Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Issues Draft Food Guidance with Information on Nanotechnology Applications

The Food and Drug Administration (FDA) has issued **draft guidance** that, in part, addresses the use of nanotechnology in food processing. Among other matters, "FDA considers food manufacturing processes that involve nanotechnology in the same manner as any other food manufacturing technology," although the agency also apparently recognizes that "nanotechnology and other emerging technologies may introduce issues that warrant additional or different evaluation during a safety assessment of a food substance. For example, so-called nano-engineered food substances can have significantly altered bioavailability and may, therefore, raise new safety issues that have not been seen in their traditionally manufactured counterparts."

Accordingly, FDA states, "When a food substance is manufactured to include a particle size distribution shifted more fully into the nanometer range, safety assessments should be based on data relevant to the nanometer version of the food substance. Where nano-engineered food substances have new properties, additional or different testing methods may be necessary to determine the safety of the food substance. Thus, the agency recommends the use of safety assessments "as rigorous as possible" and "based on data relevant to the version of the food substance intended for use." Still, the agency observes, "[a]t this time, we are not aware of any food ingredient or FCS [food contact substance] intentionally engineered on the nanometer scale for which there are generally available safety data sufficient to serve as the foundation for a determination that the use of a food ingredient or FCS is GRAS [generally recognized as safe]." To be considered in the final guidance, public comments must be submitted within 90 days after publication in the *Federal Register*. *See FDA News Release*, April 20, 2012.

TTB to Require Labeling of Cochineal Extract and Carmine in Wine, Malt Beverages

The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) has issued a **final rule** ordering "the disclosure of the presence of cochineal extract and carmine

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on the labels of any alcohol beverage containing one or both of these color additives." According to TTB, the rule responds to a Food and Drug Administration (FDA) regulation that took effect on January 5, 2011, and requires manufacturers to label these two additives on all food and cosmetic products due to the potential for severe allergic reactions.

Effective March 16, 2012, with a final compliance date of April 16, 2013, the TTB rule notes that FDA does not compel labels to disclose that cochineal extract and carmine are derived from insects native to subtropical South America and Mexico. In issuing its final decision, TTB rejected one comment that called for listing the additives' source despite industry concerns that some consumers "would find the thought of insect derivatives unappealing." As the bureau concluded, such disclosure was not necessary "in order for consumers to have adequate information about the product" and "to allow persons with sensitivities to cochineal extract or carmine the opportunity to avoid ingestion or contact with these additives." Additional details about FDA's final rule and TTB's proposed rule appear in issues 287, 296 and 371 of this *Update*.

Humane Society Alleges Deceptive Marketing of Pork in FTC Complaint

The Humane Society of the United States (HSUS) has reportedly filed a legal complaint with the Federal Trade Commission (FTC) alleging that the National Pork Producers Council (NPPC) "is engaging in deceptive advertising related to animal well-being in violation of the Federal Trade Commission Act," according to an April 18, 2012, press release. In particular, the complaint apparently maintains that NPPC's "We Care Initiative" and "Pork Quality Assurance [PQA] Plus" program "are riddled with numerous false claims regarding the welfare of pigs, including the trade group's patently false claim that its PQA Plus program helps to 'ensure that all animals in the pork industry continue to receive humane care and handling.'"

In support of these assertions, HSUS claims to have documented pork industry practices "that most consumers do not consider humane such as the extreme confinement of breeding sows in two-foot-wide metal cages, and painful procedures such as tail 'docking,' which is typically performed without any form of pain relief." It has called for "prompt FTC action" to bar NPPC from publicizing its PQA Plus program and "We Care Initiative."

Meanwhile, NPPC has refuted the FTC complaint and promised to "vigorously defend" against it. "America's hog farmers are committed to providing humane and compassionate care for their pigs at every stage of life," NPPC told *Advertising Age*. "U.S. hog farmers are the ones who ensure the well-being of their animals and who are dedicated to producing safe, affordable and healthful foods for consumers—using standards and practices that have been designed with input from veterinarians and other animal-care experts—not

groups that spend well-over half of the donations they receive on soliciting more contributions and, apparently, the other portion on suing American farmers." *See Advertising Age* and *Pork Magazine,* April 18, 2012.

