Shook, Hardy & Bacon L.L.P.

ISSUE 293 | FEBRUARY 20, 2009

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

House and Senate Food Safety Bills Continue to Proliferate

With more than a half dozen food-safety bills already pending before the 111th Congress, legislators have continued to introduce or re-introduce legislation from prior sessions to address the government oversight problems exposed by the latest food contamination outbreak. Details about earlier measures appear in issue 291 of this Update. Among the new proposals are:

- **H.R. 999** – Re-introduced February 11, 2009, by Representative Peter Roskam (R-Ill.), this bill would establish certification standards for food-testing laboratories and require importers to certify the safety of their operations. Referred to the House Committee on Energy and Commerce.
- **S. 425** – Re-introduced February 12, 2009, by Senator Sherrod Brown (D-Ohio), this proposal would give the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) mandatory recall authority and would create a new food tracking system. Referred to the Senate Committee on Agriculture, Nutrition and Forestry.
- **S. 429** – Re-introduced February 12, 2009, by Senators Chuck Grassley (R-Iowa) and Bob Casey (D-Pa.), this bill, focusing on the safety of imported foods, would give millions to federal agencies to hire personnel to track smuggled food products, provide food defense monitoring and cross training for security and agricultural agents, and require private labs to be agency-certified, among other matters. Referred to the Senate Committee on Agriculture, Nutrition and Forestry.

USDA to Pursue Stricter COOL Regulations

Agriculture Secretary Tom Vilsack earlier this week canceled a scheduled press conference on mandatory country-of-origin labeling (COOL) regulations, but reportedly told meat industry representatives that USDA intends to pursue stricter COOL guidelines than those approved during the Bush administration.

Vilsack has asked meat providers to voluntarily adhere to more stringent standards, noting that the agency will act in the absence of industry direction. In particular, USDA is seeking to extend COOL to some "processed" items, like cured bacon, that are currently exempt from labeling requirements. Vilsack also received a letter from seven U.S. senators asking him to further clarify and restrict the use of multiple

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.

country labeling. "These loopholes essentially allow processors to label every product – including exclusively U.S. products and entirely foreign products – under the multiple country category," stated the letter spearheaded by Senator Byron Dorgan (D-N.D.).

The announcement followed an administrative hold issued by the Obama administration for the review of all new or pending legislation. Slated to take effect March 16, 2009, COOL regulations have strained trade negotiations with Mexico and Canada, which have opposed the measure as unnecessarily protectionist. Although large meat processors and retailers have also criticized COOL as cumbersome, consumer organizations and northern state ranchers in competition with Canada have welcomed the possibility of stricter rules. "The bottom line is we think people have a right to know and they can act on it based on their own opinions and preferences," a Food and Water Watch spokesperson was quoted as saying. *See Meatingplace.com,* February 6, 2009; *Meatingplace.com* and *The Associated Press,* February 18, 2009.

EU Continues to Grapple with GM Crop Dispute; U.S. Food Co-ops and Organic Companies Pledge to Avoid GM Beet Sugar

The European Commission's (EC's) Standing Committee on the Food Chain and Animal Health reportedly deadlocked on February 16, 2009, over whether France and Greece should be forced to lift their bans on a genetically modified (GM) corn seed that is the only one approved for planting in the European Union. According to a biotechnology industry spokesperson, the increase in votes favoring the cultivation of GM crops signals a new momentum in Europe to open markets to these controversial crops. EU environmentalists and consumers have long opposed their introduction, citing environmental risks and the unwelcome intrusion of large corporate interests into agriculture.

A larger vote next week may, say biotech industry executives, lead to the approval of two additional GM corn seeds for marketing in the EU. Mike Hall, a spokesperson for the developer of one of them, has reportedly indicated that the company is waiting to see if the EU approves the seed before deciding whether to keep open a case against the EC and seek damages for delay. As for the French and Greek bans, if asked by the EC, the Czech Republic, which currently holds the EU presidency, will reportedly have 90 days to choose when the bloc's governments will examine the issue. Further deadlock will force the EC to decide the matter, and it will be entitled to enforce its decision via warnings and through the European Court of Justice. The Czechs apparently favor GM crops, when they are proven safe; the only consistent supporters are Britain and Sweden. *See The International Herald Tribune*, February 16, 2009.

In a related development, the European Court of Justice has reportedly ruled that EU member states cannot conceal the location of GM crop field trials. The decision was reached in a case brought by a French resident who wanted to know where such trials had taken place in Alsace. According to the court, "considerations relating to the protection of public order and other secrets protected by law … cannot constitute reasons capable of restricting access to information listed by the [EU] directive, including in particular those relating to the location of release." *See BBC News*, February 18, 2009.

