Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

USDA Proposes Process for Generic Labeling Approval

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has issued a **proposed rule** to "expand the circumstances under which FSIS will generically approve the labels of meat and poultry products." Under the proposal, which would also combine regulations into a new CFR part, FSIS would reportedly allow establishments "to label a broader range of products without first submitting the label to FSIS for approval." As the agency explained in a December 5, 2011, press release, "all mandatory label features would still need to comply with FSIS regulations."

In particular, FSIS noted that the current generic label regulations are too restrictive in practice, compelling the agency to pre-approve "a significant amount of labeling" instead of dedicating resources to other consumer protection and food safety activities. "For example, the label for a non-standardized product, such as pepperoni pizza (bearing no special statements or claims) that was sketch approved by FSIS would need to be resubmitted for sketch approval if the establishment makes a minor formula change that affects the order of predominance in the ingredients statement," stated the agency. *See Federal Register,* December 5, 2011.

"It is important that we make the labeling process more effective and efficient, while still ensuring consumers have the best information available when shopping for food," said USDA Undersecretary for Food Safety Elizabeth Hagen. FSIS will accept comments on the proposed rule until February 3, 2012.

FDA Agrees to Issue Ruling on BPA Petition

A federal court has approved an agreement between the Food and Drug Administration (FDA) and the Natural Resources Defense Council (NRDC) resolving NRDC's complaint that the agency unreasonably delayed issuing a final decision on its petition seeking a regulation that would prohibit the use of bisphenol A (BPA) in food packaging. *NRDC v. HHS*, No. 11-5801 (U.S. Dist.

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Ct., S.D.N.Y., consent judgment filed December 7, 2011). Under the agreement, FDA will issue its final decision on or before March 31, 2012.

Noting that its petition was filed three years ago, an NRDC spokesperson said, "While we are glad FDA is finally going to make a decision [on] BPA in food packaging and this is a major step forward in the legal process, it is discouraging that FDA has not responded and that we had to ask the court to intervene just to get FDA to do its job. The agency has been dragging its feet on making a decision about BPA for far too long." FDA reportedly indicated in 2010 that it had some concerns about BPA's effect on children, but it has also indicated that the chemical's use in food packaging does not pose a health risk. *See FoodProductionDaily.com*, December 8, 2011.

Meanwhile, in a separate matter, NRDC has also sued FDA alleging that it has violated the Freedom of Information Act (FOIA) by failing to disclose responsive records concerning BPA. *NRDC v. FDA*, No. 11-8662 (U.S. Dist. Ct., S.D.N.Y., filed November 29, 2011). According to the complaint, NRDC sought records from FDA in October 2011 involving "the regulation of BPA in food packaging, the extent of human exposure to BPA through food packaging and the health effects of such exposure, and testing and research on BPA conducted or funded by FDA and other federal agencies collaborating with FDA. The request also seeks communications between FDA and the American Chemistry Council, governmental agencies, members of Congress or the public, and other outside entities regarding BPA."

NRDC alleges that FDA has responded by producing a small number of documents, which are apparently from a public docket, and allegedly do not satisfy the FOIA request. The agency also purportedly indicated that a response to other portions of the request would be forthcoming. As of November 14, 2011, the FOIA deadline for a response, "FDA has failed to provide NRDC with a complete response to its request." NRDC seeks a declaration that the agency has violated FOIA and an injunction ordering FDA to provide the requested records.

CSPI Petitions FDA for Front-Label Disclosure of Artificial Coloring

The Center for Science in the Public Interest (CPSI) has **petitioned** the Food and Drug Administration (FDA) to require the disclosure of food color additives on front-of-package labeling. Citing "the ubiquity of food colorings" in the American diet, the petition claims that consumers are misled when colorings are used to either mask less-nutritious ingredients or make a product "appear to be of higher quality or nutritional value than it actually is." The group also points to studies suggesting a link between certain food additives and behavioral effects in children.

CPSI urges FDA to "amend the labeling requirements set forth at 21 C.F.R. § 101.22" to require foods containing such additives to state "Artificially Colored"

"on the product display package next to the product name in bold letters not less than half the height and weight of the name of the food." According to CPSI, FDA already possesses the statutory authority and regulatory framework to make this change, which would "promote public health" and "prevent consumer deception."

