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FOOD & BEVERAGE LITIGATION UPDATE

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FIRM NEWS

Shook Lawyers Address Tomato Growers' Taking Claim Ruling in *Law360*

Agribusiness & Food Safety Associates Ann Havelka and Jara Settles have co-authored an article titled "FDA Warning Isn't Enough Proof for Takings Claim" published on October 17, 2014, by *Law360*. The authors discuss a recent Court of Federal Claims ruling that rebuffed a takings claim filed by tomato growers who alleged that a 2008 Food and Drug Administration (FDA) warning about a *Salmonella* outbreak purportedly associated with certain raw red tomatoes caused tomato sales to decline dramatically. The outbreak was eventually linked to Mexican peppers. The article concludes that while the plaintiffs may have focused on the wrong argument to support their claims, the ruling "should prevent a flood of takings claims in the wake of garden-variety governmental warnings," which, the authors contend, will allow FDA the flexibility it needs to protect public health. Additional information on the ruling appears in Issue 539 of this *Update*.

Shook Authors Discuss U.S. Regulatory and Litigation Landmines in IBA Newsletter

Global Product Liability Partners Greg Fowler and Marc Shelley have co-authored an article titled "Food and beverage labelling and advertising in the United States: Regulatory and litigation landmines," appearing in the September 2014 issue of the International Bar Association's *Product Law and Advertising Newsletter*. The article considers the public and private challenges facing U.S. food and beverage companies that promote their products as beneficial to health, "natural" or "all natural," or include in their products genetically modified ingredients, high-fructose corn syrup or "evaporated cane juice." The authors address trends in consumer-fraud lawsuits and settlements, competitor litigation and suits brought by morality and decency watchdogs. The article concludes by recommending the inclusion of a legal team in marketing strategies to enhance the likelihood that companies will successfully navigate these risks while distinguishing themselves in the marketplace.

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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.

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LEGISLATION, REGULATIONS AND STANDARDS

WTO Rules Against United States on COOL Rules

Confirming early reports discussed in Issue 536 of this *Update*, the World Trade Organization (WTO) has again ruled in favor of Canada and Mexico regarding U.S. country-of-origin labeling (COOL) regulations requiring pork and beef products originating outside of the United States to bear labels indicating where each step in the production process occurred. The compliance panel found that the measure "accords to Canadian and Mexican livestock less favorable treatment than that accorded to like US livestock." The panel also found that the rule's 2013 amendment "increases the original COOL measure's detrimental impact on the competitive opportunities of important livestock in the US market, because it necessitates increased segregation of meat and livestock according to origin; entails a higher recordkeeping burden; and increases the original COOL measure's incentive to choose domestic over imported livestock."

Following the decision's release, Mexican and Canadian trade officials issued a joint statement calling the COOL rule "a blatant breach of [the United States'] international obligations as a member of the WTO." In accordance with the ruling on the "clearly protectionist policy," Canada and Mexico "remain committed to using the WTO process to reach a satisfactory resolution to our concern, including if and as necessary, seeking authorization to implement retaliatory measures on U.S. agricultural and non-agricultural products."

Sen. Debbie Stabenow (D-Mich.), head of the Senate Agriculture Committee, noted that WTO recognized the United States' right to require COOL labeling despite finding issues with the proposed method of regulating the labels. "The World Trade Organization has once again ruled that consumers have a right to know where their food comes from," she said in an October 20, 2014, statement. "We can spend decades litigating this issue at the WTO, or we can work together to find a solution that encourages international trade and gives consumers what they need to make choices for their families."

HHS and USDA Schedule Meeting of 2015 Dietary Guidelines Advisory Committee

The U.S. Department of Health and Human Services (HHS) and Department of Agriculture (USDA) have scheduled a meeting of the 14-member committee charged with developing the federal government's "2015 Dietary Guidelines for Americans" for November 7, 2014, from 10 a.m. to 5:30 p.m. EST. The meeting is accessible to the public by Webcast only and registration is required to view the proceedings. Aimed at promoting consumption of foods and beverages that assist in maintaining a healthy weight and preventing disease, the guidelines were first issued in 1980, are revised every five years and provide the basis for federal food and nutrition policy and education

efforts. The next iteration of the guidelines will be published during fall 2015. Information about the November 7 meeting agenda, Webcast registration and the committee's requests for written comments may be found at the Office of Disease Prevention and Health Promotion's **Website**. *See Federal Register*, October 20, 2014.

