

ISSUE 327 | NOVEMBER 13, 2009

FOOD & BEVERAGE LITIGATION UPDATE



CONTENTS

١	l eais	ation	Requ	lations ar	nd Stanc	lards

Senators Introduce Legislation to Bolster Food Safety, Humane Slaughter Practices; Restrict Food and Beverage Advertising to Kids
Gulf States Fight FDA Raw Oyster Ban2
Congressman Requests Investigation into <i>E.Coli</i> Risk in School Lunches
PETA Renews FTC Complaint Against California Milk Advisory Board3
OSHA Plans Meetings to Discuss Combustible Dust Hazards4
Health Canada Announces Recall of Beverages Marketed to "Vulnerable Population"
California Lawmakers Hear Testimony on Sweetened Reverages 5

Li

	Population"4					
	California Lawmakers Hear Testimony on Sweetened Beverages5					
tigation						
	MDL Court Disposes of Motions in Bisphenol A Litigation; Formula Labeling Claims Preempted					
	Fast Food Chain Sued for Alleged Failure to Disclose Presence of Chicken Stock in Vegetarian Offerings6					
	Class Fraud Claims Filed Against General Mills and Kellogg over Non-Natural Fiber Products					
	U.S. Attorney Files Suit to Stop Sale of Maryland Cattle with Excessive Antibiotic Residues					
	New Jersey Court Dismisses Salt Lawsuit Against Denny's					
	Peanut Butter Defendant Seeks Dismissal of Punitive Damage Claim and Transfer of Some Plaintiffs' Claims					

Other Developments

Scientific/Technical Items

Two Studies Dispute Reproductive	Risks	
of BPA Exposure	1	1

LEGISLATION, REGULATIONS AND STANDARDS

Senators Introduce Legislation to Bolster Food Safety, Humane Slaughter Practices; Restrict Food and Beverage Advertising to Kids

U.S. Senator Debbie Stabenow (D-Mich.) has reportedly introduced the Growing Safe Food Act (S. 2758) to "help educate and train farmers and food processors in food safety." Similar to the FDA Food Safety Modernization Act (S. 510) now stalled in the U.S. House of Representatives, the Growing Safety Food Act would create "a national food safety training, education, extension, outreach and technical assistance program for agricultural producers," including small and mid-sized farms, food processors and wholesalers. The bill also requests \$50 million to administer a competitive grant program, which would assist small and mid-sized businesses in "the areas of handling practices, manufacturing, produce safety standards, risk analysis, sanitation standards, safe packaging, storage, traceability, record-keeping, and food safety audits," according to a November 10, 2009, press released issued by Stabenow, who penned the legislation after small farmers expressed concern that the Food Safety Modernization Act would impose prohibitive inspection fees and other costly requirements.

"With all the recent scares over contaminated food, this legislation will help restore consumer trust in the safety of our food supply," stated Stabenow. "Providing training to farmers and processors on things like handling practices and safe packaging will go a long way toward restoring this confidence." See U.S. Agricultural & Food Law and Policy Blog, November 11, 2009; Law 360.com, November 12, 2009.

In a related development, U.S. Senator Dianne Feinstein (D-Calif.) has indicated in a letter to U.S. Department of Agriculture (USDA) Secretary Tom Vilsack that she intends to propose legislation establishing an Office of Humane Slaughter within USDA's Food Safety and Inspection Service. The senator apparently announced the impending bill after the Humane Society of the United States released videotape of allegedly inhumane treatment of veal calves at a Vermont-based meat packing company. According to Feinstein, the new bill would also (i) "Close the loophole that allows for the slaughter of downed calves, and direct the Department to develop standards for the treatment and transport of calves to be sold as bob veal"; and (ii) "Authorize new funding to hire additional full-time humane slaughter inspectors."



ISSUE 327 | NOVEMBER 13, 2009

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.

