White Paper

Preparing to Meet the Requirements of

The Food Safety Modernization Act

The Food Safety Modernization Act of 2011 places the responsibility for food safety squarely on food producers, with requirements that will come into force as finalized and funded. Food processors and manufacturers should begin now to prepare their operations to meet these requirements, rather than waiting for them to come into full force. This paper recommends actions that food processors can take now to prepare for the full implementation of the law, including reviewing the effectiveness of their existing product inspection systems and their ability to provide the reporting data FSMA requires.

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1 Introduction

With the signing into law in January 2011 of the Food Safety Modernization Act (FSMA), the federal government has mandated legal requirements affecting the production and distribution of food products for companies throughout the food supply chain. These requirements will affect companies from food growers through processors and manufacturers to those that deliver food products to consumers. This paper addresses those requirements affecting food processors and manufacturers.

What will these new requirements mean for food processors and manufacturers? How will they change the way your company works? How can you best prepare for the new FDA inspections?

The FSMA gives broader powers to the Food and Drug Administration (FDA) that will shift the FDA's approach to food safety from responding to outbreaks of foodborne illnesses to preventing them from occurring. This will be accomplished by holding food production facilities accountable for implementing safe and effective measures to maintain food safety, including developing written procedures for eliminating and/or controlling potential hazards. This accountability will be enforced by an expanded inspection capability that FSMA gives to the FDA, along with the authority to issue mandatory recalls for food products it has reasonable belief of being unsafe. The new law also re-quires companies to maintain more thorough and accurate records of their operations and their hazard control activities.

This paper briefly outlines the elements of the new law and then focuses on the direct effect they will have on food processing and manufacturing companies in terms of new procedures and new record keeping. It also recommends actions that food processors can take now to prepare for the full implementation of the law and reviews the progress of the implementation of the new requirements.

2 Basic Provisions of the Food Safety Modernization Act

The following is a brief overview of the four main areas of the FSMA law:

Improving the Capacity to Prevent Food Safety Problems

FSMA alters FDA's approach to food safety from a system that responds to outbreaks to one that works to prevent them. This new approach holds food processing companies accountable for controlling contamination and is a significant change in the food safety system. Food production facilities will have to evaluate the hazards in their operations and develop effective measures to prevent food contamination, supported by written documentation. Facilities will also be required to create a plan for taking corrective action when it may become necessary.

Improving the Capacity to Detect and Respond to Food Safety Problems

FSMA requires each food production facility to register with the FDA. Each registered facility is required to conduct a hazard analysis of its operation and develop and implement a written preventive controls plan to ensure that food is not adulterated, misbranded or incorrectly labeled. The written plan must include these elements: hazard analysis, preventive controls (including preventive controls at critical control points, if any), monitoring, verification, corrective actions, and record keeping.

Improving the Safety of Imported Food

FSMA expands the FDA's ability to achieve greater oversight of the millions of food products coming into the United States annually from other countries, which constitutes an estimated 15 percent of the U.S. food supply, 60 percent

of fresh fruits and vegetables and 80 percent of seafood. This includes overseeing the ingredients, flavorings, etc., imported by U.S. food processors. More specifically, to increase import food safety, FSMA:

- Requires importers to perform supplier verification activities to ensure that imported food is safe
- Authorizes the FDA to refuse admission to imported food if the foreign facility or country refuses to allow an FDA inspection
- Authorizes the FDA to require certification, based on risk criteria, that the imported food is in compliance with U.S. food safety requirements
- Provides an incentive for importers to take additional food safety measures by directing the FDA to establish a voluntary program through which imports may receive expedited review of their shipments if the importer has taken certain measures to assure the safety of the food

Miscellaneous Provisions

These provisions cover funding of the food safety functions of the FDA, expansion of the FDA workforce (adding more specialists, inspectors, etc.) and includes whistle-blower protections for those reporting failures to the FDA.

3 FSMA Requirements that Affect Food Production Facilities

The following are the primary requirements that FSMA imposes on food production facilities:

Registration

Food production facilities are required to register with the FDA biennially. As of January 2012, approximately 140,000 U.S. and nearly 200,000 foreign facilities had registered. Registration is critical, since food from an unregistered facility may not be imported into the United States or be introduced into U.S. interstate or intrastate commerce.

