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LEGISLATION, REGULATIONS & STANDARDS

Proposed Amendment Would Provide Funds for FDA Oversight of CBD

Rep. Jerry McNerney (D-Calif.), in partnership with the Natural Products Association, has reportedly filed an amendment to the House Agriculture appropriations bill that would give the U.S. Food and Drug Administration (FDA) funding to undertake the process to identify a safe daily intake level of cannabidiol (CBD). "Since the passage of the 2018 Farm Act – which eliminated hemp from the definition of marijuana under the Controlled Substances Act – we've seen a significant increase in the production and sales of CBD products," said McNerney in a June 18, 2019, press release. "With more and more CBD appearing on supermarket shelves across the country, it's time for American consumers to have accurate information on CBD and for producers to be properly regulated to make the marketplace safe and reliable."

FDA has also announced the extension of the comment period for the public hearing intended to "obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds." Comments will be accepted until July 2, 2019.

The Government of Canada has finalized regulations for the production and sale of edible cannabis and cannabis extracts, which will take effect October 17, 2019. License holders must provide 60 days' notice to Health Canada of their intent to sell new products, so the announcement states that edible cannabis and cannabis-extract products will appear in "physical or online stores" "no earlier than mid-December 2019."

FDA Issues Statement on PFAS in Food

The U.S. Food and Drug Administration (FDA) has issued a statement on per- and polyfluoroalkyl substances (PFAS) in food following a presentation published in the media that indicated the agency found the substances in meat, fish and chocolate. "Overall, our findings did not detect PFAS in the vast majority of the foods tested," the statement reads. "In addition, based on the best available current science, the FDA does not have any indication that these substances are a human health concern, in other words a food safety risk in human food, at the levels found in this limited sampling. These data give our scientists a benchmark to use as we continue our critical work studying this emerging area of science."

Executive Order Aims to Ease "Regulatory Maze" for GMOs

President Donald Trump has reportedly signed an executive order that directs federal agencies to simplify the path to regulatory approval for genetically modified organisms (GMOs). The order also apparently recommends that trading partners should be urged to take similar approaches to regulating GMOs.

EFSA Scientists Recommend Limits on Phosphates as Food Additives

The European Food Safety Authority (EFSA) has announced a change in guidance on the use of phosphates as food additives. The agency's scientists recommended a group acceptable daily intake of 40 milligrams per kilogram of body weight, or about 2.8 grams for the average 70-kilogram adult. According to the

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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.

announcement, the existing maximum permitted levels "range from 500 to 20,000 milligrams per kilogram."

Guidance Finalized for Added Sugar Labeling in Syrups

The U.S. Food and Drug Administration has finalized guidance on labeling for added sugars in single-ingredient packages of "pure honey, pure maple syrup, and other pure sugars and syrups, which are not required to bear the words 'Includes Xg Added Sugars' but must still include the percent Daily Value (DV) for added sugars on their labels." The agency also indicated its intention "to exercise enforcement discretion with respect to the use of truthful and not misleading statements on single-ingredient packages and/or containers."

U.K. Releases Food Safety Audit

The U.K. National Audit Office has released a report that "examines the effectiveness of the current regulatory arrangements to ensure that food is safe to eat and is what it says it is." The report found that spending on maintaining food safety systems in the country has declined, and some local authorities "are failing to meet statutory objectives to conduct interventions." The agency also purportedly found that the "regulatory system lacks the full range of enforcement powers to ensure businesses supply safe food."

FDA Proposes Third-Party Food Safety Certification

The U.S. Food and Drug Administration (FDA) has indicated that it will seek public comment on a proposal that would allow the accreditation of third-party certification bodies "to conduct food safety audits of eligible foreign food facilities, and issue food and facility certifications, pursuant to the FDA Food Safety Modernization Act." The notice responds to a number of comments received following a comment period on the proposed collection of information, including a note that the third-party

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.

certification system could help the government "prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply" because current resources are limited.

Canada to Ban Single-Use Plastics

The Government of Canada has announced that it "is taking additional steps to reduce Canada's plastic waste, support innovation, and promote the use of affordable and safe alternatives" by banning "harmful single-use plastics as early as 2021 (such as plastic bags, straws, cutlery, plates, and stir sticks)." The announcement indicates that the "measures will be grounded in scientific evidence and will align, where appropriate, with similar actions being taken in the European Union and other countries."

Dietary Guidelines Meetings Announced

The U.S. Department of Agriculture and Health and Human Services have announced meetings to hear public comments on the 2020 dietary guidelines revisions. The 2020 Dietary Guidelines Advisory Committee will allow three-minute pre-registered comments from the public at its meetings on July 11, 2019, and January 25, 2020, and registration for the July meeting closes at 5:00 p.m. on July 1.