For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

> Mark Anstoetter 816-474-6550 manstoetter@shb.com



01

Madeleine McDonough 816-474-6550 202-783-8400 mmcdonough@shb.com



If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com);

Meanwhile, U.S. Representatives James Moran (D-Va.) and Bill Pascrell (D-N.J.) have authored the Healthy Kids Act (H.R. 4053), which aims to establish an Office of Childhood Overweight and Obesity Prevention and Treatment within the Department of Health and Human Services' (HSS) Office of Public Health and Science. Intending to address the "public health crisis" of childhood obesity, the act would also empower HHS, the Federal Trade Commission (FTC) and the Federal Communications Commission (FCC) to further restrict the advertising of foods and beverages "of low nutritional value" to children. The legislation would require FTC to promulgate rules "specifying categories of foods and beverages for or about which any advertisement, promotion, or marketing directed at children and youth shall be an abusive, unfair, or deceptive act or practice in or affecting commerce." In addition, the Healthy Kids Act would call on HHS to devise advertising guidelines that take into account "the emotional vulnerability of children and adolescents and their cognitive ability to distinguish between commercial and non-commercial content... and society's interest in protecting the health and well-being of its children and the long-term health of its population."

"We didn't know this was coming," one lobbyist for the Association of National Advertisers told *The Wall Street Journal*. "I see a lot of First Amendment challenges in the bill's future." *See The Wall Street Journal*, November 13, 2009.

Gulf States Fight FDA Raw Oyster Ban

U.S. Senators Bill Nelson (D-Fla.) and Mary Landrieu (D-La.) have introduced legislation seeking to block a Food and Drug Administration (FDA) proposal that would prohibit the distribution of raw oysters from the Gulf of Mexico during warm-weather months. "Specifically, the legislation, which was co-sponsored by Senator David Vitter (R-La.), would prevent [FDA] from using funds to implement a ban on sales of oysters that don't undergo a sterilization process," according to a November, 5, 2009, press release issued by Landrieu.

Slated to take effect in 2011, the FDA plan would apparently require processing for Gulf oysters harvested between April and October. The agency has pointed to the risk that raw oysters can cause fatal *Vibrio vulnificus* infections in people with compromised immune systems, resulting in approximately 15 deaths per year. California has already enacted similar measures that bar the sale of untreated raw Gulf oysters in the state, which has reported no *Vibrio vulnificus* fatalities since 2003. But efforts by Louisiana and other Gulf communities to educate the public have purportedly failed to reduce deaths by 60 percent, a goal set 10 years ago by federal regulators. "It's really a people-over-profit story," an FDA spokesperson said.

Meanwhile, the oyster industry has warned that the proposal could cost 3,500 jobs and decimate the business. U.S. Representative Charles Melancon (D-La.) has likewise criticized FDA for focusing on raw oysters while neglecting to increase inspections on crawfish and catfish imports that compete with Louisiana products. "Divide 15 deaths by 50 states... It's de minimis, it's miniscule," stated Melancon. "I think 15 is a pretty reasonable number." See Slate.com, November 11, 2009; The Baltimore Sun, November 12, 2009.



ISSUE 327 | NOVEMBER 13, 2009

Congressman Requests Investigation into E.Coli Risk in School Lunches

The chair of the U.S. House of Representatives' Education and Labor Committee has reportedly asked the Government Accountability Office (GAO) to investigate the risk of *E.coli* contamination in school lunches. In a <u>letter</u> to GAO, U.S. Representative George Miller (D-Calif.) wrote that he remains "concerned about the safety of our nation's food supply and whether there is an undue risk for food contaminated with dangerous pathogens to be unknowingly purchased by schools for use in the school meals program."

While the U.S. Department of Agriculture (USDA) currently requires *E. coli* testing for all ground beef acquired by schools through the commodity program, there are no minimum testing standards for ground beef that schools purchase off the commercial market. Miller has thus asked GAO to determine whether adequate protections are in place for school meals at the local, state and federal levels, and whether the safety and quality of ground beef available to schools are comparable to the safety and quality of ground beef available to restaurants and other commercial buyers. *See Miller Press Release and The Associated Press*, November 9, 2009.

