Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

ICGA Submits Comments on Use of PHOs in Chewing Gum

The International Chewing Gum Association (ICGA) recently **submitted** comments to the U.S. Food and Drug Administration (FDA) about the agency's proposal to revoke the generally recognized as safe (GRAS) status for partially hydrogenated oils (PHOs). Noting that PHOs are used in some chewing gum products "as softeners or texturizers at levels typically in the range of 0.2 to 2 percent of the finished gum," ICGA has criticized FDA's tentative determination as "misguided and overly broad."

In particular, the association has argued that FDA's blanket revocation violates "the legal and scientific elements of the GRAS standard, which require a safety assessment for intended use by experts in ingredient safety." According to ICGA, the tentative determination not only represents "a significant departure" from past efforts to reduce *trans* fat consumption through labeling initiatives, but discards a previous determination that PHOs in amounts less than 0.5 grams per serving "are effectively not present" in a product. In addition, the industry has cited a lack of PHO alternatives at reasonable prices, claiming that "it will take time to test and fully qualify products for performance, stability and consumer acceptance before they are marketed."

"[W]hile the use of partially hydrogenated oils in food has been drastically reduced in recent years, they continue to be important functional ingredients at lower levels in many food products," concluded ICGA, which has asked FDA to avail itself of other regulatory approaches to reducing *trans* fat in the diet. "As such, eliminating the GRAS status in all foods would have major ramifications for reformulating products in the food industry. We believe there are safe and valid applications for partially hydrogenated oils in food that FDA should consider before making a regulatory decision to eliminate all uses."

FDA to Revise Spent Grain Proposal

After reportedly receiving more than 2,000 comments criticizing its proposal to tighten regulations concerning the transaction of spent grain between brewers and farmers, the U.S. Food and Drug Administration (FDA) has apparently decided to revise its original plan, stating that it will release an amended version of the proposal this summer.

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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According to news sources, brewers, who for years have donated or sold their spent grain to farmers to use as animal feed, were outraged at the proposed regulation—part of FDA's Food Safety Modernization Act—claiming it would turn an ages-old practice into a heavy burden, requiring them to alter processes and testing requirements and add additional recordkeeping tasks. Brewers also note that under the currently proposed terms, they would either be required to dry and package spent grain before sending it off as animal feed or to discard it entirely, leaving it to sit in landfills. *See VoiceofSanDiego.org*, April 3, 2014; *BrewBound.com*, April 4, 2014.

FDA Issues Industry Guidance on Prior Notice of Imported Foods

The U.S. Food and Drug Administration (FDA) has **issued** draft guidance for the food industry titled "Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3)." Intended to address questions received since publication of the second edition in May 2004, the guidance includes information related to the Food Safety Modernization Act, which requires prior notice indicating whether a food article has been refused entry by any country. FDA will accept comments at any time, but suggests submitting them by May 30, 2014, to ensure consideration before the agency begins work on the final version. *See Federal Register*, March 31, 2014.

EPA Orders Halt to Sales of Food Storage Products

The U.S. Environmental Protection Agency (EPA) has issued a stop sale, use or removal order against New Jersey-based Pathway Investment Corp. concerning company food storage products containing nano silver. According to the agency, these products—Kinetic Go Green Premium food storage containers, Kinetic Smartwist Series containers, TRITAN food storage, and StackSmart Storage—are marketed "as containing nano silver, which the company claims helps reduce the growth of mold, fungus and bacteria." As such the products contain pesticides and must be registered under the Federal Insecticide, Fungicide and Rodenticide Act. These products were not registered and were not subjected to efficacy testing. EPA has also notified retailers that have sold the products on their Websites to cease doing so. *See EPA News Release*, March 31, 2014.