Registered food facilities are required to conduct thorough hazard analyses of their operations and to develop and implement written preventive hazard controls plans. This analysis is to be updated every three years, and more often if a significant change is introduced into the production process. Registered food facilities must also maintain detailed records for at least two years, including copies of their hazard analyses and preventive controls plans, related records, and additional records to assist the FDA in tracking and tracing high-risk foods.

Preventive controls

Preventive controls are science and risk-based practices that facilities will use to address hazards that their products might be exposed to. The FDA is currently finalizing what those practices will involve. These controls may include:

- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where food is exposed to a potential environmental contaminants;
- A food allergen control program
- A recall plan
- Current Good Manufacturing Practices under 21 C.F.R. Part 110
- Supplier verification activities related to food safety

Once these preventive controls are in place, facilities will be required to monitor them to ensure that they are performing as designed.

Inspections

Under FSMA, the FDA is required to identify high-risk facilities and to allocate resources to inspect registered facilities according to their risk profile, based on the following factors:

- The known safety risks to the food manufactured, processed, packed, or held at the facility
- The facility's compliance history, including past recalls, outbreaks, and violations
- The rigor and effectiveness of the facility's hazard analysis and preventive controls
- Whether the facility or its products have been certified by an accredited third-party auditor (See **Certification** below)
- Whether the food manufactured, processed, packed, handled, prepared, treated, distributed, or stored at the facility meets the criteria for priority under FD&C Act section 801(h)(1)

Record Keeping

The manner in which companies respond to a FDA records request remains unchanged, as does the type of documents that may have to be provided to the FDA in response to a records request. But FSMA expands the FDA's former records access (formerly to records related to a specific product that the FDA reasonably believes is adulterated) to now include records relating to any article of food that is reasonably likely to be adulterated.

The owner, operator, or agent in charge of each facility is required to maintain a copy of its written preventive controls plan. Facilities must also maintain for at least two years their records of monitoring, instances of nonconformance that are material to food safety, corrective actions, verification and the efficacy of preventive controls and corrective actions. Such records must be made available to the FDA promptly upon oral or written request.

4 Preparing to Comply with the FSMA Requirements

The new law mandates 50 major deliverables from the FDA – regulations, guidance positions for industry and more than a dozen reports to Congress – all due over the first two or three years of the law's life. Few have been actualized to date. Criticism about the delays has come from many areas of the food industry. However, in spite of these delays and criticisms, there is no doubt in the industry that FSMA will be fully in force in the near future.

Therefore, rather than wait for the regulations to be in force, manufacturers are strongly advised to prepare for them by performing the risk assessments on their processing lines and creating the written documentation that FSMA requires. As a processor, you will be held accountable for putting into place reliable technical systems and controls that minimize your risks, such as implementing inspection solutions to detect foreign object contamination, damaged packaging, mislabeling and other defects that can affect food safety. METTLER TOLEDO, as an experienced supplier of quality product inspection systems including metal detection, X-ray inspection, checkweighing and vision, has food safety regulation experts ready to assist in all compliance matters.

Preventive Action

To begin the assessment required by FSMA, your facility should immediately begin to review its existing production procedures to identify current hazards, critical control points, auditing and documentation, and your existing

hazard analysis plan, then correct hazardous conditions and create a written description of the assessment and the corrective actions taken. If your facility does not have an existing hazard analysis plan in place, it is even more critical to begin immediately to create one, employing specialized consultants if necessary to ensure its thoroughness.

It is also important to do a thorough examination of your facility's records and record keeping procedures to ensure that they are ready for an FDA inspection. This should include examining how your production equipment and controls assist by keeping up-to-date records, including numbers of rejects, reworks, etc. For example, in the past, the primary concern in evaluating product inspection systems was the sensitivity of the inspection devices. But enactment of FSMA has caused that emphasis to shift towards compliance and documentation. METTLER TOLEDO views an inspection system as a component of a complete foreign body prevention program, properly installed, validated and continuously monitored, and able not only to conduct inspection but also to keep records that will satisfy future FDA inspections.

