

ARTICLE

Food And Beverage Policy Trends To Watch This Year

*Law360*January 1, 2020

A number of significant statutory and regulatory initiatives have transformed the food and beverage industry over the last three years. For example, the U.S. Department of Agriculture issued its long-awaited bioengineered disclosure label rule, and the U.S. Food and Drug Administration provided updates to the nutrition facts panel on human food, implemented menu labeling requirements for certain types of restaurants, and is (almost) finished implementing vending machine label requirements.[1]

These efforts have progressed despite numerous compliance date delays, and the FDA's willingness to employ enforcement discretion. Many of these efforts stemmed from regulatory proceedings started in the Obama administration, taking several years to go from a statutory requirement or FDA regulatory vision to a proposed and final rule with an effective compliance date.

One example of how long these processes can take: The FDA just issued its proposed rule on laboratory accreditation as mandated by the FDA Food Safety Modernization Act, which Congress passed in 2011. As this process unwinds within the current administration, we are beginning to see a relative slowdown in both formal rulemaking and new initiatives at the FDA — at least in relation to food.

This makes it difficult to predict what 2020 has in store for the food and beverage industry. But a few topic areas continue to stand out as we enter the new year.

Trump FDA Nominee Confirmed

Practice Areas

Food & Drug

wiley.<mark>law</mark>

President Donald Trump nominated Stephen Hahn as the next FDA commissioner, filling a vacancy left by Scott Gottlieb, who he stepped down in April 2019. Hahn hails from Houston, where he worked as a radiation oncologist and chief medical officer at M.D. Anderson Cancer Center. On Dec. 12, the U.S. Senate confirmed Hahn with a vote of 72-18

In his prepared statement to the US Senate Health, Education, Labor, and Pensions Committee, Hahn stated that he "believes strongly in the importance of science, data and the law," and would use new and improved ways of assessing data to "better evaluate new products and ensure food safety, all with even greater accuracy and certainty."[2]

CBD Products: Enforcement (and Confusion)

Since Trump signed the Agriculture Improvement Act of 2018, which provided a pathway for the sale of CBD-containing products in the United States, there has been much legal wrangling around this ingredient — and the wrangling is likely to persist.

Currently, CBD is considered an active drug ingredient. The Federal Food, Drug, and Cosmetic Act makes it illegal to introduce or deliver into interstate commerce any food containing an active drug ingredient. The FDA continues to maintain that it is prohibited to market food to which CBD has been added.[3]

In 2019, the FDA sent 21 warning letters to companies that market food and other related products that contain CBD.[4] At first, these warning letters focused on food products that contained unapproved drug claims. The latest round of warning letters focuses more heavily on CBD not being generally recognized as safe for use in human or animal food.

Plant-Based Meat Here to Stay, as Significant State Action Persists

Plant-based meat, or PBM, products are here stay — but expect continued state action in this area. PBM products are intended to replicate the tastes, textures and smells of animal tissue, but only use plant-based materials. Such products are not to be confused with cell-cultured meat, or CCM, products, which are those grown from real animal tissue, such as tissue from beef, pork, poultry or seafood, under controlled conditions using actual cells from living animals.

PBM products are already on the market, and retail sales are expected to increase to \$22.9 billion by 2023. While there are no CCM products currently on the market, companies continue to raise significant capital and progress toward bringing the first CCM product to market — possibly in 2020.

The significant success of PBM products (and the anticipated success of CCM products) has led to a host of state initiatives to restrict and/or ban PBM and CCM products from using traditional standards of identity, or SOI, nomenclature (e.g., "ground beef," "chicken"). Missouri started the effort to restrict SOI nomenclature use,

and now roughly 30 other states have or are pursuing legislation to regulate CCM and PBM products.[5]

We expect confusion around the enforceability of these state actions to continue, as both the FDA and the USDA evaluate their options relating to PBM and CCM products' use of SOI nomenclature.

State Action on Food Safety and Online Food Delivery Companies

Online grocery shopping is expected to double from \$14.2 billion in 2017 to \$29.7 billion in 2021.[6] As this business continues to grow, some states are looking to amend their food codes to take into account supposed last-mile issues involving food safety (i.e., when a food delivery driver or cyclist transports and delivers food to a consumer that was ordered from an online delivery platform).

Currently, the FDA's model Food Code, which state and local jurisdictions can adopt (with or without modifications) as their own food health and safety code, does not directly address food delivery platforms. But some states are beginning to take action by attempting to amend their health and safety codes to address this issue.