LITIGATION

FDA to Designate High-Risk Foods Under Consent Decree

A California federal court has entered a consent decree compelling the U.S. Food and Drug Administration (FDA) to designate a list of high-risk foods as required by the Food Safety Modernization Act. *Ctr. for Food Safety v. Azar*, No. 18-6299 (N.D. Cal., entered June 7, 2019). The decree is the result of a lawsuit brought by the Center for Food Safety and Center for Environmental Health seeking to compel the agency to promulgate a list of "high-risk

foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health" as well as host the list on the FDA website. The decree lists deadlines for FDA to meet—including September 8, 2020, for the designation—but allows the agency to seek extensions if it needs one "despite FDA's best efforts (meaning commitment of agency time, money, energy, and resources that FDA reasonably anticipates will result in meeting the schedule in this Consent Decree)."

Plaintiff Denied Class Certification for Third Time in Tropicana Suit

A New Jersey federal court has denied class certification to a plaintiff challenging Tropicana's marketing representations of its juice as "pure" and "natural." *In re Tropicana Orange Juice Mktg. & Sales Practices Litig.*, No. 11-7382 (D.N.J., entered June 19, 2019). The court first denied certification for a New York class because the plaintiff only purchased Tropicana in California, then it turned to the requirement of predominance. "Plaintiff has not demonstrated that a uniform misrepresentation was made to the class sufficient to satisfy predominance as to the '100% pure and natural orange juice,' '100% pure,' '100% natural,' '100% juice' 'fresh,' 'grove to glass,' 'squeezed from fresh oranges,' 'straight-from-the-orange,' and Orange/Straw labels," the court found. "[T]he Court would be required to perform an individualized inquiry into each product purchased to determine what combinations of labels were visible before determining whether that combination is deceiving to a reasonable consumer. These variations are the poster child for lack of predominance." The court did find a uniform representation for Tropicana's claim that its orange juice was "pasteurized," however, so it moved onto materiality.

"There is scant evidence in the record regarding reasonable customers' understanding of the 'pasteurized' label and whether it was likely to deceive a reasonable consumer," the court found. "Even [the plaintiff] during her deposition had difficulty articulating what she understood 'pasteurized' to mean." Accordingly, the court held that the representation was not material and thus did not establish that a common issue predominated for the proposed class.

Former LaCroix Employee Alleges Firing Stems from BPA Claims

A former vice president of National Beverage Corp. has alleged that he was fired because he objected to the company president's intention to use cans lined with bisphenol A (BPA) while marketing its LaCroix products as natural and BPA-free. *Dejewski v. Nat'l Beverage Corp.*, No. PAS-L-1802-19 (N.J. Super. Ct., Passaic Cty., filed June 6, 2019). The complaint alleges that Albert Dejewski was fired in retaliation for objecting to Joseph Caporella's plan to "prematurely announce" that the company's LaCroix cans would be BPA-free; Dejewski argues that Caporella knew LaCroix would not be sold in BPA-free cans until "at a minimum 4-6 months" after the announcement. Dejewski seeks damages under New Jersey's whistleblower-protection law.

MEDIA COVERAGE

American Chemistry Council Responds to The Guardian's "Toxic America" Series

The American Chemistry Council (ACC) has issued a response to a series by *The Guardian* purporting to examine the role of chemicals in Americans' lives. "Sadly, in those stories, they decided to peddle misinformation and promote well-worn accusations from anti-industry activists that can create unnecessary fear and confusion about the products we use in our daily lives," ACC argues.

"It's important to know that the mere presence of a substance does not imply that a chemical will lead to adverse effects. As the Centers for Disease Control and Prevention (CDC) emphasizes, 'The measurement of an environmental chemical in a person's blood or urine does not by itself mean that the chemical causes disease.'"

The article also responds to a number of specific claims made in the "Toxic America" series, including that "We should try to limit our exposure to essentially all chemicals," which is attributed to Philippe Grandjean. ACC notes, "There is no way to limit exposure

to chemicals. It is impossible because everything—including our bodies—is made of chemicals. There is no such thing as 'chemical free.' So maybe he is trying to say we should avoid man-made chemicals? That is also a misleading claim. A chemical is not more hazardous simply because it is synthetic, and a chemical isn't safer simply because it is natural. Any chemical—even water and oxygen—can be toxic if too much is ingested or absorbed into the body. The important thing is to understand hazard, exposure and risk."