PETA Renews FTC Complaint Against California Milk Advisory Board

People for the Ethical Treatment of Animals (PETA) has filed a new complaint with the Federal Trade Commission (FTC) claiming that the California Milk Advisory Board "is deliberately misleading consumers by advertising in its sales-promotion campaigns that cows on California dairy farms live in 'comfort,' are 'very well cared for,' and are 'happy." According to the animal rights organization, "these statements do not stand up to even passing scrutiny." An organization spokesperson alleges that, "conditions commonly found on California's factory dairy farms have been scientifically proven to cause cows extreme physical pain and mental distress."

According to a news source, PETA filed a similar complaint with the FTC in 2002, but it was not resolved. PETA apparently claims that its new complaint is necessary because conditions have worsened on California dairy farms. The organization has also reportedly filed litigation over the issue, but the lawsuit was dismissed when the courts ruled that the milk board is not subject to unfair advertising laws.

Among other matters, PETA contends in its complaint that the ads show cows "living peacefully in wide-open green pastures, but in reality, most cows on dairy farms live in barren, manure-filled dirt lots," a significant percentage of cows "suffer from painful udder infections" because they lack basic veterinary care, and California dairy farm cows "are so weakened by their inhumane treatment that dairy producers send them to slaughter when they are only 5 years old." See PETA Press Release and The Modesto Bee, November 10, 2009.

In a related development, an American Farm Bureau Federation representative has reportedly indicated that the industry expects disputes over animal rights to impose significant costs on animal agriculture in the future. According to a press report, Mary Kay Thatcher, director of the bureau's Ag Policy Team, referred to millions



ISSUE 327 | NOVEMBER 13, 2009

recently spent in Ohio to counter a ballot proposal supported by the Humane Society of the United States and called it a drop in the bucket given the 27 states that allow ballot initiatives and the Humane Society's large budget. *See Oklahoma Farm Report*, November 9, 2009.

OSHA Plans Meetings to Discuss Combustible Dust Hazards

The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) has <u>announced</u> a series of stakeholder meetings intended to address the "views, concerns, and issues surrounding the hazards of combustible dust," which may be formed in workplaces that include agricultural and grain-handling industries, and factories that manufacture food, animal food, pesticides, and pharmaceuticals. With the first meeting slated for December 14, 2009, and additional meetings planned for early 2010, OSHA is soliciting feedback on (i) possible regulatory approaches to handling the hazards of combustible dust; (ii) the scope of any rulemaking; (iii) the organization of a prospective standard; (iv) the role of consensus standards; and (v) consequent economic impacts.

The agency recently published an advance notice of proposed rulemaking that requested comments, including data and other information, on issues related to the hazards of combustible dust in the workplace. According to OSHA, "Materials that may form combustible dust include, but are not limited to, wood, coal, plastics, biosolids, candy, sugar, spice, starch, flour, feed, grain, fertilizer, tobacco, paper, soap, rubber, drugs, dried blood, dyes, certain textiles, and metals (such as aluminum and magnesium)." See Federal Register, November 10, 2009.

Health Canada Announces Recall of Beverages Marketed to "Vulnerable Population"

Health Canada has advised consumers not to purchase Chaotic Beverages sold under the brand names Mind Strike, Fearocity, Elixir of Tenacity, and Power Pulse "because they are unauthorized products marketed to a vulnerable population (children) with ingredients that may pose a health risk." According to an agency press release, "The drinks are tied to a trading card game, animated TV series and Web site," but contain unknown amounts of caffeine, "several herbs... not included in Health Canada's list of botanicals with a history of safe use in children," and unacceptably high levels of taurine, niacin and vitamin A. Power Pulse also allegedly contains "chromium picolinate at levels of possible concern in a product taken by children."

