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LEGISLATION, REGULATIONS AND STANDARDS

FDA Issues Final Rule on Mica-Based Pearlescent Pigments in Distilled Spirits

The U.S. Food and Drug Administration (FDA) has issued a final rule allowing "the safe use of mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in certain distilled spirits." Mica-based pearlescent pigments are currently approved as color additives in many foods and beverages, including distilled spirits containing "not less than 18 percent and not more than 23 percent alcohol by volume." Effective November 5, 2015, the new rule permits the use of these pigments at a level of up to 0.07 percent by weight in distilled spirits containing not less than 18 percent and not more than 25 percent alcohol by volume, while finding that "certification of mica-based pearlescent pigments prepared from titanium dioxide is not necessary for the protection on the public health."

"Regarding cumulative exposure from the current and petitioned uses of mica-based pearlescent pigments, we note that in our recent final rule that provided for the safe use of mica-based pearlescent pigments as color additives in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, non-alcoholic cocktail mixers and mixes, and in egg decorating kits for coloring shell eggs, we estimated the CEDI for the use of mica-based pearlescent pigments in food (§ 73.350) and ingested drugs (§ 73.1350) to be 0.25 g/p/d at the mean and 0.50 g/p/d at the 90th percentile for the U.S. population," states FDA. "Since the petitioned use of mica-based pearlescent pigments will generally substitute for currently-permitted uses of mica-based pearlescent pigments in other alcoholic beverages with no change in the maximum use level of 0.07 percent by weight, we have determined that the petitioned use of mica-based pearlescent pigments will not result in an increase in consumer exposure to these pigments." *See Federal Register*, September 30, 2015.

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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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USDA Links Virus That Killed Millions of Pigs to Reusable Feed Bags

The U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) has **linked** a 2013-2014 outbreak of porcine epidemic diarrhea virus (PEDv) that killed more than 7 million piglets to Flexible Intermediate Bulk Containers (FIBCs), the reusable tote bags used to transport and store pig feed. According to an APHIS report, which seeks to explain why PEDv occurred in the United States but not Canada or the European Union, the bags were most likely contaminated in their origin country before distribution to feed mill customers across the Midwest, where they contaminated "feed or ingredients destined for delivery to the farm."

"Several of the farm investigations as well as an early case-control study suggested feed or feed delivery as the source of the outbreak; however, there were no common feed manufacturers, products, or ingredients in the initially infected herds," states the report, which notes that the PEDv strain found in the United States matched a similar strain from China. "In addition to meeting the investigation criteria, the contaminated FIBC scenario explains the apparent anomalous association of the epidemic to feed."

UK Regulator Announces New Rules for Non-Broadcast Food and Soft Drink Ads to Youth

The **Committees of Advertising Practice (CAP)**, a group that works in conjunction with the U.K. Advertising Standards Authority, has announced a pre-consultation with various stakeholders in advance of new rules targeting non-broadcast advertising of food and soft drinks high in fat, salt or sugar to children. Non-broadcast channels of advertising include online, outdoor, print media, cinema, and direct marketing.

"Our decision to carry out a public consultation responds, in part, to changes in children's media habits and evolving advertising techniques," according to CAP. "It also reflects a growing consensus, shared by public health and industry bodies, about the role of advertising self-regulation in helping to bring about a change in the nature and balance of food advertising targeted to children."

CAP reportedly plans to launch the public consultation in early 2016. *See CAP News Release*, September 29, 2015.

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Russia Halts Domestic Production of GM Foods

Russia has imposed a moratorium on the use of genetically modified organisms in domestic food production. Deputy Prime Minister Arkady Dvorkovich reportedly made the announcement during a biotechnology conference in Kirov on September 18, 2015. Russia's action follows similar moves by France, Germany and Scotland. *See Reuters*, September 18, 2015.

LITIGATION

Peanut Corp. Managers Sentenced to Prison

One week after the sentencing of three Peanut Corp. of America (PCA) executives, two managers have been sentenced to prison for their roles in a *Salmonella* outbreak linked to nine deaths and hundreds of illnesses. Samuel Lightsey and Daniel Kilgore, former operations managers at PCA's Blakely, Georgia, plant, were sentenced to three years and six years respectively.

"By making sure that the individuals involved in the corporate fraud at PCA were held accountable, I am confident that the message to other executives is clear," said U.S. Attorney Michael Moore. "Because we all know that it is people who make decisions about what goes on behind the corporate curtain, we'll be looking to hold those individuals personally accountable when they steer their businesses down the path of fraud. Mr. Kilgore and Mr. Lightsey acknowledged their wrongdoing, and today their sentences reflect not only their acceptance of that responsibility, but also the requirement of accountability."

