Preparing for FSMA: A Focus on Records Maintenance and Access

By Elizabeth Barr Fawell and Maile Gradison Hermida

Historically, food manufacturers have had to share very few records with the Food and Drug Administration (FDA). That will radically change when several of the major provisions in the FDA Food Safety Modernization Act (FSMA) become effective. Under FSMA, food manufacturers will be required to maintain a wide scope of records and make those records available to FDA. This will significantly alter the character of a facility inspection. Even those companies that have traditionally shared their records voluntarily with FDA during an inspection will need to review and revise their recordkeeping practices because FDA will use its records review authority to hold manufacturers accountable for food safety. As a result, there are several steps that companies can start taking now to prepare for inspections under this new paradigm.

New Recordkeeping Requirements

FSMA affects recordkeeping requirements in several areas. The most substantial new recordkeeping requirements are found in the Hazard Analysis and Risk-Based Preventive Controls and Foreign Supplier Verification Program (FSVP) provisions of the Act.[1] These two provisions affect all registered food facilities and all food importers, respectively; are the most significant and comprehensive provisions in the

Ms. Fawell is an Associate at the law firm of Hogan Lovells in Washington, DC.

Ms. Hermida is an Associate at the law firm of Hogan Lovells in Washington, DC.

law; and are the agency's priority for implementation.

Preventive Controls. The preventive controls provision of FSMA, Section 103, requires registered facilities to maintain a written food safety plan and all supporting documentation. Specifically, facilities will need to document their hazard analysis and the preventive controls they are implementing to address those hazards, including any critical control points. They also will need to maintain records documenting the monitoring of those preventive controls, "instances of nonconformance material to food safety, testing results and other appropriate means of verification, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions." Because preventive controls include sanitation procedures, hygiene programs, allergen control programs, current Good Manufacturing practices, supplier verification activities, and more, there are number of different types of records that are included within this provision. In addition, manufacturers will need to create and maintain food defense plans and related records.

Foreign Supplier Verification. All food importers also will be required to create and maintain documents regarding their FSVPs. Section 301 of FSMA requires the maintenance of all records related to such programs. Therefore, importers will need to maintain records documenting their risk assessments and verification activities. Verification records may include monitoring records for shipments, lot-by-lot certifications of compliance, on-site inspection audit reports, suppliers' food safety plans, incoming product testing results, and/or whatever other means the manufacturer or importer uses to meet this new requirement.

Records related to food safety plans and the foreign supplier verification program must be maintained for two years.

FDA's Records Access Authority

Corresponding to the new recordkeeping obligations for industry, FDA now has access to these records. Therefore, among other things, FDA will have the ability during inspections to review manufacturing records, environmental and product testing programs and results, certificates of analysis, audits and other verification activities of suppliers and co-manufacturers, and food safety plan validation materials. It is possible that the agency may consider other types of documents to fall within this scope as well. FDA will need to clarify such issues as the agency engages in rulemaking to implement FSMA's preventive controls and FSVP requirements.[2] Certain categories of documents that have long been exempt from disclosure under the Federal Food, Drug, and Cosmetic Act, such as organizational charts, proprietary formulas, and financial records, remain exempt under FSMA. Nonetheless, the scope of records FDA has the authority to review is quite broad.

As a result, the nature of a facility inspection will change as FDA shifts from its current approach, where inspections are largely based on observations in a facility, to one more like an audit, where FDA will engage in a detailed review of a facility's records. Food companies should bear in mind that failure to provide FDA with access to records to which it is entitled is a prohibited act. At the same time, failure to keep those records also is a prohibited act. Because FDA has the authority to review such a broad range of food safety records, food companies will need to work with inspectors to ensure that that the agency reviews those records most relevant to the facility's food safety controls. Those food companies producing products currently subject to mandatory HACCP requirements such as juice, seafood, and meat and poultry products, should draw on their experience with inspections under those programs as they prepare for FSMA.

Food manufacturers also should keep in mind that FDA has extensive access to records during emergencies, when the agency has "a reasonable belief that an article of food presents a threat of serious adverse health consequences or death." Expanding on the authority initially created by the Bioterrorism Act of 2002, under FSMA FDA now has authority to access and copy all records relating to "any other article of food that the Secretary [of Health and Human Services] reasonably believes is likely to be affected in a similar manner." Such related articles would likely include food produced with the same suspect ingredient or on the same manufacturing line. Of note, this expanded authority is already in effect.