Meanwhile, manufacturer and importer U&ME Marketing has reportedly agreed to reformulate its products by removing all the herbs, taurine and niacin. "At the time of the recall, we had been approved by Health Canada for a site license and were in the process of applying for a Natural Health Product certification," a spokesperson was quoted as saying. "We regret any alarm this has caused with our customers and consumer base, and wish to assure everyone that we are taking the necessary steps to reformulate Chaotic beverages to the standards of Health Canada." See Health Canada Press Release, November 5, 2009; FoodNavigator-USA.com, November 9, 2009.



ISSUE 327 | NOVEMBER 13, 2009

California Lawmakers Hear Testimony on Sweetened Beverages

Nearly 20 organizations reportedly testified last week about the purported link between sugar-sweetened beverages and obesity at a special joint hearing of California's Senate Select Committee on Obesity and Diabetes and the Senate Health Committee.

Several researchers reportedly linked sugar-sweetened beverage consumption and obesity, but an American Beverage Association representative cited research showing that 5.5 percent of calories come from sweetened beverages and that a lack of exercise and other foods also contribute to obesity. She said that solely targeting soft drinks will fail to properly address the obesity issue, claiming research has shown that half of adults who don't consume soft drinks are also overweight.

Senator Elaine Alquist (D-San Jose) reportedly chided industry representatives: "To be told that all calories are equal, that sweetened soda pop is not contributing to obesity...the public is not stupid. We know you can do better." See The Los Angeles Times; Reuters, November 5, 2009.

LITIGATION

MDL Court Disposes of Motions in Bisphenol A Litigation; Formula Labeling Claims Preempted

A multidistrict litigation (MDL) court in western Missouri has issued orders disposing of a number of motions in the dozens of cases transferred to it in litigation involving claims of fraud against companies that make baby bottles and sippy cups, reusable drink containers, and baby formula sold in metal cans lined with a substance containing bisphenol A (BPA). *In re: Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, MDL No. 1967 (U.S. Dist. Ct., W.D. Mo., W. Div., orders entered November 9, 2009).

The court has dismissed breach of express warranty claims and claims that depend on misrepresentations (as opposed to omissions) for insufficient pleading under *Ashcroft v. lqbal*; and breach of implied warranty of fitness for a particular purpose. Remaining are claims for fraudulent omissions, violation of state consumer protection statutes, breach of implied warranty of merchantability, and unjust enrichment.

The court denied defendants' motion to dismiss on the ground of primary jurisdiction, which applies when a claim involves issues within the special competence of an administrative body. According to the court, while the Food and Drug Administration (FDA) may have determined that BPA is safe, "Plaintiff's claims are independent of the FDA's 'safety' determination," because they involve whether defendants failed to disclose material information to plaintiffs and whether defendants' products were merchantable. The court also noted that plaintiffs do not challenge the FDA's safety determinations and, with respect to the type of relief requested, plaintiffs seek monetary remedies only, "which the FDA cannot provide."



ISSUE 327 | NOVEMBER 13, 2009

The court determined that the claims were not impliedly preempted because they were not in direct conflict with federal law. According to the court, "the FDA's approval of BPA as safe without labeling requirements establishes only a regulatory *minimum*; nothing in these regulations either required or prohibited Defendants from providing the disclosures sought by Plaintiffs." Relying on the U.S. Supreme Court's ruling in *Wyeth v. Levine*, the court found that federal law did not prevent the manufacturers from strengthening their labels "as necessary to comply with the standard imposed by state law."

The makers of infant formula argued express preemption under the Food, Drug, and Cosmetic Act's misbranding provisions and the FDA's accompanying regulations. The court agreed with them, finding that federal law prohibits states from requiring food labels "not identical" to those required under federal law. Thus, the court dismissed all claims against the formula manufacturers as preempted.

Fast Food Chain Sued for Alleged Failure to Disclose Presence of Chicken Stock in Vegetarian Offerings

A Jewish California resident who follows kosher practices has filed a putative class action on behalf of Hari Krishnas, Hindus, Jains, Buddhists, Taoists, Sikhs, Muslims, and Jews against Panda Express, Inc., claiming that the restaurant chain fails to disclose that its vegetable menu items are actually made with significant amounts of chicken stock. *Adelpour v. Panda Express, Inc.*, No. BC425869 (Cal. Super. Ct., County of Los Angeles, filed November 12, 2009).

