Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Issues Report on Antimicrobial Resistance

The U.S. Food and Drug Administration (FDA) has **released** an executive report summarizing the data collected by the National Antimicrobial Resistance Monitoring System (NARMS) since 1996. Implemented by FDA, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture, NARMS tracks antibiotic resistance in foodborne bacteria, focusing on antibiotics "that are considered important to human health as well as multidrug resistance [MDR]" to three or more antibiotic classes.

According to an August 11, 2014, news release, FDA identified "positive and negative trends in antimicrobial resistance in bacteria isolated from humans, retail meats and food animals." For non-typhoidal *Salmonella,* which showed no resistance in 85 percent of samples isolated from humans, the report found that "MDR among humans, slaughtered chicken and slaughtered swine was the lowest [in 2011] since testing began," though "MDR *Salmonella* from retail poultry meats generally increased." NARMS also concluded that "erythromycin resistance in *Campylobacter jejuni* remained at less than 4% in isolates obtained from humans, retail chicken and slaughtered chicken," while "ceftriaxone resistance among *E. coli* isolates from retail chicken increased from 8% in 2002 to 13% in 2011," with ground turkey isolates showing a 9 percent increase in ceftriaxone resistance during the same period.

In addition, FDA noted how restrictions on the use of certain antibiotic classes have affected drug resistance levels in poultry, cattle and retail meats. "Resistance to third-generation cephalosporins, another important drug class for the treatment of *Salmonella* infections, rose among isolates from retail ground turkey between 2008 and 2011 and among certain *Salmonella* serotypes in cattle between 2009 and 2011," states the report. "In April 2012, FDA prohibited certain uses of cephalosporin drugs in cattle, swine, chickens, and turkeys. NARMS will continue to monitor these trends over time."

Amended Food Additive Regulations to Allow for Additional Use of Vitamin D^3

The U.S. Food and Drug Administration (FDA) has **amended** food additive regulations pertaining to the safe use of vitamin D3 in response to a petition from Abbott Laboratories. The company requested that FDA approve use of

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the fat-soluble hormone "as a nutrient supplement at levels not to exceed 500 IUs per 240 mL in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and that are represented for use such that that the total amount of vitamin D3 provided by the product does not exceed 1,000 IU per day, and at levels not to exceed 1.0 IU per kilocalorie in food represented for use as a sole source of nutrition for enteral feeding." Objections to FDA's approval of Abbott's petition or requests for a hearing must be filed by September 11, 2014. *See Federal Register*, August 12, 2014.

USDA Announces New Traceback and Recall Procedures for Beef

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has **announced** plans to implement "new traceback procedures when FSIS or another agency finds raw ground beef or bench trim presumptive positive for *Escherichia coli* O157:H7." Under the new system, which takes effect October 14, 2014, the agency will ask suppliers to recall products that test positive for *E. coli* O157:H7 later in the supply chain if FSIS or another agency determines that contamination most likely occurred at the supplier's establishment and if the product in question was sent to other grinding facilities.

As explained in an August 13, 2013, press release, these new procedures "will allow the agency to trace contaminated ground beef back to its source more quickly, remove it from commerce, and find the root cause of the incident to prevent it from recurring." To this end, FSIS will begin traceback investigations as soon as it receives a presumptive positive result instead of waiting the two days needed to confirm *E. coli* O157:H7 contamination. The agency estimates that "dozens more recalls may occur once these new protections are in place."

"A critical component of preventing foodborne illness is quickly identifying sources of contamination and removing unsafe products from store shelves," said USDA Deputy Under Secretary for Food Safety Brian Ronholm. "The expedited traceback procedures being announced today will allow FSIS to take action more quickly, which will make a significant difference in food safety investigations and in preventing foodborne illnesses." *See Federal Register,* August 13, 2014.

