Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

White House Establishes Pollinator Health Task Force

The White House has **issued** a June 24, 2014, memorandum creating a federal strategy "to promote the health of honey bees and other pollinators." Highlighting the critical role of pollinators in agriculture and the economy, the memorandum establishes an interagency Pollinator Health Task Force and directs members to develop a National Pollinator Health Strategy by December 21, 2014.

Among other things, the strategy requires an action plan for understanding, preventing and recovering from pollinator losses through the use of longitudinal studies, expanded data collection and sharing, assessment of native pollinator populations, and development of affordable seed mixes for the maintenance of honey bees and other pollinators. Agency representatives appointed to the task force will also implement a number of policies designed to incorporate pollinator health into the management of federal land, rights-of-way, and restoration and reclamation projects.

To this end, the White House has called for further education to help address the loss of pollinators. "Given the breadth, severity and persistence of pollinator losses, it is critical to expand Federal efforts and take new steps to reverse pollinator losses and help restore populations to healthy levels," states the memorandum. "These steps should include the development of new public-private partnerships and increased citizen engagement." *See Federal Register,* June 24, 2014.

House Bill Would Give USDA Greater Recall Authority

Reps. Rosa DeLauro (D-Conn.) and Louise Slaughter (D-N.Y.) have introduced the Pathogens Reduction and Testing Reform Act, which would require the U.S. Department of Agriculture (USDA) to issue food recalls for meat contaminated with antibiotic-resistant pathogens such as *Salmonella*. Citing better protections for consumers and past deference to voluntary recalls as support for their bill, the lawmakers argue in a prepared statement that "USDA has failed to recall meat contaminated with antibiotic-resistant pathogens

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because they do not believe they have the legal authority to do so. This bill would ensure there is no confusion." The measure would require USDA to recall meat, poultry and egg products contaminated by illness-causing pathogens resistant to two or more classes of antibiotics commonly used to treat human illnesses. *See The Washington Post*, June 25, 2014.

FDA Finalizes Guidance on Nanotech Use in Food

The U.S. Food and Drug Administration (FDA) has **released** its final guidance on the use of nanotechnology in food as well as draft guidance on use of the technology in animal food. Rather than categorically judging nanotech as either safe or harmful, the agency indicated that it will consider specific characteristics of products with nanotech as they are produced. Among FDA's nonbinding recommendations are encouragement for food manufacturers' considerations of composition, safety and regulatory status as well as assurance that the guidance does not change the status of products already generally recognized as safe. The agency also recommends that manufacturers assess whether their implementation of nanotech will change their safety and regulatory status by determining what the physiochemical changes of the food product may be and invites consultations with the FDA about those determinations. "Our goal remains to ensure transparent and predictable regulatory pathways, grounded in the best available science, in support of the responsible development of nanotechnology products," FDA Commissioner Margaret Hamburg said in a news release. "We are taking a prudent scientific approach to assess each product on its own merits and are not making broad, general assumptions about the safety of nanotechnology products."

CDC Issues Report on Effects of Excessive Alcohol Use

The Centers for Disease Control and Prevention (CDC) has **published** a report that attributes the loss of approximately 2.5 million years of potential life, one in 10 deaths of working-aged adults and $223.5 billion in health-care and productivity costs annually to excessive drinking. The study examined data from CDC's Alcohol-Related Disease Impact application for 2006 to 2010 to calculate the number of deaths that could be attributed to alcohol based on a list of 54 alcohol-related causes, including immediate deaths due to, for example, alcohol poisoning, as well as deaths from alcohol-related diseases like liver cirrhosis.

The researchers focused especially on excessive alcohol use, defined as binge drinking (on a per-occasion standard), heavy drinking (on a drinks-per-week standard), pregnant drinking, and drinking by minors. "This analysis illustrates the magnitude and variability of the health consequences of excessive alcohol consumption in the United States," the researchers conclude. "More

widespread implementation of interventions recommended by the Community Preventive Services Task Force (19), including increasing alcohol prices by raising alcohol taxes, enforcing commercial host (dram shop) liability, and regulating alcohol outlet density, could reduce excessive alcohol consumption and the health and economic costs related to it."

