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FOOD & BEVERAGE LITIGATION UPDATE

SHOOK HARDY & BACON

LEGISLATION, REGULATIONS & STANDARDS

FDA Warns Company Selling CBD Oil

The U.S. Food and Drug Administration has published a warning letter it sent in September 2019 to a company selling cannabidiol (CBD) oil as a dietary supplement. "This product is labeled as a dietary supplement; however, it cannot be a dietary supplement because it does not meet the definition of a dietary supplement," the letter stated. "Under those provisions, if an article (such as CBD) is an active ingredient in a drug product that has been approved [], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was 'marketed as' a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD. FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition [], but you may present FDA with any evidence that has bearing on this issue."

Meanwhile, Sen. Richard Blumenthal (D-Conn.) reportedly held a press conference demanding that FDA implement safety regulations for cannabidiol (CBD). "Right now there are no guidelines, no rules of the road, no guidance for consumers to know what's healthy and what has side effects," Blumenthal is quoted as saying.

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.

For additional information about Shook's capabilities, please contact

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California, Companies Agree to Restrict Chlorpyrifos

The California Environmental Protection Agency (CalEPA) has announced that "virtually all use of the pesticide chlorpyrifos in California will end" in 2020 "following an agreement between the Department of Pesticide Regulation (DPR) and pesticide manufacturers to withdraw their products." The companies apparently agreed to end sales of chlorpyrifos by February 6, 2020, and growers will not be permitted to use or possess chlorpyrifos after December 31, 2020. Uses before that deadline "must comply with existing restrictions, including a ban on aerial spraying, quarter-mile buffer zones and limiting use to crop-pest combinations that lack alternatives."

"To ensure consistency for growers and for enforcement purposes, DPR is applying the terms and deadlines in the settlements to seven other companies that are not part of the settlement agreement but are subject to DPR's cancellation orders," CalEPA's press release states.

EFSA Opens Public Consultation on Aflatoxins in Food

The European Food Safety Authority (EFSA) has launched a public consultation on the risks associated with consuming aflatoxins, mycotoxins produced by two species of Aspergillus that "are known to be genotoxic (capable of damaging DNA) and carcinogenic." Most human exposure to aflatoxins comes from contaminated grains and derived products, although they can also be found in milk, according to the notice. Comments will be accepted until November 15, 2019.

U.S. Agencies Announce Actions on Organics, NPIP, Hazard Analyses

The U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) announced a number of developments in their work on organic food, poultry and food safety.

- FDA released an update on the implementation of the Food Safety Modernization Act (FSMA), announcing it will track outcomes for FSMA rules for inspections and recalls via the Food Safety Dashboard. One metric the agency will track is how quickly a company issues a public notice for a Class 1 recall for human and animal food.

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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

- FDA has also released guidance on recall plans for its multipart guidance on "how to comply with the requirements for hazard analysis and risk-based preventive controls under our rule entitled 'Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.'"
- USDA updated the National Poultry Improvement Plan (NPIP) Program Standards to incorporate proposed changes published in April 2019, including the amendment of the testing protocol for *Mycoplasma*, amending *Salmonella* isolation procedures and updating hatching egg and hatchery sanitation.
- USDA announced the results of the 2019 sunset review process for the National List of Allowed and Prohibited Substances, including the renewal of several materials. The notice also indicated that the National Organic Standards Board recommended vitamin B1, oxytocin, procaine and konjac flour for removal, but any removal determinations will be addressed in a separate rulemaking.

inspections, subject to FDA, USDA and FTC regulation.

LITIGATION

Cal. Chamber Of Commerce Challenges Prop. 65 Acrylamide Warning

The California Chamber of Commerce (CalChamber) has filed a lawsuit aiming to prevent the state from "enforcing a requirement to provide a false, misleading, and highly controversial cancer warning for food and beverage [] products that contain the chemical acrylamide." *Cal. Chamber of Commerce v. Becerra*, No. 19-0962 (E.D. Cal., filed October 7, 2019). CalChamber asserts that acrylamide "is not intentionally added to foods" but rather "is formed naturally in many types of foods when cooked at high temperatures or otherwise processed with heat."

The complaint argues that although "certain governmental and scientific entities" have identified acrylamide as a carcinogen, "[s]cientific studies in humans, however, have found no reliable evidence that exposure to acrylamide in food products is associated with an increased risk of developing any type of cancer. In fact, epidemiologic evidence suggests that dietary acrylamide—i.e., acrylamide that forms naturally in normal cooking of many food products—does not cause cancer in humans or pose an increased risk of cancer in humans. Indeed, some food products that contain acrylamide (e.g., whole grains and coffee) have been shown to reduce the risk of certain diseases, including cancer."