For example, California's A.B. 1360, the Third-Party Food Delivery Bill,[7] if enacted, would require food delivery workers to obtain proper training related to maintaining potentially hazardous foods at required temperatures (or to obtain a food handler card).

Animal and Human Food: Food Safety Plan Violations Increasing

Several years into the implementation of the FSMA, we are seeing an increase in the number of preventive control inspections and violations, as the FDA continues to establish acceptable programs and benchmarks in this area.

For example, in fiscal year 2017, the FDA found 100% of the 169 food safety plans it inspected compliant. In fiscal year 2019, the FDA found only 91% of the 601 food safety plans it inspected compliant.[8] Expect the FDA to conduct more inspections surrounding food safety plans in 2020 (along with an increase in the number of violations), as the agency continues to outline specific benchmarks for industry under these regulations.

Congress Responds to Recent Pathogen Outbreaks

In late November, romaine lettuce recalls were back in the spotlight due to possible E. coli contamination. The FDA, the USDA and the Centers for Disease Control and Prevention issued public health safety warnings, urging consumers not to eat certain California-grown romaine lettuce.

The cause of these outbreaks continues to baffle industry and regulators alike, despite significant investment in preventative measures. There has been an increased focus, however, upon confined animal feeding

operations as potential source points.

In that context, Sen. Kristen Gillibrand, D.-N.Y., introduced the Expanded Food Safety Investigation Act of 2019 to provide the FDA more authority to conduct microbiological sampling at such animal feed operations in order to better "facilitate a foodborne illness outbreak investigation, determine the root cause of an outbreak of foodborne illness, or address other public health needs."[9] The bill would make refusal to provide reasonable access to collect microbiological samples a prohibited act under the FFDCA.[10]

State Initiatives on Animal Welfare Standards

California voters passed Proposition 12 in November 2018, banning the sale of certain animal products in the state (e.g., eggs, pork and veal) that do not comply with animal-raising standards. For example, Prop 12 will require all eggs sold in the state to come from cage-free hens by 2022.

This is similar to voter initiatives in other states, such as Massachusetts's ban on certain farm animal confinement practices. The broader issue here is the ability for states to effectively dictate animal care standards on a national level. In some cases, this means that meat-consuming states are dictating animal-raising standards to meat-producing states.

Recently, the North American Meat Institute sued to halt California's Prop 12. However, on Nov. 22, the U.S. District Court for the Central District of California denied NAMI's request for a preliminary injunction.

Robert G. Hibbert is a partner and Ryan M. Fournier is an associate at Morgan Lewis & Bockius LLP.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

- [1] On Oct. 28, the FDA published a final rule for calorie labeling on foods sold from certain vending machines. The FDA extended the compliance date for updated type size labeling requirements to July 1, 2021. See 84 Fed. Reg. 57,603, Food Labeling: Calorie Labeling of Articles of Food Sold from Certain Vending Machines; Front of Package Type Size, available at https://www.federalregister.gov/documents/2019/10/28/2019-23276/food-labeling-calorie-labeling-of-articles-of-food-sold-from-certain-vending-machines-front-of.
- [2] See Prepared Statement of Stephen M. Hahn, M.D., Nominated to Be Commissioner of Food and Drugs, Food and Drug Administration, Department of Health and Human Services, available at https://www.help.

senate.gov/imo/media/doc/Hahn.pdf.

- [3] See https://www.fda.gov/media/119427/download.
- [4] See Warning Letters and Test Results for Cannabidiol-Related Products, available at https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products.
- [5] For example, Mo. Rev. Stat. § 265.494(7); Ark. H.B. 1407 (March 18, 2019); S.C. H.B. 4245 (May 9, 2019), available at https://www.forbes.com/sites/darrentristano/2019/03/21/online-grocery-sales-surge-through-digital-platforms-as-consumers-crave-convenience/#1dc813ba2b8f.
- [6] See Darren Tristano, Online Grocery Sales Predicted to Surge by 2021, But Where Will That Growth Come From?, Forbes, Mar. 21, 2019.
- [7] See https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=201920200AB1360.
- [8] See https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/pc-and-cgmp-measures#5.
- [9] Expanded Food Safety Investigation Act of 2019, S. 2958, 116th Cong. (2019), available at https://www.congress.gov/bill/116th-congress/senate-bill/2958/text.

[10] ld.