Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

"REAL Beef Act" Would Require LFTB Labeling

U.S. Representative Chellie Pingree (D-Maine) has reportedly introduced legislation that would require manufacturers to label products containing lean finely textured beef (LFTB) trimmings. Dubbed the "Requiring Easy and Accurate Labeling" or REAL Beef Act, the proposal would mandate such labels "at the final point of sale" to inform consumers that they are purchasing what Pingree described in a March 30, 2012, press release as "pink slime." Citing an online petition calling for an end to LFTB in school lunches, Pingree argued that consumers "have made it pretty clear they don't want this stuff in their food. If a product contains connective tissue and beef scraps and has been treated with ammonia, you ought to be able to know that when you pick it up in the grocery store."

Meanwhile, the U.S. Department of Agriculture (USDA) has apparently agreed to grant manufacturers' requests to voluntarily label LFTB trimmings in their products. According to media sources, USDA food safety spokesperson Dirk Fillpot confirmed that the agency will approve such requests in an effort to help firms reach an acceptable outcome with customers. "If the product had been labeled from the start, I doubt we'd see anything like the consumer backlash that the media has stirred up in the past few weeks," surmised one author whose blog, "The Lunch Tray," allegedly persuaded officials to allow schools to drop LFTB from menus. *See MSN.com,* April 5, 2012.

In a related development, AFA Foods, Inc., a company that produces "case-ready ground beef and individually quick frozen hamburger patties," has filed for bankruptcy. Its customers include major food retailers and fast-food chains. In the process of making its products, the company apparently uses the beef trimmings called into question by the media. According to the declaration of the company's interim CEO, the controversy "has dramatically reduced the demand for all ground beef products," further exacerbating its financial problems.

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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USDA Extends Quality Monitoring Program to Olive Oil

The U.S. Department of Agriculture (USDA) recently **announced** the expansion of its Quality Monitoring Program to include extra virgin and organic extra virgin olive oil. According to an April 3, 2012, post on the USDA blog, the program hopes to address questions raised in the last few years about olive oil quality and provide consumers with assurance that the products they purchase meet grade standards.

Under the program, which already evaluates other commodities such as canned, frozen and fresh fruits and vegetables, the Agricultural Marketing Service will verify "olive oil quality and purity using criteria based on the U.S. grade standards… and international criteria," as well as conduct "unannounced plant visits to review product processes, quality assurance measures, and recordkeeping systems." Products from the first program participant, Baltimore-based Pompeian, Inc., have reportedly met "chemical testing and flavor analysis requirements" and the company has agreed to additional site inspections.

UK's FSA Announces Moratorium on "Desinewed Meat"

The U.K. Food Standards Agency (FSA) has **announced** a moratorium on the production of "desinewed meat" (DSM) from cattle, sheep and goats after the European Commission decided "that DSM does not comply with European Union [EU] single market legislation." Produced using "a low pressure technique" to remove meat from bone but retain the structural integrity of the muscle fibers, DSM reportedly resembles "minced meat" and "is regarded as meat" by FSA.

Although the Commission evidently does not view DSM as a health concern, it reportedly threatened to ban U.K. meat exports unless FSA issued a moratorium and reworked legislation to comply with the EU definition of "mechanically separated meat" (MSM), that is, "the product obtained by removing meat from flesh bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure."

Meanwhile, the British Meat Processors' Association (BMPA) has lambasted the Commission's action as unnecessarily "ferocious" and likely to cost producers and consumers approximately £200 million in labelling changes, reformulated products and job losses. As BMPA explained in an April 5, 2012, press release, DSM differs from MSM in both production method and consistency, with the latter reduced to a "paste-like" texture after being separated from bone. "While acceding to the Commission's demands, the Government and we hold that current practice in the UK is lawful. This product is not MSM. It is meat, and there are no food safety concerns in its usage," said BMPA Director Stephen Rossides in defense of DSM. "This is a criminal waste of a valuable product at a time of a shortage of proteins, and when we are being urged to reduce food wastage. Common sense has gone out of the window… All this has happened at break-neck speed. The industry must be given more time to adjust to any change in requirements and market circum-

stances in a controlled and properly managed way in order to minimize market disruption and financial damage."

