FOOD & BEVERAGE LITIGATION UPDATE

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SHOOK HARDY & BACON

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Cracks Down on Sales of Pure Powdered Caffeine

The U.S. Food and Drug Administration (FDA) has **issued** five warning letters to the distributors of pure powdered caffeine, citing two fatalities linked to caffeine toxicity as evidence that the products "are dangerous and present a significant or unreasonable risk of illness or injury to consumers." Equating 1 teaspoon of pure caffeine to 25 cups of coffee, FDA also warns consumers not to purchase or use powdered caffeine as "it is nearly impossible to accurately measure pure powdered caffeine with common kitchen measuring tools and you can easily consume a lethal amount."

In particular, the agency plans to "aggressively monitor the marketplace" for pure powered caffeine being sold as a dietary supplement. The warning letters not only find the products adulterated under the Federal Food, Drug, and Cosmetic Act, but argue that labeling directs consumers to use difficult measurements such as one-sixteenth of a teaspoon. "Consumers are unlikely to have a one-sixteenth teaspoon measuring tool, as this tool is not generally available in standard consumer measuring spoon sets," FDA tells one company. "Even if such a tool were available, it would be difficult to use it to measure a 50 milligram serving of your product, as 50 milligrams is approximately one-quarter of a one-sixteenth teaspoon measuring tool based on the numbers on the chart you provided."

As the agency's letters conclude, "In light of the potential toxicity of your product; the fact that your product is packaged to contain an amount that would be lethal to many consumers; the fact that the packaging requires the consumer to separate out a safe serving from this potentially lethal amount; and the fact that the product labeling incorrectly implies that this process of separating out a safe serving from a potentially lethal amount can be done with certain common household measuring tools,

when in fact it would require a precise scale; we have determined that your product presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling."

ATSDR Issues Perfluoroalkyls Profile for Renewed Public Comment

Citing a "plethora of new data" published since issuing its toxicological profile for perfluoroalkyls in 2009, the Agency for Toxic Substances and Disease Registry (ATSDR) has **reissued** the profile seeking additional information about the alleged health effects of exposure to the synthetic chemicals. PFOA and PFOS are the two perfluoroalkyls produced in the largest amounts in the United States and are used in coatings for paper and cardboard packaging to repel oil, grease and water. Comments are due by December 1, 2015. *See Federal Register*, September 2, 2015.

Ireland Objects to "Artisan" McDonald's Burger

The Food Safety Authority of Ireland (FSAI) has reportedly objected to McDonald's Corp.'s use of "artisan" in describing its new product, the McMór hamburger. The Ireland-exclusive burger is marketed as an "artisan" product that incorporates several ingredients from Irish cuisine, including bacon, cabbage, baby kale, Ballymaloe relish, Charleville cheese and a "potato-flaked" bun.

FSAI established guidelines in May 2015 about the use of "artisan" that stipulate the word should describe products made only (i)"in limited quantities by skilled craftspeople," (ii) without a "fully mechanized" process that "follows a traditional method," (iii) "in a micro-enterprise at a single location," and (iv) with "characteristic ingredients" that are "grown or produced locally, where seasonally available and practical." McDonald's issued a statement indicating that it would remove "artisan" from its marketing. Additional details about FSAI's food marketing guidance appear in Issue 566 of this *Update*. *See The Irish Times*, September 1, 2015.

Heinz Ketchup to Be Labeled "Tomato Seasoning" in Israel

Israel's Ministry of Health has reportedly ruled that Heinz ketchup can no longer be called "ketchup" because of its low tomato content. Israeli food company Osem first targeted the product in January 2015

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.

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by sending a letter to supermarkets blasting the product and filing an $18-million class action on behalf of consumers. Osem argued that lab tests showed small bottles of Heinz ketchup contained 20 percent tomato concentrate and large bottles just 17 percent—compared to the 39 percent advertised on the bottle—despite Israeli regulations dictating that ketchup must contain at least 35 percent tomato concentrate.

The health ministry agreed with Osem, finding that Heinz can no longer call its product "ketchup" and must be labeled "tomato seasoning" instead. The ruling does not affect Heinz's English-language labels. Heinz's local importer, Diplomat, has filed a petition to lower the minimum requirements from 10-percent tomato solids (the equivalent of 35-percent tomato concentrate) to 6 percent, which the health ministry reportedly supports. *See Haaretz*, August 18, 2015.

