

CONTENTS

FIRM NEWS

Cruz-Alvarez, Canfield Analyze
SCOTUS Ruling in *Tyson Foods,
Inc. v. Bouaphakeo* 1

LEGISLATION, REGULATIONS AND STANDARDS

USDA Drafts New Organic Livestock
and Poultry Practices 2

FDA Amends Food Additive
Regulations to Provide
for Safe Use of Folic Acid
in Corn Masa Flour 3

Salt Institute Disputes Sodium
Recommendations in Federal
Dietary Guidelines 3

LITIGATION

Origin Lawsuit Against
Red Stripe® Beer Dismissed 4

Melitta Mislabels Artificial Flavors,
Proposed Class Action Contends . . . 5

Presence of Citric Acid
at Heart of Putative Class Action
Challenging Vivaloe's "Natural"
and Preservative-Free Claims 6

Biotech Firm Sues Beverage
Cos. Alleging Probiotic
Patent Infringement 6

SCIENTIFIC/TECHNICAL ITEMS

New Study Reevaluates Effect
of Fat Intake on Cholesterol
and Heart Disease Risk 7

FIRM NEWS

Cruz-Alvarez, Canfield Analyze SCOTUS Ruling in *Tyson Foods, Inc. v. Bouaphakeo*

“The U.S. Supreme Court recently deviated from its historically stringent view on class certification and affirmed an Eighth Circuit decision to uphold certification of a class of Tyson Foods, Inc. employees who brought suit against Tyson for a violation of the Fair Labor Standards Act of 1938 (FLSA),” Shook Miami attorneys [Frank Cruz-Alvarez](#) and [Rachel Canfield](#) explain in an April 13, 2016, [analysis](#) for the Washington Legal Foundation’s *Legal Pulse*.

The article first describes the suit’s origins; Tyson initially paid all employees for an equal amount of time spent donning and doffing protective gear but later adjusted the policy to pay some employees for additional “don and doff” time. Cruz-Alvarez and Canfield note that “Plaintiffs alleged Tyson’s failure to compensate them for time spent performing this ‘integral and indispensable’ work activity violated the FLSA by lengthening their workweek beyond forty hours without providing them with overtime pay.”

They also note that Tyson did not keep records of don-doff time, so “employees relied on representative evidence,” all aimed at calculating the average time that each group of employees spent to don and doff their protective gear. The company challenged “whether certification based on representative evidence was sufficient to satisfy Rule 23(b)(3)’s requirement that ‘questions of law or fact common to class members predominate over any questions affecting only individual members.’”

“Whether *Tyson* foreshadows an overall shift in the Court’s attitude toward class-action certification remains to be seen,” Cruz-Alvarez and Canfield conclude. “*Tyson*’s language indicates the decision is limited. The decision itself articulates a more clearly defined predominance analysis and highlights important factors to consider in the future, such as whether a business should maintain adequate records of statutorily required information or whether to implement uniform policies. It also alerts litigators to the importance of raising a *Daubert* challenge or considering whether challenging a plaintiff’s proposal to restructure the proceedings is favorable in the long term.”

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 600 | APRIL 15, 2016

LEGISLATION, REGULATIONS AND STANDARDS

USDA Drafts New Organic Livestock and Poultry Practices

The U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) has proposed amendments to organic livestock and poultry production requirements to clarify "how producers and handlers must treat their livestock and poultry to ensure their health and well-being throughout life." Based on recommendations from the National Organic Standards Board, the draft rules also specify "which physical alterations are allowed and prohibited" and establish "minimum indoor and outdoor space requirements for poultry."

In particular, the proposed amendments provide for "a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants), resulting in appropriate body condition." They also limit physical alterations to those performed only at "a reasonably young age, with minimal stress and pain and by a competent person," and only in cases determined to "benefit the welfare or hygiene of the animals, or for identification purposes or safety." In addition to disallowing needle teeth trimming and tail docking in pigs except in documented situations where alternative methods to prevent harm failed, the amendments would prohibit the following practices: "de-beaking, de-snooding, caponization, dubbing, toe trimming of chickens, toe trimming of turkeys unless with infrared at hatchery, beak trimming after 10 days of age, tail docking of cattle, wattling of cattle, face branding of cattle, tail docking of sheep shorter than the distal end of the caudal fold, and mulesing of sheep."