Irish Broadcasting Authority to Regulate Food Advertising

The Broadcasting Authority of Ireland (BAI) has announced a **public consultation** regarding draft commercial codes that would prohibit the advertising of foods high in fat, sugar and salt (HFSS) during TV programs where more than 50 percent of viewers are younger than age 18. According to a March 30, 2012, BAI press release, the consultation considers new drafts of the General Commercial Communications Code and Children's Commercial Communications Code, the latter of which currently makes commercials, sponsorships and other product placements "of particular interest to children, or those broadcast during children's program[s],… responsible in their messaging and portrayal of food and drink to those aged under 18." Drafted after receiving more than 226 submissions from a previous consultation, the proposed codes would specifically regulate advertisements for HFSS products as well as adopt a "nutrient profiling model" "to assess the nutritional profile of food and non-alcoholic drink."

In particular, the draft Children's Commercial Code would not only bar HFSS food and drink ads during children's programs but would forbid celebrities, sports stars, program characters, or licensed characters from appearing in these types of commercial communications. BAI would also bar such advertisements from making health claims or promotional offers, while its general code would further limit HFSS food marketing "so that no more than 25% of sold advertising time and only one in four advertisements for HFSS products [would be] permitted across the broadcasting day."

"We are putting the Draft Codes out to public consultation over the next eight weeks so that all interested members of the public—including those from the health sector; food production industry, broadcasters and advertisers—can offer their view on the BAI's proposals," said BAI Chair Bob Collins, who noted that the new rules attempt "to strike a balance" between groups advocating a complete ban on certain foods until the 9 pm watershed and those urging exemptions for foods "considered to be of high economic importance." The agency will accept responses to the consultation until May 31, 2012.

Indian State Seizes Red Bull®, Caffeine Content Above Legal Limits

The Maharashtra Food and Drug Administration (MFDA) has reportedly seized more than 1 million cans of Red Bull®, an energy drink containing 250-300 parts per million (ppm) of caffeine, on the ground that the product exceeds the 145 ppm limit for carbonated beverages. According to a press report, no separate standards for caffeine in energy drinks exist, but the Food Safety and Standard Act 2006 states that all drinks containing caffeine should follow the carbonated beverage rules. The nation's Food Safety and Standards Authority is developing a new energy drink category that could allow higher caffeine content.

The action is apparently the second in India; Tamil Nadu has also evidently targeted the beverage for exceeding caffeine limits. MFDA Commissioner Mahesh Zagade reportedly said, "Caffeine is addictive and it has a long-term impact. Youngsters today are increasingly consuming alcohol with Red Bull. Parents should be keeping a check on what their children are drinking." He also reportedly noted, "Manufacturers claim it's an energy drink and not a carbonated drink. But when you open a Red Bull can, there's fizz and it contains carbon dioxide. We are preparing for legal battle." *See Hindustan Times*, March 30, 2012.

LITIGATION

SCOTUS Requests Government View in Patent Dispute over GM Soybeans

The U.S. Supreme Court has invited the U.S. solicitor general to submit a brief addressing the issues raised in a dispute over patent exhaustion and second-generation genetically modified (GM) seeds. ***Bowman v. Monsanto Co.*, No. 11-796 (U.S., order entered April 2, 2012)**. An Indiana farmer, who was found to have infringed Monsanto's patents by planting the Roundup Ready® soybeans he purchased from a grain elevator, filed a petition for *certiorari*, arguing that when the company sold its patented seeds to a different famer, who later sold the soybeans to the grain elevator, it exhausted its rights to that seed and all of its descendants. He was not required to sign a licensing agreement before buying "commodity" soybeans and thus claims that he was free to plant them and then save and re-plant each crop in future seasons. Monsanto reportedly contends that each generation is a separate product and that the farmer is, in effect, "manufacturing" infringing soybeans. *See arstechnica.com*, April 4, 2012.

Texas Federal Court Refuses to Dismiss TOSTITOS SCOOPS!® Infringement Suit

A federal court in Texas has determined that a trademark and patent infringement lawsuit involving Frito-Lay North America's corn chip products can be maintained in the Eastern District of Texas because it has jurisdiction over the defendants and the defendants failed to show that it was "clearly more convenient" to litigate the matter in Arkansas. *Frito-Lay N. Am., Inc. v. Medallion Foods, Inc.*, No. 4:12-CV-74 (U.S. Dist. Ct., E.D. Tex., Sherman Div., order entered March 30, 2012). Details about the case are included in **Issue 427** of this *Update*.

According to the court, after Frito-Lay notified the defendants that their BOWLZ product infringed its patent and trade dress rights, the defendants filed a complaint for declaratory relief in the Eastern District of Arkansas. Frito-Lay filed its suit the same day in the Eastern District of Texas. The Arkansas court stayed that action pending the Texas court's ruling on jurisdiction and venue, noting that "[i]f the Eastern District of Texas decides that it has personal jurisdiction and denies the motion to transfer, the [Arkansas] action will be dismissed."

