, and added sugar content. “Last time the food industry developed a front-of-package labeling system it was a complete flop that put ‘Smart Choice’ icons on junk foods like Froot Loops,” opined CSPI Executive Director Michael Jacobson in an October 27, 2010, press release.

New York University Professor Marion Nestle also greeted the pledge with skepticism, blogging that the industry “would *much* rather label their products with all the things that are good about them” while avoiding any “negative” information. “There is only one explanation for this move: heading off the FDA’s [FOP] initiatives,” concludes Nestle, who urges the food regulator to adopt mandatory measures. See *Food Politics*, October 28, 2010.

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### Corporate Watchdog Calls for Information About Threats to Food Disparagers

A corporate watchdog organization, Corporations and Health Watch, has [issued](#) a call for food industry critics who have been threatened with litigation for saying “anything critical about food,” to submit information about their experience to the organization. According to the group, corporations are using the food disparagement laws now in effect in 13 states “as leverage to silence their critics, frequently sending threatening letter[s] to those who speak out or those who publish [their critiques], threatening to sue under these menacing laws.”

### Fast Food Workers Vote Against Unionizing

Employees at 10 Minneapolis-based Jimmy John’s sandwich shops have reportedly voted against joining the Industrial Workers of the World (IWW), which has since alleged that the close election “was marred by misconduct.” According to *The New York Times*, “[U]nion supporters were predicting victory, noting that about 60 percent of the restaurants’ 200 workers had signed pro-union cards asking the labor board to hold a unionization vote.”

But when the National Labor Relations Board called the October 22, 2010, election, it reported that union backers fell short of a majority by three votes. With seven days to file objections, the Jimmy John’s Worker Union has charged MikLin Enterprise with 22 violations of the National Labor Relations Act, including bribery and intimidation. “We do not recognize these election results as legitimate and will continue to fight for our demands,” stated the group’s spokesperson in a press release.

The vote was apparently IWW’s second attempt to unionize fast food workers after failing with Starbucks baristas. “This is a group hellbent on bringing down someone, anyone, in the fast-food industry, and we just happen to be next on the list,” MikLin owner Michael Mulligan said. See *The New York Times*, October 22, 2010.

### Legal and Cultural Issues Related to Sugar Are Focus of Two New Articles

In a recent *FindLaw* article, Cornell Law School Professor Sherry Colb addresses whether New York City Mayor Michael Bloomberg’s proposal to prevent food stamp recipients from buying sugar-sweetened sodas and beverages violates any constitutional proscriptions. Titled “No Buying Soda with Food Stamps? Considering Mayor Bloomberg’s New Health Initiative,” Colb’s article concludes that arguments about equal treatment for the poor and consumer freedom in general hold no weight given the overwhelming risks to public health posed by “unhealthy, empty-calorie food.” She expresses confidence that food stamp recipients will experience measurable benefits by

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avoiding some unhealthy foods, which will convince public officials to expand such initiatives “to take on various industries that profit at the expense of human health.”

Meanwhile, a *New York Times* article discusses what prompted a writer and former Rutgers professor to begin the “Candy Professor” blog, which apparently “dives deep into the American relationship with candy, finding irrational and interesting ideas everywhere.” Samira Kawash, PhD, who authors the blog, was reportedly struck by the “moral and ethical baggage” carried by candy when she offered jelly beans to two 3-year-olds during her daughter’s play date at a new friend’s house. Despite the presence of cookies and sugary fruit juices in the friend’s kitchen, the parents reacted with shock, with the mother noting her child had never eaten candy and the father comparing candy to crack cocaine.

According to at least one nutrition scholar, candy is deemed “bad” because it does not have the “health halo” attributed to food products such as granola bars and fruit juices. Yet, candy apparently provides just 6 percent of added sugars in the American diet, while sweetened beverages supply 46 percent. Kawash reports having a complicated relationship with candy. Growing up in the 1970s, she apparently recalls an “endless and mostly frustrating quest for candy,” because her parents limited her intake to a small indulgence on Sundays. She reportedly binged on candy to carry her through her undergraduate days and has since used the technique of flushing handfuls of candy down the toilet to keep herself from eating it, admitting, “Obviously, my own relationship with candy is not totally healthy.”

Kawash has found that once candy became widely available in the 1880s, it was advertised as a food product that could promote health. It has also, at times, been scorned as too stimulating or otherwise hazardous and been subject to public fears about tampering and contamination. Doctors even blamed candy for the spread of polio early in the 20<sup>th</sup> century, without any evidence, according to Kawash. Citing the recent proposal to prohibit the use of food stamps in New York City to buy soft drinks, she has also found that “When moneyed classes indulge in sugar, it’s part of an acceptable leisure activity. But when poor people do the same thing, it’s considered pathological.” See *The New York Times*, October 26, 2010; *FindLaw.com*, October 27, 2010.

## MEDIA COVERAGE

### ***Choices Magazine* Targets Economic Implications of Obesity**

*Choices Magazine*, an outreach publication of the Agricultural and Applied Economics Association, has released its [3rd Quarter 2010 issue](#) focusing on the economic implications of rising U.S. obesity rates. Topics include medical

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costs and implications for policymakers; consumer behavior; farm policy; the diverse effects of food assistance programs; nutrition labeling; taxes on sweetened beverages; and the “behavioral economics” associated with what Americans eat.