The plaintiff alleges that the company does not state in its restaurants, promotional materials or online that its vegetable dishes, such as "Mixed Veggies," "Eggplant Tofu," "Chow Mein," and "Fried Rice," are prepared with chicken stock and that she was led to believe that these dishes were vegetarian. She also alleges that she was "explicitly informed" by company servers or shift supervisors that such menu items were vegetarian.

The named plaintiff seeks to certify a class of "All California residents who abstain from consuming animal flesh or animal products for any reasons such as dietary restrictions, religious beliefs or ethical reasons, and who purchased" specified vegetable food products from any Panda Express restaurant in the state "at anytime during the period of four years preceding the filing of the Complaint to class certification."

She alleges intentional and negligent misrepresentation, fraud and violations of California's False Advertising Act, Unfair Business Practices Act, and Consumer Legal Remedies Act. Specifically alleging monetary loss and emotional distress, the named plaintiff seeks compensatory and general damages, restitution and disgorgement, injunctive relief to ensure compliance with statutory law, payment to a *cy pres* fund, corrective advertising, an apology, punitive damages, pre- and post-judgment interest, attorney's fees, and costs.



ISSUE 327 | NOVEMBER 13, 2009

Class Fraud Claims Filed Against General Mills and Kellogg over Non-Natural **Fiber Products**

An Illinois consumer has filed a putative class action against two food companies in federal court, alleging that they fail to disclose that their high-fiber snacks contain a non-natural fiber derived from chicory root which is purportedly not as effective as natural fiber and can cause harm to some individuals. Turek v. General Mills, Inc., No. 1:09-cv-07038 (U.S. Dist. Ct., N.D. III, E. Div., filed November 9, 2009). The complaint specifically targets General Mills' Fiber One Chewy Bars® and Fiber One NonFat Yogurt[®], as well as the Fiber Plus Antioxidants Chewy Bars[®] made by Kellogg Co.

The named plaintiff seeks to certify a class of Illinois residents who purchased these products and alleges violations of the Illinois Consumer Fraud and Deceptive Practices Act. She seeks an order (i) requiring the disclosure of all information in the companies' possession about the "purported health benefits or non-benefits" of the companies' products and ingredients, (ii) barring the companies from destroying any records relating to this information, and (iii) barring the companies from attempting to induce putative class members to sign releases involving the class claims. The plaintiff also seeks compensatory damages, restitution and disgorgement, injunctive relief, corrective advertising, and attorney's fees and costs.

The complaint alleges that the companies' products "contain chicory root extract, which is primarily inulin, which is a non-natural fiber. Current scientific evidence does not show that inulin's health benefits are equal to those of natural fibers." The companies allegedly fail to "inform the consumer that this fiber is not natural fiber and that this non-natural fiber has not been shown by current scientific evidence to possess all of the health benefits of natural fiber."

The plaintiff cites Web MD for its warning that "using too much inulin causes stomach problems and that women who are pregnant or breast feeding should not use inulin." According to the plaintiff, the companies fail to disclose any of these "negatives of inulin" and mislead consumers into believing that "inulin possesses all of the same health benefits of natural fiber."

U.S. Attorney Files Suit to Stop Sale of Maryland Cattle with Excessive **Antibiotic Residues**

A U.S. attorney in Maryland has filed a complaint for injunction against a dairy operation and its owner seeking to stop their alleged long-term misuse of antibiotics in animals that were sold for consumption. United States v. Old Carolina Farm, No. n/a (U.S. Dist. Ct., D. Md., filed November 3, 2009). According to the complaint, U.S. Department of Agriculture, Food and Drug Administration and Maryland Department of Agriculture investigations since the mid-1990s showed that drug residues in the tissues of animals the defendants sold exceeded established limits for a number of antibiotics.