EFSA Issues Scientific Opinion on Pathogens in Fresh and Frozen Berries

The European Food Safety Authority's (EFSA's) Panel on Biological Hazards (BIOHAZ) has **issued** a scientific opinion on the risk posed by *Salmonella* and Norovirus in fresh and frozen berries. According to BIOHAZ, which reviewed the limited data pertaining to the prevalence of these foodborne pathogens in berries, the risk factors for contamination are likely to include environmental conditions, contact with animal reservoirs and insufficiently treated compost, the use of contaminated water for irrigation or chemical applications, and cross-contamination by harvesters, food handlers or equipment. To mitigate these risks, BIOHAZ urges primary producers to implement Hazard Analysis and Critical Control Points (HACCP) systems as well as Good Agricultural Practices, Good Hygiene Practices and Good Manufacturing Practices (GMP).

More specifically, the scientific opinion identifies Norovirus in frozen raspberries and strawberries as "an emerging public health risk," stressing the need for additional data to develop microbiological criteria for improved control of Norovirus in these products and gauge the effectiveness of food safety management systems. "A high proportion of berries consumed in the EU are imported from non EU countries, mostly as frozen berries, and attention should be paid to the application of these mitigation options during production and processing in the countries of origin," concludes the opinion. "Food safety management based on GMP and HACCP principles should be applied by processors, distributors, retailers, and caterers involved in production of ready-to-eat berries."

California Repeals Requirement That Food Handlers Wear Gloves

In a unanimous vote, the California Senate has voted to repeal a new provision in the health code requiring restaurant workers to wear gloves when handling food. The provision took effect in January 2014 throughout California with a compliance grace period set to end in July 2014. The measure was intended to curb food-borne illness, but restaurant industry workers petitioned to repeal the provision, arguing that hand washing is as effective as wearing gloves without the added financial or environmental cost. They also suggested that gloves would add a false sense of security because, according to a study conducted by the Centers for Disease Control and Prevention, gloved workers were less likely than ungloved workers to wash their hands

when they should. Assemblyman Richard Pan (D-Sacramento), author of the bill to repeal the provision, was quoted as saying, "It is the industry standard in restaurants to prioritize cleanliness when handling food, and the repeal of the glove law will still emphasize these standards." *See The Los Angeles Times*, June 26, 2014.

LITIGATION

No Reconsideration for Expert Exclusion in DHA Omega-3-Fortified Milk Suits

A federal magistrate in Florida has denied the plaintiffs' request in multidistrict litigation challenging marketing claims that DHA Omega-3-fortified milk supports brain health to reconsider an earlier order excluding the testimony of their expert. *In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig.*, MDL No. 2324 (U.S. Dist. Ct., S.D. Fla., order entered June 17, 2014). Details about the magistrate's ruling excluding the plaintiffs' expert appear in Issue 522 of this *Update*.

The magistrate rejected the plaintiffs' arguments for their failure to raise them when the motion to exclude the evidence was before him and determined that an intervening U.S. Food and Drug Administration final nutrient content rule on DHA is not new evidence and does not address the ground on which the magistrate struck the expert—his failure to show how the studies on which he relied could be extrapolated to cover the broad class of product purchasers.

