Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

HHS Announces Public Meetings to Discuss Codex Sessions on Fresh Produce, Fisheries

The U.S. Department of Health and Human Services (HHS), U.S. Department of Agriculture (USDA), and Office of the Acting Secretary for Food Safety have announced two public meetings to address upcoming sessions of the Codex Alimentarius Commission, the international food standards body established by the U.N. Food and Agriculture Organization and World Health Organization. Slated for September 2, 2009, the first **meeting** will consider U.S. draft positions pertaining to the 30th Session of the Codex Committee on Fish and Fishery Products (CCFFP) to be held September 29-October 2 in Agadir, Morocco. The second public **meeting** is scheduled for September 17, when the agencies will discuss the 15th Session of the Codex Committee on Fresh Fruits and Vegetables (CCFFV) to be held October 19-23 in Mexico City, Mexico. Both Codex committees set international standards, codes and other texts related to the preparation, labeling and marketing of their respective products. *See the Federal Register,* August 7 and 11, 2009.

FDA to Offer New Warning-Letter Process for Food Safety Violations

The Food and Drug Administration (FDA) has **announced** a new warning-letter system to notify food companies of safety regulation violations. Scheduled to begin on September 15, 2009, the system stems from an effort to speed up the process from the time a company receives an "FDA 483" inspection report to the issuance of a warning letter. It allows companies 15 working days to respond to the 483 form, and if they do not respond during that time, FDA will send a warning letter. If FDA does receive a response in that time, it will "conduct a detailed review of the response before determining whether to send a warning letter."

According to a *Federal Register* notice, many companies respond in writing once they get the 483 report by describing completed or ongoing corrective actions or promise of future corrections. "In fact, some inspected establishments submit multiple responses to FDA, sometimes over many months," states FDA. "Delayed and multiple responses to an FDA 483 have resulted in delays in the issuance of warning letters while these responses are reviewed and addressed. FDA's timely issuance of a warning letter should help to achieve prompt voluntary compliance and is therefore in the public interest."

The notice clarified that FDA can issue warning letters at any time, and that companies are expected to implement needed corrections independent of any response procedure. FDA will evaluate the new process after 18 months to decide whether to continue it with or without adjustments. *See Federal Register*, August 11, 2009.

FDA Authorizes Raid by U.S. Marshals on Louisiana Sandwich Company

After Food and Drug Administration (FDA) investigators found rodent infestation, "insanitary" conditions, poor employee hygiene, and violations of hazard analysis critical control point regulations at a food plant in Louisiana, it dispatched U.S. Marshals to seize tuna salad sandwiches and other food products, totaling more than $72,000 in value. While no illnesses have apparently been linked to consumption of the sandwiches produced by the Bearden Sandwich Company, Inc., the FDA has reportedly pledged to act "swiftly and aggressively" against processors and manufacturers that do not comply with food safety rules. According to an agency spokesperson, "When FDA investigators find violations inside a company's facility, we will do what is necessary to keep insanitary and potentially harmful products out of consumers' hands." *See FDA News Release*, August 7, 2009.

LITIGATION

Challenge to "Natural" HFCS Beverage Claims Not Preempted by Federal Law

The Third Circuit Court of Appeals has determined that federal food labeling law does not preempt the state law-based claims filed by a consumer who challenged Snapple's designation of beverages containing high fructose corn syrup (HFCS) as "natural." ***Holk v. Snapple Beverage Corp.*, No. 08-3060 (3d Cir., decided August 12, 2009)**. The appeals court reversed a lower court ruling dismissing the claims on the basis of implied preemption.

The complaint, originally filed in state court, but removed to federal court in 2007 under the Class Action Fairness Act, initially asserted that Snapple products were not "All Natural" because they contained HFCS; they were not "Made from the Best Stuff on Earth"; and Snapple falsely labeled some beverages, naming them after fruit-juice varieties that were not actually in the beverages. The plaintiff alleged unjust enrichment and common law restitution, breach of express and implied warranties and violations of the New Jersey Consumer Fraud Act.

By the time the litigation reached the Third Circuit, the only claim remaining was that Snapple products containing HFCS were deceptively labeled "All Natural." The district court dismissed the claim, because it found that the Food, Drug, and Cosmetic Act and the Food and Drug Administration's (FDA's) implementing regulations established a detailed and extensive regulatory scheme, and state limitations and requirements would "create obstacles to the accomplishment of Congress's objectives." The district court referred to the FDA's informal policy on use of the term "natural" as evidence that the agency "has in fact contemplated the appropriate use of the term."

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.