Meanwhile, the Center for Food Safety, Food and Water Watch, As You Sow, and the Sierra Club, among others, have established a "Non-GM Beet Sugar Registry" that more than 70 U.S. companies have signed. Representing mostly food cooperatives and organic food producers, the signatories have pledged "to avoid using GM beet sugar in our products" and asked "the Sugar Beet industry to not introduce GM beet sugar into our food supply." One of the registry's sponsors reportedly said, "We need to avoid the all-too-common situation of finding out a product is harmful after it has been approved and widely distributed." According to the Center for Food Safety, "The registry shows the food industry's increasing apprehension about the government's ability to adequately regulate food production technologies." *See Foodnavigator-usa.com*, February 17, 2009.

EFSA Panel Rejects Health Claim for Cranberry Products

The European Food Safety Authority's Panel on Dietetic Products, Nutrition and Allergies (NDA) has rejected a health claim dossier submitted by Ocean Spray Cranberries, Inc., that sought to link consumption of its products to a reduced risk of urinary tract infection (UTI) in women. Ocean Spray asserted that dried cranberries and juice drinks containing 80 milligrams of cranberry proanthocyanidins (PAC) lessened UTI risk in women older than age 16 by "inhibiting the adhesion of certain bacteria in the urinary tract."

Although NDA acknowledged that some *in vitro* trials have supported this claim, the panel ultimately cited a lack of convincing clinical trials and ruled that the evidence failed to establish "a cause and effect relationship" between the product and the purported health benefit. Of the 12 studies presented by Ocean Spray, NDA dismissed six because they did not involve normal populations; one because it referenced a higher PAC dosing; and five because they did not provide adequate randomization, statistical power or trial length. Ocean Spray has since vowed to meet the panel's requirements, noting that its dossier relied on studies which had been "well received, and published in respected, peer-reviewed journals including *JAMA*." *See FoodNavigator-USA.com,* February 17, 2009.

Cal/EPA Moves Forward with Rules to Address Prop. 65 Chemicals in Foods

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) convened a conference call for stakeholders February 18, 2009, to discuss how to move forward with plans to require food retailers to warn the public about the presence of Proposition 65 (Prop. 65) chemicals in foods. OEHHA's general objectives are to prepare regulatory language vetted by stakeholders and undertake formal notice-and-comment regulatory proceedings by June.

The agency seeks assistance on drafting provisions about (i) manufacturer versus retailer responsibilities relating to warning information; (ii) structure, process and operation of a proposed information/warning clearinghouse; (iii) methods of delivering warnings; and (iv) establishing the content of warning messages. Volunteers are currently being solicited to join drafting groups, and initial drafts are expected

to be completed by April 17. OEHHA will post the drafts on Cal/EPA's Web site, and another stakeholders' meeting will be held on April 23.

Prop. 65 requires warnings about chemicals known to the state to cause cancer or birth defects. With hundreds of chemicals currently listed and thousands of food products on retailers' shelves containing many of them, industry interests have questioned the need for such regulation, noting that a number of the listed chemicals are actually beneficial nutrients and that early draft proposals will do little more than confuse consumers and generate litigation.

California's Request for Nanotech Information Provokes Concerns

In late January 2009, California's Department of Toxic Substances Control sent a letter to more than two dozen businesses and research centers "requiring information regarding analytical test methods, fate and transport in the environment, and other relevant information from manufacturers of carbon nanotubes." Among the specific questions the agency posed are (i) "What is the value chain for your company? For example, in what products are your carbon nanotubes used by others? In what quantities? Who are your major customers?"; (ii) "What is your knowledge about the safety of your chemical in terms of occupational safety, public health and the environment?"; and (iii) "When released, does your material constitute a hazardous waste under California Health & Safety Code provisions?"

Environmentalists are reportedly concerned that the questions are "vague" and that companies should be required to provide more specific data. They also apparently complain that giving the companies a year to respond is "generous." Industry sources are apparently calling the "open-ended" questions a matter for careful consideration by manufacturers because the responses "could be used as an admission against interest in [Hazard Communication Standard] enforcement actions or tort/product liability actions." They also caution respondents to assume that the information provided will be widely available.

In a related development, McDonald's Corp. shareholders have apparently submitted a proposed resolution calling for the board to "publish a report to shareholders on McDonald's policies on the use of nanomaterials in its products and packaging, at reasonable expense and omitting proprietary information, by October 1, 2009. This report should discuss any new initiatives or actions, aside from regulatory compliance, that management is taking to reduce or eliminate potential human health or environmental impacts." According to the resolution, McDonald's is "known to use nanomaterials in its hamburger packaging," and "has also been reported to use nanomaterials in milk shakes." The initiative is apparently one of many currently being undertaken by investor activists. More information about these resolutions appears in issue 288 of this Update. *See InsideEPA.com*, February 13, 2009.