British Survey Shows "Upward Trend" in Acrylamide Levels for Some Retail Foods

The U.K. Food Standards Agency (FSA) has **released** its fourth Food Surveillance Information Sheet analyzing acrylamide and furan levels in 248 retail products from 10 food groups. Conducted from 2007 to 2011, the survey apparently revealed "an upward trend in acrylamide levels in processed cereal-based baby foods (excluding rusks), and a reduction in other products, such as pre-cooked French fries, potato products for home cooking and bread." Although FSA did not note any concern for human health risks, it reported that, of the 248 products surveyed, 13 samples contained acrylamide levels "that exceeded the 'indicative value' (IV) for their food group" and therefore warrant investigation by "the relevant local authority."

"The Agency advises that chips should be cooked to a light golden color. Bread and bread products should also be toasted to the lightest color possible," stated FSA, which will send its findings to the European Food Safety Authority for further assessment. *See FSA New Release,* April 17, 2012.

Sweden Bans BPA in Food Packaging for Kids

Sweden has banned the use of bisphenol A (BPA) in food packaging intended for children younger than age 3. Mainly affecting the lids of baby food jars, the April 13, 2012, edict also gave the Swedish Chemicals Agency three months to investigate whether the chemical should be prohibited in certain types of thermal paper, such as tickets and receipts, and other relevant agencies the opportunity to determine the extent of its use in drinking-water pipes, toys and other children's goods.

Minister for the Environment Lena Ek, who said she plans to raise the BPA issue soon with the European Commission and European Union (EU) member states, noted that the ban ensures that the country's current voluntary phase-out of BPA-free packaging becomes permanent. "As a matter of caution, we are now acting in all areas that the agencies believe play a significant role in the exposure of young children," she said. "The EU should take more far-reaching initiatives than today to limit children's exposure to bisphenol A and other known endocrine disruptors." *See Sweden Ministry of the Environment Press Release*, April 13, 2012.

LITIGATION

JPML Rejects Motion to Consolidate and Centralize Tainted Beef Litigation

The Judicial Panel on Multidistrict Litigation (JPML) has denied a motion seeking to consolidate and transfer to a multidistrict litigation court three cases filed in federal courts against companies allegedly responsible for a 2009 *E. coli* outbreak involving contaminated ground beef. *In re: Ne. Contaminated Beef Prods. Liab. Litig.*, MDL No. 2346 (J.P.M.L., decided April 17, 2012).

According to the court, the cases do not "contain significant overlapping questions of fact sufficient to warrant centralization of the few involved actions," and "the likelihood that additional actions will be filed concerning this *E. coli* outbreak—which occurred nearly two and a half years ago and affected under 30 individuals—seems low. With only three actions pending in two adjacent districts involved in this litigation, movant has failed to convince us that centralization is needed." The court indicated that it would be "practicable and preferable" for the parties, courts and counsel to informally cooperate in preparing the cases for trial.

Insurers Seek Reimbursement for Costs of Defending Restaurant in Food Toxin Suit

The insurance carriers for Rubio's Restaurant have filed a motion for summary judgment in a dispute with the company that insured the restaurant's fish supplier, following the settlement of claims pursued by a restaurant patron who alleged that he has permanent and severe neurological injuries from exposure to a toxin from the mahi-mahi in a Rubio's fish burrito. *Fireman's Fund Ins. Co. v. Nationwide Mut. Fire Ins. Co.*, No. 3:11-cv-0114-IEG (U.S. Dist. Ct., S.D. Cal., motion filed April 9, 2012). While the patron and his wife reportedly sought $7 million in damages, the settlement amount remains undisclosed.

According to the plaintiffs, the defendant must reimburse them for the costs of defending the restaurant and the amounts they contributed to the settlement on the restaurant's behalf. The restaurant was evidently an additional insured under the defendant's policy with the fish supplier, and the plaintiffs argue that a duty to defend exists when there is a potential that the policy provides coverage. The defendant apparently argues that its duty to cover the restaurant is triggered only if it can be proved with certainty that the fish which caused the injury was supplied by its insured and that the restaurant has failed to do so. *See Law360*, April 10, 2012.

Class Notification Ongoing in Diamond Walnut Settlement of Omega-3 Fraud Claims

Under a court order preliminarily approving a settlement of consumer fraud claims involving purported health benefit labeling used to sell Diamond Foods walnuts, the class notification program has apparently begun. *Zeisel v. Diamond Foods, Inc.*, No. 10-01192 (U.S. Dist. Ct., N.D. Cal., preliminary approval order entered January 30, 2012). The court previously certified a nationwide class of consumers who have until July 30, 2012, to opt out of or object to the settlement. Additional details about the certification ruling appear in **Issue 397** of this *Update*. The deadline for filing a claim is September 7.