FDA to Solicit Public Input on Supplemental Proposed Rules Under FSMA

The U.S. Food and Drug Administration (FDA) has **scheduled** a November 13, 2014, public meeting in College Park, Maryland, to solicit stakeholder comments and respond to questions about revisions to four rules first proposed in 2013 to implement the Food Safety Modernization Act (FSMA). The proposals address (i) Preventive Controls for Human Food, (ii) Produce Safety, (iii) Preventive Controls for Animal Food, and (iv) Foreign Supplier Verification Programs. Information about registration and making oral presentations may be found at FDA's **Website**. *See Federal Register*, October 23, 2014.

USDA Should Strengthen Approach to Pathogens in Poultry Products, GAO Says

The Government Accountability Office (GAO) has **released** a report assessing the U.S. Department of Agriculture's (USDA's) current approach to *Salmonella* and *Campylobacter* in chicken and turkey products and recommending that the agriculture secretary direct the Food Safety and Inspection Service (FSIS) to take steps to improve the approach. The report reviews past USDA action on these pathogens, including the establishment of standards limiting *Campylobacter* contamination and the tightening of existing *Salmonella* contamination standards. GAO recommended that the agriculture secretary direct FSIS to develop *Salmonella* and *Campylobacter* performance measures to monitor whether efforts to bring processing plants into compliance with the poultry products standards are meeting the agency's goals. GAO also recommended that effectiveness measures be included in future revisions of compliance guidelines for controlling the pathogens. According to the report, USDA agrees with the recommendations.

EFSA Assesses Health Risks Related to Perchlorate in Food

The European Food Safety Authority (EFSA) has **published** a scientific opinion calling chronic dietary exposure to perchlorate a potential concern, "in particular for the high consumers in younger age groups of the population with mild to moderate iodine deficiency." In addition to considering scientific literature on perchlorate levels in fruit juices, alcohol beverages, milk, and infant formula and breast milk, EFSA's Panel on Contaminants in the Food Chain (CONTAM) analyzed 4,731 fruit and vegetable samples to estimate chronic and short-term exposure to perchlorate in the food chain. The report also identified several contamination sources, including natural fertilizers, industrial emissions and chlorine-based products that degrade to perchlorate.

According to the CONTAM Panel, which found the highest mean perchlorate concentrations in leafy vegetables and herbs, the average chronic dietary exposure for adults ranged from a minimum lower bound (LB) of 0.03 µg/kg body weight (bw) per day to a maximum upper bound (UB) of .13 µg/kg bw per day. The average chronic dietary exposure for toddlers ranged "from 0.18 to 0.41 µg/kg bw per day (minimum LB-maximum UB)," while the exposure for infants was calculated at 0.14-0.20 (LB-UB) and 0.47-0.53 (LB-UB) µg/kg bw per day, based on the only two consumption studies available for this age group.

Noting that perchlorate "competitively inhibits the uptake of iodine" in the human thyroid, the CONTAM Panel concluded that "the chronic adaptive changes to compensate for a sustained inhibition of thyroid iodine uptake could lead to long term effects such as the development of multinodular toxic goiter, in particular in populations with mild to moderate iodine deficiency." The report also warned that short-term exposure "is of concern for breast-fed infants and small children with low iodine intake."

"The CONTAM Panel recommended that more data should be collected on the occurrence of perchlorate in food in Europe, especially for vegetables, infant formula, and milk and dairy products," states the scientific opinion. "The CONTAM Panel identified the need for biomonitoring data for perchlorate and the associated iodine status in Europe, including data on urine and breast milk, and noted that additional data on the level and duration of thyroid iodine uptake inhibition that has an impact on thyroid hormone levels in the vulnerable subpopulation groups would improve the risk assessment."