Multnomah County, Oregon, Adopts Menu Labeling Laws

Multnomah County commissioners have reportedly adopted **regulations** requiring restaurant chains with 15 or more locations nationwide to display calorie content alongside individual items on their menus. Effective March 12, 2009, the law also requires these establishments to provide information about sodium, saturated fat, *trans* fat, and carbohydrate content at the point of sale. Restaurants must institute these new policies before the end of the year, when the health department can begin issuing citations and civil fines for violations. "No one says this will solve the problem of obesity in Multnomah County, but it's an important first step. This is about giving people information. That's fundamentally different than saying you can't eat this hamburger, it's bad for you," county commissioner Jeff Cogen was quoted as saying. *See The Oregonian,* February 12, 2009.

LITIGATION

Federal Appeals Court Upholds Validity of NYC Menu Board Ordinance

The Second Circuit Court of Appeals has affirmed a lower court ruling that rejected the restaurant industry's preemption and First Amendment challenge to New York City's health code provision mandating that certain restaurant chains post calorie information on their menu boards. ***New York State Rest. Ass'n v. NYC Bd. of Health, No. 08-1892 (2d Cir., decided February 17, 2009)***. The rule has been in effect since July 2008 and applies to restaurants that are part of chains with at least 15 outlets nationwide. The New York State Restaurant Association contended that the rule was preempted by the Nutrition Labeling and Education Act and infringed its members constitutional rights by compelling speech.

According to the court, "In requiring chain restaurants to post calorie information on their menus, New York City merely stepped into a sphere that Congress intentionally left open to state and local governments. Furthermore, although the restaurants are protected by the Constitution when they engage in commercial speech, the First Amendment is not violated, where as here, the law in question mandates a simple factual disclosure of caloric information and is reasonably related to New York City's goals of combating obesity." Additional information about the lower court's ruling appear in issue 257 of this Update. *See FindLaw.com*, February 17, 2009.

Tomato Industry "Racketeering" Investigation Elicits Two Guilty Pleas

Federal investigators seeking to crack down on corruption in California's tomato-processing sector have apparently secured guilty pleas from two industry employees, one with a tomato paste supplier and the other with a processed tomato purchaser. Jennifer Dahlman, who worked for a California company under investigation for alleged bribery, price-fixing and mislabeling, reportedly pleaded guilty to causing the introduction of adulterated and misbranded food into interstate commerce with intent to defraud.

Dahlman apparently mislabeled products that should have been discarded because of high mold content, purportedly at the direction of company managers, thus

giving her company an unfair advantage over competitors and leading to increased consumer prices for processed tomato products, such as sauces, soups and salsas. While she is cooperating with authorities, Dahlman faces up to three years in prison. According to U.S. attorneys involved in the investigation, the mislabeled products posed no health hazard to consumers.

James Wahl, who formerly worked as a purchasing manager for a Texas-based food manufacturer, pleaded guilty to accepting bribes from a sales broker with Dahlman's company to which he steered contracts. He is also cooperating with the Justice Department's investigation, but faces up to 20 years in prison. As we reported in issue 276 of this Update, the nationwide investigation involves alleged artificial inflation of prices for tomato products. Prosecutors, who are also looking into similar allegations involving the egg, fertilizer, cheese, milk, and citrus-fruit industries, are referring to the alleged graft as a "racketeering enterprise," although companies targeted by the investigation claim they have done nothing wrong. *See San Francisco Chronicle*, February 19, 2009.

Peanut Corp. of America Files for Bankruptcy; Plaintiffs' Lawyer Seeks to Lift Stay

The Peanut Corp. of America, whose *Salmonella*-tainted peanut butter and peanut paste products led to one of the largest food recalls in the United States, has reportedly filed for Chapter 7 bankruptcy protection in Virginia. The day it did so, Texas health officials apparently announced a recall of all products manufactured at the company's peanut-processing facility in that state after discovering dead rodents, droppings and bird feathers in unsealed gaps above a food production area. A Virginia plant operated by the company has also been closed. A state agriculture spokesperson reportedly said that inspectors found minor problems at the facility in 2007 and 2008, including flaking paint and evidence of rodents.

Food lawyer William Marler, who has sued the company on behalf of several families allegedly affected by the *Salmonella* outbreak, claimed that he has hired a law firm that helped him "manage both the Chi-Chi and Topps Bankruptcies," and would file a motion to lift the stay of bankruptcy to protect his clients' interests. More than 1,900 food products made by 85 companies have now apparently been recalled due to the *Salmonella* outbreak, which has purportedly sickened more than 600 people in 44 states and allegedly caused nine deaths. *See Marler Blog*, *Foodnavigator-usa.com,* February 16, 2009; *MSNBC.com*, February 17, 2009.

