

## FOOD & BEVERAGE LITIGATION UPDATE

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## LEGISLATION, REGULATIONS AND STANDARDS

### Congress Set to Reconcile FDA, USDA Budget for Fiscal Year 2010

The U.S. Senate has reportedly approved a fiscal year 2010 budget for the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) that would increase the combined funding for both agencies by 11 percent. Similar to a House of Representatives measure (H.R.2997) passed on July 9, 2009, the \$125 billion appropriations bill ([S. 1406](#)) includes financial support for farm subsidies, food safety, land conservation, and the federal food stamp program. However, the House version continues a prohibition on cooked chicken imports from China and strips out funding for a voluntary national animal identification systems (NAIS), while the Senate has outlined steps to overturn the Chinese chicken ban and would preserve one-half of the \$14.6 million requested by President Barack Obama (D) for NAIS. A House-Senate negotiating panel will meet to reconcile these differences before the bill heads to both chambers for a final vote. "These projects help to improve farm profits, reduce our dependence on fossil fuels, conserve our soil and water and boost our rural economy," Senator Tom Harkin (D-Iowa) was quoted as saying. See *Bloomberg.com*, August 4, 2009; *Meetingplace.com*, August 5, 2009.

### FDA Publishes Draft Guidance to Eliminate Microbial Contamination in Produce

The Food and Drug Administration (FDA) has published three draft [guidance documents](#), with industry input, that provide recommended practices to prevent foodborne hazards associated with fresh produce. The documents pertain specifically to tomatoes, leafy greens and melons and "provide a guide for growers and processors to follow so they may better protect their produce from becoming contaminated," according to Health and Human Services Secretary Kathleen Sebelius.

With specific suggestions ranging from clean water supplies to human hygiene, key elements include (i) an acceptable baseline standard of industry practices that help domestic and foreign firms minimize microbial contamination risks throughout the entire supply chain; (ii) specific recommendations relating to growing, harvesting, packing, processing, transporting, and distributing the product; and (iii) record-keeping recommendations to help FDA quickly trace back to the source when an outbreak occurs. The agency is asking that comments on the drafts be submitted within 90 days from publication in the *Federal Register*. See *USDA News Release*, July 31, 2009.

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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

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



or

**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); 816-474-6550.

### USDA Proposes Labeling Program for Biobased Products

The U.S. Department of Agriculture (USDA) has issued a proposed [rule](#) that would create a voluntary labeling program for 'biobased' products under section 9002 of the Farm Security and Rural Investment Act of 2002, as amended by the Food, Conservation and Energy Act of 2008. According to USDA, "Biobased products are products that are composed wholly or significantly of biological ingredients – renewable plant, animal, marine or forestry materials." Looking to encourage the increased use of these products in all market sectors, USDA has already indentified 15,000 commercially available biobased products across approximately 200 categories, from cleaning products to construction materials. Manufacturers seeking a BioPreferred label must ensure that their items meet or exceed USDA-established minimum biobased content requirements. USDA is accepting comments on the proposed rule until September 29, 2009. See *the Federal Register* and *USDA Press Release*, July 31, 2009; *Meatingplace.com*, August 3, 2009.

### Canadian Food Safety Agency Warns Public About Maple Leaf Foods Frankfurters

The Canadian Food Inspection Agency has issued a warning and reported the voluntary recall of frankfurters and wieners manufactured by Maple Leaf Foods, the company whose *Listeria*-tainted meat products in 2008 purportedly sickened thousands across Canada and were apparently ruled a "contributing cause" in the deaths of 22. According to the agency, the processed meat products now at issue "may be contaminated with *Listeria monocytogenes*." While no reported illnesses have been associated with the products' consumption, the "potential problem" was identified "as a result of the new mandatory testing and reporting requirements placed on industry in February 2009." Details about the settlement Maple Leaf reached in litigation arising from the 2008 outbreak appear in issue 303 of this Update. See *Canadian Food Inspection Agency Health Hazard Alert*, August 3, 2009.

### Massachusetts Health Department Advises Parents to Avoid BPA Products

The Massachusetts Department of Public Health has issued an [advisory](#) for bisphenol A (BPA), urging caretakers of children under two years old to avoid formula and breast milk storage products that contain the chemical. The health department has also advised pregnant and breastfeeding women to avoid using plastic food and beverage containers made with BPA, and to eat fresh or frozen products instead of canned foods that may have contact with BPA liners. In addition, state officials have recommended that all consumers (i) limit their exposure to transparent plastic containers with the recycling number 7 and the letters PC; (ii) avoid heating these containers "in microwave ovens, in water on the stovetop, or by adding boiling water into them"; (iii) wash containers "by hand with warm water and soap, instead of in dishwashers"; and (iv) replace worn or scratched polycarbonate plastic with stainless steel and glass containers.

A [pamphlet](#) released with the advisory notice claims that possible health effects of BPA "include, but are not limited to: changes in the infant's developing nervous system, such as thyroid function and brain growth; changes in behavioral development, such as hyperactivity; and changes in the normal development of the

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prostate gland."The department's advisory further notes, "Recent preliminary studies also suggest that BPA may interfere with the effectiveness of breast cancer chemotherapeutic drugs in cell culture, and may also be associated with diabetes and cardiovascular conditions in adults." See *Massachusetts Health Department Press Release*, August 3, 2009; *FoodProductionDaily.com*, August 4, 2009.

