White Paper

Preparing to Meet the Final Requirements of The Food Safety Modernization Act

The Food Safety Modernization Act of 2011 (FSMA) placed the responsibility for food safety squarely on food producers, with requirements that were to come into force as finalized and funded. The dates by which those requirements will take effect have now been finalized and are rapidly approaching.

Many food processors and manufacturers have wisely been preparing their operations to meet these requirements, rather than waiting for them to come into full force. Others were waiting to see whether the requirements would indeed become law or would be once again delayed, or even cancelled. Now the decision has been made, and the time for action has arrived.

This paper recommends actions that food processors should now take to meet the full requirements of the FSMA law, including reviewing the effectiveness of their existing product inspection plan and the systems that will help put it into action, and confirming their ability to provide the reporting data that FSMA requires.

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METTLER TOLEDO

1 Introduction

With the signing into law in January 2011 of the FSMA, the federal government mandated legal requirements affecting the production and distribution of food products for companies throughout the food supply chain. These requirements affect companies from food growers through processors and manufacturers to those that deliver food products to consumers. This paper addresses only 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, effective and documentable 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 requires 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, then focuses on the direct effect they will have on food processing and manufacturing companies in terms of new procedures and new recordkeeping. It also recommends actions that food processors can take to meet the requirements governing verification of foreign supplier food safety programs and recommendations about inspection equipment and electronic data collection systems that can help you meet those 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:

Relying on Your 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 concrete plan for taking corrective action when it may become necessary.

Improving Your 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 recordkeeping.

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 include whistleblower protections for those reporting failures to address food safety hazards 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 and renew their registration biennially in even-numbered years. The FDA reported in 2015 that 166,753 food facilities globally had registered with FDA. 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 company's 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

The FDA's FSMA Preventive Controls for Human Food rule is now final, and compliance dates for some businesses will begin in September 2016.

The FDA's final Rule for Preventive Controls for Human Food includes elements of both its original and supplemental proposals, in addition to new requirements that are the outgrowth of public input received during the comment

period for earlier proposals. The rule does require preventive controls based only on hazard analysis, but describes those controls as being "similar" to the traditional HACCP system, and including controls that may be required at points other than the traditional Critical Control Points.

The rule revises FDA's current good manufacturing practice (cGMP) regulations regarding the manufacturing, processing, packing, or holding of human food in two fundamental ways. First, it adds new preventive controls provisions as required by FSMA. Second, it updates, revises, or otherwise clarifies certain requirements of FDA's existing cGMP regulations, which were last updated in 1986.

The preventive controls provisions apply to facilities that are required to register under FSMA. These controls require those facilities to:

- Create and maintain a written food safety plan that includes an analysis of hazards and risk-based preventive controls;
- Perform hazard analysis;
- Establish preventive controls for hazards that are reasonably likely to occur;
- Monitor controls performance through verification activities;
- Take corrective actions;
- Validate that controls are effective; and
- Maintain associated records.

One of the most significant changes from the original FSMA law contained in the final rule is that the application of the preventive controls would be required only in cases where facilities determine that hazards are reasonably likely to occur. The FDA does not expect that all possible preventive measures and verification procedures will be applied to all foods at all facilities. This means that each food manufacturer or packager will be able – within reason and with FDA acceptance – to tailor its preventive controls to its specific products and facilities.

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).

Recordkeeping

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 food product that the FDA deems 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 Dates by Which FSMA Requirements Will Take Effect

In settlement of a lawsuit brought by two consumer advocacy groups to compel deadlines for final publication of the rules that form the cornerstone of FSMA, the FDA has published, or will publish, the final rules in the following timeline:

- August 30, 2015 – Preventive control rules for human food and preventive control rules for animal feed
- October 31, 2015 – Produce safety standards, foreign supplier verification program, and accreditation of third party auditors
- March 31, 2016 – Sanitary transport of food and feed
- May 31, 2016 – Intentional adulteration of food

The additional time needed to publish these final FSMA regulations has encouraged some in the industry to question whether FDA will ever completely enforce FSMA. This has led some food companies to believe they will be able to operate "below the radar" of FSMA and FDA, even after FSMA is fully implemented in 2016.