Draft French Health Bill Targets Binge Drinking and Mass-Produced Food

French Health Minister Marisol Touraine has reportedly proposed a law that would establish standards for ingredient transparency in mass-produced food, blank cigarette packets and "fixing rooms" that allow drug addicts to inject themselves in a safer environment, as well as impose fines—or possible jail sentences up to one year—for selling "products that make alcohol appear pleasant." The draft law's binge-drinking provisions have attracted media attention for their seeming contradiction with French culture, but a 2013 report from France's National Institute for Prevention and Education in Health found that excessive consumption of alcohol among French young people is rising, with as many as one in six children between ages 11 and 14 reporting that they have been drunk at least once. Under the proposed law, "Directly provoking a minor to excessive consumption of alcohol will be punished by a year imprisonment and a fine of €15,000." The law would reportedly also punish anyone found guilty of inciting someone else to "drink until drunk" with six months' imprisonment and a €7,500 fine; in addition, it more specifically targets "inciting people to drink on the Internet" and, according to an RTL radio interview with Touraine, "games or objects that glorify the excessive consumption of alcohol." *See The Local* and *The Guardian*, October 15, 2014; *The Washington Post*, October 16, 2014.

Belarus National Assembly Considers Bill to Restrict Alcohol Ads to Alcohol Beverages

The Belarussian Chamber of Representatives has reportedly approved draft legislation that would stop the practice of advertising products and events other than alcohol beverages with names and logos that are confusingly similar to alcohol brands. Some bottled waters, for example, are apparently promoted with names, fonts and images that are associated with vodka brands with just a slight change in the name—a practice referred to as "umbrella" advertising. Existing advertising law would be tightened to help reduce the use of alcohol, combat alcoholism and reduce tobacco consumption—the latter by applying the same standards to ad campaigns bearing a resemblance to tobacco product brands. The bill will become law unless rejected by the National Assembly's Council of the Republic or the president. *See Minskby.com*, October 23, 2014.

LITIGATION

SCOTUS Declines Review of Challenge to California's Foie Gras Ban

The U.S. Supreme Court (SCOTUS) has denied a petition seeking review of a Ninth Circuit Court of Appeals ruling upholding a California law prohibiting the sale of commodities, such as foie gras, produced by "force feeding a bird for the purpose of enlarging the bird's liver beyond normal size." *Association des Éleveurs de Canards et d'Oies du Québec v. Harris*, No. 13-1313 (U.S., certiorari denied October 14, 2014). Details about the Ninth Circuit decision appear in Issue 497 of this *Update*. Among other matters, the Ninth Circuit had found that a number of the issues presented by the plaintiffs were premature because they had appealed the denial of a motion for preliminary injunction. The question that out-of-state fois gras producers presented to SCOTUS was "[w]hether the Commerce Clause allows California to impose a complete ban on the sale of wholesome, USDA-approved poultry products from other States and countries—in this case, foie gras—based solely on the agricultural methods used by out-of-state farmers who raise their animals entirely beyond California's borders."

FDA Agrees to Finalize GRAS Rule by August 2016

According to a proposed consent decree filed in a D.C. district court, the U.S. Food and Drug Administration (FDA) will "submit a final rule regarding 'Substances Generally Recognized as Safe' [GRAS] to the Federal Register for publication no later than August 31, 2016." *Ctr. for Food Safety v. Burwell*, No. 14-0267 (U.S. Dist. Ct., D.D.C., consent decree filed October 20, 2014). The Center for Food Safety apparently brought the action over concerns that food

makers have been able to use an interim GRAS process and secure agency approval for allegedly unsafe ingredients, such as volatile oil of mustard, "olestra" and "quorn," based on self-assessments.

According to the Center's **complaint** against the agency, FDA has unlawfully exempted GRAS substances from regulation as food additives under a rule proposed, but never finalized, some 15 years ago. That proposed rule purportedly eliminated a petition process requiring food companies to demonstrate that a substance satisfies GRAS eligibility criteria, "including general scientific agreement about its safety, and provide FDA with all backup information supporting the petition." The proposed rule allegedly replaced the petition process with "a simplified notification process" under which a person may notify FDA that a substance's proposed use is GRAS via a "GRAS exemption claim," which "includes a short description of the substance, the applicable conditions of its use, and the basis for the GRAS determination (i.e., through scientific testing or common use in food). The notifier no longer needs to provide backup information, and instead must only summarize the information and make it available to FDA for review upon FDA's request." The Center claimed that "FDA no longer conducts its own detailed analysis to evaluate the data. In fact, FDA no longer affirms whether or not a substance's use is GRAS at all—it merely issues an opinion on a notifier's independent determination that it is."

