Throwing the First Tomato ? What Will 2017's Food Fights Look Like'

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PRACTICES Procurement and Supply Chain Management, FDA Regulatory and Compliance, Food, Beverage and Restaurant, Franchise and Distribution

Just weeks into the new Administration, perhaps the only certain thing is that there will be uncertainty as the Administration makes its mark and works to fulfill campaign promises. Meanwhile, restaurant chains and food companies are trying to allocate resources to best address business priorities and hot legal issues. They are left to wonder: What will 2017’s food fights look like?

Where We Are Now

In 2016, the US Food and Drug Administration (FDA), made significant progress on several high profile initiatives, including:

1. Food Safety Modernization Act (FSMA) implementation, including releasing the final rule on the Sanitary Transportation of Human and Animal Food (with which many companies must comply in April 2017) and the final rule on Mitigation Strategies to Protect Food Against Intentional Adulteration (for which compliance dates are still years away);
2. Menu labeling, including releasing final guidance in April 2016 for covered food establishments (generally, those chains of 20 or more selling restaurant-type foods) to prepare for a May 2017 compliance date;
3. Soliciting public comments on hotly debated (and often litigated) terms like “natural” and “healthy”; and
4. The first major overhaul in more than 20 years of the nutrition information that consumers see, with the issuance of the final rules on updated nutrition facts and supplement facts panels and changes to Reference Amounts Customarily Consumed (RACC) for many food products and labeled serving sizes, particularly for convenience-type single serving containers.

In the final weeks of the Obama Administration, the FDA continued to work at a steady pace, including by issuing guidance documents on the updated nutrition and supplements facts labels and RACC.

2017 Begins with Open Questions

While the FDA made a lot of progress on food-related priorities in 2016, there are open issues that may remain unresolved. Because of the January 30, 2017, Executive Order titled "Reducing Regulations and Controlling Regulatory Costs" (*i.e.*, two out, one in), and statements by President Trump indicating that he intends to significantly cut FDA regulations, it may become much harder for the FDA to release new regulations. The Executive Order also impacts the guidance documents upon which companies rely to understand how the FDA interprets laws and applies its regulations.

The President's Executive Order requiring federal agencies to eliminate two regulations for every new regulation instituted applies to guidance documents as it covers "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency…." On February 2, the Director of the Office of Management and Budget (OMB) provided agencies with more information on implementation of the Executive Order. OMB stated that "[n]ew significant guidance or interpretive documents will be addressed on a case-by-case basis." Therefore, at present, companies must prepare to meet upcoming compliance dates without necessarily relying upon the FDA to issue much needed guidance documents.

For example, in late August, the FDA extended the compliance date for certain provisions of the FSMA rule on Preventive Controls for Human Food, indicating that it intended to issue further guidance. To date, the FDA has not issued such guidance. It is not clear when the FDA will be able to issue the guidance. In addition, the FDA's plans to update other parts of its food labeling regulations to address nutrient content claims impacted by the final rules on nutrition facts labeling and serving sizes are likely now delayed or in jeopardy. Moreover, it seems that the FDA is unlikely to take action to further define "natural."

Of course, the FDA is just one part of the patchwork of the regulation of food. For example, with the issuance of the Executive Order on the Affordable Care Act, some have questioned whether menu labeling would be impacted (so far, it's not). However, even if menu labeling does change at the federal level, it is likely that state and local laws enacted prior to the issuance of the FDA's final menu labeling rule would fill the gap, requiring companies to adapt to multiple standards instead of preparing for a single uniform standard in May 2017. That is, even in the absence of significant federal developments or the same level of federal enforcement that became the norm in recent years, there is no indication that state and local governments intend to sit idly by.

While it remains to be seen whether the same level of federal enforcement that has become the norm will continue in 2017, it is important to note that in 2017, the FDA has so far issued two dozen warning letters, with 10 going to food companies. Six warning letters relate to violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, indicating a continuing trend of the FDA inspecting and issuing such letters to seafood processing facilities, including those located outside of the United States.

The FDA's 2017 warning letters also include a warning letter to Aspen Hills for the presence of Listeria monocytogenes in its processing facility following recalls by several ice cream brands (including Blue Bell) and other food companies in late 2016 after the incorporation of Aspen Hills' cookie dough into food products. Aspen Hills has since announced its intent to wind down its operations and close.

The FDA also issued a warning letter to a maker of tofu for violations of Current Good Manufacturing Practices (CGMP), and to a dairy farm for the sale of an animal for slaughter as food with the presence of a harmful drug residue and for holding animals under inadequate conditions such that medicated animals are likely to enter the food supply. Finally, the FDA issued a warning letter to a juice processing facility for violations of the juice HACCP regulation. Notably, the firm failed to respond to a prior Form FDA-483 that preceded the FDA's warning letter.

Finally, lawsuits concerning nearly every aspect of product labeling continue to plague the industry. Plant-based food products continue to come under attack, with popular brands of almond milk recently the subject of claims related to calling such products "milk" (the use of which the dairy industry has long tried to restrict) and promoting such products as an alternative to cow's milk.

Sugar also continues to grab the attention of plaintiffs' lawyers when it comes to attacking labels and claims about products.

Planning for the Year Ahead – Supply Chain Issues Continue to Warrant Attention to Detail

Currently, it seems that the food industry will be left to continue plans to implement the FDA's recently issued rules, including those on FSMA, food product labeling, and menu labeling, in preparation for upcoming compliance dates – but without counting on the FDA to issue many additional rules or perhaps even guidance documents in the near future. Unfortunately, as noted above, this will leave gaps. While the FDA's reduced ability to issue new regulations may stall certain initiatives, as noted above, state and local governments are still actively invested in regulating the food industry. It will also continue to be important for restaurant chains and the food industry to continue to strengthen their supply chains in 2017.

First, the FDA's FSMA rules require active oversight of food supply chains. The first compliance date for importers subject to the FSMA Foreign Supplier Verification Programs rule is approaching in May. Under the Sanitary Transportation of Human and Animal Food, for which the first compliance date for affected companies is in April, responsible parties are expected to have documented policies and procedures and, where applicable, supply chain contracts that allocate responsibilities under the rule.

Second, though federal enforcement priorities may begin to change the likelihood of a robust government investigation, outbreaks of foodborne illnesses and other product adulteration (e.g., allergens) will likely continue to cause wide scale recalls, reputational damage to affected brands, and significant expenses. It remains true that many such circumstances might be avoided by paying greater attention to suppliers and keeping in mind that no contract can replace periodic audits and other efforts to increase transparency, quality, and safety. And as to supply chain contracts, greater attention to details like allocating responsibilities for evaluating the need for a recall can provide for more certainty should the unforeseen happen.

Third, a review of contractual insurance coverage requirements and actual policies is in order for the food industry in 2017. Some insurers continue to try to deny coverage of costs, including costs related to food companies defending against potentially covered labeling disputes and seeking to recover losses related to recalls and other product issues.

It will take time to adapt to the changes that are underway and, as noted, supply chain issues will continue to require a significant investment of time and resources. On the bright side for 2017, however, a (so far) strong stock market and reduced regulations may provide the right climate for another wave of mergers and acquisitions of restaurant and food companies.

For more information please contact the lawyer listed below.

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