"Betty Crocker is certainly free to make virtually carrotless carrot cake, and Tropicana is free to make berryless and cherryless juice," CSPI Executive Director Michael Jacobson said in a December 8, 2011, press release. "But consumers shouldn't have to turn the package over and scrutinize the fine print to know that the color in what are mostly junk foods comes from cheap added colorings."

European Policymakers Urged to Adopt Anti-Tobacco Tactics in War on Obesity

During a recent discussion about family and childhood nutrition sponsored by the Brussels-based think-tank Friends of Europe, the World Health Organization's representative to the European Union reportedly called for imposing steep taxes on salty and sugary foods to address excessive eating. Roberto Bertollini apparently claimed that the campaign against tobacco, including high taxes and government regulation of tobacco use and advertising, provides a model to address increasing rates of obesity. He also called for restrictions on junk-food advertising and government efforts to promote healthy eating habits and exercise. Others participating in the forum reportedly suggested that parents and schools play a role in getting children to adopt healthier lifestyles. *See EurActiv*, December 6, 2011.

LITIGATION

First Circuit Orders Further Proceedings in Sugar Documentary Defamation Case

The First Circuit Court of Appeals has determined that, while Dominican Republic plantation owner executives are limited-purpose public figures for purposes of a defamation lawsuit involving a documentary film critical of their operations, the district court erred in denying a motion to compel the disclosure of documents that could pertain to actual malice. ***Lluberes v. Uncommon Productions, LLC*, No. 10-2082 (1st Cir., decided November 23, 2011)**. So ruling, the court affirmed in part but vacated the district court's grant of summary judgment and remanded the case for a review of the purported privileged documents in camera, if necessary, and a determination as to whether sufficient evidence of actual malice has been shown.

The film apparently focused on living conditions in the company towns in which the plantation workers live and identified the plaintiffs "as bearing some measure of responsibility for their disrepair." The plaintiffs argued on

appeal that they were not limited-purpose public figures and that the lower court thereby erred in finding that they had to show actual malice to prove defamation. The First Circuit disagreed, noting that the plaintiffs actively pursued a public relations campaign to counter negative press about the company towns and had become limited-purpose public figures in the Dominican Republic. The court refused to find that they were not also public figures in the United States because the controversy over the workers' living conditions "was not confined to the shores of the Dominican Republic. Rather, it resounded in the United States for obvious humanitarian reasons and a less-obvious geopolitical one: a long-standing import quota system under U.S. law that subsidizes Dominican sugar producers, including the Vicinis."

Pom Wonderful Loses Deceptive Claim Lawsuit Against Ocean Spray

According to a news source, Pom Wonderful LLC, which was seeking $18.1 million in lost sales from Ocean Spray Cranberries Inc. for falsely selling a pomegranate juice product with just trace amounts of pomegranate juice, lost its case following less than two hours' deliberation by a federal jury. *Pom Wonderful LLC V. Ocean Spray Cranberries Inc.*, No. 09-00565 (U.S. Dist. Ct., C.D. Cal., verdict reached December 6, 2011). The trial apparently became a battle of experts who cited conflicting statistics on whether Ocean Spray misled consumers about the quantity of pomegranate juice in its Cranberry & Pomegranate® juice blend, which evidently contains mostly grape and apple juice. Pom Wonderful sought to show that Ocean Spray took advantage of Pom's extensive medical research into the purported health benefits of pomegranate juice. The company has reportedly lost two other consumer deception cases filed against Welch Foods Inc. and Tropicana Products Inc. *See The National Law Journal*, December 6, 2011.

Ferrero Settles with California Plaintiffs in Nutella® False Advertising Class Action

According to a news source, the company that makes the hazelnut spread Nutella®, which is advertised as part of a healthy breakfast for children, has reached a settlement in the class action certified by a federal court in California last month. *In re Ferrero Litig.*, No. 11-205 (U.S. Dist. Ct., S.D. Cal., minute entry November 28, 2011). A docket notation reportedly indicates that the parties settled the claims during a November 28, 2011, mandatory settlement conference and will "submit a joint motion for preliminary approval of the class settlement no later than December 19, 2011." Additional details about the court's class certification order appear in **Issue 418** of this *Update*. The plaintiffs had alleged that the product contains "dangerous levels of fat and sugar." *See BNA Product Safety & Liability Reporter*, December 5, 2011.