In the Center's view, this procedure took effect on publication in the *Federal Register* in the 1990s, and the public did not have an opportunity to comment on it in violation of the Administrative Procedure Act. Pending court approval of the agreement, the Center has declared victory for consumers, contending that forcing FDA to finalize the rule will render the agency "fully accountable for instituting a GRAS system that adequately protects the public from harmful food additives." A Center spokesperson said, "Having a final rule in place will open the entire GRAS system to the scrutiny it deserves." She was also quoted as saying that additional legal action may be considered based on the final rule's substantive provisions. *See Law360*, October 23, 2014.

Court Approves $6.5-Million Settlement in Race-Discrimination Lawsuit Against Grocery Chain

An Arizona federal court has preliminarily approved a settlement in a lawsuit alleging that Bashas' Inc. paid Hispanic workers less than comparable non-Hispanic workers from 1998 to 2007 in violation of Title VII of the Civil Rights Act of 1964. *Parra v. Bashas' Inc.*, No. 2-591 (U.S. Dist. Ct., D. Ariz., order entered October 21, 2014). The plaintiffs were employees at Bashas' Inc.'s Food City stores, which cater mostly to Hispanic customers and whose staff was about 75-percent Hispanic. They alleged that they were paid on a lower pay scale than the mostly white employees at Bashas' Inc.'s A.J. Fine Foods and Bashas' stores. According to the plaintiffs, Bashas' Inc.'s president personally set the pay scale each year, and an experienced Food City store clerk was

allegedly paid $0.82 per hour less than a comparable Bashas' store clerk in 1999—amounting to a loss of about $1,640 per year for a full-time employee. Under the agreement, Bashas' Inc. will pay $6.5 million into a settlement fund, with about $1.62 million earmarked for attorney's fees. The settlement also includes a $400,000 administrative fund to locate as many class members as possible because about 90 percent of the plaintiffs no longer work at Bashas' Inc. and those who left may have moved to other countries. A fairness hearing is slated for April 2015. *See Law360*, October 22, 2014.

Settlement Approved in "Low-Glycemic," "Low-Carbohydrate" Pasta Class Action

Under a settlement agreement approved by a New Jersey federal court, Dakota Growers Pasta Co. will pay $7.9 million to resolve claims that it deceptively markets, advertises and sells Dreamfields Pasta as having a low glycemic index and only five grams of digestible carbohydrates per serving, making it a "healthy alternative to traditional pasta." *Mirakay v. Dakota Growers Pasta Co.*, Inc., No. 13-4429 (U.S. Dist. Ct., D.N.J., order entered October 20, 2014). The agreement stipulates that for one year, Dakota will remove from its packaging (i) the claims of a low glycemic index and low carbohydrates and (ii) the claim that the product can reduce spikes in blood glucose levels. Dakota will also pay $2.9 million in attorney's fees and $5 million into a settlement fund for distribution to class members, who will receive $1.99 for every box of pasta ordered online without limit as well as for each box purchased in a store, up to 15 boxes. Unclaimed funds will first be used to increase members' awards up to 50 percent, and the remainder will be donated to the American Diabetes Association. More than 333,000 members received notification of the settlement via email.

Several objections to the settlement were filed before the September 2014 fairness hearing; objectors argued that the agreement did not provide best notice to potential class members because, they said, the settlement notification should have been posted on Dakota's Website and product packaging, posted at retailers and communicated to heart and diabetic associations. They also objected to the "unreasonable" attorney's fees, the potential amount of the *cy pres* donation and the period of time that Dakota will adjust its advertising. The court dismissed the objections, certified the class and approved the settlement agreement.