### LITIGATION

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#### Probiotic Yogurt Plaintiff Seek Class Certification in Florida Court

A woman who alleges that General Mills, Inc. deceives the public by claiming its Yo-Plus® probiotic yogurt is beneficial for human digestion has filed a motion for class certification in a federal court in Florida. *Fitzpatrick v. General Mills, Inc.*, No. 09-60412 (U.S. Dist. Ct., S.D. Fla., filed August 4, 2009). More information about the litigation appears in issue 296 of this Update. The plaintiff contends that the company cannot substantiate its claims that the yogurt's trademarked "unique blend of live probiotic cultures and natural fiber," "helps keep your digestive system right on track." She seeks damages in excess of \$5 million, alleging that consumers paid premium prices for a product that has upset the yogurt market and gained a significant market share.

Relying on a favorable class certification ruling in similar litigation against Dannon Co., Inc. in California, the plaintiff contends that the claims readily meet Rule 23 class certification requirements. She cites defendants' conduct and whether their claims are false or misleading as common factual issues and whether General Mills' promise creates a warranty as a common legal issue. Among the predominant common issues discussed in the motion is "whether it is true that Yo-Plus® is proven to provide the stated health benefits, as it advertises. This claim can be evaluated by scientific and medical studies—just as General Mills asserts has been done."

#### Poultry Plant Workers File Donning and Doffing Lawsuit

South Carolina poultry production line workers have reportedly sued their employer, claiming they are not paid for the time they spend donning and removing safety gear. According to a news source, the complaint alleges that this can extend a worker's shift by some 75 minutes each day. The employees also alleged that they are required to stand in line before clocking in to start their shifts so they can purchase the protective gear they need, such as gloves, hair nets, face masks, earplugs, and arm sleeves. Apparently, this gear is damaged regularly while in use, so the workers must buy the supplies at the worksite with a company debit card several times each week.

The employer has reportedly countered that it "does not consider time spent in line for supplies and time donning and doffing the minimal gear as compensable time." According to the company, which was recently indicted for knowingly hiring illegal workers, the employees are the "primary beneficiaries" of the protective gear. See *GreenvilleOnline.com*, July 31, 2009.

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## OTHER DEVELOPMENTS

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### Annual Obesity Report Released, Two-Thirds of Adults and Nearly One-Third of Children and Adolescents Overweight or Obese

Trust for America's Health, with a grant from the Robert Wood Johnson Foundation, has released its annual obesity [report](#). Titled *F as in Fat: How Obesity Policies are Failing America*, the sixth annual edition finds, among other matters, that adult obesity rates continued to rise in nearly half the states and that the states with the highest rates of adult, child and adolescent obesity are in the South. The report, which charts obesity-related diseases, physical activity and income level by state, also tracks trends in state legislation addressing nutritional standards for school meals and vending machines as well as laws requiring BMI screenings for school age children, health education, and farm-to-school programs.

The report acknowledges "the current economic crisis," suggesting that it will increase the cost of nutritious food; overextend safety-net programs and services and increase levels of depression, anxiety and stress, "which often can be linked to obesity." To combat the problem, the report recommends making obesity prevention and control a high priority of health care reform and launching a national strategy to combat obesity.

Among the specific recommendations are to (i) designate an official in every Cabinet-level agency to focus on obesity-related policies, (ii) update and increase Medicare, Medicaid and the Children's Health Insurance Program obesity-related coverage, (iii) eliminate junk food advertising to children, (iv) adopt a federal law to require retail food outlets to provide menu labeling, (v) impose state and local menu labeling requirements, and (vi) use local zoning laws to balance the ratio of fast-food restaurants to grocers and farmers' markets.

## SCIENTIFIC/TECHNICAL ITEMS

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### California Scientists Claim Link Between Pesticides and Parkinson's

University of California researchers studying rural residents in California's Central Valley have apparently found that those drinking water from private wells have a 90 percent higher risk of developing Parkinson's disease if the wells are near fields sprayed with certain pesticides. [Nicole Gatto, et al., "Well Water Consumption and Parkinson's Disease in Rural California," \*Environmental Health Perspectives\*, July 31, 2009](#). Supported by the National Institute of Environmental Health Sciences, the study estimated potential well water contamination on the basis of agricultural application records for 26 pesticides and involved 368 cases and 341 population controls enrolled in the Parkinson's Environment and Genes study.

The researchers found that people with the disease "were more likely to have consumed private well water, and had consumed it on average 4.3 years longer" than those without the disease. The strongest link to disease was found in areas sprayed with propargite, a pesticide used mostly on nuts, corn and grapes. Strong links were also found for the insecticides methomyl and chlorpyrifos, which was

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banned for residential use in 2001, but is still widely used on cotton, corn, fruit trees, and other crops. Methomyl is used on alfalfa. According to a news source, while the study fills some research gaps, scientists did not test the private wells and thus do not specifically know what each person may have been exposed to. *See Environmental Health News*, August 5, 2009.

### Researchers Restore Corn's Ability to Combat "Billion-dollar Bug"

Scientists have reportedly restored a genetic trait to North American corn that causes the roots to emit a chemical distress signal when under attack by western corn rootworm, a beetle species known as the "billion-dollar bug" for its widespread crop destruction. Jörg Degenhardt, et al., "Restoring a maize root signal that attracts insect-killing nematodes to control a major pest," *Proceedings of the National Academy of Sciences*, August 3, 2009. Researchers inserted oregano genes into domestic corn to reconstruct the defense mechanism, which once existed in most maize varieties and still persists in some European corn. This underground SOS apparently attracts parasitic roundworms, or nematodes, to feed upon the beetle larvae, resulting in yields with less root damage and 60 percent fewer adult beetles compared to unmodified crops.

"We used a controversial approach, with genetic engineering, to enhance a very much favored [among environmentalists] approach, which is biological control," one study author was quoted as saying. "This is probably the first study to demonstrate that the two are compatible." *See National Geographic.com*, August 3, 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

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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.