While the company admits no wrongdoing, it has ceased using the disputed product labels and has removed a "Live Well" section from its Website. It also agreed to cease using unqualified health claims, but reserves "the right to use the FDA-approved qualified health claim for walnuts, any language or symbols developed by or in conjunction with the American Heart Association ('AHA') and any truthful and not misleading statements regarding the health benefits of its Walnut Products" at the company's discretion and in compliance with state and federal laws.

Class members without proof of purchase may recover $8.25 for each of up to three 3-pound bags of walnuts purchased through a single retailer or $3.25 for each of up to five of any other size bags. Those with proof of purchase may submit claims for more than three 3-pound bags and five bags of any other size to a maximum of 24 bags. Diamond will distribute any residual restitution to third party food banks. The company has reserved the right to withdraw from the agreement if the submitted claims total more than $2.6 million or more than 300 settlement class members opt out. It has also agreed not to oppose an application for $850,000 for attorney's fees and expenses, including a $5,000 incentive award to the named plaintiff. The court will conduct a final approval hearing in August.

Court Guts Most Claims in Muscle Milk® Consumer Fraud Litigation

A federal court in California has granted in part and denied in part the defendant's motion to dismiss claims that its product labels, ads and Website representations for Muscle Milk® ready-to-drink beverages and snack bars violate state unfair competition and false advertising laws and the California Consumers Legal Remedies Act, and constitute fraud, negligent misrepresentation and unjust enrichment. *Delacruz v. Cytosport, Inc.*, No. C 11-3532 (U.S. Dist. Ct., N.D. Cal., decided April 11, 2012). While the court determined that the plaintiff has standing to pursue the putative class claims and that the claims are not preempted by federal law nor should be stayed under the primary jurisdiction doctrine, it found many of her claims insufficiently pleaded.

According to the court, the only claim that survives the motion to dismiss alleges that the term "healthy fats" on the 14-ounce Muscle Milk® ready-to-drink label could constitute deceptive product labeling, because "[a] reasonable consumer would be likely to believe that the drink contains unsaturated, not saturated, fats." Given that unsaturated fats are the "healthy fat," and that the label also states that the product is a "nutritional shake," the court found that "this representation, while 'difficult to measure concretely' like a similar claim in *Williams*, contributes to a sufficient claim of deceptive product labeling." So ruling, the court rejected the defendant's argument that the nutrient label on the package shielded it from liability for deception.

Among other matters, the court found the following terms to be non-actionable puffery: "Go from cover it up to take it off," "From invisible to OMG!," "From frumpy to fabulous," and "an ideal nutritional choice." The court also found that the plaintiff had not sufficiently alleged that the beverage contains "unhealthy amounts of fat, saturated fat or calories from fat, compared to its protein content, based on any objective criteria." The complaint simply compared the products to certain Krispy Kreme doughnuts. According to the court, "this analogy is not helpful. Plaintiff does not explain how much protein, vitamins and minerals are in such a doughnut or posit an objectively healthy ratio of protein to fat." The court relied on *Kwikset v. Superior Court*, 51 Cal. 4th 310 (2011), to explain that allegations that a plaintiff was denied the benefit of her bargain are sufficient to state a claim of injury.

While the court found that the plaintiff sufficiently alleged reliance on product label misrepresentations by claiming that she was "exposed to" the product labels, it also determined that she had inadequately pleaded reliance on the defendant's "long-term advertising campaign." "Plaintiff does not plead that she actually saw and relied upon any particular statements in Defendant's advertising" and failed to allege "that Defendant's advertising campaign approached the longevity and pervasiveness of the marketing at issue in *Tobacco II*." The court gave the plaintiff seven days to amend her complaint to remedy "the defects addressed above if she is able truthfully to do so without contradicting the allegations in her original complaint."

Additional details about the complaint and a Food and Drug Administration warning letter addressed to the defendant appear in issues **403** and **404** of this *Update*, respectively.

Employer Settles ADA Claim Filed on Behalf of Obese Woman

According to the U.S. Equal Employment Opportunity Commission (EEOC), the owner and operator of a long-term residential treatment facility for chemically dependent women and their children has agreed to pay $125,000 to the estate of an employee allegedly terminated from her position because she was severely obese. *EEOC v. Res. for Human Dev., Inc.*, No. 10-03322 (U.S.

Dist. Ct., E.D. La., consent decree entered April 10, 2012). Additional information about the court decision denying the employer's motions for summary judgment and recognizing obesity as a disability under the Americans with Disabilities Act (ADA) appears in **Issue 421** of this *Update*.