LITIGATION

Claims Trimmed in "All-Natural" Pretzel Labeling Suit Against Frito-Lay

A California federal court has dismissed several of the plaintiffs' claims in a putative class action accusing Frito-Lay North America Inc. of mislabeling its Rold Gold pretzels as "low fat," "fat free" or "all-natural" despite allegedly

containing high sodium levels and unnatural ingredients. *Figy v. Frito-Lay North America Inc.*, No. 13-3988 (U.S. Dist. Ct., N.D. Cal., order entered August 12, 2014). The court found that the plaintiffs had standing to sue on behalf of purchasers of several non-purchased products because Frito-Lay's health claims were the same for each and the only difference was the shape of the pretzel products.

The court then dismissed several of the plaintiffs' claims. It found that it did not have subject matter jurisdiction to grant injunctive relief because Frito-Lay had triggered the plaintiffs' obligation to prove jurisdiction by submitting declarations and extrinsic evidence of the plaintiffs' lack of standing to seek an injunction, and the plaintiffs had then failed to present any evidence on the subject. The claims were dismissed with leave to amend. The court also dismissed the plaintiffs' class claims for a California subclass with prejudice—the plaintiffs could not bring claims on behalf of California purchasers who were not residents—and for all other class claims without prejudice.

Turning to substantive issues, the court dismissed the plaintiffs' misbranding claims because they failed to show that they relied on the alleged misrepresentation to purchase the product but instead relied on the assumption that the products were sellable. The plaintiffs' claims that the "all-natural" label was misleading were also dismissed for a failure to offer "more than conclusory assertions that the ingredients they complain of are unnatural. It is insufficient under Rule 9(b) to simply assert, no matter how foreign or synthetic-sounding an ingredient's name might be, that an ingredient is unnatural." The court granted the plaintiffs leave to amend the claims.

The plaintiffs also contended that the product labels led them to believe that the products did not contain any nutrients at unhealthful levels, but the court dismissed this argument. "It is utterly implausible that Plaintiffs or reasonable consumers would see an undisputedly true statement about fat and then draw conclusions about other totally unrelated nutritional characteristics like sodium content or conclude the Products 'made only positive contributions to a diet.'" The claims were dismissed with leave to amend.

Court Rejects Spoliation Claim in Kellogg Recall Case

A Michigan federal court has denied a motion filed by FPC Flexible Packaging Corp. and The International Group, Inc. to dismiss evidence for spoliation in a case accusing the packaging company and the wax maker of providing Kellogg defective cereal liners, resulting in a $70-million recall. *Kellogg Co. v. FPC Flexible Packaging Corp.*, No. 11-272 (U.S. Dist. Ct., W.D. Mich., S. Div., order entered August 12, 2014). Kellogg allegedly received several consumer complaints of unusual odors in its products, and the company said it obtained samples of products from two of the consumers. The cereal samples have since disappeared, but Kellogg preserved a piece of the plastic liner provided

by one of the consumers. International and FPC argued that the loss of evidence could not have been accidental because Kellogg managed to keep the sample of the liner, but the court dismissed their arguments. "An appropriate jury instruction addressing the use of the lost consumer samples, if necessary, will be determined at trial," the court said. Additional information on the lawsuit appears in Issue 387 of this *Update*.

EPA Settlement Creates Pesticide-Free Zones in Pacific States to Protect Salmon

The U.S. Environmental Protection Agency (EPA) and several conservation groups have agreed to a settlement that limits pesticide use near salmon habitats in three states in a lawsuit accusing the agency of failing to assess the effects of pesticides on salmon despite a 2004 court decision ordering it to consult with National Marine Fisheries Service (NMFS) on the issue. *Nw. Ctr. for Alts. To Pesticides v. EPA*, No. 10-1919 (U.S. Dist. Ct., W.D. Wash., stipulated settlement agreement filed August 13, 2014). The settlement bans aerial spraying of five pesticides—carbaryl, chlorpyrifos, diazinon, malathion, and methomyl—within 300 feet and ground applications within 60 feet of salmon habitats in California, Oregon and Washington. The restrictions will be in place while NMFS analyzes the impact of the pesticides on salmon, and according to the settlement, EPA will then be required to enact permanent protections based on the findings. The Fourth Circuit struck down similar provisions in 2013 due to arbitrariness, and following the decision, the National Academy of Sciences issued a report detailing risks of pesticide exposure to endangered species that established more guidelines in an attempt to eliminate the arbitrariness in the government's pesticide risk management. Additional information about the case striking down the previous restrictions appears in Issue 407 of this *Update*.