Congress, however, built into FSMA a powerful deterrent to discourage any food company from trying to avoid the FSMA preventive processes or otherwise allow unsafe food to enter the supply chain. FSMA encourages employees to report employers' unsafe food practices to the FDA. In addition, in February 2014, the Occupational Safety and Health Administration (OSHA) published interim final regulations that govern FSMA's whistleblower provisions, establishing systems and time frames for the filing, handling and investigation of, and ruling on, FSMA-related retaliation complaints.

5 Complying with the FSMA Requirements

The FSMA law mandated 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 as scheduled, but all the regulations have now been, or are in the final stages of being, finalized. Criticism about the delays has come from many areas of the food industry. However, in spite of these delays and criticisms, it is clear that FSMA's requirements will be fully in force in the very near future.

Manufacturers are strongly advised to prepare to be able to meet them by performing the required risk assessments on their processing lines and creating the written documentation that FSMA demands. 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. The use of including metal detection, X-ray inspection, checkweighing and vision inspection can assist food processors with all compliance matters.

Preventive Action

To begin the assessment required by FSMA, if your facility has not done so already, it should immediately begin to review its existing production procedures to identify current hazards, critical control points, auditing and documentation capabilities, and your existing hazard analysis plan. It should then correct existing 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 conduct a thorough examination of your facility's records and recordkeeping 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 shifted that emphasis towards compliance and documentation. An inspection system is 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 recordkeeping regarding product tracing. Consultative experts can help you determine whether it is possible to trace both forward and backward each product movement, and enhance that capability as necessary. This data will be critical in determining where in your supply chain adulteration may be likely to occur and taking necessary corrective action.

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 often one of the determining factors in 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 current Good Manufacturing Practices (cGMP);
- 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 focuses 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.

6 Supply Chain Requirements

One of the larger developments to come out of the new regulations is the requirement that manufacturers establish a supply chain verification program. Specifically, it requires that suppliers of raw materials to manufacturers adhere to the regulations as well and makes it the responsibility of the manufacturer (or "receiving facility") to ensure this is the case: "A receiving facility has an obligation to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated….That obligation includes responsibilities for raw materials and other ingredients when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier". While this may seem like an unreasonable burden to place on the receiving facility, the FDA clarified in a response to comments that supplier verification activities can be conducted by other entities earlier in the supply chain – although the receiving facility will still need to have documentation demonstrating the aforementioned activities were performed properly.

The motivation for this requirement is clear; the largest food recalls in recent memory were caused by adulteration of raw materials which contaminated products throughout the supply chain. With uncertainty as to where exactly their raw materials were coming from and which lots had been potentially contaminated, manufacturers had no choice but to recall millions of dollars' worth of product. From the FDA's point of view, a stronger supply chain program would have detected the adulteration sooner in the process, possibly even before the materials in question were shipped out to manufacturers.

Another function of the supply chain requirement is to ensure that food products coming into the country have been produced under the new regulations. This is referred to as the Foreign Supplier Verification Program, or FSVP. In essence, the FSVP includes importers under the requirements of the supply chain program. The verification activities are slightly less comprehensive, but importers are required to possess sufficient documentation from their sources which "provide assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented".

Supplier verification activities can include on-site audits, sampling and testing of the raw material or ingredient, review of the supplier's food safety records and any other "appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or ingredient". This last requirement is vague and will most likely be clarified by the FDA later on, but for now this vagueness makes it dangerous for manufacturers and receiving facilities to cut any corners in terms of creating and executing their safety plan.

The supply chain program also keeps the FDA from having to directly pressure foreign suppliers to follow the regulations. Instead, it makes conducting business with a company that does not have a food safety plan that follows the regulations unattractive. The receiving facility in that case would need to compensate for all food safety issues which could arise during the manufacturing or processing of the raw materials they are sent.