EEOC also indicated that under the consent decree, the employer will "provide annual training on federal disability law to all human resources personnel and corporate directors of RHD [Resources for Human Development] nationwide." The agreement further requires the company to report to EEOC "for three years on all complaints of disability discrimination and all denials of a request for reasonable accommodation of a disability." RHD has agreed as well to name a children's room in its Terrytown, Louisiana, facility, where the now-deceased employee worked, and to permanently install a memorial plaque in her honor.

EEOC Houston District Office Regional Attorney Jim Sacher said, "This case highlights the fact that severely obese people who can do their jobs are every bit as protected by the ADA as people with any other qualifying disability. Any notion that these individuals are not protected, based on the wrongheaded idea that their condition is self-inflicted, is simply wrong and without legal basis." While some legal scholars contend that the obese are protected under the ADA only if their condition was caused by a diagnosed medical disorder, the court rejected that argument, stating that because severe obesity qualifies as a disability under the ADA, "there is no requirement to prove an underlying physiological basis." *See EEOC Press Release*, April 10, 2012.

Class Action Filed Against Seafood Producer Challenging "Omega-3" Claims

California resident Tricia Ogden has filed a putative class action in federal court against Bumble Bee Foods, LLC, alleging that it misbrands its seafood products by claiming they "are an excellent and affordable source of protein, nutrients and Omega 3 fatty acids" and "Rich in Natural Omega-3." *Ogden v. Bumble Bee Foods, LLC*, No. 12-01828 (U.S. Dist. Ct., N.D. Cal., San Jose Div., filed April 12, 2012). The only injury apparently alleged is economic, i.e., "Plaintiff would have foregone purchasing Defendant's products and bought other products readily available at a lower price," and "Plaintiff would not have purchased Defendant's Misbranded Food Products had he [sic] known they were not capable of being legally held or sold."

According to the complaint, such representations and labeling establish that the company's products are drugs under federal law "because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" and are sold without prior Food and Drug Administration approval. The plaintiff also contends that food producers using an Omega 3 nutrient content claim must specify whether the claim refers to "ALA, DHA, or EPA omega 3 fatty acids" and that the company fails to do so. Further, the

complaint alleges that the company's food products bearing the Omega-3 labels "make such claims despite disqualifying levels of unhealthy components without proper disclosure," and cites fat, sodium and cholesterol warning-statement omissions.

Seeking to certify a nationwide class of consumers, the plaintiff alleges violations of California's unlawful and fraudulent business acts and practices laws, misleading and deceptive advertising, untrue advertising, violation of the Consumers Legal Remedies Act, unjust enrichment, and breach of warranty under the Beverly-Song Act and Magnuson-Moss Act. She asks for damages, restitution or disgorgement, punitive damages, attorney's fees and costs, interest, and an order for injunctive relief "requiring Defendant to immediately cease and desist from selling its Misbranded Food Products in violation of law; enjoining Defendant from continuing to market, advertise, distribute, and sell these products in the unlawful manner described herein; and ordering Defendant to engage in corrective action."

Egg Farmer Calls California Cage Limitations Unconstitutional

A California egg farmer has filed a lawsuit challenging the constitutionality of Proposition 2 (Prop. 2), a voter-approved ballot initiative that, beginning January 1, 2015, will subject egg producers to criminal sanctions for confining egg-laying hens to cages preventing them from "lying down, standing up, and fully extending . . . [their] limbs" and "turning around freely." *Cramer v. Brown*, No. 12-03130 (U.S. Dist. Ct., C.D. Cal., E. Div., filed April 10, 2012). Contending that Prop. 2 violates his due process rights because it is vague and will result in arbitrary enforcement, the plaintiff claims that he and others will likely shut down their farms before the effective date and that the price of eggs will skyrocket for state consumers and supply shortages will occur if it goes into effect.

The plaintiff also alleges that Prop. 2 violates the Commerce Clause by failing to provide local benefits and greatly burdening interstate commerce. According to the complaint, "when California egg farmers shut down their operations, billions of eggs in the national supply chain will be affected. Relocation of farms will be expensive, and that cost will be borne by egg consumers." The plaintiff notes that proposed federal legislation which would establish specific cage-size requirements, if enacted, will preempt the state law; the bill is attached to the complaint as an example of statutory language that is not vague. The court is requested to declare Prop. 65 unconstitutional and enter preliminary and permanent injunctive relief to prohibit its enforcement.

OTHER DEVELOPMENTS

Animal Welfare Groups Pull Reins on Proposed Horse Slaughterhouse

A New Mexico rancher has reportedly petitioned the U.S. Department of Agriculture (USDA) to operate the first horse slaughterhouse since the ban for such operations was lifted in November 2011. Since 2006, the federal government has essentially blocked horse slaughterhouses because Congress did not fund their legally required USDA inspections. Those inspections, however, were approved by lawmakers in last year's agricultural spending bill.