California Courts Wait for FDA Guidance in Two ECJ Cases

Following similar decisions from courts across the country, two California federal courts have delayed final rulings in cases accusing Kashi and Trader Joe's of mislabeling their products by using the term "evaporated cane juice" (ECJ) in their ingredient lists rather than simply "sugar," which the plaintiffs allege is the same substance. *Gitson v. Trader Joe's Co.*, No. 13-1333 (U.S. Dist. Ct., N.D. Cal., order entered August 7, 2014); *Saubers v. Kashi Co.*, No. 13-899 (U.S. Dist. Ct., S.D. Cal., order entered August 11, 2014). In the proposed class action against Kashi, the plaintiffs accused the Kellogg-owned company of "misbranding" more than 75 different food products by listing ECJ instead of sugar on its labels to conceal its inclusion in the foods. The court found that the plaintiffs' claims relied "heavily, if not entirely, on the premise that the [U.S. Food and Drug Administration (FDA)] has concluded that 'evaporated cane juice' is not the common or usual name for any sweetener" based on FDA informal guidance issued in 2009. However, the court said, FDA indicated

in March 2014 that it will issue formal guidance on the matter, which "will undoubtedly affect issues being litigated in this action." Following the primary jurisdiction doctrine, the court dismissed the case without prejudice.

In the putative class action against Trader Joe's, the plaintiffs also accused the company of mislabeling its products by listing ECJ on its ingredient lists. In addition, they alleged that the food store's soy milk labels may lead a consumer to believe the milk is dairy and that several of its products contained added chemicals despite claiming otherwise. As in *Kashi*, the court held that the ECJ claim could be determined by the forthcoming FDA guidance. Rather than dismissing the case, the court ordered a stay for all the claims, noting that "it would be a waste of judicial and party resources to carry out this lawsuit piecemeal." Additional information about the case appears in Issues **477** and **500** of this *Update*.

Witness Testifies About Sampling Fraud in Prosecution of Peanut Corp. Executives

As the criminal prosecution of Peanut Corp. of America executives continues into its second week, the former south Georgia peanut-processing plant manager reportedly admitted lying to federal investigators about positive tests for *Salmonella* in company products and the frequency of testing "to play damage control, [and in an effort] to protect the company." According to news sources, Samuel Lightsey, who agreed to plead guilty to seven criminal counts to reduce his potential prison sentence in exchange for his testimony against his former colleagues, also testified that the company cheated on safety testing by switching samples and shipping thousands of pounds of peanut products after learning they were contaminated or before testing could be completed. The contaminated peanut paste, traced to the Peanut Corp. facility, allegedly sickened more than 700 people and killed nine in a 2008-2009 *Salmonella* outbreak that led to one of the largest food recalls in U.S. history.

Asked to examine photographs of the plant he managed, Lightsey further reportedly confirmed evidence of water leaks and sanitation problems. He said that the photos showed mold and mildew, water stains and condensation. "There was multiple areas in the plant that were leaking," he said, and explained that workers covered food products with plastic to keep them dry. Lightsey also reportedly testified that workers kept a pellet gun near at hand to shoot birds that entered the facility.

To date, his testimony has apparently implicated defendant Michael Parnell, the company's food broker, in the scheme to hide bad test results from customers. When Lightsey brought concerns to him, Parnell reportedly told him not to worry about it, purportedly saying, "We've been shipping to them with false COAs (false certificates of analysis) since before you got here."

Lightsey has not yet been cross-examined, and his testimony was interrupted so that four other witnesses, including one from out of town, could testify. They included two Georgia Department of Agriculture employees and a Food and Drug Administration microbiologist, who testified about taking environmental swabs from the plant; two of the swabs tested positive for *Salmonella*. Counsel for former company owner Stewart Parnell reportedly sought to discredit this witness by questioning him about the procedures he followed in conducting his investigation. *See Associated Press* and *WFSB 3,* August 11, 2014; *Associated Press* and *ABC News*, August 14, 2014

Meanwhile, the court has denied the defendants' motion to compel, ruling that the government's witness disclosures were adequate. *United States v. Parnell*, No. 13-cr-12 (U.S. Dist. Ct., M.D. Ga., Albany Div., order entered August 8, 2014). So ruling, the court found that the defendants were able to anticipate the content of the experts' testimony from disclosures consisting of curricula vitae and reports, including interviews conducted by government agents and many of the experts' actual reports.