EFSA to Hold Workshop on Re-Evaluation of Food Additives

The European Food Safety Authority (EFSA) will **host** a workshop on April 28, 2014, in Brussels, to discuss the agency's work related to the re-evaluation of food additives, as required by Commission Regulation No. 257/2010 of the European Parliament and the Council on Food Additives. With an aim to "engage with interested business operators, scientific experts, the European Commission representatives, EFSA scientific staff and other interested parties," the workshop will include sessions that address (i) "why, how and when

scientific uses, use level data and other information should be made available to EFSA"; and (ii) "the extent to which the engagement of stakeholders during the re-evaluation process would be of mutual benefit for EFSA and stakeholders themselves." Participants may register until April 10, 2014.

ECHA Publishes Final Decisions for 14 Potentially Hazardous Substances

After review by member states and unanimous agreement by the Member State Committee, the European Chemicals Agency (ECHA) has **published** a group of evaluation decisions on 14 substances considered to pose potential risks, creating obligations for companies in the European Union to conduct tests and provide further data about their use. The decisions are the culmination of the European Parliament Council's substance evaluation process under Regulation No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

In addition to bisphenol A, ECHA has made final decisions on the following substances: isoheptane; imidazole; a mixture of cistetrahydro-2-isobutyl-4-methylpyran-4-ol; transtetrahydro-2-isobutyl-4-methylpyran-4-ol; oligomerisation and alkylation reaction products of 2-phenylpropene and phenol; N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine; carbon tetrachloride; 1,3-diphenylguanidine; hexyl salicylate; 2,2'-iminodiethanol; 2-ethylhexanoic acid; decahydronaphthalene; alkanes, C14-17, chloro (MCCP, Medium chained chlorinated paraffins); and 2-(4-tertbutylbenzyl) propionaldehyde.

NJ Lawmakers Introduce Bill Addressing Calorie-Content Posting of Foods Sold in Entertainment Facilities

New Jersey lawmakers have introduced a bill (**A2990**) that seeks to amend legislation requiring retail food establishments to provide calorie information for food and beverages. Proposed by Assembleywomen Nancy Pinken (D-Middlesex) and Linda Stender (D-Middlesex, Somerset and Union), the bill would require entertainment facilities to provide calorie information for food and beverage items offered for sale, subject to the same requirements that currently apply to chain restaurants. The bill defines "entertainment facility" as "any privately or publicly owned or operated facility that is used primarily for sports contests, entertainment, or both, such as a theater, stadium, museum, arena, automobile racetrack, or other place where performances, concerts, exhibits, games or contests are held."

LITIGATION

"Whiskey Fungus" Claims Not Preempted

A federal court in Kentucky has determined that distillery neighbors may proceed with state law-based tort claims alleging that the facility's emissions cause "whiskey fungus" to accumulate on their real and personal property. *Merrick v. Diageo Americas Supply, Inc.*, No. 12-0334 (U.S. Dist. Ct., W.D. Ky., Louisville Div., order entered March 19, 2014). Additional details about the lawsuit appear in Issue 444 of this *Update*.

Finding conflicting authority on whether the Clean Air Act (CAA) preempts the plaintiffs' claims for negligence and gross negligence, temporary and permanent nuisance and trespass, the court carefully analyzed related U.S. Supreme Court, federal court and state court rulings. It concluded that the Third Circuit's analysis in *Bell v. Cheswick Generating Station*, 734 F.3d 188 (3d Cir. 2013), and the Sixth Circuit's in *Her Majesty the Queen in Right of the Province of Ontario v. City of Detroit*, 874 F.2d (6th Cir. 1989), "capture[] the prevailing law for CAA preemption" by interpreting "the CAA's savings clauses to permit individuals to bring state common law tort claims against polluting entities."

The court dismissed the plaintiffs' negligence claims, however, agreeing with the defendant that they had failed to plead facts showing that Diageo owed them a duty or that it breached any duty. The court also found that the plaintiffs "failed to show how they, as property owners, could maintain a private cause of action based on Diageo's alleged violation of a city ordinance or regulation." While the court allowed the plaintiffs to proceed as to their temporary and permanent nuisance claims, finding them adequately pleaded, it noted that the plaintiffs will eventually have to elect between them and that the claim for permanent nuisance may be time barred. Because the parties had not addressed the latter issue, the court declined to decide it. The court further allowed the plaintiffs to pursue their claims for intentional trespass and injunctive relief, finding them sufficiently pleaded.