Among other things, AMS has also added wording to (i) clarify when organic producers can administer approved synthetic medications and vaccinations; (ii) prohibit the administration of hormones for production or reproduction; and (iii) establish that milk "from animals undergoing treatment with prohibited substances cannot be sold as organic or fed to organic livestock." New provisions would require comprehensive plans to minimize parasite problems and forbid organic producers from (i) withholding treatment "for injured, diseased, or sick animals, which may include forms of euthanasia as recommended by the American Veterinary Medical Association," (ii) neglecting to keep records on treated animals; (iii) practicing forced molting; or (iv) performing euthanasia by suffocation, killing pliers, burdizzo clamps, or "a blow to the head by blunt instrument." See *AMS Press Release*, April 7, 2016.

Shook 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.

For additional information about Shook's capabilities, please contact



Mark Anstoetter
816.474.6550
manstoetter@shb.com



Madeleine McDonough
816.474.6550
202.783.8400
mmcdonough@shb.com

If you have questions about this issue of the *Update* or would like to receive supporting documentation, please contact Mary Boyd at mboyd@shb.com.

FDA Amends Food Additive Regulations to Provide for Safe Use of Folic Acid in Corn Masa Flour

The U.S. Food and Drug Administration (FDA) has approved folic acid fortification of corn masa flour in response to a 2012 petition from the March of Dimes Foundation, National Council of La Raza and other groups. FDA's action allows manufacturers to voluntarily add up to 0.7 milligrams of folic acid per pound of corn masa flour.

Used in tortillas, tamales and other foods, corn masa flour is a dietary staple for many people of Mexican and Central American descent, and the petitioners sought the voluntary fortification to increase the folic acid intake for U.S. women of childbearing age who regularly consume such products. Folic acid is a synthetic form of folate, a B vitamin linked to the decreased incidence of neural tube defects. *See Federal Register*, April 15, 2016.

Salt Institute Disputes Sodium Recommendations in Federal Dietary Guidelines

The Salt Institute has penned an April 11, 2016, letter asking the U.S. Department of Agriculture (USDA) and Department of Health and Human Services (HHS) to withdraw the sodium provisions included in the 2015-2020 Dietary Guidelines for Americans, which advise individuals to consume less than 2,300 milligrams (mg) per day of sodium.

According to the Salt Institute, these provisions—in addition to those that appear in the 2010 Dietary Guidelines for Americans—violate the statutory mandate that requires them to reflect “the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.” In particular, the letter argues that both the 2010 and 2015 Dietary Guidelines Advisory Committees (DGACs) based their sodium recommendations on a 2004 Institute of Medicine (IOM) report that failed to contain enough evidence to set a recommended dietary allowance.

“Rather than thoroughly assessing the current scientific and medical knowledge, the Agencies reached a conclusion in 2005 based on insufficient evidence and then repeated the error in 2010 and again in 2015,” states the Salt Institute. “To cure this defect, the Agencies should withdraw the flawed sodium provisions and subject the topic of appropriate sodium limits to rulemaking under the Administrative Procedures Act to ensure that all interested parties are permitted to participate in a public

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 600 | APRIL 15, 2016

forum and that decision making is supported by sound and current scientific evidence.”

The letter also deems the procedure for determining these recommendations “fundamentally flawed” because the DGACs not only “injected personal bias into both the 2010 and 2015-2020 processes,” but failed to consider any negative effects of dietary sodium reduction. Among other things, the committees disregarded studies suggesting that consumers will eat larger portions of low-sodium foods “to satisfy their innate salt appetites,” and did not grapple with conflicting evidence regarding the impact of sodium intake on blood pressure.

