

Food & Beverage

LITIGATION UPDATE

Issue 286 • December 19, 2008

Table of Contents

Legislation, Regulations and Standards

- [1] President-Elect Obama Names Choice for Secretary of Agriculture1
- [2] FDA Plans More Research on Bisphenol A; Canada Urged to Protect Pregnant Women from Chemical2
- [3] FDA Seeks to Revise Recommendations for Fish Consumption During Pregnancy ..2
- [4] FDA Has No Objection to Rebiana-Based Sweeteners3
- [5] China Publishes Official List of Banned Food Additives3
- [6] New York Governor Proposes Soda Tax as Budget Stopgap4

Litigation

- [7] Plaintiffs Voluntarily Dismiss Whole Foods from Organic Milk Lawsuit4
- [8] Del Monte Seeks to Free Imported Cantaloupes from FDA Detention5
- [9] Perdue Sued for Adding Extra Giblets to Whole Chickens5

Legal Literature

- [10] Michael Roberts, "International Legal Issues Concerning Animal Cloning and Nanotechnology—More of the Same or Are 'The Times They Are A-Changin'?" *National AgLaw Center*, November 20086

Other Developments

- [11] Participatory Online News Source Blog Reports Preemption Movement Afoot6

Scientific/Technical Items

- [12] New Book Describes Systemic Effects of Obesity7

Shook,
Hardy &
Bacon LLP

www.shb.com

Food & Beverage

LITIGATION UPDATE

Legislation, Regulations and Standards

U.S. Department of Agriculture (USDA)

[1] President-Elect Obama Names Choice for Secretary of Agriculture

President-Elect Barack Obama has reportedly named former Iowa Governor Tom Vilsack (D) to serve at the helm of USDA. Political observers characterize Vilsack as a centrist who balanced his state's budget, resisted tax increases and agreed to spend tax revenues on education and health. Vilsack briefly sought the Democratic presidential nomination, but dropped out due to difficulties raising campaign funds. He is apparently a renewable energy proponent and is known as a staunch advocate of ethanol. An issue the USDA secretary will face in 2009 may be whether to grant the ethanol industry billions in federal aid as part of an economic stimulus package.

The Organic Consumers Association has already begun a campaign to stop Vilsack's confirmation by the U.S. Senate. According to the association's executive director, "Vilsack's nomination sends the message that dangerous, untested, unlabeled genetically engineered crops will be the norm in the Obama administration. Our nation's future depends on crafting a forward-thinking strategy to promote organic and sustainable food and farming, and address the related crises of climate change, dimin-

ishing energy supplies, deteriorating public health, and economic depression." Organic interests point to Vilsack's support for "concentrated animal feeding operations," genetically engineered pharmaceutical crops, and corn- and soy-based biofuels, and complain that he is "just another shill" for corporate agribusiness. They note that a biotechnology industry group named Vilsack governor of the year and that he founded and chaired the Governor's Biotechnology Partnership. See *The New York Times*, *MSNBC.com*, *Organic Consumers Association Press Release*, December 17, 2008.

A left-leaning commentator, writing for "The Beat" blog in *The Nation*, called Obama's pick for Agriculture secretary "cautious" and said he "could have done better, much better." According to John Nichols, USDA is far more than a farming overseer. Rather, the agency "is a key player when it comes to energy policy," its Forest Service "administers almost 300,000 square miles of national forests and grasslands, and the agency's secretary is "often a definitional player in trade debates." Nichols reports that the USDA has a \$97 billion annual budget and some 110,000 employees—"more than the departments of Health and Human Services, Housing and Urban Development, and Energy combined." While stating that Vilsack is a "capable administrator with the right partisan credentials," Nichols also observes, "[f]amily farm activists, fair-trade campaigners and advocates for organic foods were regularly disappointed by the stands he took." See *The Nation*, December 17, 2008.



Food and Drug Administration (FDA)

[2] FDA Plans More Research on Bisphenol A; Canada Urged to Protect Pregnant Women from Chemical

According to the director of the FDA's Office of Food Additive Safety, the agency will conduct additional analysis of the effects of bisphenol A on human health after its panel of independent science advisors called the agency's position on its safety flawed. Laura Tarantino reportedly said that a lot of work remains; she would not indicate if the reassessment would take months or years.