LITIGATION

"Freshly Baked" Bread Lawsuit Dismissed Against Supermarkets

A New Jersey federal court has dismissed putative class actions against Whole Foods Market Group Inc., Wegmans Food Markets Inc. and Acme Markets Inc. alleging that they misrepresented their bread products as "freshly baked" or "baked in-store" despite actually being frozen, processed or baked elsewhere. *Mladenov v. Wegmans Food Mkts. Inc.*, No. 15-0373 (D.N.J., order entered August 26, 2015); *Mladenov v. Whole Foods Mkt. Grp. Inc.*, No. 15-0382 (D.N.J., order entered August 26, 2015); *Mao v. Acme Markets Inc.*, No. 15-0618 (D.N.J., order entered August 26, 2015). Additional information about the three complaints appears in Issue **549** of this *Update*.

The court found holes in each of the plaintiffs' amended complaints, noting that they lacked "any detail as to what Plaintiffs purchased, the cost of these items, and the supposed value of what they received," which are necessary to a price-premium claim. "Nowhere in their complaints or opposition do Plaintiffs allege facts supporting an out-of-pocket loss, i.e. that the products they purchased were worthless," the court said. "Plaintiffs, claiming to be health conscious consumers, do not even allege that the relevant products lacked nutritional value or were somehow less nutritious due to their not being made from scratch in store. Plaintiffs' apparent dissatisfaction in the bread and bakery products

they purchased, without more, does not suffice under this theory of ascertainable loss." Further, the plaintiffs "seem to suggest that the products they purchased are more like pre-packaged bread than fresh bread, but that comparison fails." Accordingly, the court dismissed the claims in all three lawsuits.

Safeway to Pay $30 Million for Online Grocery Markup

A California federal court has determined that Safeway is liable for $30 million in damages for claims alleging that the company charged different prices for products sold online despite a contractual agreement that in-store and online prices would be the same. *Rodman v. Safeway Inc.*, No. 11-3003 (N.D. Cal., order entered August 31, 2015). The court granted partial summary judgment to the plaintiffs in December 2014, finding that Safeway breached the contract. Details about the decision appear in Issue **549** of this *Update*.

The court arrived at the damages amount by calculating the sum that Safeway earned from the concealed markup between April 2010 and December 2012. The court also rejected the plaintiffs' attempt to expand the class to include purchases before 2006, when Safeway switched from paying a third party to manage online sales to running the website in-house.

Challenge to Jim Beam® "Handcrafted" Label Dismissed

A California federal court has dismissed a putative class action alleging that Jim Beam Brands and Beam Suntory Import mislabel Jim Beam® bourbon bottles because the label calls the product "handcrafted" despite its machine-based manufacturing process. *Welk v. Beam Suntory Imp. Co.*, No. 15-0328 (S.D. Cal., order entered August 21, 2015). The plaintiff had alleged that a reasonable consumer would be fooled by the bourbon label because the production process for the "handmade" product requires "little to no human supervision, assistance or involvement." Details about the complaint appear in Issue **556** of this *Update*.

The court first denied the distillery's motion to dismiss under California's safe harbor doctrine, finding that although Jim Beam could prove the Alcohol and Tobacco Tax and Trade Bureau had approved the label, the evidence did not indicate whether the agency investigated and approved the use of "handcrafted." The court then considered similar cases,

including decisions finding for Jim Beam and its sibling brand Maker's Mark®, and concluded that the precedents were persuasive. "A reasonable consumer wouldn't interpret the word 'handcrafted' on a bourbon bottle to mean that the product is literally 'created by a hand process rather than by a machine.' Thus, it isn't 'reasonably interpreted as a statement of objective fact.'" Accordingly, the court granted Jim Beam's motion to dismiss. Additional information about the Maker's Mark® dismissal appears in Issue **564** of this *Update*.

Center for Food Safety Sues USDA for Ignoring FOIA Requests About GE Crops

The Center for Food Safety (CFS) has filed a lawsuit against the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) alleging that the agency has routinely failed to respond to Freedom of Information Act (FOIA) requests for records related to genetically engineered (GE) crops. *Ctr. for Food Safety v. Animal & Plant Health Inspection Serv.*, No. 15-1377 (D.C., filed August 25, 2015).

CFS asserts that APHIS has unlawfully delayed its responses to at least 29 FOIA requests or appeals related to its decision to withdraw proposed regulations that would update existing management of GE crops. "APHIS has a track record of irresponsible and inadequate regulation of GE crops," CFS Staff Attorney Cristina Stella said in an August 25, 2015, press release. "In the absence of thorough government oversight, public access to information about these crops becomes all the more critical. This lawsuit is necessary to stop APHIS from continuing to ignore its duty to provide the public with information that affects farmers, communities, and the environment." In the complaint, CFS requests that the court declare APHIS' FOIA request handling as unlawful, direct the organization to produce the records it requested and prohibit the agency from continuing its "pattern or practice of failing to timely respond to Plaintiff's FOIA requests."