"Flavor Infringement" Claim by Rival's Italian Restaurant Is "Half-Baked"

A Texas federal court has rejected the argument that the founders of Gina's Italian Kitchen infringed New York Pizzeria, Inc.'s (NYPI's) trademark flavor in its Italian dishes. *New York Pizzeria, Inc. v. Syal*, No. 13-335 (U.S. Dist. Ct., S.D. Tex., order entered October 20, 2014). NYPI alleged that its former vice president and his business partner stole trade secrets, including recipes, and used them to infringe NYPI's distinctive flavors and plating methods at their

new restaurant, Gina's Italian Kitchen. They allegedly obtained a franchisee's username and password and used it to log onto NYPI's franchisee Website, which held, among other things, recipes for NYPI's menu items. The court refused to dismiss the claims for violations of the Computer Fraud and Abuse Act and the Stored Communications Act stemming from alleged access to the franchisee Website.

The court then addressed NYPI's Lanham Act claims. Asserting that "no special legal rule" prevents the trademark of flavor, NYPI argued that its "specially sourced branded ingredients and innovative preparation and preservation techniques contribute to the distinctive flavor" of its products. The court compared flavor to color because trademarking a color is only allowable if it has developed a secondary meaning that identifies the product's source in the mind of the public. "But even then, there is another hurdle to achieving trade dress status: functional product features are not protectable," said the court, which cited a Trademark Trial and Appeal Board decision denying a pharmaceutical company a trademark in the orange flavor of its pills. "If the hurdle is high for trademarks when it comes to the flavor of medicine, it is far higher—and possibly insurmountable—in the case of food. People eat, of course, to prevent hunger. But the other main attribute of food is its flavor, especially restaurant food for which customers are paying a premium beyond what it would take to simply satisfy their basic hunger needs. The flavor of food undoubtedly affects its quality, and is therefore a functional element of the product." Pointing out that "NYPI is unable to cite any case recognizing a trademark in the flavor of food," the court dismissed the "plainly half-baked" claim.

The plating of food, in contrast, may "in some rare circumstances" earn trade-dress protection, the court said. "When plating is either inherently distinctive or has acquired a second meaning, when it serves no functional purpose, and when there is a likelihood of consumer confusion, it may be possible to prove an infringement claim. It is conceivable that certain well-known 'signature dishes' could meet this very high standard." NYPI failed, however, to identify precisely what plating methods it claimed were protected by the Lanham Act beyond insufficiently specifying that the infringement "'includes, but is not limited to' its baked ziti, eggplant parmesan, and chicken parmesan dishes," the court found, so it dismissed the claim.

OTHER DEVELOPMENTS

Pew/CSPI Report Calls on USDA to Modernize Meat Inspection

The Pew Charitable Trusts and Center for Science in the Public Interest (CSPI) have released an October 2014 **report** urging the U.S. Department of Agriculture (USDA) to reevaluate its current meat and poultry inspection system. Seeking to identify innovations that could better protect consumers, *Meat*

and Poultry Inspection 2.0 compares U.S. regulations to those used in Australia, Denmark, the Netherlands, New Zealand, and Sweden. It also examines scientific assessments undertaken by the U.K. Food Standards Agency and the European Food Safety Authority (EFSA) as part of their efforts to modernize food safety regulations.

"Modernizing government inspection of meat and poultry plants would focus resources on the food safety risks posed by bacteria and other microbiological and chemical hazards, and away from some human and animal diseases, such as tuberculosis and brucellosis, that have been successfully controlled in most developed countries," argues the report. "However, out of a concern that modernizing government inspection could have unintended consequences, several countries, as well as the European Union, have begun the process by first commissioning scientific assessments by expert bodies that examined the impact of potential changes to their current inspection systems."

Although all five countries surveyed for the report apparently "conduct carcass-by-carcass inspection of red meat at slaughter" and "require inspectors to be present in slaughterhouses during slaughter," "only New Zealand and the Netherlands conduct daily processing inspections similar to those required in the United States." In addition, EFSA apparently found that "many post-mortem inspection practices do not contribute to controlling pathogens of human importance," instead proposing that regulations adopt "standardized metrics such as the prevalence of a hazard at different stages of the food chain or indirect measures of the hazards that correlate to human health risks."

To this end, Pew and CSPI call on USDA to invest in similar expert assessments, improve its data collection practices and consider "incorporating food chain information and comprehensive data management and review into its meat and poultry inspection system." As the report concludes, "While many of these innovations are relatively new and data have yet to be collected and analyzed to determine their impact on foodborne illnesses, they represent models with the potential to improve public health and better target regulatory resources."

