

MEMORANDUM

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Re: **FDA Food Safety Modernization Act Implementation Update**

Next week, the FDA Food Safety Modernization Act (FSMA) will be nine months old. In the short time period since the Act was signed into law by President Obama on January 4, 2011, the Food and Drug Administration (FDA) has been very busy implementing the new law and preparing for upcoming rulemaking activities. FDA has conducted extensive pre-rulemaking outreach to interested stakeholders and already has completed an initial set of statutory requirements. In addition, several provisions in the new law already are in effect. FDA's activities will only accelerate in the next several months, particularly as it promulgates regulations to implement key provisions in the Act. Accordingly, this memorandum briefly surveys FDA's activities to date, outlines where we can expect to see activity in the coming months, and notes several key issues warranting close attention by the food industry.

FDA Outreach

In accordance with a new Executive Order issued last winter [1/](#), FDA has conducted an unprecedented amount of pre-rulemaking outreach activities in order to gain stakeholder input for their extensive rulemaking mandate. These activities may be summarized as follows:

- **Public Meetings.** This spring, FDA conducted three day-long public meetings dedicated to FSMA's import, preventive controls, and inspection and compliance provisions, respectively.
- **Dockets.** In association with each of these public meetings, FDA opened a docket for stakeholders to submit written comments on rulemakings related to these provisions. In addition, FDA opened a docket for guidance documents to support the preventive controls rulemaking.
- **Trade Association Meetings.** FDA held several meetings with multiple trade associations to discuss key implementation issues.

[1/](#) Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011).

- Subject Matter Expert Meetings. The agency also has held several smaller meetings pairing FDA personnel with industry subject matter experts, thereby allowing for a more detailed discussion on specific provisions in the upcoming rulemakings.
- Other Communication. Mike Taylor, Deputy Commissioner for Foods, has given numerous speeches on FSMA and has published an article on the new law in the New England Journal of Medicine. ^{2/} FDA also has a website and blog dedicated to FSMA, and has posted short videos on its website of FDA experts explaining key provisions in the Act.

FDA Actions

FDA has met a number of the early statutory deadlines, as follows:

- Recall Website. As required by FSMA, FDA created a consumer-friendly searchable database for recalls.
- Interim Final Rules. FDA published interim final rules to implement the expanded prior notice requirement and the expanded administrative detention provision in the Act.
- Traceability Pilots. FDA selected the Institute of Food Technologists to conduct the traceability pilot projects. FSMA specifies that FDA must initiate the pilot projects within nine months of enactment.
- Anti-Smuggling. FDA issued its strategy to better identify and prevent the entry of smuggled food into the U.S. FSMA required FDA and the Department of Homeland Security (DHS) to develop and implement this strategy within 180 days of the law's enactment.
- Fee Notice. FDA published a notice outlining the fee schedule for new fees authorized by FSMA. The notice also summarized the circumstances where FDA intends to assess the new fees, particularly the new reinspection fees. ^{3/}
- Qs & As. FDA has published numerous Questions and Answers regarding provisions in the law on its website.
- Statements on Implementation. Significantly, FDA has clarified during meetings with stakeholders that the agency will not enforce two key provisions in the law, preventive controls and the foreign supplier verification program, until the agency has promulgated final regulations on those provisions and allows time for implementation.

^{2/} See Hogan Lovells memoranda *Michael Taylor Publishes Article about FSMA in the New England Journal of Medicine*, August 19, 2011.

^{3/} See Hogan Lovells memoranda, *Food Safety Modernization Act and Fiscal Year 2012 FDA Fee Schedule*, August 1, 2011.

- Other. FDA also has: (a) issued a draft guidance clarifying its expectations for new dietary ingredient notifications; (b) updated its guide to the seafood industry on hazards associated with fish and fishery products and appropriate controls for those hazards; (c) issued several reports mandated by FSMA; and, (d) taken steps to ensure better coordination with states.

Provisions Already in Effect

Several provisions of FSMA have already taken effect, as follows:

- Suspension of Registration. FDA is authorized to suspend a facility’s registration if the agency determines that food manufactured, processed, packed, or held by that facility “has a reasonable probability of causing serious adverse health consequences or death.” Informal hearings to challenge a suspension determination are permitted, but FDA has not yet issued regulations outlining the hearing procedures or the process for reinstatement. Note that any facility with a suspended registration will be prohibited from importing or otherwise introducing food into interstate commerce.
 - For a facility that merely packs, receives, or holds food, the standard for suspension of registration is narrowed to those circumstances where the facility “knew or should have known” that the food posed a reasonable probability of causing serious adverse health consequences or death. This standard prevents a warehouse operator from being held accountable for contamination caused by the manufacturer.
- Mandatory Recall Authority. FDA now has mandatory recall authority if a company refuses to voluntarily recall a product for which “there is a reasonable probability” that the food is adulterated or contains an undeclared food allergen and consumption of the food will cause “serious adverse health consequences or death.” This is the same standard as applies to a Class I recall. Civil money penalties and other fees can be assessed if a company fails to comply with a mandatory recall order.
- Expanded Prior Notice Requirement. A prior notice for an imported food must identify any country to which the article of food has been shipped, but refused entry.
- Expanded Administrative Detention Authority. FSMA broadens FDA’s administrative detention authority that was granted under the Bioterrorism Act of 2002 and provides FDA with authority to administratively detain food whenever the agency “has reason to believe” that a food “is adulterated or misbranded.” However, administrative detention remains an adjunct to the formal seizure process and may only be put in place temporarily (restricted to a maximum of 20-30 days) while the seizure process is pending.
- Expanded Emergency Records Access. Under authority granted by the Bioterrorism Act of 2002, FDA previously had “emergency access” to and authority to copy all records relating to an article of food that the agency reasonably believes will cause serious adverse health consequences or death to humans or animals. This authority is expanded

by FSMA to also include “any other article of food” that FDA “reasonably believes is likely to be affected in a similar manner.”

- Reinspection Fees. As of October 1, 2011, FDA will assess fees of \$224/per person/per hour (or \$325 if foreign travel is required) against: (1) domestic and foreign facilities to cover reinspection-related costs; (2) importers to cover reinspection-related costs; and (3) any facility to cover recall-related activities performed by FDA if the facility refuses to comply with a mandatory recall order.
 - FDA will assess import reinspection fees in at least the following four specific situations: (1) reconditioning of imported food; (2) importers seeking admission of an article that has been detained; (3) entities requesting removal from an import alert for detention without physical examination; and (4) destruction of food that has been refused admission.

Issues to Watch

The following issues are likely to gain increased attention as FDA’s implementation efforts progress:

- Remote Access to Food Safety Plans. FDA continues to express considerable interest in requiring food facilities to electronically submit their food safety plans to the agency, even though the final legislation, unlike the House bill, did not contain a provision granting the agency remote access to records.
- Mandatory Product Testing. The agency appears to be considering the extent to which product testing programs in food facilities should be required as part of the facility’s food safety plan verification activities.
- Traceability. In its Q&A on the traceability pilot projects, FDA explained that, although FSMA specifies that new traceability requirements must apply only to high risk foods, FDA will be seeking input from stakeholders in considering whether to develop voluntary guidance for foods beyond those designated as high risk to enhance product tracing in the supply chain.
- Third Party Audits. FDA appears open to considering the use of third party audits as a verification activity under the foreign supplier verification program.
- Consultative Audits. In its Q&A, FDA has stated that auditors who perform consultative audits, which are audits for internal purposes only, must immediately notify FDA if they discover a condition that could cause or contribute to a serious risk to the public health. More information on this issue should be provided in the agency’s forthcoming proposed rule on third-party accreditation.
- Warehouses. The American Bakers Association and a number of other trade associations have filed a petition with FDA seeking an exemption for warehouses from the preventive

controls requirement that each registered facility have a food safety plan. FSMA grants FDA the authority to issue this exemption, at the agency's discretion.

- User Fees. When the Prescription Drug User Fee Act (PDUFA) is reconsidered in Congress next year, FDA may ask Congress to impose additional user fees on food companies to help fund implementation of FSMA.

What's Next

Food companies should expect to see FDA issuing several proposed rules late this fall, likely in November or perhaps early December. The agency's current priorities appear to be preventive controls, fresh produce standards, the foreign supplier verification program, and third party accreditation standards. We anticipate that the comment periods for these proposals will be relatively short – no longer than sixty days. Given the statutory deadlines for implementation and FDA's considerable pre-rulemaking activities, we do not anticipate the agency will grant extensions to the comment periods. Final rules are likely to be issued next summer and no later than the end of 2012.

Conclusion

FDA has been very open and engaging with industry during this initial pre-rulemaking phase. At the same time, the agency appears driven to meet the statutory deadlines in the Act. We predict this drive will continue, and perhaps accelerate next year as the fall 2012 elections approach. Therefore, food companies should already be preparing, as implementation and enforcement of key new responsibilities are just around the corner.

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We will continue to monitor FDA's implementation of FSMA. Please contact us if we can help analyze the law and its potential effects or develop comments to the agency as FDA promulgates implementing regulations.