CalChamber argues that California's Office of Environmental Health Hazard Assessment (OEHHA) requires businesses to warn

consumers about potential exposure to acrylamide under the state's Safe Drinking Water and Toxic Enforcement Act (Prop. 65) despite that "neither OEHHA nor any other governmental entity has determined that acrylamide is a known human carcinogen, and in fact OEHHA has acknowledged that the agency does not *know* that acrylamide increases the risk of cancer in humans." Therefore, CalChamber argues, the acrylamide warning requirement violates the First Amendment "by compelling Plaintiff's members and other entities that produce, distribute, or sell acrylamide-containing food products to make false, misleading, and highly controversial statements about their products."

Union Sues USDA For Swine Processing Rules

An international union and several of its local chapters have filed a lawsuit seeking to compel the U.S. Department of Agriculture (USDA) to change its final rule promulgated on October 1, 2019, that eliminates maximum processing speeds and permits processing plants to employ their own health and safety monitors. *U. Food & Commercial Workers Union, Local No. 663 v. USDA*, No. 19-2660 (D. Minn., filed October 7, 2019). "As thousands of commenters told USDA during the rulemaking process, the Rule will jeopardize the lives and safety of both consumers of pork products and workers like Plaintiffs' members," the complaint argues.

USDA erroneously dismissed such comments by arguing that it did not have authority to "regulate issues related to establishment worker safety," the complaint asserts. "For decades, USDA has considered its actions' impacts on worker safety," the union argues. "USDA's failure to consider the impacts of its actions on worker safety was arbitrary and capricious, as was its failure to acknowledge and explain its departure from past practice considering such impacts."

Court Declines To Block Missouri "Meat" Law

A Missouri federal court has reportedly declined to issue a preliminary injunction blocking the state from enforcing its law defining meat as derived from animals. The law requires plant-based or laboratory-grown food to feature a label indicating its source. Turtle Island Foods, the American Civil Liberties Union and the Good Food Institute have reportedly appealed the judge's denial.

Court Dismisses Capri Sun Citric Acid Lawsuit

An Illinois court has dismissed a lawsuit alleging Kraft Heinz Foods Co. misleads consumers by marketing Capri Sun as free of preservatives despite containing citric acid. *Tarzian v. Kraft Heinz Foods Co.*, No. 18-7148 (N.D. Ill., E. Div., entered October 10, 2019). The court first found that (i) the plaintiffs "failed to allege that the situs of the transactions at issue occurred 'primarily and substantially' in Illinois" and dismissed one allegation on behalf of nonresident plaintiffs for lack of standing and (ii) the plaintiffs lacked standing to seek injunctive relief.

The court then turned to the argument that Kraft Heinz' statements about "no artificial preservatives" were false or misleading. "Plaintiffs' allegations detail the practices commonly used to manufacture citric acid throughout the industry before concluding: 'Thus, Defendant's citric acid is artificial.' That is too great of an inferential leap," the court held. "To satisfy the pleading standards, Plaintiffs need to draw a connection between the common industry practice and the actual practice used by Kraft. Even drawing all reasonable inferences in the Plaintiffs' favor, the complaint fails to draw this nexus, and the Court cannot draw it for Plaintiffs. Because Plaintiffs' allegations do not link the allegedly artificial citric acid to the actual citric acid used by Kraft, Plaintiffs have failed to allege sufficient facts showing that Kraft's 'no artificial preservatives' statement was false."

Plaintiff Argues Premature Honey Harvest Reduces Antioxidants, Misleading Consumers

A consumer has filed a putative class action arguing that Dutch Gold Honey Inc. sells honey that lacks the antioxidants for which consumers purchase buckwheat honey, allegedly amounting to fraudulent misrepresentation and fraudulent concealment. *Wolfe v. Dutch Gold Honey Inc.*, No. 19-4562 (E.D. Penn., filed October 1, 2019). "Unknown to Plaintiff and the Class, the Buckwheat Honey sold by Dutch Gold does not contain the antioxidants that consumers prize in buckwheat honey," the plaintiff asserts. "Moreover, because Dutch Gold buys honey that has been harvested prematurely, Dutch Gold (or the sources it purchases honey from) must dry the honey out, so it heats its Buckwheat Honey to high temperatures for a long enough time that the antioxidants normally found in buckwheat honey are destroyed."

The plaintiff challenges in particular a statement from Dutch Gold's website asserting that its buckwheat honey "has been demonstrated to have higher levels of antioxidants than other honeys and was featured as an effective cough soother in a research project completed by Penn State College of Medicine." Further, "[b]ecause honey harvested prematurely is not 'honey' as that term is understood in the industry, Dutch Gold's label describing its product as honey is also false and misleading."