Among the issues the FDA is apparently exploring is the cumulative exposure people face over a lifetime given the chemical's presence in food and beverage containers, plastic medical devices and coatings on gel tablets. A spokesperson for an environmental organization was quoted as saying, "More years of research by FDA to determine what thousands of scientists worldwide already know about the toxic chemical is a waste of time, taxpayer dollars, and will place millions of babies yet to be born at risk." See *The Washington Post*, December 16, 2008.

Meanwhile, public health and environmental advocates are reportedly calling on Canadian officials to prohibit bisphenol A altogether. They claim that the government's proposed ban on bisphenol A in baby bottles will not protect pregnant women from exposure, and they expressed concern about its affect on developing fetuses. Health Canada is apparently studying fetal exposures and has identified pregnant women and fetuses as "a potentially sensitive subpopulation," but has no exposure data yet. According to a news source, bisphenol A exposure primarily occurs through diet, but it is also

found in household dust and is used in dozens of other consumer products such as compact discs and dental sealants. See *Globe and Mail*, December 16, 2008.

In a related development, researchers in Cincinnati, Ohio, have reportedly concluded that low doses of bisphenol A inhibit the release of a key fatty tissue hormone that increases insulin sensitivity and reduces tissue inflammation. [Eric Hugo, et al., "Bisphenol A at Environmentally Relevant Doses Inhibits Adiponectin Release from Human Adipose Tissue Explants and Adipocytes," *Environmental Health Perspectives*, December 2008.](#) The authors observe, "any factor that suppresses adiponectin release could lead to insulin resistance and increased susceptibility to obesity-associated diseases." They examined human adipose tissue from the breast and abdomen of patients undergoing breast reduction and abdominoplasty and exposed the tissue to low nanomolar concentrations of bisphenol A, which, they conclude, "may indeed be the bona fide endocrine disruptor that adversely affects metabolic homeostasis and its manifestations."

[3] FDA Seeks to Revise Recommendations for Fish Consumption During Pregnancy

FDA has reportedly sent a draft report to the White House Office of Management and Budget, seeking to reverse the government's recommendation that women of childbearing years, pregnant or nursing mothers, infants, and children limit their fish intake due to possible mercury contamination. The agency has claimed that the positive health effects of omega-3 fatty acids and other beneficial nutrients found in fish outweigh the risks of dietary mercury, which can behave as a neurotoxin during early development. The draft report would update a



2004 joint advisory statement issued by FDA and the Environmental Protection Agency (EPA) warning women and children to avoid four types of fish high in mercury: swordfish, shark, tilefish, and king mackerel. In addition, the federal government advises these consumers to reduce their fish consumption to less than 12 ounces per week, including at most 6 ounces of canned albacore tuna.

FDA apparently acted unilaterally in submitting its latest assessment, drawing the ire of EPA officials who questioned the scientific validity of the draft report's predictive model. In addition, Senator Patrick Leahy (D-Vt.) has suggested that FDA is falling in line with the seafood lobby before President-Elect Barack Obama takes office in January. "Once again, the Bush administration seems intent on ignoring sound science on mercury poisoning," he was quoted as saying. *See The Washington Post and Environmental Working Group Press Release*, December 12, 2008; *Chicago Tribune*, December 14, 2008.

[4] FDA Has No Objection to Rebiana-Based Sweeteners

FDA has reportedly stated that it has no objection to granting GRAS (generally recognized as safe) status to stevia for use as a zero-calorie natural sweetener in foods and beverages. An extract form is currently marketed as a supplement, but FDA said it lacked the necessary scientific data to lift an import restriction on food-grade stevia, which is also known as rebaudioside A (Reb A). Several food companies recently requested approval for stevia-based sweeteners after supplying regulators with data that demonstrated the safety of the food additive at 95 percent purity or above. *See BeverageDaily.com*, December 18, 2008.