Class Definition in Yo-Plus® Litigation Redefined on Remand

A federal court in Florida has redefined a plaintiffs' class in deceptive advertising litigation against the company that claims its Yo-Plus® yogurt provides digestive health benefits. *Fiztpatrick v. General Mills, Inc.*, No. 09-60412 (U.S. Dist. Ct., S.D. Fla., order entered December 2, 2011). While the Eleventh Circuit Court of Appeals upheld the class certification decision, it remanded the case for the lower court to redefine the class to omit any reference to plaintiffs' reliance on company claims, which reliance need not be proved under the Florida Deceptive and Unfair Trade Practices Act. Additional information about the Eleventh Circuit ruling appears in **Issue 388** of this *Update*. The class will now be defined as "all persons who purchased Yo-Plus in the State of Florida until the date notice is first provided to the class."

Contaminated Cantaloupe Plaintiff Sues Food Safety Auditor and Others

A Nebraska resident alleging that his consumption of *Listeria*-contaminated cantaloupe grown by Jensen Farms in Colorado caused his infection and subsequent hospitalization, has filed a personal injury action against the grower, distributor, retailer, and the company hired by the grower to conduct a food safety audit before the outbreak. *Braddock v. Jensen Farms*, No. 11-402 (U.S. Dist. Ct., D. Neb., filed November 30, 2011). According to the complaint, Primus Group, Inc. was negligent in performing the audit and failing to detect *Listeria* or conditions leading to *Listeria* contamination at the grower's facilities and, in breaching its contract with the grower, harmed the plaintiff, a third-party beneficiary. The plaintiff also alleges strict product liability, breach of warranty, negligence, and negligence per se against the other defendants and seeks general, special and incidental damages.

Putative Class Contends One-Cup Coffee Cartridges Are Not Fresh Ground

A New Mexico resident has filed a putative statewide class action in federal court claiming that a company which makes one-cup coffee cartridges for Keurig® single-serve coffee machines falsely labels and markets its cartridges as fresh coffee when they are actually filled with instant coffee. *Bracewell v. Sturm Foods, Inc.*, No. 11-01024 (U.S. Dist. Ct., D.N.M., filed November 18, 2011). Alleging violations of New Mexico and Illinois consumer fraud laws and unjust enrichment, the plaintiff seeks statutory damages, injunctive relief, attorney's fees, and costs.

Chicken Chain Claims "Eat More Kale" Infringes Its Trademark

After Vermont-based folk artist Bo Muller-Moore decided to apply for a federal trademark to protect his "Eat More Kale" T-shirt design, fast-food chain Chick-fil-A reportedly accused him of infringing its "Eat Mor Chikin" trademark. The kale design has apparently caught on with consumers, who pay $25 each

for the T-shirts and have purchased a sufficient quantity for Muller-Moore to support his family.

With powerful allies such as Vermont Governor Peter Shumlin (D), who reportedly said, "Don't mess with Vermont. Don't mess with kale. And Chick-fil-A, get out of the way because we are going to win this one," Muller-Moore has vowed to defend the claim. Publicity about the fracas has apparently generated a rash of sales, which Chick-fil-A hopes to stop; the company has also apparently sought an order requiring Muller-Moore to turn over his Website, eatmorekale.com. *See NPR.org*, December 6, 2011.

Court Dismisses Challenge to OEHHA's Listing of 4-MEI as Carcinogen Under Prop. 65

A California court has determined that California EPA's Office of Environmental Health Hazard Assessment (OEHHA) complied with the law in determining that 4-methylimidazole (4-MEI), a chemical present in many common foods and beverages, is a carcinogen known to the state to cause cancer. *Cal. League of Food Processors v. OEHHA*, No. 34-2011-80000784 (Cal. Super. Ct., decided November 21, 2011). As noted by the court, "The chemical is used in the manufacture of various products like pharmaceuticals, and it is a by-product of fermentation found in food products like soy sauce, roasted coffee, and caramel coloring added to colas and beer."

