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SPOTLIGHT

# FDA Announces Next Steps in Cannabis Regulation

The U.S. Food and Drug Administration (FDA) has <u>announced</u> that it will take a number of steps to advance its consideration for the potential regulatory framework for cannabis and cannabidiol (CBD) products. Specifically, this includes a public hearing, an agency working group, question-and-answer updates and the possibility of enforcement actions.

A <u>public hearing</u> on May 31, 2019, aims to obtain "scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds." Electronic or written comments will be accepted until July 2, 2019. FDA is seeking comments, data and information related to (i) what levels of cannabis cause safety concerns; (ii) how the mode of delivery (e.g., ingestion, absorption, inhalation) affects the safety of, and exposure to, cannabis; (iii) how cannabis interacts with other substances; and (iv) standardized definitions for cannabis-related ingredients, supply chain quality control, effective marketing and labeling of risks to the general public or vulnerable populations.

FDA also intends to form a "high-level" internal agency working group to explore pathways for dietary supplements and food products containing CBD to be legally marketed. In addition, the agency has updated its <u>questions-and-answers page</u> regarding FDA regulation of cannabis and cannabis-derived products.

Cannabis products may also become subject to potential enforcement actions. In his most recent Congressional testimony,

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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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FDA Commissioner Scott Gottlieb stated that the agency is using "enforcement discretion" and is taking action against perceived "over-the-line" claims against those marketing CBD and "claiming that it can cure cancer or prevent Alzheimer's disease … because that can mislead a patient into forgoing otherwise effective therapy." The agency has warned multiple companies—including Advanced Spine and Pain LLC, Nutra Pure and PotNetwork Holdings Inc.—that their claims about the benefits of CBD establish their products as new drugs.

For more information about cannabis-related legal issues, please contact Shook Partners <u>Greg Wu</u> or <u>Katie Gates Calderon</u>.

Reporting provided by Shook Partner <u>Greg Wu</u> and Associate Ruth Anne French-Hodson.

#### LEGISLATION, REGULATIONS & STANDARDS

## Europe May Limit Use of "Meat" for Plant-Based Products

The EU agriculture committee has <u>reportedly</u> approved a prohibition on the use of the term "meat" to describe vegetable-based products, including bean burgers, vegan sausages and tofu steaks. The provision would limit the use of "steak," "sausage," "burger," "hamburger" and "escalope" to only describe "edible parts of the animals."

One French politician reportedly described the bill as beneficial for consumers. "We felt that steak should be kept for real steak with meat and come up with a new moniker for all these new products. There is a lot to be done in this front, a lot of creativity will be needed," *The Guardian* quotes Member of the European Parliament Éric Andrieu as saying. "People need to know what they are eating. So people who want to eat less meat know what they are eating – people know what is on their plate." Before the provision can take effect, the full European Parliament and member states must vote to approve it.

## EFSA Accepting Comments on Sodium and Chloride Intake

The European Food Safety Authority (EFSA) is <u>accepting</u> <u>comments</u> on draft dietary reference values for sodium and chloride. The draft values deem 2 grams of sodium and 3.1 grams



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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.

of chloride per day to be "safe and adequate, considering evidence on the risk of cardiovascular disease on the one hand and nutrition adequacy on the other." EFSA will accept comments until May 7, 2019.



#### LITIGATION

## AriZona Tea Lacks Promised Ginseng, Consumers Allege

Two consumers have filed a putative class action alleging that Beverage Marketing USA Inc. markets its AriZona iced green tea products as containing "ginseng for energy" despite lacking "any detectible amounts of ginseng, if indeed it contains any ginseng at all." *Niles v. Beverage Marketing USA Inc.*, No. 19-1902 (E.D.N.Y., filed April 2, 2019). The complaint asserts that ginseng demand "has skyrocketed while supply has dwindled, causing prices to surge to above \$1,000 per pound. Ginseng is so coveted in the marketplace that certain species of ginseng have been harvested to the edge of extinction."

The plaintiffs allege that they "retained two respected food laboratories to conduct three tests of the Product for ginsenosides," "the main chemical constituent of ginseng," and apparently found that "none of the three tests were able to detect any amount of ginsenosides in the Product." Additional tests allegedly showed that AriZona's competitors' products did contain ginseng.

Because the products did not contain ginseng as advertised, the plaintiffs allege, "the Product has no, or, at a minimum, a much lower, value" to them. They seek an injunction, damages, class certification and attorney's fees for allegations of fraud, negligent misrepresentation, unjust enrichment, breach of warranties and violations of the consumer-protection laws of 49 states.