Whole Foods Hit with Second Lawsuit Based on *Consumer Reports'* Yogurt Findings

Echoing a putative class action filed in Massachusetts federal court on August 1, 2014, a plaintiff has filed a lawsuit against Whole Foods Market in Pennsylvania state court accusing the retailer of mislabeling its 365 Everyday Value yogurt's sugar content as 2 grams despite containing 11.4 grams, according to test results published in the July issue of *Consumer Reports*. *Clemente v. Whole Foods Market Inc.*, No. 140801271 (Ct. of C.P. of Pa., Philadelphia Cnty., filed August 11, 2014). The plaintiffs accuse Whole Foods of knowingly mislabeling its yogurt, citing a statement on the Whole Foods Website that allegedly reads, "Our Private Label registered dietician reviews each nutrition label for accuracy and completeness before the label is printed. All attempts are made to review nutrition labels on a regular basis to ensure accuracy." In the complaint, the plaintiffs argue, "Unless this statement on Defendant's website is false, then Whole Foods Market was fully aware of the contents of its store brand Greek yogurt and of the fact that the yogurt's sugar content does not match what is stated on the label." They seek class certification for Pennsylvania consumers who purchased the product, an injunction, attorney's fees, and treble damages. Additional information on the Massachusetts case appears in Issue **533** of this *Update*.

Court Orders Schwan's to Reimburse Work-Related Use of Personal Cell Phones

A California appeals court has determined that the state Labor Code requires employers to reimburse employees who "must use their personal cell phones for work-related calls"; so ruling, the court reversed a class-certification denial and ordered the lower court to reconsider the motion in light of this interpre-

tation of the law. ***Cochran v. Schwan's Home Serv., Inc.*, No. B247160 (Cal. Ct. App., decided August 12, 2014)**.

The trial court denied certification due to lack of commonality and because a class action was not a superior method to litigate the claims. In its view, if an employee did not pay the cell phone charges because someone else did or the employee purchased a different cell phone plan that accommodated the calls, individual inquiries into the plans and payments would be necessary to determine liability. According to the appeals court, the issue in the case is whether an employer must always "reimburse an employee for the reasonable expense of the mandatory use of a personal cell phone," or is the "obligation limited to the situation in which the employee incurred an extra expense that he or she would not have otherwise incurred absent the job."

The court held that, under section 2802 of the Labor Code, "[t]he answer is that reimbursement is always required. Otherwise, the employer would receive a windfall because it would be passing its operating expenses onto the employee. Thus, to be in compliance with section 2802, the employer must pay some reasonable percentage of the employee's cell phone bill." The court also noted that "it is no concern to the employer that the employee may pass on the expense to a family member or friend, or to a carrier that has to then write off a loss. It is irrelevant whether the employee changed plans to accommodate work-related cell phone usage. Also, the details of the employee's cell phone plan do not factor into the liability analysis."

Simply put, according to the court, "[t]o show liability under section 2802, an employee need only show that he or she was required to use a personal cell phone to make work-related calls, and he or she was not reimbursed. Damages, of course, raise issues that are more complicated."

Swiss Tribunal Rules "Absinthe" Is Generic, Not Tied to Place of Origin

Ruling against Val-de-Travers absinthe producers, the Swiss Federal Administrative Tribunal has reversed a 2010 Federal Office of Agriculture decision confirming the "protected geographical indications" registration of the terms "absinthe," "fée verte"—the green fairy— and "la bleue." ***Guignon v. Ass'n interprofessionnelle de l'Absinthe*, No. B-4820/2012 (Tribunal administratif fédéral, decided August 13, 2014)**. The court said in a press release that it believed "that this denomination refers to a type of good, regardless of its origin, and not to a product originating specifically from Val-de-Travers." According to the court, just a small percentage of people in Switzerland associate the terms with this region, a district in the Neuchâtel canton.

