Perspectives on the Evolving Regulatory Landscape for US Food and Beverage

August 2022

There are a number of product safety challenges and risks facing the food and drink industry in the US, including balancing innovative products with regulatory compliance. In this article, we explore what these risks are, how companies can prepare, how the recall landscape is evolving and our predictions for the future.

What Do You See as the Biggest Product Safety Challenges and Risks Facing the Food and Drink Industry?

Risks From Novel Foods and Health Claims

The Food and Drug Administration (FDA) in the US continues to issue warning letters for food products with novel ingredients, such as CBD. Any substance added to food is a food additive and must either be submitted for premarket review and approval, or be generally recognized as safe among qualified experts (GRAS). CBD generally is not recognized as GRAS or approved by FDA for use in food; therefore, food with CBD is prohibited from entering interstate commerce. Further, some companies add product claims that imply treatment/mitigation of a disease or effects on the structure/function of the body – causing the food to qualify as a new drug or a dietary supplement. Entities seeking to enter into the CBD market in the US, for humans or animal food products, should carefully assess the risks and engage legal counsel to review the products and claims being used.

Food and drink businesses in the US increasingly seek to cater to health-conscious consumers with claims such as "gluten-free," "dairy-free," or highlighting a lack of artificial flavors, etc. Industry participants need to be aware that each of these claims may be subject to FDA regulation. Consumers with allergies or dietary restrictions need to be able to rely on the veracity of such claims. For example, FDA is expected to release guidance on the Labeling of Plant-based Milk Alternatives: Draft Guidance for the Industry. The question of whether plant-based products, such as almond and oat milk, can be classified as a "milk" as part of their statement of identity has been a hotly contested issue in the US.

Infant Formula Shortage Highlights Supply Chain Risks in the US

The infant formula shortage in the US has highlighted risks in the food supply chain when a market relies on a few manufacturers – especially for specialty products for individuals with allergies or food sensitivities. The shortage also indicates the risks associated with delaying or postponing safety inspections because of the COVID-19 pandemic. In February 2022, FDA inspected a major infant formula manufacturer's production facility in Michigan and found potential contamination with *chronobacter sakazakki*, among other violations. The manufacturer initiated a voluntary recall of the suspected products on February 17, 2022. When the factory shut down, the market was not able to keep up with demand and FDA did not issue guidance permitting importation of formula from other countries until May 16, 2022. Even though the manufacturer entered into a Consent Decree reopening the facility in May 2022, close to six months later, there is still a nationwide shortage of formula, exacerbated by the plant shutting down a second time due to flooding in June 2022.

The Year of the "Pink Sauce" and Cybercriminals – Navigating e-Commerce

E-commerce is a booming industry in the US, but comes with risks and safety concerns. From the "pink sauce" that went viral on the video-sharing application TikTok, to cybersecurity concerns, entities seeking to sell their products online need to apprise themselves of the relevant regulations and risks that come with the worldwide web. While some states have passed "cottage food" laws for intrastate sale of certain products, typically shelf-stable, nonhazardous products like baked goods, jams and jellies, FDA regulates the interstate sale of food in the US. Startup food and beverage companies should be familiar with the applicability of both state and federal law and seek counsel before selling their products across state lines.

Further, businesses seeking to sell food and beverage products online should implement cybersecurity policies, including implementation of strong passwords and phishing training. In September 2021, the FBI issued a notification regarding ransomware attacks targeting the food and agriculture sector operations. The notification highlighted several examples of these ransomware attacks in 2021, including a US bakery that lost access to its server, files and applications, which shut down the company for a week, and a US farm that lost US$9 million when a cybercriminal gained administrator-level access to its servers. Just one year ago, JBS USA, one of the world's largest meat processing plants, paid the equivalent of US$11 million in ransom to end a cyberattack on its operations. While IT and implementing strong protocols may be costly upfront, the risk of shutdown and reputational damage from these attacks are worth the investment.

What Should Companies Be Doing to Prepare for These Challenges and Risks?

Companies should review and assess their standard operating procedures (SOPs) for compliance with FDA regulations and guidance, including the Food Safety Modernization Act. Companies should also assess entities in their supply chain, including as required under the Foreign Supplier Verification Program. This could include remote and on-site audits for new suppliers, review of supplier SOPs, consultant and legal review of product labeling, and periodic assessment of claims against updated FDA guidance.