## Plaintiff Alleges Danone Misleadingly Markets Coconut Milk As Healthy

A consumer has filed a putative class action alleging that Danone US Inc. markets its So Delicious Coconut Milk to health-conscious consumers using health and wellness claims despite coconut milk's level of saturated fat. *Heymsfield v. Danone US Inc.*, No. 19-0589 (S.D. Cal., filed March 29, 2019). The plaintiff alleges that coconut milk "is unhealthy" because it "is essentially just coconut oil in water," and coconut oil "is mainly saturated fat."



The complaint cites studies purportedly linking saturated fat consumption and elevated risks of cardiovascular disease.

Danone allegedly markets itself as "a company 'making food that's good for you' and products 'that you can feel good about sipping, biting, pouring, scooping licking and chugging throughout your day," the complaint argues. In addition, "the Product was expressly promoted as being able to help consumers maintain healthy bones and prevent osteoporosis." The complaint provides screenshots of the So Delicious website, which compares the magnesium and caloric content of coconut milk to cow's milk and yogurt.

For alleged violations of California's consumer-protection statutes, the plaintiff seeks class certification, a corrective advertising campaign, destruction of misleading advertising materials, damages and attorney's fees.

### Court Rejects Trader Joe's Tuna Settlement

A California federal court has rejected a <u>settlement</u> <u>agreement</u> between Trader Joe's and consumers who alleged that the store's tuna cans contained too much slack fill. *In re Trader Joe's Tuna Litig.*, No. 16-1371 (C.D. Cal., entered April 1, 2019). The court rejected the agreement on choice-of-law grounds, finding that the plaintiff failed to "conduct the required analysis" needed to apply California law to a nationwide class of purchasers. The denial was issued without prejudice, and the court granted leave to refile within 60 days of the order.

#### MEDIA COVERAGE

## Washington Post Covers Pork Inspection Change

The meat industry is moving towards self-regulation for identifying diseased animals, an <u>article</u> in *The Washington Post* asserts. The article documents a series of changes shifting responsibility for identifying contamination in meat production, especially pork and poultry, from the U.S. Department of Agriculture (USDA) to employees of the regulated production plants.

The *Post* spoke to a former hog inspector who worked under the trial program for testing the proposed system. "I saw the alleged inspections that were performed by plant workers; they weren't

inspections. They were supposed to meet or exceed USDA standards — I never saw that happen," the *Post* quotes him as saying.

USDA also states that plants participating in the trial program had fewer worker injuries, but Texas State University researchers reportedly found it "impossible" for the agency "to draw any statistically valid conclusion about worker injury rate differences" based on data the researchers obtained through a public information request.

The *Post* compares the projected shift in regulatory oversight to the relationship between aircraft manufacturers and the Federal Aviation Administration (FAA). "Look at the FAA. It took a year or so before the crashes happened," a former chief veterinarian for the USDA Food Safety and Inspection Service is quoted as saying. "This could pass, and everything could be okay for a while, until some disease is missed, and we have an outbreak all over the country. It would be an economic disaster that would be very hard to recover from."

#### FIRM NEWS

### Shook's Food & Beverage and Class Action Content Recognized by JD Supra 2019 Readers' Choice Awards

JD Supra 2019 Readers' Choice Awards selected Shook, Hardy & Bacon as the "Top Firm for Food & Beverage" news. Shook was chosen from a crowded field of more than 50,000 authors whose work was published on the site in 2018. Shook was recognized for the second consecutive year for insights and commentary in the Food and Beverage Litigation Update, achieving the "highest visibility and engagement for their particular expertise" in the practice area. The legal news site's readers chose ten top authors and one top firm in each of 26 categories.

Shook Partner <u>Mark Anstoetter</u> was ranked first among the "Top Authors" in <u>Food & Beverage</u>. According to *JD Supra*, honorees were selected for their coverage of "topics at the intersection of food, beverages and the law," including U.S. Food and Drug Administration labeling, risk mitigation, trademark protection and export issues. Anstoetter was also noted in a subsequent article, "<u>5 Takeaways For Authors from JD Supra's 2019 Readers' Choice Awards</u>." The article included the *Food & Beverage Litigation Update* as a "feature readers can count on."

In addition, Shook Firm Chair <u>Madeleine McDonough</u> and Anstoetter were ranked in the Top 5, for the second year, as "Top Authors" in the <u>Class Action</u> category, where contributors were recognized for "addressing reader interest in data breaches, the CFPB arbitration rule, class certification and related matters."

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