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## LEGISLATION, REGULATIONS & STANDARDS

### U.S. Lawmakers Urge FDA to Act on CBD

A group of U.S. lawmakers, led by Reps. Chellie Pingree (D-Maine) and James Comer (R-Ky.), have urged the U.S. Food and Drug Administration to “quickly adopt a policy of enforcement discretion and to consider issuing an interim final rule to regulate [cannabidiol (CBD)] as a dietary supplement and food additive while simultaneously moving forward with a robust framework for evaluating the safety and accurate labeling of these products.” The letter stated that the agency’s “current regulatory posture on CBD has created significant regulatory and legal uncertainty for participants in this quickly evolving industry. We are discouraged by FDA’s estimation that a rulemaking process could span 3 to 5 years. We believe there are more expeditious measures that FDA could take that would establish regulatory clarity while pursuing enforcement actions against bad actors.”

In the U.S. Senate, Majority Leader Mitch McConnell (R-Ky.) reportedly took a different path in an effort to reach the same ends by proposing to amend the Senate appropriations bill to insert language that would compel FDA to issue temporary guidance on how it will enforce rules on the sale of products containing CBD. The proposed amendment would require the agency to inform Congress within 90 days about its progress in

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creating its regulatory policies on CBD and implement a temporary policy within 120 days.

The House of Representatives also received a letter from four banking industry organizations expressing support for the Secure and Fair Enforcement (SAFE) Banking Act of 2019. The bill “would permit depository institutions to serve the needs of their customers in states where cannabis is legal.” According to the letter, the proposed legislation “provides a mechanism for the cannabis industry and its service providers to deposit their cash in regulated financial institutions, which allows our members to meet the needs of their communities and helps those communities reduce cash-motivated crimes, increase the efficiency of tax collections, and improve the financial transparency of the cannabis industry.”

## FSIS Finalizes Pork-Processing Rule

The U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) has announced a “final rule to modernize swine slaughter inspection and bring it into the 21st century.” The rule “amends the regulations to require all swine slaughter establishments to develop written sanitary dressing plans and implement microbial sampling to monitor process control for enteric pathogens that can cause foodborne illness” and “allows market hog establishments to choose if they will operate under [the New Swine Slaughter Inspection System] or continue to operate under traditional inspection.”

In April 2019, *The Washington Post* compared the proposed rule to the relationship between aircraft manufacturers and the Federal Aviation Administration, and FSIS responded with a press release stating, “Shame on you, Washington Post. This story earns you at least four Pinocchios.”

## Ad Board Recommends Change to Animal Welfare Claim

The National Advertising Division (NAD) has recommended that Clemens Food Group and its flagship brand, Hatfield Quality Meats, “discontinue the claim ‘Ethically Raised by Family Farmers

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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.

Committed to a Higher Standard of Care, Governed by Third Party Animal Welfare Audits.” NAD acknowledged that the Food Safety and Inspection Service (FSIS) reviewed the claim, but the “record here did not demonstrate that FSIS considered consumer impact or that it explained its reasoning with respect to its determination on the ‘ethically raised’ claim. Accordingly, NAD undertook its own review of the challenged claims.”

The challenger, Animal Welfare Institute (AWI), argued that the claim misled “a high percentage” of consumers “because they took the claim to mean that the animals’ treatment and living conditions exceed industry standards.” NAD noted that AWI provided a consumer perception survey, and the board found the survey to be methodologically sound. Hatfield submitted “caretaker standards, third-party auditing and related practices, and its relationship with animal welfare expert, Dr. Temple Grandin who helped to develop Hatfield’s sow houses and processing facilities.”

NAD “concluded that this support is not sufficient to substantiate the claim at issue because the practices cited by Hatfield as innovative are not directly relevant to any third-party auditing program as stated in the challenged claim.” Although the ad board was “encouraged by Hatfield’s commitment to continue implementing animal welfare practices in the future,” it ruled that “these aspirational programs were not sufficient to support the challenged claim for Hatfield’s commercially-available products.”

## FDA Announces Food Safety Meeting

The U.S. Food and Drug Administration (FDA) has announced “[A New Era of Smarter Food Safety](#),” a public meeting “to get input from a broad cross-section of stakeholders on a modern approach the Agency is taking to strengthen its protection of the food supply.” The meeting, which will be held October 21, 2019, is intended to “foster a dialogue with our domestic and international regulatory and public health partners, industry, consumers, academia, and others,” and input will “be used to shape an FDA Blueprint for a New Era of Smarter Food Safety.”

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.



# Silk Cholesterol Suit to Continue, Hit with Separate Vanilla Suit

A California federal court has refused to dismiss a lawsuit alleging that Danone US Inc. creates “a misleading impression regarding the health-promoting benefits” of its Silk Coconutmilk because it markets the product with an accurate representation of the product as free of cholesterol. *Marshall v. Danone US, Inc.*, No. 19-1332 (N.D. Cal., entered September 13, 2019). Danone argued that the cholesterol representation was made in close proximity to the nutrition panel showing that the product contained three grams of saturated fat, but the court noted that the total is one gram more than permitted under federal regulations on the use of “cholesterol-free.”

“Danone is missing the point,” the court held. It noted that the U.S. Food and Drug Administration (FDA) “has expertise in, and responsibility for, determining what food labeling practices may mislead consumers” and that the agency “believes that consumers may understand ‘cholesterol-free’ to convey certain health benefits that in fact do not exist if the product contains saturated fats above a certain level. Whether the FDA is right or wrong on that point, or whether Danone may ultimately prevail on the merits for any number of reasons, there simply is no doubt that plaintiff has stated a *plausible* claim that the labels are misleading.” Accordingly, the court refused to dismiss the complaint.

Danone’s Silk Almondmilk was also targeted in a consumer’s putative class action, which alleged that the company misrepresents its almondmilk as containing vanilla. *Trust v. Silk Operating Co.*, No. 19-8442 (S.D.N.Y., filed September 11, 2019). The complaint asserts that the “vanilla” in the name of Silk Almondmilk’s vanilla-flavored product is an indication of the ingredient of vanilla rather than a characterizing flavor composed of “natural flavor” alternatives such as tree bark, lignin or ethyl vanillin. The lawsuit echoes similar complaints filed against food companies, including Friendly’s and Stewart’s Fountain Classics as well as Danone’s yogurt products.

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## Study Examines Effects of Antibiotic Use in Meat Production in Low-Income Countries

A group of researchers from universities in Belgium, India, Switzerland and the United States have published a study examining how the use of antibiotics in meat production in low- and middle-income countries has affected antibiotic resistance worldwide. Van Boeckel et al., “[Global trends in antimicrobial resistance in animals in low- and middle-income countries](#),” *Science*, September 20, 2019. The researchers reportedly found growing rates of antimicrobial resistance (AMR) in several countries, including India, China, Pakistan, Egypt and Brazil. “Regions affected by the highest levels of AMR should take immediate actions to preserve the efficacy of antimicrobials that are essential in human medicine by restricting their use in animal production. . . . [T]here is a window of opportunity to limit the rise of resistance by encouraging a transition to sustainable animal farming practices,” the researchers concluded. “High-income countries, where antimicrobials have been used on farms since the 1950s, should support this transition—for example, through a global fund to subsidize improvement in farm-level biosafety and biosecurity.”

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