Indiana Court Rejects Constitutional Challenge to Chilled Beer Sales Limit

An Indiana federal court has upheld a state statute that limits the sale of cold beer to package liquor stores, barring other beer sellers like convenience stores from selling beer cooler than room temperature. ***Ind. Petroleum Marketers & Convenience Store Ass'n, v. Huskey*, No. 1:13-cv-784 (U.S. Dist. Ct., S.D. Ind., order entered June 16, 2014)**. Indiana law divides beer sales permits into three categories: (i) a beer retailer permit for restaurants and bars; (ii) a dealer permit for package liquor stores; and (iii) a beer dealer permit for convenience stores, grocery stores and drug stores. The beer dealer permit places limits on retailers, prohibiting them from selling alcohol on Sunday, establishing a minimum age of clerks who can sell the beer, and barring them from selling beer cooled, chilled or iced. An association representing convenience stores challenged the constitutionality of the permit limitations in May 2013, arguing that the statute violated the association's member convenience stores' rights to due process of law and equal protection under the Fourteenth Amendment as well as the liberty clause of the state constitution. The court rejected the association's arguments, holding that the statute (i) is not vague, either on its face or as applied to the association, so it does not violate the

stores' Fourteenth Amendment rights to due process; (ii) "applies uniformly to Plaintiffs' business model—convenience stores, grocery stores, and drug stores that operate pursuant to beer dealer permits," and thus does not violate the stores' equal protection rights based on their business models; and (iii) has a rational basis for dividing beer dealers, retailers and liquor stores and giving them different privileges. Thus, the court granted the state's motions for summary judgment on all counts and denied the plaintiffs' motion for an injunction.

No Class Certification in Baby Food Labeling Suit

In light of the large number of baby food products at issue and differing product labels used during the six-year class period in litigation alleging misbranding and deceptive labeling against Gerber Products Co., a federal court in California has determined that the class is not ascertainable, a flaw "fatal" to the plaintiff's motion for class certification. *Bruton v. Gerber Prods. Co.*, No. 12-2412 (U.S. Dist. Ct., N.D. Cal., San Jose Div., decided June 23, 2014). Information about an earlier court ruling narrowing the claims in the case appears in Issue **511** of this *Update*.

While the court rejected the company's reliance on Third Circuit precedent that ruled a class is not ascertainable when purchaser records are unavailable, it did agree with uncontested evidence that consumers would be unable to reliably determine whether they are eligible to join the class. Sixty-nine products were at issue, and 66 of them were "labeled both with and without the challenged labels during the class period." The plaintiff's method for identifying class membership would require consumers to recall whether they had purchased certain products in a qualifying flavor in the appropriate packaging and with a challenged label statement.

Accordingly, the court found, "The number of products at issue in this case, the varieties included and not included in the class definition, the changes in product labeling throughout the class period, the varied and uncertain length of time it takes for products with new labels to appear on store shelves, and the fact that the same products were sold with and without the challenged label statements simultaneously make Plaintiff's proposed class identification method administratively unfeasible." The court further granted Gerber's sealing request in part as to pricing strategy and other confidential business matters. As to the part not granted, the court denied it without prejudice so that Gerber may file a narrower sealing request.

Court Excludes Defendant's Neuropsychologist in Peanut Co. Lawsuit

Following a hearing on the admissibility of expert testimony proffered as to Stewart Parnell's ability to form the intent to commit alleged crimes arising from a national *Salmonella* outbreak linked to the Peanut Corp. of America,

the company he formerly owned, a federal court in Georgia has excluded the expert, finding his testimony unhelpful and lacking a link to the criminal allegations. *United States v. Parnell*, No. 13-12 (U.S. Dist. Ct., M.D. Ga., Albany Div., order entered June 24, 2014). Details about the criminal charges appear in Issue 472 of this *Update*.

Clinical psychologist Joseph Conley would have testified that Parnell has an Attention Deficit Hyperactivity Disorder condition that was so severe he likely never read, nor understood the significance of, many of the emails on which the government's case relies. According to the court, "Dr. Conley's testimony is a 'diminished capacity defense' designed to show that Parnell did not form an intent to defraud customers, but that testimony is unhelpful to the jury. The allegations in this case involve a complex scheme to defraud and allegations of willfulness—not errors and mistakes in processing 'the daily plethora of calls and emails required in managing three companies.'"