But despite the lack of research backing population-wide sodium reduction, the U.S. Food and Administration (FDA) is poised to set voluntary salt reductions in food products—a move that the Salt Institute describes as little more than a capitulation to the Center for Science in the Public Interest. “A call for voluntary salt reduction in food products holds clear dangers for consumers,” concludes the letter, which also calls attention to the effects of regulation on food producers. “It is troubling that the Agencies have, to this point, adopted a mentality of continuous justification of a preordained conclusion rather than doing their statutory duty and setting standards based upon a rigorous assessment of all available scientific and medical evidence. However, we encourage you to change this practice and abandon the sodium provisions in the Dietary Guidelines in favor of an open, transparent rulemaking proceeding. Continuing to build policy and regulation on a fatally flawed foundation is both bad government and does nothing to protect our citizenry.”

LITIGATION

Origin Lawsuit Against Red Stripe® Beer Dismissed

A California federal court has dismissed a lawsuit alleging that Diageo PLC misrepresents Red Stripe® beer as brewed in Jamaica, finding “no reasonable consumer would be misled into thinking that Red Stripe is made in Jamaica with Jamaican ingredients based on the wording of the packaging and labeling.” *Dumas v. Diageo PLC*, No. 15-1681 (S.D. Cal., order entered April 6, 2016). Details about the complaint appear in Issue [574](#) of this *Update*.

Bottle trays for six and 12-packs of Red Stripe® include, as the court explained, “the language ‘Jamaican Style Lager and ‘The Taste of Jamaica,’” the Diageo-Guinness USA logo and a disclaimer on the bottom

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 600 | APRIL 15, 2016

of the packaging that states, “Brewed and bottled by Red Stripe Beer Company Latrobe, PA.” Citing a Second Circuit opinion finding that the description of a knife as a “Swiss Army knife” does not imply it was made in Switzerland, the court found that the “mere fact that the word ‘Jamaica’ and ‘Jamaican’ appear on the packaging is not sufficient to support a conclusion that consumers would be confused regarding the origin and ingredients of the beer.”

The court distinguished another case finding Anheuser-Busch Co. liable for misrepresentation claims for marketing Beck’s® beer with statements that it “Originated in Germany” and was “Brewed under the German Purity Law of 1516,” when considered in the context of the “overall marketing campaign and Beck’s 139-year history of being brewed in Germany.” The court also disagreed with the plaintiffs’ argument that Diageo failed to alert consumers to the production move from Jamaica to Pennsylvania, finding no support for the argument that Diageo had a “heightened duty” to counter consumers’ pre-conceived notions about the beer being brewed in Jamaica. Details about settlement of the Beck’s® case appear in Issues [570](#) and [582](#) of this *Update*.

Melitta Mislabeled Artificial Flavors, Proposed Class Action Contends

A putative class action against Melitta USA Inc. alleges the company’s coffee product packaging fails to distinguish between “natural and/or artificial flavor” per federal regulations. *Decerbo v. Melitta USA Inc.*, No. 16-0850 (M.D. Fla., filed April 11, 2016).

The plaintiff argues that under U.S. Food and Drug Administration rules, food manufacturers must “accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food and its characterizing properties or ingredients,” including whether a characterizing flavor is natural or artificial. However, “‘Hazelnut Crème’ is not flavored with hazelnuts, there is no vanilla in ‘French Vanilla,’ and ‘Pumpkin Spice’ flavor contains neither nutmeg nor cinnamon, or pumpkin or any customary pumpkin spice either, as these Products’ labels would explicitly lead a consumer to conclude,” the complaint argues. The plaintiff further notes that other coffee-product manufacturers “have responsibly decided to correctly label their products,” purportedly giving the company an unfair advantage over competitors. She seeks class certification, restitution, disgorgement of benefits, damages and an injunction for alleged violations of consumer-protection statutes of New Jersey, of which the plaintiff is a resident.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 600 | APRIL 15, 2016

Presence of Citric Acid at Heart of Putative Class Action Challenging Vivaloe's "Natural" and Preservative-Free Claims

A consumer has filed a putative class action alleging Outernational Brands, Inc. mislabels its Vivaloe aloe-vera beverages as "All Natural" and preservative-free even though the products contain citric acid. *Chen v. Outernational Brands, Inc.*, No. 16-1634 (E.D.N.Y., filed April 4, 2016).