You should also evaluate your facility's capabilities and record keeping regarding product tracing. METTLER TOLEDO food safety regulation experts can help you determine whether it is possible to trace forward and trace back each product movement, and enhance that capability as necessary. This data will be critical in determining where in the supply chain adulteration may be occurring and taking necessary corrective action.

Imports

If your facility imports ingredients, flavorings, etc., you should determine whether current supplier qualification and audit methods are being used and whether they are sufficient to meet the requirements of the FDA. Today, electronic shipping data and COAs (Certificates of Analysis) are becoming more common and more reliable, and can greatly simplify the assembly of these records for inspections.

Your quality control group should also determine if the product and ingredient testing methods you currently use to evaluate incoming products and raw materials when necessary are adequate to meet FDA certification requirements.

Certification

With the FSMA's more stringent requirements in mind, many manufacturers and suppliers are seeking certification from a globally-accepted food standard to reinforce their commitment to proactive prevention of contamination and assessment of their preventive systems. Such certification is one of the determining factors for FDA's decision to initiate an inspection.

The Global Food Safety Initiative (GFSI) was set up in 2000 as a non-profit foundation with the intention of ensuring worldwide consumer confidence in food safety. GFSI benchmarks existing food standards against food safety criteria with the goal of standardizing certifications and eliminating multiple audits.

The four most widely used manufacturing certification schemes approved by GFSI are:

- BRC Global Standard for Food Safety
- FSSC 22000
- IFS (International Featured Standard) Food
- SQF CODE

All GFSI-accepted standards, whether for primary or secondary production, must meet three main areas of certification requirements:

- Companies must demonstrate that they have a food safety management system
- Companies must demonstrate Good Manufacturing Practices (GMP)

- Companies must demonstrate that they have conducted a Hazard Analysis and identified the Critical Control Points in line with HACCP principles

Certification does not in itself eliminate the likelihood of an FDA inspection, but it demonstrates a facility's commitment to meeting the requirement that it focus on safety and creates a structure for continually improving production quality processes. In addition, recognized certification that proper manufacturing procedures are in place benefits both the company and its customers, and therefore also helps to enhance the manufacturer's brand reputation and profitability.

5 Summary

The Food Safety Modernization Act is generally regarded as a positive change, both by food safety proponents who have lobbied for it for at least ten years, and by the food industry itself, which recognizes not only the benefit it brings of avoiding illnesses and saving lives, but also of reducing the likelihood of the product recalls and liability lawsuits that have led to substantial unpredicted costs and loss of brand value in the past.

The new law will require both added effort and financial expense from food producers, but these should be viewed as investments leading to the reduction of potential costly losses due to unsafe foods entering the marketplace. The close review of production procedures and equipment for safety hazards required by FSMA also offers the opportunity for greater productivity as systems are upgraded and streamlined as a result. Newer systems – both production and inspection systems – that may be installed as a result of the review will also introduce increased automation into production lines, further increasing productivity and reducing labor costs.

The sooner facilities begin the analysis and documentation process, the more confident they will be of meeting the new FSMA requirements and avoiding potential costly inspections, recalls and liability suits.

6 Additional Resources

- FDA, Food Safety Modernization Act, FSMA – www.fda.gov/food/foodsafety/fsma/
- METTLER TOLEDO, Meet Global Food Safety Standards and Increase Productivity and Profitability – www.mt.com/food-regulations
- METTLER TOLEDO, The Guides to Implementing Effective Metal Detection, X-ray Inspection, Checkweighing and Vision Inspection Programs – www.mt.com/pius-guides
- METTLER TOLEDO, White Papers – www.mt.com/pi-whitepapers
- METTLER TOLEDO, On-demand Webinars – www.mt.com/pius-ondemand
- Food Safety Exchange – www.foodsafetyexchange.com
- Global Food Safety Initiative (GFSI) – www.mygfsi.com
- GLOBAL TRENDS IN FOOD SAFETY, Robert J. Parrish, Vice President Global Food, SGS Geneva – Consumer Testing Services – www.sgs.com

Notes

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