Putative Class Actions Filed Against Chobani and Fage for Alleged Deceptive Labeling

A pair of plaintiffs has filed putative class actions against Chobani LLC and Fage Dairy Processing SA in New York federal court claiming that the yogurt producers deceptively marketed yogurt as healthy despite its high sugar content. *Stoltz v. Chobani LLC*, No. 1:14-cv-3827 (U.S. Dist. Ct., E.D.N.Y., filed June 19, 2014); *Stoltz v. Fage Dairy Processing SA*, No. 1:14-cv-3826 (U.S. Dist. Ct., E.D.N.Y., filed June 19, 2014). The nearly identical suits allege that Chobani and Fage used a label intended "to create consumer confusion by causing purchasers to impute any meaning to the 0 percent that consumers wish, such as that the products lack sugar, carbohydrates, calories or any other content which a consumer may believe is unhealthy," according to the complaint against Fage. The complaints include pictures of the defendants' products and pictures of competitors' products to illustrate the industry standard of including what nutrition levels the "0 percent" refers to, such as fat or sugar, in contrast to Fage's and Chobani's labels, which do not indicate what nutrient is at 0 percent. The complaint against Chobani includes an additional accusation of deception based on the use of the term "evaporated cane juice" (ECJ), which plaintiffs allege is simply sugar. More information about ECJ and deceptive labeling lawsuits appears in Issue 525 of this *Update*.

Split New York High Court Says No to NYC's Sugary Drink Size Limitations

In a 4-2 ruling with one judge not participating, New York's highest court has affirmed lower court rulings invalidating a New York City Board of Health rule that would have limited the size of the containers in which sugary drinks are sold in certain venues. ***In re N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. NYC Dept. of Health & Mental Hygiene*, No. 134 (N.Y. June 26, 2014)**. Details about the intermediate appellate court ruling appear in Issue 492 of this *Update*.

Finding that the board lacks legislative authority, the majority weighed the separation-of-powers factors that are analyzed to determine whether a particular action is legislative or regulatory and determined that the board had overstepped its authority by engaging in political compromise, choosing between ends and making difficult and complex policy choices. It contrasted agency action regulating the purity of drinking water, the use of interior lead paint or the use of guards in the windows of high-rise apartments housing children—matters with a "very direct" connection to "the preservation of health and safety," where there is "minimal interference with the personal autonomy of those whose health is being protected, and value judgments concerning the underlying ends are widely shared."

In the majority's view, "By contrast, when an agency in our present time either prohibits the consumption of sugary beverages altogether or discourages it by regulating the size of the containers in which the drinks are served, its choices raise difficult, intricate and controversial issues of social policy. Few people would wish to risk the physical safety of their children who play near high-rise apartment windows for the sake of unobstructed views. However, the number of people who over-indulge in sugary drinks, at a risk to their health, is clearly significant. An agency that adopts a regulation, such as the Portion Cap Rule or an outright prohibition on sugary beverages, that interferes with commonplace daily activities preferred by large numbers of people must necessarily wrestle with complex value judgments concerning personal autonomy and economics. That is policy-making, not rule-making."

The court did not address an issue considered by the trial court, i.e., whether the Portion Cap Rule is "arbitrary and capricious."

The two dissenting jurists argued that "the majority misapprehends, mischaracterizes and thereby curtails the powers of the New York City Board of Health to address the public health threats of the early 21st century." According to the dissent, the board has broad authority to regulate public health and its regulations have the force and effect of state law, thus the only question should be whether it "acted reasonably within the bounds of its state-delegated powers." The dissent further observed that the majority "just does not believe it to be a good idea for the Board to mandate the portion size of sugary drinks, apparently on the theory that the Council should be the sole arbiter of 'the choices of New York City residents concerning what they consume,' at least in those situations where the choices are not immediately life-threatening. I can appreciate this vision of the world as a philosophical matter, but I see no legal basis for it here."