"The term 'All Natural' only applies to those products that contain no non-natural or synthetic ingredients and consist entirely of ingredients that are only minimally processed," the complaint asserts. The plaintiff argues that the presence of citric acid, "which is not extracted from citric fruits but industrially synthesized via complex chemical synthetic routes and thus cannot be considered 'minimally processed,'" precludes Outernational from labeling Vivaloe as "All Natural" or free of preservatives.

The complaint admits the U.S. Food and Drug Administration has not defined "natural," but argues "there is no reasonable definition of 'All Natural' that includes ingredients that, even if sourced from 'nature,' are subjected to extensive transformative chemical processing before their inclusion in a product." For allegations of misrepresentation and New York consumer-protection law violations, the plaintiff seeks class certification, compensatory and punitive damages, an injunction, restitution and attorney's fees.

Biotech Firm Sues Beverage Cos. Alleging Probiotic Patent Infringement

Ganeden Biotech Inc. has filed a lawsuit against American Brewing Co., Inc. and its 2015 acquisition, B&R Liquid Adventure, alleging the companies infringe its patents on a particular strain of probiotic bacteria through the marketing and sale of their búcha[®] beverage. *Ganeden Biotech, Inc. v. Am. Brewing Co., Inc.*, No. 16-0876 (N.D. Ohio, E. Div., filed April 13, 2016).

Ganeden asserts that it holds a patent on a specific GBI-30 strain of *Bacillus coagulans* as used in tea and another patent on the strain as used in all other products. B&R began selling búcha[®] in 2013 and lists the GBI-30 strain as an ingredient, according to the complaint. "Because Ganeden holds a patent on GBI-30 and is the legitimate source of GBI-30, Ganeden believes that Defendants' products likely contained *Bacillus coagulans* (which Defendants could have obtained elsewhere) but not always the GBI-30 strain as labeled," the biotech company

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 600 | APRIL 15, 2016

ABOUT SHOOK

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.

Shook 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.



argues. For allegations of patent infringement and unfair competition, Ganeden seeks a declaration finding infringement, a permanent injunction, an accounting, treble damages and attorney's fees.

SCIENTIFIC/TECHNICAL ITEMS

New Study Reevaluates Effect of Fat Intake on Cholesterol and Heart Disease Risk

A study reevaluating “the traditional diet-heart hypothesis” concludes that replacing dietary saturated fat with vegetable oils lowers serum cholesterol but does not reduce the risk of death from coronary heart disease or other causes. Christopher Ramsden, et al., “Re-evaluation of the traditional diet-heart hypothesis: analysis of recovered data from Minnesota Coronary Experiment (1968-73),” *BMJ*, April 2016.

Using previously unpublished data from the Minnesota Coronary Experiment (MCE)—“a double blind randomized controlled trial designed to test whether replacement of saturated fat with vegetable oil rich in linoleic acid reduces coronary heart disease and death by lowering serum cholesterol”—researchers examined data on diet, serum cholesterol and health outcomes for 9,423 women and men ages 20 to 97 years. Their results evidently showed that substituting saturated fat with linoleic acid showed no benefits for coronary atherosclerosis or myocardial infarcts, even though participants in the dietary intervention group exhibited a significant reduction in serum cholesterol compared with controls.

“The pooled results of the MCE and four similar trials failed to find any reduction in mortality from coronary heart disease,” notes a concurrent *BMJ* editorial. “In the past decade, old certainties regarding dietary fats have been questioned, and some have been abandoned... With these new findings, the recommendation to consume less than 10% of calories per day from saturated fats will be under increased scrutiny.”