According to a news source, Rick De Los Santos, part-owner of Valley Meat Co. in Roswell, plans to slaughter 20 to 25 horses a day and export the meat to Mexico for human consumption. He asserts that more than 100,000 American horses are shipped to slaughterhouses in Mexico and Canada, with some of the meat exported to Europe and Asia. "Everyone who's ever eaten tacos in Mexico, I guarantee you they've eaten horse meat down there," De Los Santos said. "It would never be my intention to sell it in the U.S."

The Humane Society of the United States (HSUS), American Society for the Prevention of Cruelty to Animals, Front Range Equine Rescue, Animal Protection of New Mexico, and others oppose De Los Santos' plans.

"American horses are our partners in sport, work and recreation—not dinner," said Keith Dane of HSUS. "The entire process of horse slaughter is filled with nonstop terror, pain and misery for horses, and it is proven to have a severe negative impact on surrounding communities." *See Albuquerque Journal* and *HSUS Press Release,* April 13, 2012.

MEDIA COVERAGE

NYT Highlights Food Desert Controversy

An April 17, 2012, *New York Times* article has drawn attention to two recent studies questioning the perception that poor urban neighborhoods are "food deserts" with little access to fresh produce, vegetables and other healthy options. According to *Times* science correspondent Gina Kolata, reports published in *The American Journal of Preventive Medicine* (February 2012) and *Social Science and Medicine* (March 2012) have concluded that such neighborhoods "not only have more fast food restaurants and convenience stores than more affluent ones, but more grocery stores, supermarkets and full-service restaurants, too."

"Maybe we should call it a food swamp rather than a desert," said RAND Corporation Senior Economist Roland Strum, whose study matched height, weight, diet, and residential data from participants in the California Health

Interview Survey with information about nearby food outlets. Meanwhile, the second report funded by the Public Policy Institute of California (PPIC) relied on a federal study of 8,000 children and data on all the businesses in the nation to determine that poor neighborhoods "had nearly twice as many fast food restaurants and convenience stores as wealthier ones," but also "nearly twice as many supermarkets and large-scale grocers per square mile."

In particular, PPIC Policy Fellow Helen Lee noted that previous studies responsible for the notion of food deserts often failed to effectively combine data about income, body weight and food outlet locations, or else focused on areas that were too large to see "what happened in pockets of poverty within those regions." As she reportedly explained to Kolata, "Some researchers counted only fast food restaurants and large supermarkets, missing small grocers who sold produce. Some tallied food outlets per 1,000 residents, which made densely populated urban areas appear to have fewer places per person to buy food. A more meaningful measure… is the distance to the nearest stores."

SCIENTIFIC/TECHNICAL ITEMS

Study Questions Alleged Link Between Junk Food in Schools and Childhood Obesity

A recent study attempting "to isolate the causal effect of junk food availability on children's food consumption and body mass index (BMI)" has concluded that access to competitive foods in schools "does not significantly increase BMI or obesity among this fifth-grade cohort despite the increased likelihood of in-school junk food purchases." **Ashlesha Datar and Nancy Nicosia, "Junk Food in Schools and Childhood Obesity," *Journal of Policy Analysis and Management*, Spring 2012**. According to the researchers, who used data from the Early Childhood Longitudinal Study—Kindergarten Class as well as an instrumental variables (IV) approach leveraging "the well-documented fact that junk foods are significantly more prevalent in middle and high schools relative to elementary schools," the results evidently revealed that where previous models had identified "any small positive associations" between junk food availability and obesity, those associations became insignificant "when controls for BMI at school entry and fixed state effects are added."

In particular, the statistical models used by the study authors not only suggested that "the caloric contributions of in-school junk food purchases are likely to be small," but that "the *total* amount of soda and fast food consumed in- and out-of-school is not significantly higher among those children with greater exposure to junk food in school (i.e., attending a combined school)." In addition, they also found little support "for the notion that children substitute calories from healthy foods or increase their physical activity to compensate for increased junk food intake."

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As a result, the authors questioned legislation and regulation designed to curb the availability of competitive foods in schools while noting that further research was needed to determine whether school contracts with food and beverage companies "influence students' food choices in the longer run through product or brand recognition." Nevertheless, they concluded, "In light of our findings, certain policy measures, such as outright bans on competitive food sales (at least among elementary school children), might appear premature given that they remove a key source of discretionary funds."

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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.