Under a stream-of-commerce theory of personal jurisdiction, the court found jurisdiction proper as to defendant Medallion because it manufactures the allegedly infringing tortilla chips and "has fulfilled and continues to fulfill repeated purchase orders for the allegedly infringing tortilla chips for . . . a 'major customer' of Defendants. Medallion knows that these allegedly infringing tortilla chips are then sold in Texas, and Medallion continues to reap the benefit of the sales of the tortilla chips in Texas." The court also found jurisdiction over defendant Ralcorp proper taking the plaintiff's allegations as true, i.e., that Ralcorp and Medallion identify themselves interchangeably on Ralcorp's Web site, the two companies share some corporate officers, "an employment opportunity at a Medallion plant is considered employment with Ralcorp," and "the companies sued Plaintiff together in the Eastern District of Arkansas, jointly seeking a declaration of their rights to the allegedly infringing tortilla chip product."

Analyzing a number of private and public interest factors as to the convenience of the forum, the court found that six were neutral and two weighed slightly against transfer. Thus, the matter will proceed before the Texas federal court.

Plaintiffs Lack Standing to Challenge FDA Raw Milk Rules

A federal court in Iowa has dismissed claims filed by a legal defense fund and a number of raw-milk producers challenging Food and Drug Administration (FDA) regulations prohibiting the shipment of raw milk for human consumption across state lines. *Farm-to-Consumer Legal Defense Fund v. Sebleius*, No. C 10-4018-MWB (U.S. Dist. Ct., N.D. Iowa, W. Div., decided March 30, 2012). According to the court, none of the plaintiffs alleged that "the FDA has applied or sought to apply the challenged regulations to them, and Wagoner's contentions are merely conclusory and based on speculation."

Raw milk producer Eric Wagoner had apparently alleged that a Georgia Department of Agriculture official "ordered an embargo of raw milk that he had transported from South Carolina, where it is legal to buy raw milk, to Georgia, where it is not" and claimed that "the embargo was ordered at the direction of the FDA." There was no evidence of FDA involvement, and because the agency further indicated that it did not intend to take any enforcement action against the plaintiffs, the court granted the government's motion for summary judgment. Without an injury in fact, the court lacked subject matter jurisdiction to consider the case.

New *Trans* Fat Class Action Filed Against Frito-Lay

Contending that snack maker Frito-Lay North America makes "improper nutrient content claims on products containing disqualifying levels of fat, saturated fat, cholesterol or sodium," a new plaintiff has filed a putative class action against the company and its parent in a California federal court. *Wilson v. Frito-Lay N. Am., Inc.*, No. 4:2012cv01586 (U.S. Dist. Ct., N.D. Cal., filed March 29, 2012). Several other cases have recently been filed against the company, challenging its "all natural" claims for products allegedly containing genetically modified ingredients. The

new action targets the company's "0 grams of trans fat" representations on its Lay's Classic Chips® "despite disqualifying levels of fat that far exceed the 13g disclosure level." The plaintiff reportedly cites Food and Drug Administration warnings to other companies "for the same type of improper 0 grams trans fat nutrient content claims at issue in this case." *See Foodnavigator-usa.com*, April 4, 2012.

California Court Nixes Effort to Stop McDonald's from Selling Happy Meals with Toys

A California superior court has dismissed with prejudice putative class claims filed against McDonald's Corp. seeking to enjoin the company from advertising Happy Meals® to children featuring toys. *Parham v. McDonald's Corp.*, No. CGC-10-506178 (Cal. Super. Ct., San Francisco County, decided April 4, 2012). Additional information about the case appears in Issues **375**, **391** and **420** of this *Update*.

While the court did not explain why it sustained the company's demurrers to the plaintiff's first, second and third causes of action, it did so without giving the plaintiff leave to amend her complaint. According to the Center for Science in the Public Interest (CSPI), which was representing the plaintiff, consideration is being given to filing an appeal.

In its memorandum of law in support of its demurrers, the company argued that the plaintiff failed to state a claim for relief under the state's Unfair Competition Law, Consumers Legal Remedies Act and False Advertising Law. Among other matters, the company contended that the plaintiff (i) lacked standing because "she received the Happy Meal she intended to purchase," (ii) failed to allege causation because "she made an informed decision to purchase Happy Meals," (iii) failed to allege that McDonald's Happy Meal® advertising is "unfair," (iv) did not allege that the company made a material misrepresentation or that she relied on one, and (v) did not allege "that a reasonable consumer would be deceived by a specific McDonald's advertisement."

