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FIRM NEWS

The Cannabis Conundrum: The Evolving Landscape & Risk Mitigation for Hemp & CBD

The cannabis industry, including marijuana, hemp and cannabidiol (CBD), is complex and rapidly evolving. Shook Partners [Mike Barnett](#), [Lindsey Heinz](#), and [Jim Muehlberger](#) lead a discussion about how the legal landscape is changing for this burgeoning area and why it matters to the food and beverage industry. The presentation covers the differences between marijuana and industrial hemp; how the 2018 Farm Bill altered the current federal regulatory landscape; the impact on food, food supplement and consumer product industries; and the different approaches states have taken in the absence of Food and Drug Administration guidance.

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Muehlberger Discusses Food and Beverage Class Actions for Corporate Disputes

Shook Partner [Jim Muehlberger](#) has participated in a [Corporate Disputes roundtable](#) on food and beverage litigation. He answers

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questions on the increase in litigation in the sector and what companies can do to assess their liabilities when facing a lawsuit.

“Food and beverage putative class action filings show no signs of letting up,” Muehlberger explains. “In the U.S., the FDA has indicated that it is investigating several issues that could prompt plaintiff’s attorneys to pursue new lawsuits, including the use of animal-associated terms to apply to plant-derived products such as ‘almond milk’ or ‘veggie burger.’” He also suggests that the introduction of cannabidiol into the food and beverage industry—if the agency ultimately permits its use—may trigger a number of lawsuits related to marketing claims and labeling, among other issues.

“Outside counsel can help food and beverage manufacturers comply with governmental agency rules and labelling guidelines before litigation is contemplated,” Muehlberger notes. “If a potential liability is identified—such as the use of plaintiff’s attorneys’ targeted ingredient du jour—outside counsel can help track how courts are interpreting complaints related to the ingredient so that case evaluation is simpler if a case is filed against the company later. Many plaintiff’s attorneys file cut-and-paste complaints against numerous companies, so observing how courts have received nearly identical complaints can be helpful for manufacturers and their counsel.”

LEGISLATION, REGULATIONS & STANDARDS

FDA Issues Consumer Update on CBD

The U.S. Food and Drug Administration (FDA) has issued an update for consumers explaining its investigations into cannabis and cannabis-derived compounds, including cannabidiol (CBD). The agency indicates that it is “working to learn more about the safety of CBD and CBD products,” specifically: (i) “[t]he effects CBD could cause in the body, such as toxicity to the liver, when someone ingests CBD regularly over a long period of time”; (ii) “[t]he cumulative exposure to CBD if people access it across a broad range of consumer products”; (iii) “[t]he effects of CBD on special populations (e.g., the elderly, children, adolescents, pregnant and lactating women) or types of animals (e.g., species,

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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.

breed, or class”); and (iv) “[t]he safety of CBD use in animals (e.g., species, breed, or class) including pets.”

FDA also advises that “unapproved CBD drug products have not been subject to FDA review as part of the drug approval process, and there has been no FDA evaluation regarding whether they are safe and effective to treat a particular disease, what the proper dosage is, how they could interact with other drugs or foods, or whether they have dangerous side effects or other safety concerns.” Further, “FDA has also tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed to contain. We have also heard reports of CBD potentially containing contaminants (e.g., pesticides, heavy metals); we are looking into this.”

Sen. Ron Wyden (D-Ore.) issued a letter urging FDA “to issue guidance announcing a formal enforcement discretion policy by August 1, 2019, and—pending publication of a permanent final rule—issue an interim final rule that ensures a regulatory pathway for lawful use of CBD as a food additive and as a dietary ingredient in dietary supplements.”

“I appreciate FDA’s current risk-based enforcement approach toward hemp-derived CBD products in the marketplace, which has focused on those firms making egregious disease claims not otherwise permitted for conventional foods or dietary supplements,” Wyden states. “I view this approach as absolutely critical for the advancement of this new and rapidly growing industry. However, absent formal enforcement discretion guidance, hemp producers and their customers will continue to be left in a regulatory gray zone. ... I, and many in the CBD industry, find FDA’s indication that it may take three to five years to issue a final regulation authorizing the lawful use of hemp-derived CBD in foods and dietary supplements fully unacceptable. The regulatory confusion and uncertainty surrounding CBD cannot continue for that length of time.”

UK to Require Allergen Labeling

U.K. Environment Secretary Michael Gove has reportedly announced that a law requiring a full listing of ingredients on prepackaged food will take effect by the summer of 2021 and will

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.



include a two-year implementation period allowing businesses to adapt. “Natasha’s Law” bears the name of a 15-year-old who died from anaphylaxis after an allergic reaction caused by consumption of a Pret A Manger baguette. Current regulations require that prepackaged food made on-site must be displayed near a sign prompting customers to ask about allergens.

DeLauro, Durbin Introduce Safe Food Act of 2019

U.S. Sen. Dick Durbin (D-Ill.) and Rep. Rosa DeLauro (D-Conn.) have introduced the Safe Food Act of 2019, “which would create a single, independent food safety agency.” In addition, the proposed law would “[r]equire full food traceability to better identify sources of outbreaks” and “[s]trengthen oversight of foreign food facilities and improve food import inspections.” The proposal echoes similar legislation the pair proposed in 1999.