The dissent also asked why the majority even applied the separation-of-powers doctrine which arose in a case involving a constitutional provision vesting legislative power in the state, given that this case involves local government, and would have instead determined whether the regulation is

"so lacking in reason for its promulgation that it is essentially arbitrary." Under this test, the dissenters would have upheld the regulation, concluding, "What petitioners have truly asked the courts to do is to strike down an unpopular regulation, not an illegal one. Indeed, petitioners constantly stress just how unpopular the Portion Cap Rule is."

The Center for Science in the Public Interest (CSPI) called the ruling "disappointing" and suggested that making reduced consumption of "these nutritionally worthless products" should be a priority for "boards of health, city councils, state legislatures, and even Congress." *See CSPI Statement*, June 26, 2014.

Whole Foods Agrees to Penalties for Overcharging Customers

Following a year-long investigation of Whole Foods Markets in California, state and county weights and measures inspectors found that it was charging more than advertised for a wide variety of food items; the company has reportedly agreed to pay nearly $800,000 in penalties and to conduct its business for the next five years under strict oversight. According to the Santa Monica City Attorney's Office, Whole Foods (i) failed to account for the weight of containers when charging for self-serve foods at the salad and hot bars, (ii) labeled foods sold by pound with higher weights than actually contained in the package, and (iii) sold items by the piece that should have been sold by the pound.

Retailers bound by the judgment include those operated by Whole Foods Market California, Inc. and Mrs. Gooch's Natural Foods Markets, Inc. The company has also agreed to appoint two "state coordinators" who will oversee pricing accuracy at all stores throughout the state, designate an employee with responsibility for accurate pricing at every store, conduct four random audits at every store annually, and "charge accurate prices and provide the advertised weight on all items." Of the $798,394 in penalties and costs, $630,000 constitutes civil penalties, $100,000 will be paid to a statewide weights and measures enforcement trust fund, and more than $60,000 will reimburse the investigative costs of city attorneys in Santa Monica, San Diego and Los Angeles. *See Santa Monica City Attorney's Office News Release*, June 24, 2014.

OTHER DEVELOPMENTS

EWG Claims Excessive Fortification Poses Health Risk to Kids

The Environmental Working Group (EWG) has **released** a June 2014 report claiming that the fortification of foods with large amounts of vitamins and minerals could pose a health risk to children. Citing a study by the National Institutes of Health and California Polytechnic State University, EWG alleges

that children younger than age 8 "are at risk of consuming vitamin A, zinc and niacin at levels above the Institute of Medicine's Upper Intake Level." According to the report, excessive intake of these nutrients could lead to liver and skeletal issues and immune system dysfunction, as well as short-term effects such as rash, nausea and vomiting.

Targeting "two food categories that are frequently fortified and heavily marketed to children," EWG's analysis of 1,556 cereals and 1,025 snack bars allegedly identifies (i) "114 cereals fortified with 30 percent or more of the adult Daily Value for vitamin A, zinc and/or niacin," and (ii) "27 snack bars fortified with 50 percent or more of the adult Daily Value for at least one of these nutrients." The report also faults manufacturers for accidental "fortification 'overdoses'" that "can make actual exposures greater than the amounts indicated on the nutrition label."

Based on these results, EWG urges the Food and Drug Administration (FDA) to set new Daily Value levels, update serving sizes on Nutrition Facts labels and require Daily Values specific to each age group on products marketed to children. In addition, the group recommends that children consume products with no more than 25 percent of the adult Daily Value for vitamin A, zinc and niacin. "Finally," opines the report, "it is critical that the FDA take seriously the question of how food manufacturers may misuse food fortification guidelines and nutrient content claims to sell more products, particularly those of little nutritional value."