The Center for Science in the Public Interest (CSPI), however, has called on the next Congress and President-Elect Barack Obama to reverse this "last minute" decision. The consumer watchdog cites research conducted by University of California, Los Angeles, scientists who purportedly concluded that stevia "is inadequately tested in terms of cancer and caused mutations in some laboratory tests." "The FDA has had a poor track record when it comes to allowing companies to market dubious ingredients, such as the stomach-churning fake-fat olestra and the anaphylaxis-causing Quorn mycoprotein," stated CSPI in a December 18 press release.

China

[5] China Publishes Official List of Banned Food Additives

The Chinese government has reportedly published its first official list of food additives that are prohibited in the domestic food supply. The list includes 17 acids, chemicals and other substances – such as formaldehyde, boric acid and sodium thiocyanate – used to improve the appearance, texture or longevity of food products. In addition, the country's regulators have warned of raids on high-risk companies that have thus far failed to address their own safety problems. "These lists... cannot cover all problems linked to illegally adding substances in food and abusing additives in the industry," stated the Chinese health ministry, which this month launched a food safety initiative to increase consumer confidence. *See AFP*, December 16, 2008.



State and Local Governments

[6] New York Governor Proposes Soda Tax as Budget Stopgap

New York Governor David Paterson (D) has reportedly proposed an 18 percent tax on soft drinks and other non-diet sweetened beverages as part of his plan to lessen a \$1.5 billion shortfall in the state's annual budget. The tax would purportedly raise \$404 million, but industry leaders have called the maneuver a "money grab" that would hurt union jobs at major bottlers located in the state. "We think that everybody has to keep in mind that we're in a recession, and in an economy like this, the last thing we should be doing is raising taxes on everyday needs like clothing and groceries. That doesn't wash with the consumer," an American Beverage Association spokesperson was quoted as saying. *See Times Union*, December 14, 2008; *Advertising Age*, December 15, 2008.

Meanwhile, a recent *New York Times* op-ed column hails the proposal as a "landmark effort that, if other states follow, could help make us healthier." *Times* writer Nicholas Kristof compares the soda tax to similar levies on cigarettes, citing claims made in the 2005 book *Prescription for a Healthy Nation* that "[e]very 10 percent increase on cigarettes reduced sales by about 3 percent overall, and 7 percent among teenagers." Kristof also contends that "sugary drinks are a major contributor to obesity" because "liquid calories don't register with the body," which has evolved not "to feel full when water was sloshing around our stomachs." "These days, sugary drinks are to American health roughly what tobacco was a generation ago," he concludes. "A tax would shift some consumers, especially kids, to diet drinks and water." *See The New York Times*, December 18, 2008.

Litigation

[7] Plaintiffs Voluntarily Dismiss Whole Foods from Organic Milk Lawsuit

Plaintiffs in multidistrict litigation against Aurora Dairy Corp. over claims that its "organic" milk products do not meet federal certification requirements have reportedly filed an unopposed notice of voluntary dismissal requesting that the court dismiss Whole Foods Market Group, Inc. from the case without prejudice. *In re: Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, MDL No. 08-1907 (U.S. Dist. Ct., E.D. Mo., motion filed December 13, 2008).

While Whole Foods apparently did not sell Aurora's organic milk, the company was named as successor-in-interest to Wild Oats, Inc., the chain acquired by Whole Foods in August 2007 and alleged to have sold the products. Whole Foods has reportedly argued that Wild Oats retained its assets and liabilities after the merger and has agreed to provide plaintiffs with discovery on that issue. According to plaintiffs' counsel, "If, after that discovery, we agree with your analysis, we will move the court to strike Whole Foods from the consolidated complaint."

The litigation involves claims consolidated from actions filed in federal courts around the country that Aurora Dairy sold its milk as organic but failed to comply with federal organic standards. The defendants filed a motion for dismissal in October 2008, claiming that the U.S. Department of Agriculture's decision to certify the milk as organic preempts the litigation. *See Product Liability Law 360*, December 16, 2008.