The president of the absinthe association, which registered the terms on behalf of the producers and defended the appeals filed by distillers in France, Germany and Switzerland, reportedly characterized the decision as "incomprehensible" because most of Switzerland's absinthe is produced in

Val-de-Travers and the ruling will harm artisan distillers. The town claims that the wormwood-derived drink originated in the area in the 18th century, although the country then banned it in the early 1900s. It was popular among writers, including Oscar Wilde and Ernest Hemingway, for its purported psychedelic properties. Hemingway was said to have invented the cocktail "Death in the Afternoon" which required per his instructions: "Pour one jigger absinthe into a Champagne glass. Add iced Champagne until it attains the proper opalescent milkiness. Drink three to five of these slowly." After legalization in 2005, the town's absinthe industry revived, and some nine distilleries currently operate there.

While the association is apparently considering whether to appeal the ruling, Pernod Ricard Switzerland's CEO Francisco de la Vega noted that Henri-Louis Pernod opened the first absinthe distillery in Val-de-Travers but moved it to France a few years later. "The Swiss then banned absinthe for a century, and now they pretend that it's theirs alone," he said. *See The Local*, August 12, 2014; *Law360* and *Bloomberg*, August 13, 2014; *Beveragedaily.com*, August 14, 2014.

OTHER DEVELOPMENTS

Researchers Highlight Appeal of Gene Editing Techniques

A recent *Trends in Biotechnology* review highlighting "genetically edited organisms" (GEOs) has reportedly suggested that new techniques designed to tweak the existing genome could gain greater public acceptance than older methods, which traditionally use plant bacteria to insert foreign genetic material into fruit and vegetables. According to an August 13, 2014, Cell Press news release, the review co-authored by Istituto Agrario San Michele researcher Chidananda Nagamangala Kanchiswamy also raises questions about how regulators will classify crops that possess genomes edited to optimize nutrition or longevity.

"The researchers say that genetically edited plants, modified through the insertion, deletion, or altering of existing genes of interest, might even be deemed as nongenetically modified, depending on the interpretation of the EU commission and member state regulators," notes Cell Press. In particular, these new tools could overcome legal barriers in countries slow to adopt genetically modified organisms (GMOs).

"We would like people to understand that crop breeding through biotechnology is not restricted only to GMOs," explains Kanchiswamy. "Transfer of foreign genes was the first step to improve our crops, but GEOs will surge as a 'natural' strategy to use biotechnology for a sustainable agricultural future."

Rabbit Meat Sales at Whole Foods Prompt Protests

Whole Foods Market has begun selling rabbit meat at select stores nationwide, and rabbit advocacy groups have planned protests in response. In a May 2014 press release, Whole Foods announced its plan to sell rabbit meat raised according to its animal-welfare standards, including the requirements that the rabbits have "continuous access to drinking water, feed, roughage, gnawing blocks, tunnels and places for seclusion" as well as treatment for injuries. Unsatisfied, the House Rabbit Society has planned a day of action for August 17, 2014, encouraging participants to "politely talk to Whole Foods customers about the company's decision to sell rabbit meat" with the goal of generating comment cards critical of the new policy. Whole Foods said it introduced rabbit meat in response to customer demand, and a spokesperson told *Huffington Post* that it is "sensitive to the companion animal issue." Considering the rise in popularity of rabbit meat at restaurants, a *Los Angeles Times* reporter noted, "[T]he rabbit advocacy groups may have their work cut out for them." *See Huffington Post* and *Los Angeles Times*, August 14, 2014.