**SCIENTIFIC/TECHNICAL ITEMS****California Researchers Question Fructose Content of HFCS**

The University of Southern California Childhood Obesity Research Center (CORC) has published a [study](#) claiming that high-fructose corn syrup (HFCS) contains 18 percent more fructose than estimated by soft drink manufacturers. Emily Ventura, Jaimie Davis and Michael I. Goran, “Sugar Content of Popular Sweetened Beverages Based on Objective Laboratory Analysis: Focus on Fructose Content,” *Obesity*, October 2010. According to the study, food and nutrition researchers usually assume that the ratio of fructose to glucose in HFCS is 55 to 45, based on information provided by the Corn Refiners Association. But after analyzing 23 sugar-sweetened beverages and four standard solutions with high-performance liquid chromatography, CORC allegedly determined that not only was the mean fructose content 59 percent, but that “several major brands appear to be produced with HFCS that is 65 [percent] fructose.”

The study also raises questions about the other kind of sugars used in these beverages, reporting “significant deviations in sugar amount and composition relative to disclosures from producers.” It particularly notes that “total sugar content of the beverages ranged from 85 to 128 [percent] of what was listed on the food label.” As one author opines in an October 28, CORC press release, “Given the huge amount of soda Americans consume, it’s important that we have a more exact understanding of what we’re drinking, including specific label information on the types of sugars. The lack of information—or perhaps even misinformation—we have had about the fructose levels in HFCS-sweetened beverages means that soda drinkers may be gambling with their health even more than we have previously thought.”

The research has elicited responses from the Center for the Science in the Public Interest (CPSI), Public Health Advocacy Institute (PHAI) and New York University Professor Marion Nestle, who has tentatively reversed her previous position that HFCS does not differ significantly from table sugar. “The metabolic problems that result from sugar intake are mostly due to the fructose content. Less is better for health,” writes Nestle in an October 26, *Food Politics* blog post, which also outlines some caveats about the study’s methodology, including expert opinions on the analytic processes used to analyze sugar content.

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Meanwhile, PHAI cautions that the study, if confirmed, “raises important legal questions for regulators and consumers.” In an October 27, blog post, PHAI staff attorney Cara Wilking notes that HFCS received its generally recognized as safe (GRAS) status from the Food and Drug Administration because the purported fructose to glucose ratio mirrored that of table sugar. “Federal law specifically defines HFCS ‘as mixture containing either approximately 42 or 55 percent fructose.’ These are the only HFCS formulations that are GRAS and permitted for widespread use in the food supply without prior approval,” argues Wilking, who further explores whether the new results imply violations of federal law pertaining to food adulteration as well as false and misleading advertising and food labeling.

CSPI Executive Director Michael Jacobson has also weighed in, stating that the “confirmatory studies using the best analytical method need to be done before alarm bells ring too loudly... [N]o one should think that they’d be doing themselves a huge favor by switching to soft drinks made with sugar.” See *CSPI News Statement*, October 27, 2010.

### Study Links Occupational BPA Exposure to Lower Semen Quality

A recent study funded by the National Institute of Occupational Safety and Health has reportedly linked workplace bisphenol A (BPA) exposure to “[1] decreased sperm concentration, [2] decreased total sperm count, [3] decreased sperm vitality, and [4] decreased sperm motility.” De-Kun Li, et al., “Urine bisphenol-A (BPA) level in relation to semen quality,” *Fertility and Sterility*, October 2010. Researchers apparently examined 218 Chinese factory workers—some with occupational exposure to BPA and some with only environmental exposure—concluding that, “those with detectable urine BPA had more than three times the risk of lowered sperm concentration and lower sperm vitality, more than four times the risk of lower sperm count, and more than twice the risk of lower sperm motility.”

Among the 88 study participants who did not work directly with BPA, the study authors observed “similar dose-response associations... with environmental EPA exposures at levels comparable with those in the U.S. population.” Additional details about a 2009 study linking occupational BPA exposure to high rates of impotence and sexual dysfunction appear in Issue [327](#) of this *Update*. See *The Associated Press*, October 28, 2010.

In a related development, the National Institute of Environmental Health Sciences and U.S. Environmental Protection Agency have awarded a \$2 million grant to establish the “Children’s Environmental Health and Disease Prevention Research Center at Illinois,” where Illinois and Harvard University scientists will conduct four pilot projects to determine “whether regular exposure to BPA and phthalates... can alter infant and adolescent development, cognition

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or behavior." According to the University of Illinois, "The centerpiece of the studies is a project that looks at exposure to BPA and phthalates in relation to the physical and mental development of infants." Dubbed Illinois Kids (I-Kids), the research "will follow pregnant women and their babies, measuring BPA and phthalate levels in the urine every month and collecting data on possible sources of exposure. The babies will also undergo physical, behavioral and cognitive tests." See *University of Illinois Press Release*, October 21, 2010.

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### FOOD & BEVERAGE LITIGATION UPDATE

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.