Details about the previous sentencing appear in Issue [579](#) of this *Update*. *See FBI Press Release*, October 1, 2015.

Lawsuit Challenging National Organic Program Guidance on Pesticides to Continue

A California federal court has denied the U.S. Department of Agriculture's (USDA's) motion to dismiss a lawsuit brought by environmental organizations challenging USDA's issuance of a guidance document about the use of pesticides in compost without first having solicited public comment. *Ctr. for Env't'l Health v. Vilsack*, No. 15-1690 (N.D. Cal., order entered September 29).



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The Center for Food Safety (CFS), Center for Environmental Health and Beyond Pesticides challenged USDA's actions on Administrative Procedures Act (APA) grounds, arguing the agency violated federal procedures by not allowing a formal rulemaking and public comment period about a guidance document permitting the use of compost with pesticides in the production of organic food. The court found that the organizations had sufficiently stated their claim under the APA and had standing to sue. "The agency's unilateral action to allow compost contaminated with pesticides in organic production was contrary to federal rulemaking requirements as well as contrary to the high standards of organic integrity," George Kimbrell, CFS counsel, said in a September 30, 2015, press release. "We will continue to represent the organic community in holding USDA accountable."

Monetary Class Certification Denied in Hain Celestial "Natural" Lawsuit

A California federal court has denied class certification in a lawsuit consolidated from four separate actions alleging that Hain Celestial Seasonings Teas were produced from ingredients sprayed with pesticides and contained pesticide residue, thus allegedly precluding Hain from labeling its teas as "natural." *In re Hain Celestial Seasonings Prods. Consumer Litig.*, No. 13-1757 (C.D. Cal., order entered September 23, 2015). In its answer to the complaint, Hain argued the plaintiffs conflated the definitions of "natural" and "organic" in their arguments, noting that under the plaintiffs' standards, even an apple picked directly from a tree would not be "natural" had pesticides been applied during its growth.

The court first chastised the plaintiffs for erroneous references and poorly timed supplemental filings. "Despite 18 months passing between the filing of this lawsuit and the filing of the Certification Motion, Plaintiffs effectively left the Court to drink from a fire hose, perhaps filled with tea, during the hearing," the court wrote. "In some ways the Court still felt like a pig in search of truffles."

Turning to the substantive arguments, the court found that the plaintiffs failed to prove the proposed class was ascertainable. "For example, Plaintiffs' exhibits of one tea variety at issue, the Authentic Green Tea, and one variety not at issue, the Antioxidant Green Tea, only strengthens the conclusion that there is no administratively feasible way to determine class members," the court said. "These two boxes are nearly identical. They both say "Natural Antioxidant Green Tea" in the upper left corner despite one of them being antioxidant and one being authentic. Plaintiffs

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essentially argue that the existence of a dragon instead of an elephant signals to potential class members which tea they purchased. The Court does not agree. The animals appear fungible. They are not tied to the essence of the tea, like a monkey to a banana or a rabbit to a carrot.” Accordingly, the court concluded the class could not be ascertained for monetary purposes and refused to grant certification, but allowed certification for injunctive relief.

Most Claims Dismissed in “Handmade” Lawsuit Against Vodka Maker

A Florida federal court has dismissed five putative class action claims, allowing one to continue, against Fifth Generation Inc. in a lawsuit alleging Tito’s® Handmade Vodka is not actually made by hand in “an old fashioned pot still” and thus is deceptively marketed. *Pye v. Fifth Generation Inc.*, No. 14-0493 (N.D. Fla., order entered September 23, 2015). The court cited its May 2015 decision in *Salters v. Beam* addressing similar claims against Maker’s Mark®, finding that “[m]uch of the analysis here repeats what was said there.” Details about that decision appear in Issue [564](#) of this *Update*.

The plaintiffs alleged that “handmade” means “made from scratch” or “in small units,” with human involvement in the process. The court disagreed, finding, “No reasonable person would understand ‘handmade’ in this context to mean literally made by hand. No reasonable person would understand ‘handmade’ in this context to mean substantial equipment was not used. If ‘handmade’ means in a carefully monitored process, then the plaintiffs have alleged no facts plausibly suggesting the statement is untrue. If ‘handmade’ is understood to mean something else—some ill-defined effort to glom onto a trend toward products like craft beer—the statement is the kind of puffery that cannot support claims of this kind.” Accordingly, the court dismissed five of the plaintiffs’ six claims.

The argument that the vodka is not made in an “old fashioned pot still” as claimed on the label was more plausible, the court found. “This is not the kind of dispute that can properly be resolved on a motion to dismiss. Perhaps the vodka is made with equipment that can reasonably be described as an ‘old fashioned pot still’; perhaps not. Just from reading the first amended complaint and motion to dismiss, one cannot know.” The court then allowed the claim for breach of express contract to continue. Details about similar lawsuits against Fifth Generation appear in Issues [563](#) and [575](#) of this *Update*.