Court Trims Causes of Action in Labeling Suit Against Whole Foods

A federal court in California has granted in part and denied in part the motion to dismiss filed in a putative class action against Whole Foods Market. *Pratt v. Whole Foods Mkt. Cal., Inc.*, No. 12-5652 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered March 31, 2014).

The claims relate to a number of 365 Everyday Value® products that the plaintiff purchased and involve the following allegedly unlawful or misleading label representations: "evaporated cane juice" (ECJ), "natural" and "no sugar added." Because the plaintiff abandoned in his amended complaint all claims

regarding the defendants' whipped topping product, the court dismissed all claims based on this product with prejudice as to the plaintiff and without prejudice as to any putative class member. The "no sugar added" claims were thus dismissed, "as the only product alleged to have such a misleading claim was the whipped topping." The court also emphasized that, per its August 2013 order, any claims as to unpurchased items were dismissed with prejudice as to the plaintiff and ordered these claims to be stricken from the amended complaint; the court further stated that they may not be re-alleged in any future amended complaint.

The court refused to find the remaining claims preempted or subject to dismissal under the primary jurisdiction doctrine. The court disagreed with the plaintiff that he did not need to plead reliance under the "unlawful prong" of the Unfair Competition Law and further found that the ECJ claim was not sufficiently pleaded. And while the court dismissed the plaintiff's claim for unjust enrichment, agreeing with those courts finding it duplicative of his statutory claims, it will allow the plaintiff to amend the complaint as to ECJ and unjust enrichment.

Food Labeling Claims Against Costco Narrowed

A federal court in California has dismissed the claims of one named plaintiff in a putative class action alleging that certain Costco Kirkland-branded products are misbranded and deceptive, and narrowed the claims of the other named plaintiff. *Thomas v. Costco Wholesale Corp.*, No. 1202908 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered March 31, 2014).

The plaintiff whose claims were dismissed for lack of standing had alleged that the "0 grams trans fat" labeling on Kirkland Signature Kettle Chips was untruthful or misleading. The court agreed with the defendant that she had not cured the standing defects in her second amended complaint (SAC) and thus dismissed her claims with prejudice. Among other matters, she failed to (i) allege that the chips she purchased included any amount of *trans* fat or that she received a product different from the one as labeled, (ii) demonstrate that the label violated 21 C.F.R. § 101.13(h)(1), or (iii) allege in detail how she was misled.

As to the remaining named plaintiff, the court ruled that "claims for nutrient content, antioxidant content, health, no sugar added, preservative free, propellant and slack-fill claims" were properly pleaded, may deceive a reasonable consumer and are inappropriate to resolve at this stage of the proceedings. The court dismissed with leave to amend this plaintiff's "evaporated cane juice" (ECJ) allegation because she, like plaintiffs in other cases, "included the label of the purchased product, which lists 'sugar' as an included nutrient and clearly show[s] how much sugar is contained in the product [and] indicates in the SAC that she knows that ECJ is the same as 'sugar' and

'dried cane syrup.' Further, the SAC fails to allege what Plaintiff Liddle believed ECJ to be if not sugar and does not explain what a reasonable person would believe ECJ to be."

While the court found that "the majority of courts in this district have decided that [ECJ] claims are not barred by the doctrine of primary jurisdiction," it declined to address the argument, having already dismissed the ECJ claims for failure to state a claim.