Oatly to Remove Added Sugars Claim Following Ad Board Decision

The National Advertising Division (NAD) has recommended that Oatly Inc. discontinue marketing representations that its oat milks contain “no added sugars.” According to NAD’s summary, the challenger argued that “the hydrolysis process, which turns oats into oatmilk, creates sugars ‘in situ’ as the oats are broken down into smaller components.” NAD considered whether the question fell under its jurisdiction, noting that information appearing in the Nutrition Facts Panel would be governed by the U.S. Food and Drug Administration (FDA). “Without taking a position on whether Oatly’s Nutrition Facts Panels are in compliance with FDA regulations, NAD recommended that Oatly not re-post or restate the ‘added sugars’ line of the Nutrition Facts Panel in its advertising, but noted that nothing in the decision prevents Oatly from using the ‘added sugars’ line of the Nutrition Facts Panel in a context that is not advertising, such as on product packaging for the purpose of complying with FDA regulation,” the board’s summary stated. Oatly has reportedly complied with NAD’s recommendation.

Qualified Health Claims For Omega-3s Allowed

The U.S. Food and Drug Administration (FDA) has announced that it will not object to claims that “consuming eicosapentaenoic acid (EPA) and docosahexaenoic (DHA) omega-3 fatty acids in food or dietary supplements may reduce the risk of hypertension and coronary heart disease.” FDA’s research on the claim included reviewing more than 700 studies and 22 public comments submitted on the subject.

The approved qualified health claims include that EPA and DHA “may help lower blood pressure” and “reduce the risk for hypertension” but also reference that “FDA has concluded that the evidence is inconsistent and inconclusive.”

LITIGATION

Court Blames Bees in Manuka Honey Lawsuit Dismissal

A California federal court has dismissed with prejudice a lawsuit alleging that Trader Joe’s Co.’s “pure manuka honey” was “adulterated by the inclusion of cheaper honey.” *Moore v. Trader Joe’s Co.*, No. 18-4418 (N.D. Cal., entered June 24, 2019). The court’s decision notes a transcript from oral argument in which the plaintiff explained, “[T]here could be other flowers in the immediate area where the manuka flowers are. So the bees are not just going to the manuka flowers. They are going to the clover flowers. They are going to the ... dandelions and they are all coming back to – to store the nectar in the same hive and so it’s already adulterated when it gets into the hive.”

“In sum, Plaintiffs clarified that their adulteration theory is premised on the bees visiting different floral sources and returning to the hive resulting in a lower manuka pollen count, rather than the manufacturer purposefully mixing manuka honey with non-manuka honey,” the court found. “As there is no dispute that all of the honey involved is technically manuka honey, albeit with varying pollen counts, there cannot be adulteration in violation of the [federal Food, Drug, and Cosmetic Act].”

“Since Plaintiffs cannot allege adulteration, honey is a single ingredient food, and the chief floral source is undisputedly manuka, the product labeling is accurate,” the court held. “Given the accuracy of the label, a reasonable consumer could not find it misleading, because it is not.”

Tropicana Targeted in Malic Acid Lawsuit

A consumer has filed a putative class action alleging that Tropicana Manufacturing Co. misrepresents its orange juice as “natural” because it contains a variation of malic acid that can be used as an artificial flavoring ingredient. *Johnson v. Tropicana Mfg. Co. Inc.*, No. 19-1164 (S.D. Cal., filed June 20, 2019). The complaint, echoing similar actions filed by the same plaintiff’s firm against other companies, alleges that the ingredient “malic acid” on the product’s ingredient list is not the naturally occurring l-malic acid but rather d-l malic acid, which “is manufactured in petrochemical plants from benzene or butane—components of gasoline and lighter fluid, respectively—through a series of chemical reactions, some of which involve highly toxic chemical precursors and byproducts.” The plaintiff alleges violations of California’s consumer-protection laws and seeks class certification, restitution, damages, corrective advertising and attorney’s fees.

MEDIA COVERAGE

Scotch-Production Rules Changing, Wall Street Journal Explains

The Scotch Whisky Association (SWA) will allow distillers to use a variety of casks—including those previously used to age tequila and fruit spirits—to age Scotch whisky during its required three-year maturation, according to the *Wall Street Journal*.

Regulations previously limited acceptable casks to those previously used to hold sherry, cognac, bourbon or port. Some distillers told the news outlet that the change would allow companies to create “new flavor experiences” for Scotch whisky drinkers, while others expressed apprehension. “Scotch needs to

be judged by its color, taste and traditionality,” a former chief executive of the SWA told *WSJ*. “Clearly if you then had a whisky that tasted of tequila—if it used an ex-tequila cask—it would not be a Scotch whisky.”

Consumer Reports Finds LaCroix Unlicensed for Sale in Massachusetts

Seeking to obtain information on the ingredients in LaCroix, *Consumer Reports* apparently discovered that National Beverage Corp. had failed to obtain a permit sell its products in Massachusetts, which requires the submittal of water-quality tests. *Consumer Reports* notes, “The situation reveals an unusual quirk of food safety regulations: Federal and state regulations typically treat artificially carbonated waters—including club soda, tonic water, seltzer, and sparkling water—differently than bottled water. (Sparkling mineral water, which is naturally carbonated and contains natural minerals, is regulated like bottled water.) And even in states that have added oversight of those fizzy waters, there’s apparently occasional slip-ups in enforcement.” The article, originally published June 18, 2019, was updated on June 26 to reflect that National Beverage Corp. announced it had obtained the permit required to sell LaCroix within Massachusetts.

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