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SPOTLIGHT

FDA Holds Public Meeting on Cannabis

On May 31, 2019, the U.S. Food and Drug Administration (FDA) held a widely anticipated public hearing with stakeholders on cannabis and cannabis-derived compounds to gain insights on product safety and a potential regulatory framework for products containing such substances. The hearing focused on cannabidiol (CBD)—a popular but controversial compound that has been added to products ranging from tinctures and lotions to sodas and ice cream. Interest in the product was spurred by the passage of the 2018 Farm Bill, which removed hemp (cannabis plants with less than 0.3% THC content) from the Controlled Substances Act. The Farm Bill also complicated FDA's role in regulating CBD because although the substance was de-scheduled by Congress, the Agency still regulates it as a drug—meaning that any consumer product with CBD is technically a misbranded drug in violation of FDA rules. While the Agency has taken limited actions against companies using CBD as an additive, FDA has reiterated its authority to do so if and until regulatory changes are made.

At the hearing, CBD proponents claimed the compound has beneficial and even therapeutic properties, including relieving pain, reducing anxiety and aiding sleep. But others suggested that the industry is rife with fraudulent marketing and potentially dangerous products contaminated with excessive levels of CBD, THC and even dextromethorphan, an active ingredient in cough

Mark Anstoetter

syrup. Most participants agreed that FDA should step in to set a regulatory framework for the industry but differed on how this should be achieved. FDA officials posed follow-up questions to presenters that highlighted the Agency's pressing concerns, including the safety data available to address dosing, drug interactions, side effects and use in special populations. While the Agency is clearly taking a hard look at changing the rules for CBD, FDA did not signal if or when any regulatory changes would be implemented—which, if done under the typical time frame for FDA rulemaking, could take several years.

Reporting provided by Shook Associate Margaret Horn.

LEGISLATION, REGULATIONS & STANDARDS

FDA Finds High Levels of PFAS in Meat, Fish Samples

Researchers from the U.S. Food and Drug Administration (FDA) have reportedly disclosed in a presentation that sampling showed high levels of per- and polyfluoroalykyl substances (PFAS) in food, including meat, fish, leafy greens and chocolate cake. The researchers presented the findings at a conference hosted by the Society of Environmental Toxicology and Chemistry in Finland. An FDA spokesperson reportedly told the *Associated Press* that the agency thought the contamination was "not likely to be a human health concern."

Studies finding PFAS in drinking water have prompted legislation, including proposed federal legislation, to ban the use of the material in packaging. The Maine legislature has passed a bill that would prohibit the use of PFAS in food packaging sold within the state; if signed by the governor, the law would take effect in January 2022 and would ban PFAS-containing packaging within two years of the state's Department of Environmental Protection determining that safer alternatives are "readily available in sufficient quantity and at a comparable cost." The bill would also ban the sale of food packaging containing phthalates.

OEHHA Confirms Coffee Does Not

816.559.2497
manstoetter@shb.com

M. Katie Gates Calderon
816.559.2419
kgcalderon@shb.com

Lindsey Heinz
816.559.2681
lheinz@shb.com

James P. Muehlberger
816.559.2372
jmuehlberger@shb.com

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.

Require Prop. 65 Warnings

California's Office of Environmental Health Hazard Assessment (OEHHA) has confirmed that coffee will not be required to carry warnings about risks of cancer or reproductive harm mandated by the state's Safe Drinking Water and Toxic Enforcement Act (Prop. 65). In a June 3, 2019, tweet, the agency stated that its "coffee regulation has been approved," finding that the chemicals "created by and inherent in roasting coffee beans or brewing coffee, do not pose a significant cancer risk." The agency indicates that the regulation will take effect October 1, 2019.

FDA Recommends Standardized Use of "Best If Used By"

The U.S. Food and Drug Administration (FDA) has sent a letter to food and beverage manufacturers recommending that they primarily use "Best If Used By" on their packages to help consumers who may be confused by the use of the phrase "Sell By." The letter explains that the Grocery Manufacturers Association and Food Marketing Institute have recommended that food manufacturers use the distinguishing phrases "Best If Used By"—for foods that may decline in quality after a specific date but remain safe to eat—and "Use By," which should appear on the label of perishable foods that should be discarded after a specific date for safety reasons.

"As approximately 80% of the foods in the US are regulated by the FDA, we would like to inform our regulated food industries that FDA strongly supports industry's voluntary industrywide efforts to use the 'Best if Used By' introductory phrase when choosing to include a quality-based date label to indicate when a product will be at its best flavor and quality," the letter states. "While standardizing the use of date labels for quality reasons is encouraged as a best practice, we know that labeling is not enough. FDA supports ongoing consumer education efforts by industry, government, and non-government organizations to educate consumers on what quality-based date labels mean and how to use them to further reduce food waste in the home."