In a related development, eight senators have reportedly provided critical comments to the



Federal Trade Commission over its proposal to change its rules for investigating mergers for potential antitrust violations. Whole Foods has also opposed the changes which have been applied to its ongoing dispute with the commission over its merger with Wild Oats. According to a news source, the letter was signed by both Democratic and Republican senators, including Patrick Leahy (D-Vt.), Arlen Specter (R-Pa.), Dianne Feinstein (D-Calif.), and John Cornyn (R-Texas). The senators reportedly complain about the short 30-day comment period and express concern about the commission's plan to speed up its process for assessing mergers and allowing commissioners to preside over hearings held before administrative law judges take over and to vote to investigate mergers. *See Reuters*, December 15, 2008.

[8] Del Monte Seeks to Free Imported Cantaloupes from FDA Detention

Del Monte Fresh Produce N.A., Inc. has sued the Food and Drug Administration (FDA), seeking a declaration that the agency has “engaged in a pattern or practice that constitutes agency action unlawfully withheld or unreasonably delayed” in connection with several cantaloupe shipments from Guatemala. *Del Monte Fresh Produce N.A., Inc. v. U.S.*, No. 08-02161 (U.S. Dist. Ct., D.C., filed December 11, 1008).

According to the complaint, the FDA denied release of the shipments until it completed testing for *salmonella*. The FDA has purportedly failed to respond to company requests for expedited testing and has yet to release the fruit, which is “over-ripening” and will cost the company more than \$4.5 million in losses. A 10-day hold in 2007 allegedly cost the company almost \$1 million.

Del Monte claims that independent tests have

failed to show that the shipments are infected with *salmonella* and contends that it “has never had a positive test for salmonella on its imported cantaloupes.” According to Del Monte, the company “adheres to the highest food standards and sources its cantaloupes from related party farms that are owned and operated by Del Monte Fresh Produce Company. Del Monte’s cantaloupe farms produce and pack fruit in accordance with the best practices as defined by FDA, and as stated in certificates issued by FDA to Del Monte. The farms test irrigation and packing house water and employ a hot water treatment facility in the packing houses for additional food safety benefits.”

In addition to declaratory relief, the company asks the court to issue an injunction “compelling FDA to cease unreasonable and/or unlawful delay in inspecting, examining and releasing food that Del Monte seeks to import into the United States.”

[9] Perdue Sued for Adding Extra Giblets to Whole Chickens

A New Jersey resident has filed a putative class action lawsuit in federal court against Perdue Farms, Inc., alleging that the company is forcing consumers to subsidize the company’s costs of disposing of extra giblet parts by “a secret practice” of inserting them into whole chickens sold by the pound to retail customers. *Marin v. Perdue Farms, Inc.*, No. 1:33-av-00001 (U.S. Dist. Ct., D.N.J., filed December 17, 2008). The plaintiff seeks relief on behalf of a “(b)(2) Injunctive Relief Class” consisting of “All persons who purchased Perdue whole chicken at retail” and a “(b)(3) Multi-State Sub-Class” consisting of those who purchased whole chickens at retail “in the states of New Jersey, California, Florida, Maryland, Michigan, Missouri, New York, North Carolina, Ohio, and Washington.”



The complaint alleges violations of consumer protection acts and unjust enrichment, and seeks “a declaration that “only the proportional amount of giblets are to be packaged in a whole chicken,” damages, attorney’s fees and costs, and an order “[c]ompelling Defendant to establish a program to inspect processed whole chickens to eliminate the packaging of extra giblets.” According to a Perdue spokesperson, “While it is company practice not to comment on pending litigation, I can tell you the majority of our giblets complaints are about MISSING giblets. We just received the lawsuit and will review it in more detail, but we anticipate a vigorous defense.” *Wall Street Journal* law blog lead writer Dan Slater, responding to news about the lawsuit, commented, “But aren’t gizzards the best part? Clearly these people have never tasted a good chicken giblet gravy.” See *WSJ Law Blog*, December 18, 2008.