Contending that consumers of such meats "may experience severe allergic reactions" or develop "antibiotic-resistant strains of bacteria," the complaint alleges that the dairy's owner ran afoul of the law essentially because he failed and refused to maintain treatment or drug inventory records. The U.S. government seeks



ISSUE 327 | NOVEMBER 13, 2009

permanent injunctive relief to stop the dairy from introducing adulterated food into interstate commerce and from failing to comply with the conditions of new animal drug use. The complaint also seeks an award of costs, including the costs of investigation to date.

New Jersey Court Dismisses Salt Lawsuit Against Denny's

According to a news source, a New Jersey court has dismissed fraud-related claims filed against Denny's Corp. alleging that the company failed to disclose the amount of sodium in its menu items. *DeBenedetto v. Denny's Corp.*, No. n/a (N.J. Super. Ct., dismissed November 10, 2009). Additional details about the litigation appear in issue 312 of this Update. The company reportedly indicated in a statement that the suit was dismissed because the plaintiff failed to and could not establish a physical injury under state product liability law.

The named plaintiff in this putative class action reportedly alleged that he had consumed Denny's foods for more than 20 years and was shocked when he learned how much sodium was in his favorite menu items. While he did not allege any link between the company's foods and his alleged high blood pressure, the plaintiff claimed that he would not have selected the high-sodium foods if he had been aware of their sodium content.

Stephen Gardner, litigation director of the Center for Science in the Public Interest (CSPI), which represented the plaintiff, was quoted as saying, "Essentially, the judge agreed with Denny's that New Jersey's product liability law prevented us from advancing our consumer protection claim. We are confident we would win on appeal, but we also want to make it clear to the judge that this suit is about consumer deception of a killer food ingredient." CSPI apparently plans to amend the complaint and appeal the court's ruling.

CSPI Director Michael Jacobson claimed that the lawsuit was filed to get the restaurant industry's attention in an effort to force the adoption of sodium reductions. Denny's has reportedly reformulated some of its menu items, offering lower-salt versions of the chain's hash browns and some items in its children's menu. Similar litigation was filed in Illinois; details about that lawsuit appear in issue 318 of this Update. See Nation's Restaurant News, November 11, 2009.

Peanut Butter Defendant Seeks Dismissal of Punitive Damage Claim and Transfer of Some Plaintiffs' Claims

ConAgra Foods, Inc. has asked a multidistrict litigation (MDL) court to sever and transfer the claims of some of the plaintiffs who filed a lawsuit in October 2009 against the company arising out of the purported *Salmonella* contamination of its peanut butter. *In re: ConAgra Peanut Butter Prods. Liab. Litig.*, MDL No. 1845 (U.S. Dist. Ct., N.D. Ga., Atlanta Div., motion filed November 10, 2009). The company has also asked the court to dismiss the plaintiffs' claims for punitive damages, arguing that they have not been sufficiently plead under the new plausibility standard of *Ashcroft v. lqbal*, 129 U.S. 1937 (2009).



ISSUE 327 | NOVEMBER 13, 2009

According to ConAgra's motion, this lawsuit involves five plaintiffs from four different states, raising serious questions of judicial economy and juror confusion, given that evidence is located in four different states and the legal standards of four different states would have to be applied to the claims. The plaintiffs filed their lawsuit in the same federal district in which the MDL is pending, and the company contends that nothing links the plaintiffs to that district. ConAgra speculates that the attorneys representing the plaintiffs may have wanted to "save multiple filing fees" or avoid dealing "with the logistics of drafting and filing multiple complaints." Perhaps, argues ConAgra, the attorneys "viewed the MDL forum as the most easily accessible alternative."

Meanwhile, a Georgia lawmaker is reportedly preparing legislation that would make it a felony for food processors to knowingly release contaminated food that results in injury or death. The crime would apparently be punishable by imprisonment for one to 20 years. Representative Kevin Levitas (D-Atlanta) has pre-filed the measure for the 2010 session of the Georgia Assembly. It would also require food processors to maintain written food safety plans at their facilities. Levitas appears to have been motivated by the *Salmonella* outbreak involving the Peanut Corporation of America (PCA), which, like ConAgra, had processing facilities in Georgia. *See FoodSafetyNews. com*, November 12, 2009.