JBF Food Conference Agenda Highlights Impact of Sugar Consumption on Health

The James Beard Foundation has organized its fifth annual **food conference** around the theme of "Health & Food: Is Better Food the Prescription for a Healthier America?" The October 27-28, 2014, event in New York City will reportedly provide attendees a "better sense of actual health trends … and what solution-oriented food-system leaders and the medical community can do to make a difference."

An October 27 conference segment will include a conversation titled "Sugar and Health: What Is the Connection?" between **Robert Lustig, M.D.**, and sustainability consultant **Jonathan Halperin**. Lustig, a neuroendocrinologist at the University of California, San Francisco School of Medicine, has garnered

media attention in recent years for comparing sugar to a poison and linking it to metabolic dysfunction, cardiovascular disease, diabetes, liver cancer, and other non-communicable diseases. A second conversation titled "The Sweet Truth" will feature New York University Professor **Marion Nestle** and food journalist **Corby Kummer**, author of a monthly food column for *The Atlantic* magazine.

Center for Food Safety Questions "Organic" Ocean-Based Fish Farms

The Center for Food Safety (CFS) has issued a **report** challenging the proposed organic aquaculture production regulations under consideration by the U.S. Department of Agriculture (USDA). Titled *Like Water and Oil: Ocean-Based Fish Farming and Organic Don't Mix*, the report argues that USDA should reject proposed standards that would allegedly dilute the value of organic certification by allowing the agency's seal to appear on fish products sourced from ocean-based farms.

In addition to citing the high number of fish escapes reported in the previous two decades, CFS claims that "open-ocean fish farms can never be organic," partly because synthetic chemicals prohibited under the Organic Foods Production Act (OFPA) are ubiquitous in the marine environment. The group also alleges that open-ocean farming not only alters the natural behavior of migratory fish in violation of OFPA, but harms wild fisheries by using wild-caught fish as a feed source.

"It's mind-boggling to think that USDA would seriously consider allowing fish farms at sea to be organic," said CFS Organic Policy Director Lisa Bunin in an October 21, 2014, press release. "It's absolutely impossible to control or monitor the wide range of substances, including toxic pollutants, that flow into and out of sea-based farms."

SCIENTIFIC/TECHNICAL ITEMS

Study Links Thermal Receipt Paper to BPA Levels in Humans

A recent **study** has purportedly found that "a very large amount of BPA [bisphenol A] is transferred from thermal paper to a hand as a result of holding a thermal receipt for only a few seconds immediately after using a product with dermal penetration chemicals." Annette Hormann, et al., "Holding Thermal Receipt Paper and Eating Food After Using Hand Sanitizer Results in High Serum Bioactive and Urine Total Levels of Bisphenol A (BPA)," *PLOS One*, October 2014. Designed to mimic scenarios common in fast-food restaurants, the study measured dermal, serum and urine BPA levels in

subjects asked to use hand sanitizer, handle a receipt and then consume 10 french fries.

The data evidently showed that holding a thermal receipt for 45 seconds after using a hand sanitizer "resulted in the maximum amount of BPA that was swiped from the palm and fingers," though this measurement "likely underestimates the amount of free BPA transferred from the print surface of thermal paper." Noting that hand sanitizers often contain "dermal penetration enhancing chemicals that can increase by up to 100 fold the dermal absorption of lipophilic compounds such as BPA," the study's authors reported that "there was a dramatic increase" in serum unconjugated BPA in both men and women who handled receipt paper after using sanitizer. They also found a high level of urine total BPA (approximately 20 µg BPA per gram of creatinine) collected 90 minutes after dermal and oral exposure to the substance.

"Our study provides the first data that thermal paper may be a significant factor in accounting for high levels of bioactive BPA in human serum and total BPA in urine that have been associated with diseases that are increasing in frequency in human populations," concluded the University of Missouri researchers. "Our findings also suggest that the impact of the use of dermal penetration enhancing chemicals in skin care products on transdermal absorption of environmental contaminants should be taken into consideration in risk assessments and should be a priority for future research."

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