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“Fire Flask” Trademark Dispute Settled

Sazerac Co., maker of Fireball Cinnamon Whisky®, and Stout Brewing Co. have filed a joint stipulation of dismissal with prejudice in a lawsuit alleging that Stout infringed Sazerac’s trademark by selling a malt specialty beer called “Fire Flask.” *Sazerac Co. Inc. v. Stout Brewing Co. LLC*, No. 15-0107 (W.D. Ky., stipulation filed September 24, 2015). Stout has reportedly agreed to stop selling its existing Fire Flask products and will redesign the label for future production. Each party will pay its own attorney’s fees and costs. Additional details on the August 2015 complaint appear in Issue [576](#) of this *Update*. See *Law360*, September 24, 2015.

Whiskey Maker Settles False Source Claims

Proximo Spirits, Inc. has settled a class action alleging it deceptively marketed Tincup Whiskey® as manufactured entirely in Colorado despite part of its production occurring in Indiana. *Aliano v. Proximo Spirits, Inc.*, No. 14-17429 (Ill. Cir. Ct., Cook Cnty., preliminary approval entered September 16, 2015).

Proximo has agreed to establish a \$425,000 settlement fund to pay class members with proofs of purchase \$4.50 and \$2.25 to those without, per bottle purchased. In addition, class members who purchased Tincup for on-premises consumption can receive \$0.75 up to a maximum of five drinks. Future Tincup labels will no longer feature claims that the product was manufactured entirely in Colorado and instead must identify the state or states where Proximo manufactured the product.

Proposed Class Action Challenges Welch’s Fruit Snacks Health Claims

Two consumers have reportedly filed a putative class action against Welch Foods, Inc. and Promotion in Motion Cos. alleging their Welch’s fruit snacks products are deceptively advertised as providing vitamins and nutrients despite being “no more healthful than candy.” *Atik v. Welch Foods, Inc.*, No. 15-5405 (E.D.N.Y., filed September 18, 2015).

Welch’s packaging advertises its products as produced from “real fruit” despite using only fruit concentrate, the complaint reportedly alleges, and the packaging implies the vitamins in the fruit snacks are derived from the fruit rather than introduced during the production process. This infusion allegedly runs afoul of the U.S. Food and Drug Administra-

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tion's "jelly bean rule," which targets products that would not otherwise meet the agency's standards for healthful foods without the addition of vitamins during the production process. *See FoodNavigator-USA*, September 23, 2015.

OTHER DEVELOPMENTS

Proposed Prop. 65 Changes Aim for Transparency in Penalty Payments

California Attorney General Kamala Harris has **proposed** amendments to the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65) that would require increased transparency and accountability in how the penalties paid by companies are spent by consumer groups, environmental organizations and other private enforcers of the law.

In 2014, Prop. 65 actions reportedly resulted in payments of \$29 million, of which \$21 million was spent on attorney's fees and costs. The proposed changes would require "clearly defined" purposes relevant to the violations that prompted the settlement. The proposal would also cap "in lieu of penalties" payments to ensure the Office of Environmental Health Hazard Assessment receives sufficient funding and raise the bar for demonstrating that settlements requiring reformulation confer a significant public benefit. Public comments about the proposed revisions will be accepted until November 9, 2015.

"California has led the nation for decades in protecting our residents and the environment from pollutants and toxic chemicals," Harris said in a September 28 press release. "These proposed changes maintain the intent of Proposition 65 and our vital legacy of public health and environmental protections while eliminating incentives to abuse the system. Good public policy means rejecting the false choice that suggests we must sacrifice our commitment to the environment and public health for California businesses to thrive."

"Soda Politics" Reaps Accolades in Journal Review

"If any one name evokes unfettered truths about the sociopolitical machinations of 'Big Food,' it is that of Marion Nestle, professor of nutrition, food studies and public health at New York University," proclaims physician **David Katz** in a review of Nestle's new book, *Soda Politics: Taking on Big Soda (and Winning)*. "Dominions of fizz," *Nature*, October 1, 2015.

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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.



Nestle describes, according to Katz, “softball” strategies employed by industry—“... scientific evidence on health effects, the industry’s impact on the environment and the preferential marketing of soft drinks to children, specific ethnic groups and poor people ...”—as well as “the correspondence between the tactics of the soft-drinks and tobacco industries.” Those alleged tactics, Nestle asserts, include “‘hardball’ strategies such as litigation, lobbying of Congress, and front groups such as New Yorkers Against Unfair Taxes, established by the beverage industry to oppose a soft-drinks levy.”