The company characterized the plaintiff's complaint as "a policy paper outlining CSPI's political views and regulatory agenda" and noted the lack of any allegation that the plaintiff's children were harmed by eating at McDonald's. It also argued that her legal theory was "novel" and "legally deficient" and would make any advertising to children of any product the parent does not want to buy "an unfair trade practice." Thus, "[a]dvertising any product to children would now be a *per se* violation of California consumer protection laws if the parent's decision not to buy the product 'place[s] a strain on parent-child interaction,'" something the plaintiff had alleged.

A company spokesperson reportedly said the lawsuit lacked merit and that McDonald's was "proud" of its Happy Meals® and would "vigorously defend our brand, our reputation and our food." CSPI Executive Director Michael Jacobson said, "Using toys, of all things, to lure young children to fast-food meals is not responsible corporate behavior. . . . In time, the practice of using toys to market

junk food will seem as inappropriate and anachronistic as lead paint, child labor, and asbestos." *See CSPI News Release* and *Reuters*, April 4, 2012.

French Farmers Challenge Government Ban on GM Maize Cultivation

French maize growers and seed companies have reportedly brought an appeal before the nation's highest court seeking to overturn the French government's temporary moratorium on a strain of genetically modified (GM) maize. The government action was taken in response to the court's decision to annul a previous moratorium after finding that it lacked justification. In a joint statement, the plaintiffs said, "This restriction does not rely on any serious scientific element, and maize producers, hit by (insects), sustain real financial damage." France has also reportedly requested that the European Commission suspend authorization to sow the GM maize, the only one approved for cultivation in the European Union, contending that scientific research shows that it poses "significant risks for the environment." *See Reuters*, March 29, 2012.

OTHER DEVELOPMENTS

IOM Report Looks at Role of Obesity in Cancer Survival

The Institute of Medicine (IOM) has issued a **workshop summary** examining the role of obesity in cancer survival and recurrence. Held October 31-November 1, 2011, by IOM's National Cancer Policy Forum, the workshop included presentations from experts on "the latest laboratory and clinical evidence on the obesity-cancer link and the possible mechanisms underlying that link." Participants also discussed clinical interventions to mitigate the purported effects of obesity on cancer, as well as "research and policy measures needed to counteract the expected rise of cancer incidence mortality due to an increasingly overweight and older population."

In particular, the workshop explored "the complex web of molecular mechanisms that underlie the obesity-cancer link and whether it is obesity itself, the energy imbalance that leads to obesity, or the molecular pathways that are deregulated due to obesity, that lead to increased risk of cancer initiation or progression." The group also considered more policy-specific research "that addresses diet, physical activity and other energy balance behavior, and how such behavior can be influenced by manipulating the environment to support lifestyles less likely to lead to obesity." To this end, one attendee noted that research supporting the effectiveness of certain environmental interventions would help secure "congressionally mandated financial support for these types of changes."

Among the various policy suggestions directed at both the private and public sectors, workshop participants also debated "the possibility of involving the private sector in efforts to counter obesity," "much like the private sector was involved in policies developed to counter promotion of tobacco products." In

addition, one expert mentioned focusing early obesity prevention efforts on schools. "While we have a lot of regulation about what's offered in the school meals programs, we are reimbursing the schools in terms of high-fat commodities and dairy products, and making it difficult for them to achieve these goals," she said. "We also have appallingly little regulation of what's offered in the vending machines in the schools or in school stores. We need to offer healthier food options and encourage children to choose them."

Researchers Pull Plug on GE "Enviropig"

Canadian researchers have reportedly halted the development of genetically engineered (GE) pigs after the hog producers association sponsoring the project decided to stop funding it. Created in 1999 by scientists at the University of Guelph and financed by Ontario Pork, the so-called Enviropig™ apparently contained genes from mice and an *E. coli* bacterium that enabled the animal to digest plant phosphorus "more efficiently than conventional Yorkshire pigs," thereby lessening the environmental impact of the manure. Had a company been found to take the product to market, the Enviropig™ would have become the first GE animal to enter the food supply if approved by the U.S. and Canadian governments for human consumption.

According to an April 2, 2012, *New York Times* report, however, the Enviropig™ met much resistance from environmental and consumer groups that oppose transgenic livestock for food purposes and feared the GE pig would make large-scale farming more profitable. At the same time, the GE pigs also turned out to be less cost-efficient than anticipated once a supplement that aids phosphorous digestion became more widely available and less expensive for hog farmers. Nevertheless, the researchers have preserved data and genetic material from the original herd of 16 Enviropigs™ should companies express an interest in the future. "It's time to stop the program until the rest of the world catches up. And it is going to catch up," lead researcher Cecil Forsberg was quoted as saying. "We've done enough research that we feel that if industry is interested they should be able to pick it up."

