

Food and Beverage Policy Trends to Monitor This Year

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When we wrote a *Law360* guest article on food and beverage policy trends to watch in 2020, no one could have imagined how quickly our world would change due to SARS-CoV-2 – the virus that causes COVID-19. While we were beginning to see a relative slowdown in rulemaking and new initiatives at the U.S. Food and Drug Administration moving into 2020, we can easily say COVID-19 turned our predictions on their heads.

We've never seen the FDA work as hard as it did in 2020 – on a multitude of fronts – to address the harsh realities of what is now a global pandemic. But what regulatory challenges will confront the food and beverage industries in the coming year as it navigates its way to a new normal? Below, we offer a few suggestions.

On President-elect Biden's Transition

The Trump administration focused on safely getting food back on supermarket shelves. This will not change under President-elect Joe Biden, but with food insecurity on the rise throughout the nation due to COVID-19-related unemployment, Biden is under pressure to quickly come through on campaign promises to increase food access once he is in office – including under the U.S. Department of Agriculture's Supplemental Nutrition Assistance Program.

The current administration substantially reduced benefits under SNAP. However, we already see efforts to alleviate the hunger crisis caused by the COVID-19 pandemic during the presidential transition. According to data released by the U.S. Census Bureau on Dec. 16, 2020, 14 million households with children reported not having enough food to eat.[1] The latest \$900 billion coronavirus relief package, signed by President Donald Trump on Dec. 27, 2020, provides \$13 billion in increased SNAP funding and other benefits.[2]

We already see Biden proposing changes to top leadership at all levels of relevant federal government agencies. California Attorney General Xavier Becerra is the nominee for secretary of the U.S. Department of Health and Human Services. Biden

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has yet to announce a nominee to lead the FDA.

In a more surprising announcement, Tom Vilsack will serve as the nominee for the USDA – replacing Sonny Perdue, who has served in the role since April 2017. If confirmed, this will be Vilsack's second term at the head of the USDA, where he served in the role under the Obama administration from January 2009 to January 2017.

We should expect to see funds redirected toward greater government regulation in the area of food and dietary supplements, as this became a lower priority during the Trump administration. We may also see a resurgence in FDA guidance documents, as many FDA guidance and proposed rules initiated under President Barack Obama were frozen under Trump.

Additionally, formal guidance and regulations relating to hemp and cannabidiol have been pending for well over a year, and we could see some movement in this area in 2021.

On Food Safety: Salmonella Strains as an Adulterant

Implementation of the requirements of the Food Safety Modernization Act has moved beyond its initial phase, and FDA-regulated entities can anticipate continuation of the status quo.

In the protein sector, the USDA will continue to wrestle with the challenge of reducing salmonella incidence. The limitations of the agency's performance standards approach, which has never been based upon a clear legal or scientific foundation, may continue to drive efforts to classify at least some strains of the pathogen as an adulterant.

On a broader level, it will be interesting to see if lessons learned from the COVID-19 pandemic will lead to any breakthroughs in this area. Despite inherent differences between viruses and foodborne pathogens, there is considerable overlap here within the public health arena.

On Food Labeling: New Labeling Opportunities

For decades, the regulatory system has understandably treated the food label as a finite piece of real estate, on which government disclosure requirements must be met and nonmisleading claims may be made. But it's not your grandmother's label any longer.

Increasing utilization of new tools such as web links and QR codes will open new windows to vast quantities of additional information for consumers – e.g. supply chain transparency – creating new opportunities for marketers, and new challenges for regulators. We do not see a slowdown in new and innovative labeling options in 2021.

On Standards of Identity: FDA Revoking Decades-Old Definitions

Despite the COVID-19 pandemic, the FDA is still focused on modifying foods' standards of identity, or SOI. For example, on Dec. 18, 2020, the agency issued a proposed rule to revoke the definition and SOI for French dressing.[3] And on Dec. 17, 2020, the FDA issued a proposed rule to revoke the definition and SOI and quality for frozen cherry pie.[4]

Revoking these standards is part of the FDA's Nutrition Innovation Strategy,[5] where the agency is reviewing certain SOIs and determining whether there is no longer a need to "promote honesty and fair dealing in the interest of consumers and may limit flexibility for innovation." [6] For example, removal of the frozen cherry pie SOI will allow the use of sweetener alternatives that were not allowed under the SOI.

Compare this with the USDA's recent efforts to continue to enforce its SOIs. Specifically, while the FDA is revoking certain SOIs, the USDA just issued a notice to renew standard of identity regulations involving "the common or usual name for raw meat and poultry products containing added solutions." [7]

On Enforcement: Virtual Inspections Could Be Here to Stay

The COVID-19 pandemic has pushed much of the FDA's food inspection activity into the virtual realm, and it seems reasonable to assume that much of this will continue into 2021 and beyond.

Currently, the push for virtual inspections is fueled by concerns for investigators' safety, while also ensuring the FDA continues to inspect companies it regulates. The COVID-19 pandemic has pushed the agency to utilize remote tools and technologies to conduct inspections in new ways, to ensure it still maintains proper regulatory authority while protecting worker safety.

Part of the new normal may be that even though it will be safe in the future for FDA inspectors to conduct onsite inspections, investment in these new technologies will allow the agency to continue to utilize virtual surveillance as a key regulatory enforcement tool – well beyond 2021. While foreign and domestic inspections dropped drastically in 2020, we expect this number to rise in 2021, and the FDA may be able to do more in the coming years as it relies on these alternative enforcement tools.

From an industry standpoint, there are many issues with virtual inspections. Most companies likely do not have standard operating procedures in place addressing how they would handle virtual inspections with the FDA. Moreover, virtual inspections likely involve handing videos and photographs over to the agency.