How Do You See the Food and Drink Recall Landscape Changing or Evolving in the Future?

The Evolving Food and Drink Recall Landscape in the US

FDA will likely be paying increased attention to company policies on internal audits and recalls in the wake of the infant formula shortage. In fact, FDA finalized guidance in March 2022 entitled Initiation of Voluntary Recalls under 21 CFR Part 7, Subpart C, encouraging companies to be "recall ready" and have "adequate product coding and maintain distribution records to facilitate faster, more accurate recalls." Companies should be prepared in advance to handle recalls for product safety and have policies and procedures in place – including a recall communication plan. Also, employees should be trained upon hire and receive periodic updates. Trying to get a handle on the requirements and reporting documentation in the midst of an internal investigation may cause unnecessary delays and even risk to consumer safety.

Section 204 of the Food Safety and Modernization Act provides for the tracking and tracing of food. In September 2020, FDA issued a proposed rule requiring additional recordkeeping for certain high-risk foods. The final rule is expected by November 7, 2022. Examples of foods currently on the list include cheeses, shell eggs, leafy greens and finfish. As proposed, entities subject to the rule will be required to maintain records to support accurate and timely traceability of food – for such reasons as potential contamination.

The proposed rule includes development of a traceability program requiring tracking of key data elements, critical tracking events and a traceability lot code that follows the product through the supply chain. The traceability lot code would be established and assigned when an entity originates, transforms or creates a food on the Food Traceability List (FTL). In the case of food growers, this is proposed to include records of the growing area coordinates. Practically, for a business to have this information available upon agency request, electronic records will be needed.

FDA is also "leveraging technology and other tools and approaches to create a safer and more digital, traceable food system" through its New Era of Smart Food Safety Blueprint, first announced in July 2020. The blueprint has four core elements: tech-enabled traceability; smarter tools and approaches for prevention and outbreak response; new business models and retail modernization; and food safety culture. Looking to new technology, FDA is exploring the use of artificial intelligence (AI) to improve food safety. Examples of AI uses include AI-based horizon scanning and machine learning to predict which imported food shipments pose a higher risk of violation. In fact, FDA launched a pilot study in 2020, with the second phase in 2021, using AI for inspecting imported seafood.

What Predictions Do You Have for the Future of the Industry?

Looking Forward

Legislative efforts to address safety and sustainability concerns relating to food packaging continue at both the state and federal levels in the US. There is a particular focus on Extended Producer Responsibility laws, which generally tend to place the burden on packaging manufacturers to ensure their products are recycled or otherwise disposed of appropriately. This could obligate manufacturers to invest in updating their materials to comply – costs that would likely be passed on to consumers in the form of increased prices for packaged food and beverages.

In addition to sustainability efforts, safety of food packaging materials is an area of focus for lawmakers. The FDA regulates food contact substances, meaning a substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting or holding food. The agency has been updating guidance for food packaging made of recycled materials in recognition of the potential for contaminants that remain after recycling. At the state level, chemicals of particular concern include PFAS, a class of widely present chemicals. California has passed a law banning paper-based food packaging using PFAS chemicals starting January 1, 2023, and it is expected other states will consider or pass similar laws.

Uncertainty also looms over the future of the US agriculture economy – the majority of farmers are reaching retirement age and young people are not filling the gap. With rising costs for land, fertilizer, fuels, seeds, chemicals and equipment (a new combine can cost between US$300,000 and US$500,000), startup capital may be the boost needed for US agriculture.

Many consider the current process for obtaining credit "convoluted and slow." On July 14, 2022, the House Agriculture Committee convened to discuss the state of credit for young, beginning and underserved producers. Potential solutions from the hearing may appear in the 2023 Farm Bill.

Finally, pressure on companies to reduce their carbon footprint and a desire for sustainability, are focusing global attention on food security. In response, companies look to alternative proteins as a way to increase food independence and diversify food sources. As a result, it is likely plant-based protein will overtake a larger market share in the coming decades. Companies exploring alternative proteins for their products must consider affordability, environmental tradeoffs (e.g., energy demand and land use comparisons), sustainability assessments and nutritional equivalency to animal protein.

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