Texas Hospital Refuses to Hire Employees with BMI Exceeding 35

Citizens Medical Center, located in Victoria, Texas, has reportedly instituted a prohibition on hiring any employee with a body mass index (BMI) higher than 35, or 210 pounds for an individual 5 feet, 5 inches tall or 245 pounds for someone 5-foot-10. Apparently, the hiring policy is not based on the expense of health care for the obese or purported increased absenteeism, but linked to physical appearance. The center's chief executive officer reportedly said in an interview, "The majority of our patients are over 65, and they have expectations that cannot be ignored in terms of personal appearance." Because weight is not a protected category in Texas, some believe the policy is not illegal, but others claim the weight-based discrimination violates the Americans with Disabilities Act. In either event, while

smokers have been subject to similar policies for some time, weight restrictions are apparently virtually unknown in the medical field. The center is reportedly involved in litigation over a policy involving physicians of Indian descent. *See The Texas Tribune*, March 26, 2012.

MEDIA COVERAGE

"60 Minutes" Segment Claims Sugar Is Toxic, Addictive

Anti-sugar crusader Robert Lustig was among the scientists participating in an April 1, 2012, "60 Minutes" interview claiming that studies indicate that sugar is toxic, addictive and can lead to obesity, Type II diabetes, hypertension, and heart disease. Lustig, an endocrinologist at the University of California, San Francisco, has written extensively about the topic, including an article titled "The Toxic Truth About Sugar" featured in Issue 425 of this *Update*.

Asserting that sugar is as "equally toxic" as high-fructose corn syrup, Ludwig recommended that men daily consume no more than 150 calories of added sugars and women no more than 100, which is less than the amount in one can of soda. "Ultimately this is a public health crisis," Lustig said in reference to what he deems the excessive amount of sugar in many processed foods. "When it's a public health crisis, you have to do big things and you have to do them across the board. Tobacco and alcohol are perfect examples. We have made a conscious choice that we're not going to get rid of them, but we are going to limit their consumption. I think sugar belongs in this exact same wastebasket."

SCIENTIFIC/TECHNICAL ITEMS

New Study Claims That Obese Adults Impose Higher Health Care Costs Than Smokers

Researchers studying 30,000 adult Mayo Clinic employees, retirees and dependents over a seven-year period have concluded that health care costs for the morbidly obese are far higher than those for smokers. James Moriarty, et al., "The Effects of Incremental Costs of Smoking and Obesity on Health Care Costs Among Adults," *Journal of Occupational and Environmental Medicine*, March 2012. The study found that health care costs for smokers exceed those for nonsmokers by $1,274 to $1,401 depending on retirement status, i.e., age, and health care costs for the overweight and obese (ranging from simply overweight to morbidly obese II) exceed those for individuals with normal body mass index by $382 to $5,530. The incremental costs are significantly higher at higher weight categories. While controlling for comorbidities, the researchers found lower incremental costs for obesity, but suggested that such controls "may lead to underestimation of the true incremental costs because obesity is a risk factor for developing chronic conditions." They recommend additional research to address this issue.

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Body Mass Index May Underestimate U.S. Obesity

A New York University School of Medicine **study** claims that Body Mass Index (BMI), the traditional method used to measure obesity, may underestimate the number of Americans who actually qualify as obese. Nirav Shah and Eric Braverman, "Measuring Adiposity in Patients: The Utility of Body Mass Index (BMI), Percent Body Fat, and Leptin," *PLoS One*, April 2, 2012. The researchers used BMI and a test called Dual- Energy X-Ray Absorptiometry (DXA), which provides simultaneous measurements of muscle, bone mass and body fat while measuring levels of leptin, a protein that regulates metabolism, on a cross section of 1,394 patients.

According to the study, 48 percent of the women and 25 percent of the men were misclassified as non-obese based on BMI but were considered obese based on DXA testing. The researchers concluded that people who have lost a lot of muscle mass as they age, many of whom are women, are particularly affected by the discrepancy because BMI does not directly measure body fat, only estimates it. As Braverman told a news source, "BMI is the least accurate test in medicine. It's been around since 1832 and hasn't changed. People are being told their BMI is [a healthy] 24, when their body fat is actually at 34 percent, which is obese." *See U.S. News & World Report*, April 3, 2012.

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