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The Third Circuit approached the issue with a strong presumption against preemption and rejected the applicability of both field and implied preemption. Specifically, the court found (i) no "'clear and manifest' expression of Congressional intent to occupy the field"; (ii) indications in the law that "Congress was cognizant of the operation of state law and state regulation in the food and beverage field"; (iii) the FDA has specifically stated that it does not intend to occupy the field of food and beverage labeling; (iv) FDA's "informal policy" about use of the term "natural" does not support preemption because the agency declined to undertake a rulemaking to establish a definition and it was announced before public review and comment, thus lacking a formal, deliberative process.

According to the appeals court, the FDA's informal "natural" policy and letters the agency sent to some food or beverage manufacturers asking them to remove their "natural" labels for violating that policy do not establish a policy with which state law requirements could conflict. The case was remanded for further proceedings. The district court will have to consider issues not addressed when it issued its preemption ruling, that is, whether the litigation should be dismissed under the doctrine of primary jurisdiction and that the complaint failed to state a claim under state law.

In a footnote, the Third Circuit observes that Snapple has begun reformulating its line of beverages to replace HFCS with sugar. Additional information about the litigation appears in issue 264 of this Update. A company spokesperson has been quoted as saying in response to the ruling, "We believe Snapple is all-natural and we're confident we'll ultimately prevail." *See Bloomberg.com*, August 13, 2009.

Federal Appeals Court Sends Banana Plantation Torture Suit to Guatemala

The Eleventh Circuit Court of Appeals has determined that a district court did not abuse its discretion by deciding that the Alien Tort Claims Act and Torture Victim Protection Act claims of seven Guatemalan banana plantation workers would best be heard in a Guatemalan court. ***Aldana v. Del Monte Fresh Produce N.A., Inc.*, No 07-15471 (11th Cir., decided August 13, 2009)**. The litigation arose from a 1999 labor dispute in Guatemala during which a number of trade union workers were allegedly roughed up by a private security force purportedly hired by defendant's subsidiary, which owned the large banana plantation involved in the dispute.

A circuit court panel majority agreed with the district court's *forum non conveniens* analysis, ruling that it did not err by giving preclusive effect to prior state court findings on these issues and in finding that Guatemala's courts were adequate and that "the plaintiffs' choice of forum was the only private interest factor weighing in the appellants' favor." The dissenting judge opined that the district court erred "in finding that the state court's consideration of the private interest factors had a preclusive effect in this case," and that it abused its discretion in weighing the private and public interest factors at issue. According to the dissenting judge, the district court misinterpreted the state court's factual findings and erred by "only considering the relative advantages of the Guatemalan forum" and failing to "consider any of the private interest factors which may have weighed in favor of suit in the United States."

Court Stops OEHHA From Listing Styrene as Carcinogen

A California state judge has reportedly issued a tentative ruling on the styrene industry's request to enjoin Proposition 65 (Prop. 65) regulators from listing styrene as a chemical known to the state to cause cancer. *Styrene Info. & Research Ctr. v. OEHHA*, No. 09-53089 (Cal. Super. Ct., Sacramento County, decided August 12, 2009). Further details about the litigation appear in issue 313 of this Update.

According to a news source, Superior Court Judge Shelleyanne Chang found no "known" evidence that styrene is a carcinogen and that the designation would likely have a devastating and stigmatizing effect on the product's use. Widely used in food packaging, styrene plastics are apparently crucial to the transportation and sale of strawberries, raspberries and blueberries, state industries worth $1.6 billion.

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has proposed listing styrene as a Prop. 65 substance, which would require public warnings, based on "possibly carcinogenic" findings by the World Health Organization's International Agency for Research on Cancer and a state Labor Code hazard communication standard that includes "possible" cancer-causing agents. The court reportedly has 90 days to issue a final ruling on the request for preliminary injunction, after which additional briefing and hearings will be scheduled on whether the listing should be permanently enjoined. *See The Sacramento Bee*, August 13, 2009.

OTHER DEVELOPMENTS

Chicago Tribune Investigates Pesticide Residue in Peaches

The *Chicago Tribune* has released the **results** of a preliminary 2008 U.S. Department of Agriculture (USDA) study that purportedly found "more than 50 pesticide compounds … on domestic and imported peaches headed for U.S. stores." According to the August 12, 2009, article, "Five of the compounds exceeded the limits set by the Environmental Protection Agency [EPA], and six of the pesticides present are not approved for use on peaches in the United States."

USDA reportedly sampled washed conventional peaches from more than 700 sites, including Chile, South Carolina and Georgia, as part of its Pesticide Data Program, which does not enforce violations but uses them to identify problematic practices. "Although most pesticides in peaches were at levels well below EPA tolerances," states the *Tribune*, "some scientists and activists remain concerned about even low-level exposure, especially to [sic] pregnant women and children."