A number of trade associations representing an array of food and beverage interests challenged the listing, which will require product warnings under the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). They claimed that OEHHA's reliance on a National Technology Program technical report on 4-MEI did not meet Prop. 65's requirements for listing via the authoritative body mechanism. According to the petitioners, "the Technical Report did not formally identify 4-MEI as causing cancer pursuant to the requirements of Section 25306(d) and did not provide sufficient evidence of carcinogenicity from studies in experimental animals pursuant to the requirements of Section 25306(e)(2)." The court disagreed and also rejected the petitioners' free speech challenge to the listing.

Assuming, despite contrary "persuasive" argument, that the free speech claim was properly pled and was ripe for review, the court found that the claim nevertheless failed because "commercial speakers have no right not to divulge accurate information about their products purchased by consumers" and because the warning about 4-MEI "is grounded in fact, not controverted opinion." According to a news source, OEHHA plans to move forward with plans to establish a "no significant risk level" for the chemical to help companies decide whether a Prop. 65 warning will be required for the 4-MEI exposures in their products. It was apparently unknown whether the petitioners would file an appeal. *See Inside Cal/EPA*, November 25, 2011.

LEGAL LITERATURE

Glenn Lammi, "Food Lawsuits Claiming 'Addiction' Coming to a Courtroom Near You?," *Legal Pulse*, December 6, 2011

Glenn Lammi, chief counsel for the Washington Legal Foundation's Legal Studies Division, has published an article suggesting that if "regulation-by-litigation practitioners" can convince the public and policymakers that "certain foods or substances in foods are 'addictive,'" lawsuits against food companies are sure to follow. Lammi discusses a November 27 "60 Minutes" report in which a professional flavoring company employee agreed with Morley Safer that the company was "trying to create an addictive taste." The article also cites studies purportedly showing that foods high in fats and sugars are as addictive as cocaine.

According to Lammi, obstacles to such litigation remain. "Liability claims based on consumers' 'addiction' to certain foods would still face substantial hurdles," he writes, "such as the need to show how an allegedly addictive substance in food *caused* a plaintiff to become dangerously overweight. Causation is much different from *correlation*. Lawyers would have to discount the many other factors that lead to obesity, leaving addiction as the main culprit. They would also have to show that food companies knew or should have known of the addictive nature of their product, or knowingly manipulated the product to become addictive."

OTHER DEVELOPMENTS

EWG Report Criticizes Sugar Content of Children's Cereals

The Environmental Working Group (EWG) has issued a December 2011 **report** claiming that many popular cereal brands marketed to children contain "just as much sugar as a dessert—or more." After reviewing 84 popular brands, the report's authors alleged that three out of four cereals failed "to meet the federal government's proposed voluntary guidelines for food nutritious enough to be marketed to children," with 21 cereals exceeding the sugar limit "recommended by the industry's own nutrition initiative."

In particular, EWG purportedly found that (i) 56 cereals contained "more than 24 to 26 percent sugar by weight"; (ii) 71 cereals exceeded 140 milligrams of sodium and 10 exceeded 210 milligrams; (iii) seven cereals exceeded 1 gram of saturated fat; and (iv) "at least 26 cereals are not predominantly whole-grain."

The group also criticized cereal companies for opposing the 2016 nutrition guidelines suggested by the federal Interagency Working Group (IWG) on Food Marketed to Children. According to EWG, the government's standards

rely on the Food and Drug Administration's Reference Amounts Customarily Consumed (RACC) instead of serving size, the measure used by the Council of Better Business Bureau's Children's Food and Beverage Advertising Initiative. "Cereal makers and other food, beverage and entertainment companies are lobbying to kill [IWG's] proposal," opined the report. "In an attempt to counter the federal panel's efforts to improve the nutritional value of foods marketed to children, the food industry has come up with its own so-called standards, and unsurprisingly, they give most kids' cereals a pass."