Like every other part of the regulations, the supply chain program requires rigorous documentation of its execution. This includes records of the supply-chain verification activities taken at each supplier facility, as well as a complete record of every supplier facility with which the receiving facility works. The regulations recommend that suppliers negotiate which hazards will be controlled where in the production chain, including the sourcing of raw materials. Those negotiations and agreements must also be thoroughly documented.

The only thing which does not necessarily require heavy documentation is the shipment of these materials, meaning there are no requirements for any sort of traceability of materials through the supply chain. It would not be surprising, however, to see the addition of such requirements as the FDA continues to evaluate its regulations.

International Manufacturers

As the supply chain program makes clear, the FDA expects international manufacturers to follow the regulations outlined in the regulations; specifically the hazard analysis and food safety plan creation. The same rules apply to international manufacturers as apply to local manufacturers, although the FDA does allow for countries with regulations considered comparable to the regulations to be recognized. The FDA clarifies this position in a response to a comment left on the draft, saying a system "officially recognized as 'comparable' to that of the United States would be one for which there is a signed systems recognition agreement or other agreement between the FDA and the country establishing official recognition of the foreign food safety system". The comment goes on to say that countries with a HACCP certificate issued by a foreign government would not be a substitute for an on-site audit, but that "such a certificate could be part of [a receiving facility's] justification for conducting another supplier verification activity in lieu of an annual on-site audit, or for conducting an audit on a less frequent basis than annually" (ibid).

In other words, there is an expectation that international manufacturers follow the same rules as those inside the United States, but the FDA is also making an effort to sign systems recognition agreements with other countries. While international manufacturers will likely be working with importers to bring their products into the United States, those importers are not likely to be prepared to invest in the equipment and manpower to control hazards caused during production. Indeed, any such hazard presumably cannot be controlled for by the time it is shipped into the country, placing the onus again on the receiving facility to pressure its suppliers to address the potential hazards (and perform verification that the hazard is being dealt with) if they do not want to be required to add information to their labels implying the product may be anything less than safe.

European manufacturers will most likely find these regulations easy to meet. EU regulations for food safety already require similar food safety plans. Specifically EU regulations require safety provisions covering each aspects of the food production chain, and even have similar supply chain requirements.

Key Takeaway for International Manufacturers

In order to export products to the US market, there needs to be either a comparable set of governmental regulations in place, or an external auditor must certify that appropriate processes are in place.

Fortunately, the onus for working out ways to demonstrate compliance with the regulations is not really on the shoulders of international manufacturers, but on the shoulders of importers. Even then, as long as proper documentation of food safety processes is easily accessible, a supplier verification activity such as an on-site audit once a year will be sufficient to satisfy the requirements

7 Label-Specific Regulations

Labeling is a particularly critical area in food safety, and perhaps one of the areas of the FDA's new regulations where it is easiest to see where a little extra effort can effectively future-proof against further rulings. The FDA reports that almost half of its recalls are due to incorrect or incomplete listing of ingredients on labels.

The regulations specifically state that part of the food safety plan must include controls to help ensure food "manufactured, processed, or held by [the] facility will not be misbranded". Food is considered to be misbranded if "it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless certain labeling requirements are met". The labeling requirements referred to are essentially an accurate declaration of ingredients, with allergens specifically highlighted or separated from the ingredient list.

It is important to note that "misbranding" does not mean the same thing as "mislabeling." A package with the correct label but a product that has been contaminated with an allergen would be considered misbranded in the same way that a product with the incorrect label applied would be considered as misbranded. When the regulations discuss "preventive controls" to address the hazard of misbranding, they are not specifically focusing on the label, but labeling does enter into the equation. The packaging and labeling process is specifically called out as being a necessary part of the hazard evaluation.