CSPI Asks FDA to Require Energy Drink Warning Labels

The Center for Science in the Public Interest (CSPI) has submitted a letter to U.S Food and Drug Administration (FDA) Commissioner Margaret Hamburg requesting that FDA require that "all beverages consumed in a soda-like manner, including energy drinks, comply with the same regulations that limit caffeine in 'cola-type beverages'" and that energy drinks carry warning labels that alert consumers of possible adverse reactions like convulsions or heart attacks. The letter details information obtained from FDA about adverse events related to energy drinks from 2004 to 2014, including heart failure, disability and miscarriage. CSPI also warns that energy drinks are heavily marketed to children and teens, and rates of usage among those groups are high—the letter cites a study finding that approximately 30 to 50 percent of children, adolescents and young adults reported consuming more than one energy drink per month. The consumer group further presses FDA to issue a public health warning to discourage people, and especially young people, from consuming energy drinks and to suggest to state and local governments that they bar minors from purchasing energy drinks.

SCIENTIFIC/TECHNICAL ITEMS

JAMA Viewpoint Discusses Alternative Theory of Obesity

A recent viewpoint article published in *The Journal of the American Medical Association (JAMA)* discusses an alternative theory of chronic overeating as "a manifestation rather than the primary cause of obesity." David Ludwig and Mark Friedman, "Increasing Adiposity: Consequence or Cause of Overeating?," *JAMA*, June 2014. Authored by New Balance Foundation Obesity Prevention Center Boston Children's Hospital Director David Ludwig and Nutrition Science Initiative Vice President of Research Mark Friedman, the article discusses the physiological and genetic mechanisms that may contribute to obesity, arguing that "a focus on diet composition, not total calories, may best facilitate weight loss."

In particular, Ludwig and Friedman not only point to previous studies claiming that the body adapts its metabolic responses "to defend baseline body weight," but argue that insulin disorders "highlight the potential influence of metabolic fuel concentration on body weight regulation." They also note that, contrary to a calorie-centric view of obesity, research has purportedly shown that genetic and environmental factors can induce "an excessively anabolic state that favors storage rather than oxidation of ingested calories."

"If anabolic metabolic defects precede and promote overeating, then conventional calorie-restricted diets would comprise symptomatic treatment, destined to fail over the long term for most people in an environment of unlimited food availability," report the authors. "Although reduced energy intake acutely decreases fat mass, predictable physiological and behavioral adaptations progressively lessen the ability of most people to maintain voluntary energy restriction."

Salad Arranged to Evoke Kandinsky Painting Tastes Better, Study Finds

A University of Oxford **study** has apparently found that a salad with its ingredients arranged to resemble Wassily Kandinsky's abstract *Painting Number 201* tasted better to subjects than salads with the ingredients tossed together in the middle of or laid out neatly on their plates. Charles Michel et al., "A taste of Kandinsky: assessing the influence of the artistic visual presentation of food on the dining experience," *Flavour* 3:7 (June 20, 2014). Researchers prepared ingredients for salads, arranging them in three different ways—"regular," "neat" and "art-inspired"—and then asked 60 participants to eat and rate the salads. Each salad was prepared with the same 30 ingredients in the same manner except that the sauce was distributed throughout the salad for the "regular," in an orderly pile for the "neat," and in artistic flourishes to match Kandinsky's *Painting Number 201* in the "art-inspired." Researchers compared questionnaires that the subjects completed before and after eating, finding

the only significant change was the "tastiness" variable, which rose 18 percent for the art-inspired salad, remained unchanged for the neat salad, and fell very slightly for the regular salad. They further found that the participants who ate the art-inspired salads said that they were willing to pay more for their meal than the participants who ate the regular or neat salads. "Diners intuitively attribute an artistic value to the food, find it more complex and like it more when the culinary elements are arranged to look like an abstract-art painting," the researchers concluded. *See NPR's The Salt,* June 25, 2014.

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FOOD & BEVERAGE LITIGATION UPDATE

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.