How to Start Preparing Now

Although FDA still needs to develop and issue regulations to fully implement FSMA, there are many steps that companies can start taking now to begin preparing for the new recordkeeping and access requirements.

As a general matter, companies should begin by assessing their current recordkeeping practices and take appropriate steps to ensure that their records are complete, well-organized, and readily accessible. Records are a facility's best opportunity to show FDA that it is in control of food safety. Significantly, a facility's records should be able to tell the whole story on their own, and companies should keep in mind that if an action or decision is not documented, it did not happen from an inspector's perspective.

There are two areas in particular where we recommend food manufacturers take a close look at their current practices: corrective actions and supply chain management. First, manufacturers will need to ensure they accurately document the actions they take when corrective actions are necessary. Records of corrective actions should explain both the action taken and the basis for that action. We expect that FDA inspectors will focus on a facility's corrective action records, as those are the records that show potential problems and how the facility responded.

Second, FDA will have access to supply chain management records for both domestic suppliers (as a preventive control) and foreign suppliers (as part of the FSVP). Companies should consider what records they will need to maintain to document their activities regarding their suppliers and co-manufacturers. Relevant records should demonstrate both risk assessments and verification steps.

In preparing for the agency's increased records access authority, companies also should consider the following additional issues:

Training. The employees that create records on a daily basis (e.g., monitoring preventive controls) need to understand the importance of their responsibilities. Companies should consider whether to conduct good recordkeeping trainings to ensure their records accurately reflect their food safety practices. In addition, employees will need to be educated about FDA's new authority to access records and how the nature of facility inspections will change accordingly.

Retention. It may be necessary for companies to change their records retention plans to ensure that all applicable records are available to FDA inspectors for two years after they are created.

Storage. Companies should review what records they currently have (and what records they will need to create), whose responsibility they are to maintain, and where they are kept. FDA likely will clarify further the requirements in this area as part of its rulemaking, addressing issues such as storage of records electronically or at a central facility and the amount of time within which records must be made available.

Inspections. Facilities should consider designating an employee that is responsible for reviewing records with inspectors. This individual should be familiar with the available records so that they can clearly explain to inspectors the significance of the records that they are reviewing. Companies should think about whether their facility inspection manuals should be revised to reflect FDA's new records access authority.

FSMA provides that the preventive controls provision takes effect on July 3, 2012, and the foreign supplier verification program becomes effective on January 4, 2013. We anticipate, based on public statements by agency officials,[3] that FDA will delay enforcement of these requirements until a reasonable period after it publishes final regulations implementing the new programs. Nonetheless, these dates are soon approaching and there are many things that food companies can and should start doing now to make sure they are ready when the new recordkeeping and access requirements take effect.

Conclusion

FSMA contains several new recordkeeping requirements for food companies. These new recordkeeping and access provisions will significantly change the nature of FDA inspections. As FDA's emphasis during inspections shifts to a systems-based assessment of a facility's compliance with the law, it will be essential for facilities to create and maintain complete and thorough records. Companies will be well-served to start preparing now for the new records requirements, if they have not started doing so already.

1. FDA Food Safety Modernization Act §§ 103; 301 (2011). In addition, FSMA gives FDA the authority to require additional recordkeeping for high risk foods in order to improve product tracking and tracing. There are several statutory limits on any new rules and FDA is not expected to work toward implementing new traceability requirements until after the pilot projects are completed, some time in the late spring of 2012. Further, while we anticipate that FDA will include recordkeeping requirements as part of any regulations addressing fresh produce safety, as well as the Voluntary Qualified Importer Program, FSMA does explicitly address such requirements.
2. As of this writing, FDA has not yet published proposed rules regarding preventive controls or the foreign supplier verification program.
3. Joan Murphy, *FDA Food Safety Modernization Act Dissected, Part 11: Taylor says FDA will take practical route in implementing FSMA deadlines*, 53 Food Chemical News 11 (May 20, 2011) *available at* http://www.agra-net.com/portal2/fcn/home.jsp?template=pubarticle&artid=1305827161775&pubid=ag096.