OTHER DEVELOPMENTS

South Korea Claims French Baby Formula Tainted with Meningitis Bacteria

South Korean regulators have reportedly detected a bacteria associated with infant meningitis and enteritis in a shipment of organic baby formula imported from France. The Korean National Veterinary Research and Quarantine Service (NVRQS) identified *Enterobacter sakazaki* in formula originating with the Bordeaux-based manufacturer Vitagermine, which stated that its products passed EU standards before shipment. The World Health Organization has categorized *E. sakazaki* as a harmful bacteria capable of causing serious illness and fatalities in people with

weakened immune systems and infants. South Korea has apparently imported eight shipments of Vitagermine formula weighing a total of 1,492 kilos since 2007, according to NVRQS, which noted that six of these shipments reached the market. Vitagermine has agreed to allow French authorities to conduct additional testing to ensure the safety of their product. *See FoodProductionDaily.com,* February 28, 2009.

MEDIA COVERAGE

WSJ Article Targets Water Footprints

Reporting alarming water shortage data from the United Nations and U.S. water managers, a *WSJ* reporter surveys corporate efforts to calculate the water needed to produce a single unit of consumer merchandise and find ways to reduce water "footprints." Alexandra Alter, "Yet Another 'Footprint' to Worry About: Water," *The Wall Street Journal*, February 17, 2009. With two-thirds of the world's population facing water scarcity by 2025, and 36 U.S. states expecting shortages by 2013, "water footprinting has gained currency among corporations seeking to protect their agricultural supply chains and factory operations from future water scarcity," writes Alter.

According to Alter, it can take up to 132 gallons of water to make a 2-liter bottle of soda and a cup of coffee can take about 35 gallons. Representatives from some 100 companies, including PepsiCo Inc. and Starbucks Corp., will apparently convene in Miami the week of February 23 to address the issue. Some experts apparently question the accuracy and usefulness of water footprints, because the effect of water usage on different world regions can be dramatic depending on local climate conditions. Still, conserving a finite resource has gained appeal. As the manager of a World Wildlife Fund water footprint project was quoted as saying, "Three billion more people are going to be on this planet [by 2050]. Somehow we're going to have to use the same amount of water we use today."

SCIENTIFIC/TECHNICAL ITEMS

Scientists Dispute *JAMA* Study Linking BPA Exposure to Type 2 Diabetes

Three letters published in the Febuary 18, 2009, edition of the *Journal of the American Medical Association* (*JAMA)* have raised questions about a study linking bisphenol A (BPA) exposure to cardiovascular disease, type 2 diabetes and liver-enzyme abnormalities in adults. Led by British researcher Iain D. Lang, the study concluded that participants in the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey 2003-2004 (NHANES) who had the highest BPA exposure were three times as likely to develop cardiovascular disease and twice as likely to develop type 2 diabetes. In addition, a concurrent *JAMA* editorial hailed these results as the "first major epidemiologic study to examine the health effects associated with the ubiquitous estrogenic chemical bisphenol A." The editorial board consequently urged "U.S. regulatory agencies to follow the recent action taken by Canadian authorities, which have declared BPA a 'toxic chemical' requiring aggressive action to limit human and environmental exposures."

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 293 | FEBRUARY 20, 2009

The responses to the study have apparently pointed to potential flaws in both methodology and statistical analysis. In particular, scientists from the National Institute for Statistical Sciences and the University of British Columbia noted that the NHANES "measured 275 environmental chemicals and a wide range of health outcomes." Their joint letters argued that there are approximately 9 million statistical models available to analyze the NHANES data, and urged future researchers to "develop a statistical analysis strategy that takes into account the large number of questions at issue." "Given the number of questions at issue and possible modeling variations in the CDC design, the findings reported by the authors could well be the result of chance," concludes the letter, which prompted Lang and his colleagues to describe such criticism as nothing new and to again emphasize the need for replication studies. Additional information about the original study appears in issue 275 of this Update. *See FoodProductionDaily.com,* February 19, 2009.

Study Finds Calorie Content of Classic Recipes on the Rise

A recent article claims that some *Joy of Cooking* recipes have significantly increased in serving size and caloric content when compared to their original 1936 versions. Brian Wansink and Collin Payne, "The *Joy of Cooking* Too Much: 70 Years of Calorie Increases in Classic Recipes," *Annals of Internal Medicine,* February 2009. The authors identified a 37.4 percent rise in average caloric density (or calories per serving) for the 18 recipes published in all seven editions of the iconic cookbook. They attributed this trend to a combination of larger serving sizes and an increase in overall calories per recipe, which the study linked to the availability of inexpensive ingredients. "There's so much attention that's been given to away-from-home eating and so much attention that's been focused on restaurants and the packaged food industry, it makes me wonder whether it's actually deflecting attention from the one place where we can make the most immediate change," stated Cornell University Marketing Professor Brian Wansink, who co-authored the article with New Mexico State University Professor Collin Payne. *See MSNBC.com,* February 17, 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