Legal Literature

[10] Michael Roberts, “International Legal Issues Concerning Animal Cloning and Nanotechnology—More of the Same or Are ‘The Times They Are A-Changin’?,” *National AgLaw Center*, November 2008

Roll International Corp. Senior Counsel and former Agricultural Law Professor at the University of Arkansas School of Law, Michael Roberts discusses how disputes over the use of synthetic hormones in animal husbandry and food produced from genetically modified organisms are handled from the perspective of international trade law and international agreements addressing health, safety and environmental issues. Thus, he sets the stage to speculate how international disputes over cloned animals and nanotechnologies used in the human

food chain may be addressed in the future.

Among the legal issues the author sees arising from cloning and nanotechnology are (i) what international institutions and instruments will regulate these emerging technologies; (ii) whether religious, scientific, moral, and ethical concerns implicated in these technologies will change the international regulations pertaining to food safety and labeling, (iii) what role private standard-setting will take in the international regulation of cloning and nanotechnology, and (iv) how private standards should be viewed within the context of existing international trade agreements. Roberts cautions that extending the lessons learned from the synthetic hormone and biotech controversies to emerging technologies “belies a clean analytical framework. Adding to the complexities of factors is the growing practice of food companies in the global food supply chain that adopt private standards. . . . As a result, a privatized sustainability governance scheme has emerged in a food supply world that has traditionally been regulated by state and international standard-setting public institutions.”

Other Developments

[11] Participatory Online News Source Blog Reports Preemption Movement Afoot

According to *NowPublic.com*, a self-proclaimed participatory online news network, the food industry, facing legislative initiatives that would require posting calorie and other nutritional information on restaurant menu boards, is fighting back with state-level preemption laws. Ohio recently approved legislation (H.B. 217) giving the state’s Director of Agriculture the sole authority to regulate



how and whether food service operations must provide food nutrition information to the public, thus putting an end to the disclosure movement that was apparently gaining momentum at the local level there. Legislation adopted in Georgia (H.B. 1303) would prevent political subdivisions from adopting similar local laws.

NowPublic notes that the restaurant industry lost its federal preemption argument when mounting a challenge in court to a menu disclosure law that took effect in New York City. The industry then apparently “changed its strategy” by seeking legislation in Congress that would create federal preemption of calorie posting laws and in the states that would do the same at that level. These federal or statewide preemptive approaches would enable restaurants to post calories in places other than “where customers are likely to see them.” “Georgia and Ohio are two of industry’s successes,” the blog reports. See www.nowpublic.com, December 11, 2008.

Scientific/Technical Items

[12] New Book Describes Systemic Effects of Obesity

A new book published by the not-for-profit consumer organization American Council on Health and Science (ACHS) reportedly outlines the effects of obesity on “virtually every body system” with 17 chapters penned by medical experts in the field. Titled *Obesity and its Health Effects*, the report includes a preface by Daniel Stein, M.D., Albert Einstein College of Medicine, who warns that “obesity is not just a ‘cosmetic’ problem; it negatively affects almost all aspects of human health.” For example, the book claims that obesity raises the

risk for (i) arthritis and other problems of the skeletal system; (ii) gallstones and pancreatitis; (iii) psoriasis, as well as bacterial and fungal skin infections; (iv) sleep apnea and adult-onset asthma; and (v) decreased fertility in both men and women.

“Our purpose in compiling this summary of obesity’s health effects in one consumer-friendly book was to educate people about how obesity poses a wide variety of serious health risks,” stated ACHS President Elizabeth Whelan. See *ACHS Press Release*, December 2, 2008.



Food & Beverage

LITIGATION UPDATE

Food & Beverage Litigation Update is distributed by
Leo Dreyer and Mary Boyd in the Kansas City office of SHB.
If you have questions about the Update or would like to receive back-up materials,
please contact us by e-mail at ldreyer@shb.com or mboyd@shb.com.

You can also reach us at 816-474-6550.

We welcome any leads on new developments in this emerging area of litigation.

**Shook,
Hardy &
Bacon** L.L.P.®



Geneva, Switzerland

Houston, Texas

Kansas City, Missouri

London, United Kingdom

Miami, Florida

Orange County, California

San Francisco, California

Tampa, Florida

Washington, D.C.