England Bans Plastic Straws, Drink

Stirrers

U.K. Environment Secretary Michael Gove has announced that England will ban plastic straws, drink stirrers and plastic cotton swabs beginning in April 2020. The ban includes an exemption for those who use straws for medical needs, and registered pharmacies will be allowed to administer plastic straws. The announcement also indicates that restaurants and bars "will not be able to display plastic straws or automatically hand them out, but they will be able to provide them on request."

"Today's announcement follows the success of the government's world-leading ban on microbeads and 5p charge on single-use plastic bags, which has seen distribution by major supermarkets drop by 86%," the announcement states.

APHIS Proposes GMO Rules Revisions

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has announced proposed revisions to its regulations regarding "the movement (importation, interstate movement, and environmental release) of certain genetically modified organisms" (GMOs). The proposal, "the first comprehensive revision of the regulations since they were established in 1987," would adjust how the agency handles permits for plants created as a result of genetic engineering (GE).

"While the current regulations have been effective in ensuring the safe introduction of GE organisms during the past 30 years, advances in genetic engineering have occurred since they were promulgated," the announcement states. "APHIS has now accumulated three decades of experience in evaluating GE organisms for plant pest risk. The Agency's evaluations to date have provided evidence that genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not in and of itself result in a GE plant that presents a plant pest risk. Additionally, GE techniques have been developed that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents yet may result in GE organisms that pose a plant pest risk. Given these developments, as well as legal and policy issues discussed below, it has become necessary, in our view, to update our regulations accordingly."

LITIGATION

Plaintiff Challenges Vanilla Flavoring in Yogurt

A plaintiff has alleged that Danone North America misleads consumers by labeling its Dannon and Oikos yogurts as featuring "vanilla with other natural flavors" because the products contain "less vanilla flavor derived from vanilla beans than their name suggests." *Andriulli v. Danone N. Am.*, No. 19-5165 (S.D.N.Y., filed June 2, 2019). The plaintiff asserts that the product flavor "should be labeled 'Vanilla-Vanillin Extract/Flavoring/Powder, Imitation' so consumers are not misled as to the flavor of the Products."

Further, the complaint states, Oikos vanilla-flavored yogurt includes beta carotene, which "has the effect of modifying the color of the product closer to the color consumers associate with a product flavored exclusively by vanilla bean components — a tanner, darker shade like in the following stock image." The complaint then features a light orange square. "This coloring makes the consumer less likely to question or probe into the amount and type of vanilla flavor in the Products," the plaintiff argues. For allegations of fraud, unjust enrichment and violations of California's consumer-protection laws, the plaintiff seeks class certification, injunctive relief, restitution, damages and attorney's fees.

Putative Class Action Targets Kellogg for Added Sugars

Four consumers have filed a putative class action alleging that Kellogg Sales Co. misleadingly markets its products as promoting health and wellness despite containing added sugars. *DiGregorio v. Kellogg Sales Co.*, No. 19-0632 (N.D.N.Y., filed May 28, 2019). The complaint details studies about the health effects of sugars on the human body and argues that the "high amounts of added sugar" in Kellogg's cereals and bars render regular consumption of the products as "likely to contribute to excess added sugar

consumption, and, thereby, increased risk for and contraction of chronic disease."

"Although Plaintiffs were the victims of Kellogg's longtime and general policy and practice with respect to the cereals and snack bars they purchased and the labels they saw, this Complaint and their claims are not so limited; rather, plaintiffs seek through this lawsuit to enjoin Kellogg's *policy and practice generally*, including but not necessarily limited to the products, labels, and label claims challenged herein," the complaint asserts. The plaintiffs list 43 products they seek to enjoin Kellogg from claiming to promote health and wellness, including several Raisin Bran, Frosted Mini-Wheats and Nutri-Grain bar varieties. For alleged violations of New York's consumer-protection statutes as well as negligent misrepresentation and fraud, the plaintiffs seek class certification, a corrective advertising campaign, an injunction, restitution and attorney's fees.

MEDIA COVERAGE

The Guardian Introduces "Toxic America" Series

The Guardian has released "Toxic America," a "major series to investigate the risks of contamination in our food, water, and cosmetics." Articles in the series include:

- A comparison between the "stringent health and environment review" that the European Union will apply to foods edited using CRISPR-Cas9 and the perceived lack of regulation for similar foods in the United States;
- An examination of nanoparticles, "which are largely unregulated in the US," and their use in foods;
- A discussion of additives "with industrial applications" banned in Europe but approved for use in the United States, such as materials that appear in "yoga mats, pesticides, hair straighteners, explosives and petroleum products"; and
- An interactive tool allowing readers to identify their grocery choices and purporting to inform them about "what additives, pesticides and antibiotics" are in their selections.

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