Before the new normal, FDA investigators usually only used photographs when they wanted to memorialize something they saw or found during an on-site inspection. It may be difficult to determine what records, photographs, videos and other data companies should provide to the FDA, and what requests are considered reasonable, if virtual inspections become a common occurrence.

As it relates to the USDA, the virtual inspection model may also raise additional questions about the wisdom behind the USDA's adherence, within the scope of its own jurisdiction, to its labor-intensive, onsite continuous inspection model. However, we have yet to see any meaningful action from the USDA on addressing this issue.

On Worker Safety: Meat and Poultry Workers Next in Line for Vaccine

This will undoubtedly remain a focus, as industries push for priority vaccination status for their workforces. This is especially true for USDA-regulated industries, as COVID-19 outbreaks in processing facilities have been found to rapidly affect a large number of people.

According to the U.S. Centers for Disease Control and Prevention report on the number of COVID-19 cases during April and May 2020, "16,233 cases in 239 facilities occurred, including 86 COVID-19 related deaths."^[8] These numbers have risen drastically since this report.

The CDC has now decided that "frontline food industry workers"^[9] will be among the first to be vaccinated, after health care workers and residents and staff of nursing homes and other long-term care facilities.^[10] In a recently published letter, the North American Meat Institute and other industry leaders welcomed the news.^[11]

On New Product Development: Genetically Engineered Pigs

The growth of the plant-based product category will undoubtedly continue – if not accelerate. Meanwhile, Singapore's recent regulatory acceptance of cell-cultured chicken is obviously relevant to regulatory issues pending in the U.S., as everyone waits to see how the FDA and the USDA will negotiate and resolve their joint custody arrangement over the future regulation of cell-cultured products.

In the genetically engineered animal space, the FDA just approved GalSafe pigs for use in food and medical products. GalSafe pigs now joins salmon as the only genetically engineered foods approved for human consumption in the U.S.

However, the GalSafe pigs' uses for both human food and therapeutic purposes blurs the line between the FDA's and the USDA's ultimate jurisdiction. There is more to come on this issue, as the USDA just issued an advance notice of proposed rulemaking and request for comments, to grab future pre- and post-marketing control over genetically engineered versions of most farm animals.[12]

The notice proposes that the USDA would develop the regulatory framework for genetically engineered farm animals, under authorities granted to it by the Animal Health Protection Act, the Federal Meat Inspection Act and the Poultry Products Inspection Act.[13] Currently, the FDA regulates genetically engineered versions of animals. But if the USDA proposal becomes reality, the next applicant with a genetically engineered pig meant for food production may be knocking on the USDA's door for market approval, instead of the FDA's.

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[1] Census.gov: Week 20 Household Pulse Survey: Nov. 25 – Dec. 7, available at <https://www.census.gov/data/tables/2020/demo/hhp/hhp20.html> (last accessed Dec. 22, 2020).

[2] Trump Signs Bipartisan Coronavirus Relief Bill After Calling On Congress to Approve \$2,000 Stimulus Checks, available at https://www.businessinsider.com/trump-signs-coronavirus-relief-bill-after-calls-stimulus-checks-2020-12?utm_source=markets&utm_medium=ingest (last accessed Jan. 3, 2021).

[3] FDA Proposes to Revoke the Standard of Identity for French Dressing, available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-proposes-revoke-standard-identity-french-dressing> (last accessed Dec. 21, 2020).

[4] FDA Proposes to Revoke Standard of Identity of Frozen Cherry Pie, available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-proposes-revoke-standard-identity-frozen-cherry-pie> (last accessed Dec. 21, 2020).

[5] FDA's Food Innovation Strategy, available at <https://www.fda.gov/food/food-labeling-nutrition/fda-nutrition-innovation-strategy> (last accessed Dec. 21, 2020).

[6] *Id.*

[7] Notice of Request for Renewal of an Approved Information Collection (Common or Usual Name for Raw Meat and Poultry Products Containing Added Solutions), FR Doc No: 2020-28061 (Dec. 21, 2020), available at <https://www.fsis.usda.gov/wps/wcm/connect/f6e0f9a6-6d07-42c5-b0ea-a8e5ee838773/2020-0035.htm?MOD=AJPERES>.

[8] Update: COVID-19 Among Workers in Meat and Poultry Processing Facilities – United States, April–May 2020, available at <https://www.cdc.gov/mmwr/volumes/69/wr/mm6927e2.htm#:~:text=COVID%2D19%2Doutbreaks%2Damong%2Dmeat,affect%2Dlarge%2Dnumbers%2Dof%2Dpersons.&text=Among%2D3%2Dstates%2Dreporting%2DCOVID,COVID%2D19%E2%80%93related%2Ddeaths> (last accessed Dec. 21, 2020).

[9] The CDC defines frontline essential workers as "workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2."

[10] Frontline Food Industry Workers Prioritized for Next Phase of COVID-19 Vaccination, available at <https://www.foodnavigator-usa.com/Article/2020/12/21/Frontline-food-industry-workers-prioritized-for-next-phase-of-COVID-19-vaccination> (last accessed Dec. 21, 2020).

[11] CDC Agrees: Frontline Meat & Poultry Workers High Priority for COVID-19 Vaccination, available at <https://www.prnewswire.com/news-releases/cdc-agrees-frontline-meat-poultry-workers-high-priority-for-covid-19-vaccination-301196450.html> (last accessed Dec. 21, 2020).

[12] Regulation of the Movement of Animals Modified or Developed by Genetic Engineering, 85 FR 84269 (Dec. 28, 2020), available at <https://www.aphis.usda.gov/brs/pdf/aphis-2020-0079.pdf> (last accessed Jan. 3, 2021).

[13] *Id.*