The allergen control sections of the regulations are short on specifics. This is due to a lack of any set amount of a given allergen that can be deemed 'safe.' This prevents the FDA from being able to define a minimum standard for manufacturers to target. Instead, the regulations require food safety plans be altered in the event of a product recall; essentially saying "if things go wrong, address the problem after the company has already had to pay the cost of the recall." It is very likely the FDA will eventually try to draft more specific requirements as research into allergen controls continues, but for now the requirement is regular verification that allergen controls are functioning as intended. Verification can range from testing employees' knowledge of the allergen control process to monitoring inspection equipment to ensure it is functioning properly. Any verification activities must be documented and kept in a form that is easily retrievable and presentable to the FDA should they ask for proof.

The labeling process must be subject to the same hazard analysis as every other factor of production in the facility. Manufacturers with a low number of products will not require controls to be quite as strict in their process, but every manufacturer will need a procedure to prevent any possibility of mislabeling. The judgment of what is and is not a sufficiently strict label control process is undefined. The guidelines merely make it clear that responsibility lies with the manufacturer when it comes to deciding whether or not controls are sufficiently strict. The FDA even specifically requests manufacturers send them "examples of food allergen control guides" in the comments to the document, admitting in a sense that the FDA is not yet certain what a food allergen prevention program will look like. The wording of the section makes it clear, however, that the FDA plans to develop a more rigorous set of guidelines for food allergen controls in the future.

This raises the possibility of manufacturers having to scrap their existing allergen controls should the FDA deem it necessary. The regulations state that any existing food safety plans must be corrected in the event of "new information about potential hazards associated with the food". There are two results to this. First, the FDA has the opportunity to increase the specificity of their requirements as technology improves; and secondly, it provides an incentive for manufacturers to be thorough in the development of their food safety plans to anticipate future regulations.

As an example, a manufacturer may implement a vision inspection program as part of its label control program. Vision technology is well-suited to label identification and verification applications, and can also ensure a label is not wrinkled of folded during application which would obscure the ability to read the label. Some systems can also provide detailed runtime statistics to satisfy program verification requirements. Other steps in the label control process can be added into vision systems with requirements for label control numbers and subsequent inspections to verify the proper LCN is present on the label.

Another interesting change to food labeling regulations is the additional requirement that manufacturers notify

consumers when a facility does not control for a particular hazard. This information must appear on the label and include both information on the hazard in question and "the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities)". This information must appear on the food packaging label "prominently and conspicuously" (ibid). For products which may not have a label, the regulations require the information to appear "prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales" (ibid).

Before this regulation, it was not required that manufacturers inform consumers if a food was produced in a facility along with products that include allergens or other hazards. The CGMP makes that indication mandatory if the hazard in question is not factored into the food safety plan and controlled. Even more intriguingly, the mandate that the specific facility in which that product was produced be listed on the label complicates label design, as labels would need to contain information unique to each facility—meaning for larger manufacturers, more variations of label would exist.

This regulation serves two purposes. It serves to warn consumers about the possible hazards of consuming a food not subject to the proper hazard controls. Secondly and more importantly, it encourages thoroughness in the food safety plan, as no manufacturer wants to advertise an uncontrolled hazard on their product label. Again, the final decision on how far to go in their food safety program is up to the manufacturer, but the FDA is clearly hoping manufacturers will choose to control for more hazards rather than make label design changes.

8 Summary

The Food Safety Modernization Act is generally regarded as a positive change, both by food safety proponents who have lobbied for it for more than ten years, and by the food industry itself. They recognize not only the benefit it brings of avoiding food-borne 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, since 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 can be of meeting FSMA's requirements and avoiding potential costly inspections, recalls and liability lawsuits.

9 Additional Resources

- FDA, FSMA Final Rule for Preventive Controls for Human Food: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm
- 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/pi-guides
- METTLER TOLEDO, White Papers – www.mt.com/pi-whitepapers
- METTLER TOLEDO, On-demand Webinars – www.mt.com/pi-ondemand
- Global Food Safety Initiative (GFSI) – www.mygfsi.com

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Mettler-Toledo Product Inspection
6005 Benjamin Road
Tampa, FL 33634
USA
Tel (800) 221-2624
E-mail pi.marketing@ mt.com