Chipotle Fare Is Not GMO-Free, Purported Class Action Alleges

A California woman has filed a putative class action against Chipotle Mexican Grill Inc. alleging that, despite advertised claims to the contrary, the company's restaurants do not serve food free of genetically modified organisms (GMOs). *Gallagher v. Chipotle Mexican Grill Inc.*, No.

15-3952 (N.D. Cal., filed August 26, 2015). The complaint asserts that although the company advertised in April 2015 that it would remove GMOs from its food, "Chipotle serves meat products that come from animals which feed on GMOs, including corn and soy. Chipotle's tacos and burritos are also usually served with sour cream and cheese from dairy farms that feed animals with GMOs." In addition, Chipotle sells soft drinks made with GMO corn syrup, the complaint notes.

Colleen Gallagher seeks to represent a California class to obtain damages and an injunction for alleged violations of the state's consumer protection statutes. Chipotle became the first fast-casual chain to disclose whether its ingredients contained GMOs in June 2013; details appear in Issue **488** of this *Update*.

OTHER DEVELOPMENTS

AAJ Report Decries Food Industry, Promotes Civil Justice System as "Mechanism for Deterring Negligent Behavior"

"American consumers expect and deserve safe food. Yet, time and again, food producers have cut corners on food safety knowing full well that tainted products cause serious illness or even death," asserted American Association for Justice (AAJ) President Larry Tawwater in issuing a **report** condemning industry for allegedly prioritizing profits over people.

The report contends that consumer lawsuits have become the most effective "mechanism for deterring negligent behavior and rooting out systemic problems in the food chain" absent adequate food-safety practices by food companies and appropriate monitoring by regulators. Among other things, AAJ calls on Congress to declare multi-drug-resistant *Salmonella* an official adulterant and to enact legislation creating a single food safety agency. AAJ was formerly known as the Association of Trial Lawyers of America (ATLA). *See AAJ News Release*, September 2, 2015.

MEDIA COVERAGE

Amazon Enters Farmers Market, Alcohol Sectors

With the launch of services targeting the grocery and alcoholic beverage segments, Amazon.com, Inc., has garnered media attention for its latest

forays into a new and competitive marketplace. In a September 1, 2015, article, *The Los Angeles Times* compares Amazon's Farmers Market Direct program to other food delivery startups aiming to bring fresh local products from farm to doorstep. A partnership with Connecticut-based Fresh Nation, the Farmers Market Direct program seeks to connect Southern California agricultural producers to Amazon's consumer base, promising food delivery within 36 hours of harvest. As the *Times* notes, "Development of food-delivery technology has attracted an enormous amount of money. About $710 million was invested in the segment in the first half of 2015, more than the $681 million invested all of last year."

Meanwhile, *The Wall Street Journal* reports that Amazon's one-hour delivery service for alcohol beverages joins "more than a half-dozen alcohol delivery startups… working to differentiate themselves from one another." In many cases, these companies do not require liquor licenses as they sell their apps and technology to existing physical stores to help them boost online sales. But under Amazon's model, the online retailer has acquired a Washington state liquor license to sell wine, spirits and other beverages directly to Seattle consumers. "Private investors backing the booze delivery startups remain bullish on the sector despite Amazon's entry and similar activity by delivery services such as Postmates and Instacart," states the September 1, 2015, article. "The ability to bring offline transactions online and mine the data coupled with consumer enthusiasm for summoning items from smartphones as evidenced in food, rides, laundry, and other services have made the sector a compelling one for tech investors." *See The Wall Street Journal,* September 1, 2015.

SCIENTIFIC/TECHNICAL ITEMS

New Study Questions BPA Link to Preterm Births

A study examining increased preterm birth rates in the United States has found "little evidence of a relationship been BPA [bisphenol A] and prematurity." David Cantonwine, et al., "Urinary Bisphenol A Levels during Pregnancy and Risk of Preterm Birth," *Environmental Health Perspectives,* September 2015. After analyzing urinary BPA levels throughout pregnancy in 130 cases of preterm birth (PTB) and 352 randomly assigned controls, researchers with Harvard Medical School and University of Michigan School of Public Health report that,

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.

"[i]n adjusted models, urinary BPA averaged across pregnancy was not significantly associated with PTB." They note, however, that "averaged BPA exposure during pregnancy was associated with significantly increased odds of being delivered preterm among females, but not males."

"Our study had several strengths, including a repeated time point assessment of BPA exposure, ultrasound dating of gestational age, physician-validated clinical outcomes, and a large number of subjects and preterm cases, which allowed for exploring the heterogeneous nature of PTB," concludes the study. "Still, results from our secondary analyses of subtypes of PTB and stratification on infant sex should be interpreted cautiously... We acknowledge that the few significant associations found in our analysis may be attributable to chance alone, and larger follow-up studies to replicate the findings are warranted."