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FDA CONFIRMS DELAY IN ENFORCEMENT OF KEY FSMA PROVISIONS: WHAT SHOULD YOU EXPECT IN THE MEANTIME?

The FDA Food Safety Modernization Act (FSMA) specified that its most significant requirements for industry — the hazard analysis and preventive controls requirements — were to have come into effect next week. FDA has now confirmed, however, that it will not enforce those requirements until it issues final rules and establishes effective dates for these requirements. The agency will take the same approach to the foreign supplier verification program requirements that were due to come into effect in January of 2013.

That said, the enactment of FSMA in January 2011 has already changed the landscape of food safety regulation, including the way that FDA conducts inspections of food facilities and the expectations that food manufacturers have of their suppliers and that customers and consumers have of food producers. Thus, even before FDA establishes effective final rules to implement key FSMA provisions, food manufacturers will be expected to be making great strides towards implementation. This client alert highlights key steps that food companies should consider taking in the interim, and notes the scope and boundaries of FDA's authority before key FSMA provisions are implemented.

BACKGROUND

Section 103 of FSMA,[1] requiring food facilities to develop and implement hazard analysis and preventive controls plans, is among the sections that charged FDA with a major rulemaking obligation. The statute specifies the basic requirements of a hazard analysis plan, the basic verification and monitoring activities facilities must undertake, and examples of preventive controls that FDA may require. But it requires FDA to specify the details and required content of hazard analysis plans, the details of verification and monitoring activities, and the actual preventive controls that different types of facilities must utilize. FSMA states that the hazard analysis and preventive controls requirements are effective 18 months after enactment for most facilities (July 4, 2012), and six and 18 months after the effective date of FDA's implementing regulations for small and very small facilities.

Similarly, section 301 of FSMA,[2] requiring importers to implement a foreign supplier verification program, specifies the types of verification activities that might be mandated but requires FDA to issue regulations to implement its requirements. FSMA states that these requirements were to become effective two years after enactment (January 4, 2013), and required FDA to publish a proposed regulation for these requirements by January 4, 2012.

Although FDA has met a number of FSMA's deadlines, it has not yet issued proposed rules for the hazard analysis and preventive controls requirements or the foreign supplier verification program. Because the language of FSMA could be interpreted to mean that those requirements will become

[1] Federal Food, Drug, and Cosmetic Act ("FDCA") § 418.
[2] FDCA § 805.

effective before FDA issues final rules, industry has been in the difficult position of assessing how to comply with requirements that FDA has not yet established or clarified.

FDA DELAYS ENFORCEMENT UNTIL FINAL RULES ESTABLISH EFFECTIVE DATES

FDA has, for some time, stated on its FSMA "FAQ" page that the hazard analysis and preventive controls requirements would become effective when the agency issued final rules,[3] but it had not officially — or unambiguously — announced a policy of enforcement discretion. This dilemma prompted a number of trade associations to request guidance from FDA on when the agency will begin to enforce these requirements.

Deputy Commissioner for Foods Michael Taylor issued letters responding to those requests, and stated that "FDA will expect to enforce compliance with these new FSMA requirements in timeframes that will be described in the final rules."[4] He also noted that FDA is committed to "timely" implementation of FSMA.

NEXT STEPS FOR THE FOOD INDUSTRY

Deputy Commissioner Taylor's response prompts the question of what steps companies should take in the meantime. Even if FDA were to publish proposed rules for the hazard analysis and preventive controls requirements and foreign supplier verification program in the near future, it could take a year — or longer — for the agency to digest comments, revise the rules, and obtain internal and external approval of the rules. At the same time, the delay in implementation offers a valuable opportunity to prepare, particularly as FDA inspectors have become increasingly assertive since the passage of FSMA.

Food producers may wish to consider the following when determining their next steps:

- **Put the infrastructure in place.** Regardless of what the final regulations say, companies will need subject matter experts who are well-versed in the concepts of hazard analysis, establishment of critical controls, and supplier verification. FSMA requires companies to have an understanding of current food safety risks and to apply controls commensurate with those risks. Ensuring that your quality staff is trained and up-to-date on these concepts, industry standards, and the basic requirements of FSMA will help ease the process of compliance.
- **Determine what you can (and should) do now.** FDA has stated that it plans to utilize the existing best practices of industry when determining the hazards facilities must analyze and the preventive controls they must implement. FDA has recognized that there is no need to start from scratch when many food companies and third parties have extensive experience with the types of activities that will be required. If a widely accepted best practice or industry standard exists for your type of food production, it is likely that FDA will borrow heavily from it. In such cases, adopting these practices now will likely give your company a head start on implementation.
- **Expect inspectors to dig deeper.** FDA inspectors have become more aggressive in recent months, and the agency has issued warning letters for cGMP violations at an increased rate. Now may be a good time to ensure that your plant personnel and other relevant employees are ready for an inspection. Companies may wish to review their inspection policies to ensure they are appropriate and sufficient in the current environment, and may want to be sure that key employees are appropriately trained on those policies.

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[3] FDA, Frequently Asked Questions (June 14, 2012), *available* here.
[4] Copies of those letters are posted on FDA's website, *available* here.

- **Decide what types of documents will be provided to FDA.** By referencing the entire sections of FSMA relating to the hazard analysis and preventive controls requirements and foreign supplier verification program, Deputy Commissioner Taylor's letters to industry indicate that FDA's enforcement discretion will extend to the provisions of those sections that permit FDA to access the types of records that must be kept under those sections. The letters therefore allay concerns that FDA might still invoke its authority to access existing records that might relate to these requirements even if it did not enforce the underlying substantive requirements themselves. While FDA inspectors are likely to continue requesting a broad range of records, it is important for companies to understand the bounds of FDA's authority to access and copy records. While companies may voluntarily provide records to FDA beyond those to which the agency would be entitled by statute, companies ideally should make decisions in advance of an inspection as to what documents they will provide. They should then prepare for such records disclosures by organizing them and segregating them from records that will not be provided, and by marking trade secret or confidential information as such in advance of any inspection.
- **Keep in mind that some facilities may be exempted or subject to reduced requirements.** FSMA lists several types of facilities that FDA may exempt from some of all of the section's requirements. Of note, the American Bakers Association (on behalf of a coalition) filed a citizen petition asking FDA to invoke its authority to exempt certain storage facilities from compliance with the hazard analysis and preventive controls requirements if the facility is already in compliance with applicable cGMP requirements. In addition, FDA has stated that it recognizes that these requirements are intended to be applied in a risk-based manner, meaning that the types of activities required should be commensurate with the risks involved.
- **Prepare for facility reregistration.** The biennial facility re-registration period mandated by FSMA will begin in October of this year. Companies should prepare to ensure that all facility registrations are up-to-date, and should also take the opportunity to determine whether any facilities appropriately may have their registrations cancelled. When the registration requirement was initially imposed under the Bioterrorism Act, there was no down-side to registering, and many companies took an over-inclusive approach. Now that key FSMA requirements are imposed on facilities required to register, it may be appropriate and prudent to cancel the registrations of facilities that are not truly subject to the registration requirement or are eligible for an exemption from the requirement.

Covington & Burling LLP will continue to closely monitor FDA's implementation of FSMA. We will be happy to answer any questions about FDA's statement of enforcement discretion or FSMA more generally.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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