In a related development, those purportedly injured during the PCA outbreak are apparently wondering why no criminal prosecutions have followed investigations into the incident. E-mails from PCA's top executive allegedly suggested that the company was more concerned about profits than public safety. Some legal commentators have speculated that prosecutors may either be waiting to see how the civil cases against the company will be resolved or do not see any urgency to prosecution because the company's plants have been closed. Still, a Vermont mother whose 7-year-old son was hospitalized after eating a product with PCA peanuts was quoted as saying, "The time is now. If the company's executives are spared prosecution, what does that say to the American public?" See Associated Press, November 6, 2009.

OTHER DEVELOPMENTS

Cancer Society Releases Position Paper Calling for Research into Chemical Exposures

The American Cancer Society has released a **position paper**, "American Cancer Society Perspectives on Environmental Factors and Cancer," discussing human exposures to carcinogens, including those in food. The paper calls for additional resources to (i) "accelerate testing of new and existing chemicals for potential carcinogenicity," (ii) "monitor the bioaccumulation of chemicals in humans and in the food chain," and (iii) "monitor and evaluate trends in cancers for which incidence is increasing." Among the positions the society takes on cancer prevention is that "decisions regarding prevention must inevitably be made in the face of accruing but still incomplete evidence."



ISSUE 327 | NOVEMBER 13, 2009

While the paper acknowledges that environmental exposures to carcinogens are generally minimal, its authors contend, "there is reason to be concerned about low-level exposures to carcinogenic pollutants because of the multiplicity of substances, the involuntary nature of many exposures, and the potential that even low-level exposures contribute to the cancer burden when large numbers of people are exposed." Specifically identified as sources of exposure are "additives or contaminants in food or drinking water." The paper cites limited resources and difficulties in developing quantitative estimates of risk for mixtures as obstacles to reasoned decision-making by regulatory agencies.

According to the paper, the society funds extramural research with more than \$100 million in grants annually; it does not state where additional resources for research will be found and does not say that it will lobby government to fill research gaps. Among the paper's authors are Elizabeth Fontham, Dean of the School of Public Health at Louisiana State University's Health Sciences Center, and Jonathan Samet, chair of the Department of Preventive Medicine at the University of Southern California and chair of the Environmental Protection Agency's Clean Air Scientific Advisory Committee. The paper makes numerous references to the American Cancer Society's success in advocating for tobacco regulation.

Report Warns of Lead in Balsamic and Other Red Wine Vinegars

An Environmental Health News (EHN) special report has allegedly identified significant lead levels in aged balsamic and other red wine vinegars, noting that "some vinegars had 8-9 times more lead than recommended" by California's Proposition 65 regulations. The Environmental Health Sciences Foundation purportedly tested a range of domestic and imported vinegars sold in California in 2002, claiming that "for three imported varieties... people who eat one tablespoon per day would be exposed to seven to 10 times the maximum daily level of lead set by California." Likewise, according to EHN, "eating one tablespoon a day of some balsamic or red wine vinegars can raise a young child's lead level by more than 30 percent."

Although *EHN* noted that lead levels in vinegar can "vary widely," it suggested that "aged varieties produced by the traditional method, which involved concentration in wood barrels for at least 12 years, have the highest levels." The publication has also cited experts who have called on agencies to lower federal and state guidelines for lead. "If lead intakes from vinegars can be avoided, they should be as a straightforward precautionary principle," stated one consultant who has helped agencies set lead standards. "That would be especially true if children are already near a toxicity threshold from lead paint or dust or any other sources, and vinegar lead might just be enough to nudge the blood lead to a toxicity risk zone." *See SFGate. com*, November 9, 2009.