MEDIA COVERAGE

The Globe and Mail Criticizes Society's Fear of Sugar

National Canadian newspaper *The Globe and Mail* has **traced** the history of sugar from its roots as a luxury to its current incarnation as a "forbidden fruit, the momentary pleasure infused with a lifetime of guilt." Author John Allemang argues that the human taste for sweetness is natural and that "when we denounce sugar, we are defying our nature." He describes sugar's history, from its inclusion in recipe collections dating to about 1300 that extolled its ability to relieve illness to its use in creating plates and sculptures as a model of early conspicuous consumption. From there, it took on negative overtones through its association with slavery, colonialism and environmental degradation; later, sugar consumption became a moral failing. "[Early nutritionists] understood it to be seductive," Elizabeth Abbott, author of *Sugar: A Bittersweet History*, told Allemang. "This prompted moral outrage: When you ate it, you kept wanting to have more." The Industrial Revolution brought sugar a new reputation: energy provider. "As a shortcut to instant energy, it allowed men and women to work harder than they were able to do in a sugar-free world," notes Allemang. It then became associated with public eating, fun and festivity—something a 1950s "good wife" would provide her family after dinner or during a visit to the ice cream shop.

Now, however, sugar has become "a pervasive dietary placebo," Allemang writes, and its use has been demonized. "Normally in human history, taste told you what was bad for you by being bitter and inedible," Harvey Levenstein, author of *Fear of Food: A History of Why We Worry About What We Eat*, told

Allemang. "But now with modern nutritional science, there's almost a glee in exposing the pleasurable things as bad." Allemang notes that sugar served as an equalizer, sweetening tea, coffee and chocolate from their naturally bitter states to becoming habits that cultures enjoy together. He criticizes the coupling of guilt and pleasure in North Americans. "Guilt breeds unhealthy eating and compromises our readily available pleasures," he says. He cites a study that apparently found in a free-association exercise that Americans thought of "guilt" and "fattening" in association with chocolate cake, while the French thought of happiness and celebrations. Allemang opines, "Who are the healthier people in the end?" *See The Globe and Mail*, August 8, 2014.

SCIENTIFIC/TECHNICAL ITEMS

Trio of Studies Tackle Health Effects of Salt Consumption

Three studies recently published in *The New England Journal of Medicine* (*NEJM*) have answered the Institute of Medicine's call for additional data on the effects of salt consumption on human health, raising questions about the relationships between sodium intake, blood pressure, cardiovascular events, and mortality.

Relying on the Prospective Urban Rural Epidemiology (PURE) cohort study that followed more than 150,000 adult participants from a selection of low-, middle- and high-income countries, two of the articles used urinary sodium and potassium excretion measurements to estimate dietary sodium consumption. One study reported that, despite previous research linking sodium intake to hypertension, the association between sodium and potassium excretion and blood pressure was "non-linear and most pronounced in persons consuming high-salt diets, persons with hypertension, and older persons." Andrew Mente, et al., "Association of Urinary Sodium and Potassium Excretion with Blood Pressure," *NEJM,* August 2014. Looking at mortality and cardiovascular events, the second study based on PURE data apparently found that "an estimated sodium intake between 3 g per day and 6 g per day was associated with a lower risk of death and cardiovascular events than was either a higher or lower estimated level of intake." Martin O'Donnell, et al., "Urinary Sodium and Potassium Excretion, Mortality, and Cardiovascular Events," *NEJM,* August 2014.

In addition, a third study undertaken by the Global Burden of Diseases Nutrition and Chronic Diseases Expert Group (NutriCode) used data from surveys and published reports covering 66 countries to conclude that, in 2010, "1.65 million deaths from cardiovascular causes… were attributed to sodium consumption above a reference level of 2.0 g per day." Dariush Mozaffarian, et al., "Global Sodium Consumption and Death from Cardiovascular Causes," *NEJM,* August 2014. The study's authors further noted that these results

underestimate the burden of other diseases allegedly associated with salt consumption, including kidney disease and gastric cancer. Additional details about similar findings from NutriCode appear in Issue 477 of this *Update*.

"The NutriCode investigators should be applauded for a herculean effort in synthesizing a large body of data regarding the potential harm of excess salt consumption. However, given the numerous assumptions necessitated by the lack of high-quality data, caution should be taken in interpreting the findings of the study," comments a concurrent *NEJM* editorial. "Taken together, these three articles highlight the need to collect high-quality evidence on both the risks and benefits of low-sodium diets."

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