Tennessee Whiskey Maker Challenges Storage Law

Diageo Americas Supply, Inc. has filed a declaratory judgment action against the Tennessee Alcoholic Beverage Commission director challenging the constitutionality of a 1937 law that requires licensed alcohol beverage makers in the state to store their products "only within the county authorizing the operation or in a county adjacent to the county authorizing the manufacturing operation, and such possession shall be limited to storage facilities of such manufacturer" (Storage Law). *Diageo Americas Supply, Inc. d/b/a George A. Dickel & Co. v. Bell*, No. 14-0873 (U.S. Dist. Ct., M.D. Tenn., filed March 28, 2014).

Alleging that the law has never been enforced, the complaint includes the defendant's March 20 letter warning the company that it was in violation of the Storage Law because it "is storing product (manufactured/distilled alcoholic beverages) produced at its Tullahoma, Tennessee, distillery in warehouses located in Louisville, Kentucky." According to the company, most of its distilled alcohol beverages are stored on-site in Tennessee, but it has transported "some Distilled Spirits manufactured at its George Dickel Distillery (other than George Dickel® Tennessee Whisky) to a company-owned distillery in Kentucky and stores those Distilled Spirits there."

The company contends that the law violates its Commerce Clause and Due Process rights under the U.S. Constitution, arguing that it would have to incur costs to move the Kentucky-stored spirits back to Tennessee, perhaps requiring the construction of additional storage capacity or a reduction in its manufacturing output in Tennessee with a consequent loss of jobs in the state. According to the complaint, the law "prevents Dickel from transporting its products out-of-state for storage and accordingly prevents the movement of commercial goods in interstate commerce." Seeking declaratory and injunctive relief, the company also claims that the law "mandates differential treatment of similarly-situated licensees who manufacture alcohol beverages in Tennessee."

Court Allows Most Claims in LFTB Suit to Proceed

A South Dakota court has determined that most of the claims filed by the makers of lean finely textured beef (LFTB) against ABC News, certain news correspondents, including Diane Sawyer, and former U.S. Department of Agri-

culture (USDA) employees may proceed. *Beef Prods., Inc. v. Am. Broadcasting Cos., Inc.*, No. 12-292 (Union Cnty. Cir. Ct., S.D., order entered March 28, 2014). Information about the lawsuit appears in Issue **453** of this *Update*.

While the court found the plaintiffs' claims for common law disparagement preempted by a state statute addressing the elements of a disparagement cause of action, available relief and statute of limitations, it limited its dismissal with prejudice to those alleged tortious statements expressly stating or implying that the product is not safe for human consumption.

As to the defamation claims, the court found that the three plaintiffs were appropriate parties because the complaint sufficiently alleged that people who heard the allegedly defamatory and disparaging statements "would understand that all three of the Plaintiffs were the persons being referred to by the Defendant's alleged tortious statements regarding LFTB." The court also rejected the defendants' claims that their statements were not statements of fact and thus were not actionable, finding that most of the statements were "objective facts capable of being proven true or false," rather than "unrealistic exaggeration," hyperbolic statements, epithets, or "expressions of disapproval." The court further stated in this regard, "the news reports were touted as being investigative reports based upon information from USDA scientists, Zirnstein and Custer, and a former employee of [plaintiff] BPI, Foshee."

The court rejected the defendants' claims that various statements made during the national TV broadcasts were true, stating "Defendants are not insulated from liability by the fact that the Defendant ABC News reports may have also stated in some form during the news reports that LFTB is beef, LFTB is safe, and/or LFTB is nutritious. . . . [A] reasonable factfinder could find that the statements are defamatory and/or disparaging despite any accompanying qualifying or non-tortious statements." The court also allowed tortious interference with business relationship claims to proceed, finding the elements sufficiently pleaded.