Canadian Health Check Program Revamps Front-of-Packaging Nutrition Labeling

The Canadian Heart and Stroke Foundation's Health Check™ program has reportedly <u>revised</u> its front-of-package (FOP) labeling scheme to better reflect current nutritional guidelines. Similar to the Smart Choices® system recently discontinued in the United States, Health Check allows subscribing manufacturers to use its FOP



ISSUE 327 | NOVEMBER 13, 2009

logo on products that meet specific nutritional requirements. Partly in response to criticism leveled at its U.S. counterpart, the non-profit organization has announced plans to disqualify any cookies, puddings, snack foods, flans, or frozen dairy, soy or tofu desserts from entering the program after December 28, 2009. Health Check has also set new salt, sugar and fat limits for endorsed products, stipulating that *trans* fat cannot comprise more than 5 percent of the total fat content. In addition, soups in the restaurant program must reduce sodium levels to 480 mg per 250 mL by November 1, 2010. "The Health Check nutrient criteria developed by the Heart and Stroke Foundation's registered dietitians are based on Canada's Food Guide and also reflect the latest scientific evidence, labeling regulations, nutrition trends, eating habits of Canadians, market realities, and technology," stated the organization, which requires all new candidates to adhere to these rules from the outset. *See FoodNavigator-USA.com*, November 6, 2009.

SCIENTIFIC/TECHNICAL ITEMS

Two Studies Dispute Reproductive Risks of BPA Exposure

A recent study has allegedly linked occupational exposure to bisphenol A (BPA) with high rates of impotence and sexual dysfunction among Chinese men. D. Li, et al., "Occupational Exposure to Bisphenol-A (BPA) and the Risk of Self-Reported Male Sexual Dysfunction," *Human Reproduction*, 2009. U.S. and Chinese researchers apparently examined 634 male workers exposed to BPA levels approximately 50 times higher than those encountered by the average American. According to the study, "compared with the unexposed workers, BPA-exposed workers reported significantly higher frequencies of reduced sexual function within 1 year of employment in the BPA-exposed factories." In addition, the authors observed a "dose-response relationship... with an increasing level of cumulative BPA exposure associated with a higher risk of sexual dysfunction."

The researchers have since defended their results against feedback questioning the study's relevance to the typical consumer. "Critics dismissed all the animal studies, saying 'Show us the human studies," stated one author. "Now we have a human study, and this can't just be dismissed." See the Los Angeles Times Health Blog, November 10, 2009; The Washington Post and MSNBC.com, November 11, 2009; FoodProductionDaily.com, November 12, 2009.

Meanwhile, an animal study funded by the U.S. Environmental Protection Agency (EPA) has reportedly shown that BPA has no adverse effect on the reproduction function or behavior of female rats. Bryce C. Ryan, et al., "In Utero and Lactational Exposure to Bisphenol A, in Contrast to Ethinyl Estradiol, Does Not Alter Sexually Dimorphic Behavior, Puberty, Fertility and Anatomy of Female LE Rats," *Toxicological Sciences*, 2009. After feeding pregnant and lactating rats with BPA doses between 40 and 40,000 times the estimated median amount consumed by humans, researchers concluded that "the lack of effect of BPA on female and male rat offspring after total oral exposure to low doses in our studies is consistent with the lack of adverse effects on growth, vaginal opening, fertility and fecundity of low doses of BPA in several other robust, well designed, properly analyzed multigenerational studies."



ISSUE 327 | NOVEMBER 13, 2009

Both Plastics Europe (PE) and the American Chemistry Council (ACC) have welcomed these findings as a "significant development in better understanding the safety of BPA." As a PE spokesperson was quoted as saying, "Sound scientific review must continue to be the foundation of regulatory assessments and political decisions." See FoodProductionDaily.com, November 12, 2009.

OFFICE LOCATIONS

Geneva, Switzerland +41-22-787-2000 Houston, Texas +1-713-227-8008 Irvine, California +1-949-475-1500

Kansas City, Missouri +1-816-474-6550 London, England

+44-207-332-4500 Miami, Florida +1-305-358-5171

San Francisco, California +1-415-544-1900 Tampa, Florida +1-813-202-7100

Washington, D.C. +1-202-783-8400

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.