CSPI Updates FDA on Mycoprotein Findings

The Center for Science in the Public Interest (CSPI) recently issued a **letter** to the Food and Drug Administration (FDA) to update the agency on its findings about mycoprotein, a meat-substitute marketed under the brand name Quorn. Following up on a 2002 campaign, the latest initiative claims that the RNA-reduced mold *Fusarium Venenatum* used to produce Quorn is not safe, with consumers reporting reactions such as vomiting and diarrhea, hives, and anaphylaxis.

"CPSI has now received about 500 reports of adverse reactions from Americans, as well as about 1,200 from the United Kingdom, other European countries, Scandinavia, and Australia," writes CSPI Executive Director Michael Jacobson. Believing that small-print allergen warnings are not enough in this case, the group has asked FDA to compel Quorn to display "a prominent and candid front-label disclosure" alerting consumers to the alleged side effects. CSPI has also requested a revocation of mycoprotein's generally recognized as safe (GRAS) status.

"There are plenty of nutritious, safe, and environmentally-friendly meat substitutes, made with soybeans, mushrooms, legumes, rice, and other real food ingredients," said Jacobson in a December 1, 2011, press release. "It's crazy to knowingly allow a potent new allergen into the food supply yet that's exactly what the FDA has done."

McDonald's Sidesteps San Francisco Toy Ban, Will Appeal $1.8 Million Brazilian Fine

McDonald's Corp. has reportedly responded to a San Francisco ban on giving away toys with its Happy Meals® by allowing parents to purchase the toys with a 10-cent charitable contribution when they buy a Happy Meal®. While the toy purchase is purportedly a separate transaction that complies with the new ordinance, it will still require a Happy Meal® purchase because toys cannot not be obtained by those who do not purchase the meal for their children. Previously, the toys could be purchased without buying a Happy Meal®. According to the company, the donations will help build a new Ronald

McDonald House where parents of sick children at a University of California, San Francisco, hospital currently under construction will be able to stay.

At least one public health advocate, evidently unhappy with the company's action, was quoted as saying that McDonald's "has developed a response to the law that allows them to continue marketing this unhealthful food to children in the midst of an obesity crisis. Not only have they attempted to do that, they've added in the veneer of additional whitewashing by linking the whole thing to charitable contributions."

Meanwhile, the company has reportedly been fined US$1.8 million in Brazil for selling its Happy Meals® with toys after a nonprofit organization headed by one of the richest people in the country complained that the free toy "distorts values" and encourages "unhealthy eating habits" among children. The company has not apparently commented on the litigation other than to indicate that is has already filed an appeal.

And in a related development, the Ninth Circuit Court of Appeals recently denied McDonald's petition to appeal a lower court ruling remanding to state court a class action charging the company with engaging in unfair business practices by including toys with its Happy Meals®. *Parham v. McDonald's Corp.*, No. 11-80188 (9th Cir., decided October 19, 2011). To reach the jurisdictional threshold under the Class Action Fairness Act, McDonald's sought to include in the "amount in controversy" required changes to its business practices if the plaintiff succeeds in her California Unfair Competition Law claims. According to the district court, such costs are incidental to rather than directly produced by the requested injunctive relief. More information about the lawsuit appears in **Issue 375** and **Issue 391** of this *Update*. *See SF Weekly,* November 30, 2011; *Mealey's Litigation Report: Class Actions*, December 2, 2011; *Advertising Age*, December 7, 2011.

New Report Urges Food Industry to Assess Nanomaterial Risks

The nonprofit group As You Sow has issued a **report** calling on the food industry to evaluate the safety of nanomaterials used in food packaging. Titled "Sourcing Framework for Food and Food Packaging Products Containing Nanomaterials," the report claims that better communication is needed between food companies and their suppliers to "protect themselves from financial and reputation risk."

According to the report, toxicity risks related to "nanofoods, nano food packaging and nano agrochemicals" are "very poorly understood" because of lack of federal regulations. To stay ahead of regulations, the report calls on the food industry to (i) "[f]ind out if your company has nanomaterials in its products and supply chain, (ii) "[p]ut a policy in place that suppliers must disclose if

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their products contain or were manufactured with the use of nanomaterials," (iii) require "that their supply chain disclose any use of nanomaterials and all related safety testing data and safety management procedures," and (iv) "clearly understand what the nanomaterial is, its use, and its effects."

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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.