Finally, the court addressed the motions to dismiss for lack of personal jurisdiction as to former USDA employees Gerald Zirnstein and Carl Custer who claimed limited contacts with the state and a single ABC on-camera interview to negate the element of activities purposefully directed at the forum state or its residents. The court found that the exercise of personal jurisdiction comports with due process because they knew their statements would affect South Dakota businesses, Zirnstein coined the derogatory term "pink slime" and both not only made statements that would be broadcast nationally but commented extensively about LFTB online—via Webpage comments, Facebook posts and posts on *meatingplace.com, Google Group Foodsafe,* and *foodpolitics.com*. The court also found the exercise of personal jurisdiction to be reasonable given likely jurisdiction in any number of states where the plaintiffs do business and the efficiencies of bringing one lawsuit in one jurisdiction.

MEDIA COVERAGE

Mother Jones Investigates Safety of BPA-Free Plastics

"Today many plastic products, from sippy cups and blenders to Tupperware containers, are marketed as BPA-free. But [George Bittner's] findings—some of which have been confirmed by other scientists—suggest that many of these alternatives share the qualities that make BPA [bisphenol A] so potentially harmful," writes Mariah Blake in a new investigative report examining the purported effects of BPA-free plastic on human health. Published in the March/April 2014 issue of *Mother Jones*, the report relies on research conducted by CertiChem, a laboratory founded by University of Texas-Austin Neurobiology Professor George Bittner, whose previous work in *Environmental Health Perspectives* claimed that "almost all" store-bought food containers "tested positive for estrogenic activity," including those marketed as BPA-free.

In particular, the report points to these findings as evidence that the independent studies used by industry and regulatory authorities are unreliable. "Many of the same scientists who were involved in doing tobacco industry research are now doing chemical industry-funded research on chemicals like BPA," concludes Blake. And just like [with] Big Tobacco, [where] industry-funded studies generally did not find that smoking or second-hand smoke was harmful, these studies are not finding that BPA and similar chemicals are harmful."

David Karp, "Is the Lime an Endangered Species?," *The New York Times,* March 29, 2014

A recent *New York Times* article highlighting the apparent fragility of the lime harvest has blamed a recent shortage on "weather, disease and even Mexican criminals," warning that increased wholesale prices have only compounded the problem. According to citrus researcher David Karp, a citrus greening disease known as huanglongbing (HLB) has already infiltrated groves in Mexico, which supplies 95 percent of the limes consumed in the United States. In addition to reducing the Key lime harvest by one-third in the past three years, the presence of HLB in Colima has stoked fears that the disease will spread to Persian limes located in Veracruz and other Mexican states. In addition, as industry leaders told Karp, the current shortfall has not only induced farmers to strip their trees early "to cash in on sky-high prices," but attracted the attention of criminal cartels that have reportedly started "plundering fruit from groves and hijacking trucks being used for export."

"The lime hysteria we're starting to see now may be only a taste what's to come," concludes Karp. "The produce wars on the ground are not limited to limes. Criminal cartels now control, to a shocking extent, the growing and packing of much of the Mexican produce on which United States consumers depend…

[I]t is important to recognize that we do give up a measure of food security by importing from countries destabilized by the drug trade, corruption and unchecked crime."

SCIENTIFIC/TECHNICAL ITEMS

Study Reexamines Effect of Sodium Intake on Health

A recent study has purportedly claimed that "both low sodium intakes and high sodium intakes are associated with increased mortality," raising questions about sodium consumption guidelines set by the Centers for Disease Control and Prevention (CDC) and other health authorities. Niels Graudal, et al., "Compared with Usual Sodium Intake, Low- and Excessive-Sodium Diets are Associated with Increased Mortality: A Meta-Analysis," *American Journal of Hypertension,* April 2014. After analyzing data from 23 cohort and two follow-up studies involving 274,683 individuals, Danish researchers reported that the risks of all-cause mortality and cardiovascular disease events "were decreased in usual sodium vs. low sodium intake… and increased in high-sodium vs. usual sodium intake," a result "consistent with a U-shaped association between sodium intake and health outcomes."