The newspaper also commissioned its own test of both organic peaches from California and conventional peaches bought at farmers markets in Illinois and Michigan. Using the same federal laboratory as USDA, the *Tribune* apparently found only one pesticide, fludioxonil, on the organic peaches, and three or fewer pesticides at low levels on the Michigan and Illinois peaches. The report notes, however, that fludioxonil is not approved for use in organic farming, although products containing less than 5 percent of the EPA tolerance for any legal pesticide may still be labeled organic. "You want to maximize the healthfulness of children's diets by making

sure they get plenty of fruits and vegetables," a member of the American Academy of Pediatrics Committee on Environmental Health told the *Tribune*. "But … you want to minimize their exposure to pesticides, and we know that the best way to do that is by giving them as much organic produce as possible."

MEDIA COVERAGE

Karen Kaplan, "The Science of *Salmonella*," *The Los Angeles Times,* August 10, 2009

"This is *Salmonella's* world. We're just living in it," claims science writer Karen Kaplan of *The Los Angeles Times* in this article exploring the evolution of the deadly bug responsible for recent pistachio and peanut recalls. "The bacterium appeared on the planet millions of years before humans, and scientists are certain it will outlast us too. It's practically guaranteed that *Salmonella* will keep finding its way into the food supply despite the best efforts of producers and regulators."

Kaplan writes that the rise of *Salmonella* is due in large part to the industrialization of agriculture and food processing, and that eating trends also play a role. She quotes Robert Tauxe, deputy director of the Centers for Disease Control and Prevention's division of food-borne diseases, as saying that time-strapped Americans are consuming more preprocessed meals, which means that food has had more opportunity to be contaminated by handlers, machinery and other ingredients.

The increasing popularity of raw and undercooked foods is also a factor, according to Kaplan. She points out that, as a sign of the times, the Food and Drug Administration's Web site contains a generic template for companies to announce *Salmonella*-related recalls.

SCIENTIFIC/TECHNICAL ITEMS

Study Suggests Food Stamp Program May Play a Role in Obesity

A recent study has reportedly claimed that the average American woman enrolled in the federal Supplemental Nutrition Assistance Program (SNAP) is 5.8 pounds heavier than someone of the same socioeconomic background who does not receive food stamps. Jay L. Zagorsky, et al., "Does the U.S. Food Stamp Program Contribute to Adult Weight Gain?", *Economics & Human Biology* (July 2009). According to the researchers, "this association does not prove that the Food Stamp Program causes weight gain," but may show that increased income, either from cash or food stamp coupons, increases food spending in general. "However, the estimates indicate that food demand is inelastic and increased food spending does not necessarily mean increased caloric intake. Even so, the program could still contribute to weight gain since people tend to over consume products that are free," stated the study authors.

Noting that the average recipient receives approximately $80 per month in food stamp coupons, the authors recommended that a course in nutrition should be a requirement. They also suggested that price changes to low-calorie and calorie-dense foods could be helpful. *See FoodNavigator-USA.com,* August 11, 2009.

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Study Finds No Link Between Artificial Sweeteners and Increased Cancer Risk

An Italian study has reportedly found that the consumption of artificial sweeteners, including saccharin and aspartame, does not increase the risk of developing gastric, pancreatic or endometrial cancers. Cristina Bosetti, et al., "Artificial Sweeteners and the Risk of Gastric, Pancreatic, and Endometrial Cancers in Italy," *Cancer Epidemiology Biomarkers & Prevention* (August 1, 2009). Classifying participants as either users or non-users of artificial sweeteners, researchers compared data from 230 people with stomach cancer and 547 healthy controls; 326 people with pancreatic cancer and 652 healthy controls; and 454 people with endometrial cancer and 908 healthy controls. The results confirmed "the absence of an adverse effect of low-calorie sweetener (including aspartame) consumption on the risk of common neoplams in the Italian population."

Although limited to Italy, this conclusion apparently supports the findings of a National Cancer Institute study involving 285,079 men and 188,905 women that found no statistical link between aspartame and leukemia, lymphomas or brain tumors. *See FoodNavigator-USA.com,* August 12, 2009.

Researchers Consider Use of Nanoparticles to Color Water-Based Foods

According to Louisiana and Arkansas university researchers, entrapping beta-carotene with nanoparticles could provide a way to use "natural" ingredients as food colorants. Carlos Astete, et al., "Ca^{2+} Cross-Linked Alginic Acid Nanoparticles for Solubilization of Lipophilic Natural Colorants," *Journal of Agricultural & Food Chemistry*, August 3, 2009. The research was undertaken in response to consumer concerns about the use of synthetic ingredients in food products. Using various production methods, solvents and nanoparticle sizes, the scientists found a method that produced substances which could readily be incorporated in an industrial scale process. Simply changing nanostructure concentration could, according to one of the authors, allow color changes "from dark orange to yellow."

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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.