In particular, the main findings apparently showed that "2,645-4,945 mg of sodium per day, a range of intake within which the vast majority of Americans fall, actually results in more favorable health outcomes than the CDC's current recommendation of less than 2,300 mg/day for healthy individuals under 50 years old, and less than 1,500 mg/day for most over 50 years," according to an April 2, 2014, press release. The study thus confirmed the conclusions of a 2013 Institute of Medicine (IOM) report that found little evidence to support CDC recommendations advocating lower sodium intake for all populations.

"The good news," the lead author was quoted as saying, "is that around 95% of the global population already consumes within the range we've found to generate the least instances of mortality and cardiovascular disease." Additional details about the IOM report appear in Issue **484** of this *Update*.

Coffee Found to Reduce Non-Viral Cirrhosis Risk

A recent study has reportedly demonstrated "the protective effect of coffee on non-viral hepatitis-related cirrhosis mortality." George Boon-Bee Goh, et al., "Coffee, alcohol and other beverages in relation to cirrhosis mortality: the Singapore Chinese Health study," *Hepatology,* April 2014. Funded by the National Institutes of Health, researchers examined diet, lifestyle and medical history data from 63,275 middle-aged participants enrolled in The Singapore Chinese Health Study over a mean follow-up of 14.7 years. During that time, 114 participants died from cirrhosis related to viral hepatitis (33 percent),

chronic alcohol consumption (12 percent) and hepatitis C (2 percent), as well as biliary cirrhosis, autoimmune cirrhosis, and cryptogenic or unspecified cirrhosis.

In addition to finding that alcohol consumption was "a strong risk factor for cirrhosis mortality," the study evidently showed an inverse dose-dependent relationship between caffeine intake and non-viral cirrhosis mortality. The study's authors have suggested that "the benefit of coffee on the progression of liver disease may be due to its effects on the oxidative/lipotoxicity pathway, which underlie the pathogenesis of cirrhosis related to alcohol, NAFLD [non-alcoholic fatty liver disease] and possibly, in part, CHC [chronic hepatitis C]."

"Compared to non-daily coffee drinkers, those who drank two or more cups per day had a 66% reduction in mortality risk," they concluded, suggesting that it was the coffee itself, not just the caffeine, that was responsible for the reduced risk of death from liver cirrhosis. "Our study is the first to demonstrate a differential effect of coffee consumption between non-viral and viral hepatitis-related cirrhosis morality, and thus harmonize the seemingly conflicting results on the effect of coffee in Western and Asia-based studies… Since coffee is consumed globally, it has significant clinical and public-health implications and provides further impetus to evaluate coffee as a potential therapeutic agent in patients with chronic liver diseases."

Discovery of New Listeria Species May Improve Food Testing

Cornell University researchers have reportedly identified five new species of *Listeria* that they suggest could provide new insights leading to better methods of detecting soil bacteria in food. Funded by the U.S. Department of Agriculture, the research was part of a larger study led by scientists at Colorado State University and Cornell to examine the distribution of foodborne pathogens, such as *Listeria*, *E. coli* and *Salmonella*, in agricultural and natural environments. Samples were taken from fields, soil, ponds, and streams in New York, Colorado and Florida.

Noting that of the 10 previously known species of *Listeria*, only two are pathogenic to humans, the researchers claim that *Listeria monocytogenes* is the main cause of *Listeriosis*, reportedly the cause of hundreds of deaths and illnesses each year in the United States through infected deli meats, seafood and produce.

According to lead study author Henk den Bakker, the study findings have implications for understanding the evolution of what makes *Listeria monocytogenes* pathogenic. "The most recent common ancestor [of *L. monocytogenes* and closely related nonpathogenic species] was a pathogen, and that makes it difficult to reconstruct the evolution of pathogenicity in *Listeria*," den Bakker said. But the five newly identified species apparently add more evidence to the existence of four distinct evolutionary branches of Listeria.

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"Now we see the evolutionary tree has a couple of new branches, which gives us a nice data set to reconstruct what happened on a genomic level during the evolutionary transition from a free living ancestor to a pathogen." *See Cornell Chronicle*, March 26, 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.