FSMA 101: The Must-Know Facts about the Food Safety Modernization Act
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Five of the seven rules have been released by the U.S. Food & Drug Administration and they now require owners, operators, or agents in charge of a food facility to evaluate the hazards that could affect food in that facility.

This includes identifying and implementing preventive controls, monitoring the performance of those controls and maintaining records. Here’s a quick overview of the new rules provided by the Food and Drug Administration.

**Prevention**
- Preventive controls for food facilities
- Produce safety standards
- Prevent intentional contamination

**Inspection and Compliance**
- Mandated inspection frequency
- Increased records access
- Testing by accredited labs

**Response**
- Mandatory recall
- Expanded administrative detention
- Suspension of registration
- Enhanced product tracing abilities
- Additional recordkeeping for high risk foods

**Imports**
- Importer accountability
- Third party certification
- Testing by accredited labs
- Certification for high risk foods
- Voluntary qualified importer program
- Authority to deny entry

**Enhanced Partnerships**
- State and local capacity building
- Foreign capacity building
- Reliance on inspections by other agencies
For the first time, FDA has a legislative mandate to require comprehensive, prevention based controls across the food supply. The legislation transforms FDA's approach to food safety from a system that far too often responds to outbreaks rather than prevents them.

**Preventive Controls**

Finalized in September 2015, this rule is actually two rules, one for human food and one for animal food. Under the new rule, food facilities are required to implement a written Hazard Analysis and Risk-based Preventive Controls (HARPC) plan. This involves:

- Evaluating the hazards that could affect food safety,
- Specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent those hazards,
- Specifying how the facility will monitor these controls to ensure they are working,
- Maintaining routine records of the monitoring, and
- Specifying what actions the facility will take to correct problems that arise. Animal food manufacturers must implement current Good Manufacturing Practices and Preventive Controls.

For more information:

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, [FDA-2011-N-0921](#)

**Intentional Adulteration**

This rule focuses on bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling and mixing activities. It requires a vulnerability assessment and food defense plan for covered facilities to mitigate, monitor, correct and verify risks of intentional contamination. Training and record keeping are also included.

For more information:

- Focused Mitigation Strategies to Protect Food Against Intentional, [FDA-2013-N-1425](#)

**Produce Safety**

Released in November 2015, the FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables. Those standards must consider naturally occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address soil amendments (materials added to the soil such as compost), hygiene, packaging, temperature controls, animals in the growing area and water.

For more information:

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food: Final Rule, [FDA-2011-N-0920](#)
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Final Rule, [FDA-2011-N-0922](#)

**Sanitary Transportation**

This element of FSMA requires those who transport food to use sanitary practices to ensure the safety of food.

For more information:

- Sanitary Transportation of Human and Animal Food, [FDA-2013-N-0013](#)
The Rules: Inspection and Compliance

Mandatory Inspection Frequency

FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter.

Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next five years. To accomplish this projected goal, the FDA and other agencies in the United States will work in partnership or collaborate with foreign governing bodies for help, due to lack of resources to meet the demand.

Record Keeping

This rule requires that the FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans. FDA’s access to records was expanded beyond records relating to the specific suspect article of food to records relating to any other article of food that the FDA reasonably believes is likely to be affected in a similar manner.

In addition, FDA can now access records if FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.

For more information:

- Record Availability Requirements: Establishment, Maintenance, and Availability of Records, FDA-2002-N-0153

Testing by Accredited Labs

While FSMA requires lab accreditation, the FDA has not yet released a proposed rule related to lab accreditation. FDA officials have indicated a draft regulation is now under development by the FSMA Laboratory Accreditation Work Group.
For the first time, FDA will have mandatory recall authority for all food products. While FDA expects that it will only need to invoke this authority infrequently since the food industry is largely compliant with FDA’s requests for voluntary recalls, this new authority is a critical improvement in FDA’s ability to protect the public health.

**Mandatory recall**

FSMA provides FDA with authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food after being asked to by FDA.

**Expanded administrative detention**

FSMA provides FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law (administrative detention is the procedure FDA uses to keep suspect food from being moved).

**Suspension of registration**

FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death. A facility that is under suspension is prohibited from distributing food. (Effective 6 months after enactment)

**Enhanced product tracing abilities**

FDA is directed to establish a system that will enhance its ability to track and trace both domestic and imported foods. In addition, FDA is directed to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a food borne illness outbreak.

**Additional record keeping for high risk foods**

FDA is directed to issue proposed rulemaking to establish record keeping requirements for facilities that manufacture, process, pack, or hold foods that the Secretary designates as high-risk foods.
The legislation provides significant enhancements to FDA's ability to achieve greater oversight of the millions of food products coming into the United States from other countries each year. An estimated 15 percent of the U.S. food supply is imported, including 60 percent of fresh fruits and vegetables and 80 percent of seafood.

**Foreign Supplier Verification Program**

For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe.

*For more information:*

- Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals, FDA-2011-N-0143

**Third Party Certification**

FSMA establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports. Also, the FDA has the authority to require that high-risk imported foods be accompanied by a credible third party certification or other assurance of compliance as a condition of entry into the U.S.

*For more information:*

- User Fee Program to Provide for Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, FDA-2011-N-0146

**Voluntary Qualified Importer Program**

FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities.

*For more information:*

- Draft Guidance for FDA’s Voluntary Qualified Importer Program, FDA-2011-N-0144

**Authority to Deny Entry**

FDA can refuse entry into the U.S. of food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.
The legislation recognizes the importance of strengthening existing collaboration among all food safety agencies – Federal, state, local, territorial, tribal, and foreign – to achieve the FDA’s public health goals.

**State and Local Capacity Building**

FDA must develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies. FSMA provides FDA with a new multi-year grant mechanism to facilitate investment in State capacity to more efficiently achieve national food safety goals.

**Foreign Capacity Building**

The law directs FDA to develop a comprehensive plan to expand the capacity of foreign governments and their industries. One component of the plan is to address training of foreign governments and food producers on U.S. food safety requirements.

**Reliance on Inspections by Other Agencies**

FDA is explicitly authorized to rely on inspections of other Federal, State and local agencies to meet its increased inspection mandate for domestic facilities. FSMA also allows FDA to enter into inter-agency agreements to leverage resources with respect to the inspection of seafood facilities, both domestic and foreign, as well as seafood imports.
With a basic understanding of the cornerstones of the Food Safety Modernization Act, you may be asking yourself, now what? Here are a few basic steps to help get you started to becoming FSMA-ready.

Know Where you Stand...

First, food companies need to understand which rules apply to them and go through each to better understand where your company stands. Knowing where you are now will help you understand your gaps in FSMA compliance, better target your focus areas and map out a timeline and implementation plan.

Know your Suppliers...

For many companies, getting a handle on who exactly is supplying into their operations is actually a daunting task. But if you don’t have a deep understanding of your suppliers, how are you supposed to manage risk to your supply chain? Once you are fully aware of your suppliers and their capabilities, you can better execute if and when there is a quality or safety issue.

And Know Where there is a Problem

How can you solve a problem you aren’t aware of? And the key to understanding where you have a problem is through a robust traceability software solution.

Get FSMA-Ready with FoodLogiQ

FoodLogiQ is helping food companies face the mounting regulations and call for supply chain transparency with our software FoodLogiQ Connect.

With our software platform, you can onboard all of your suppliers, capture product information from each of those suppliers, and rate them based on their own audits and assessments.

By building this community in FoodLogiQ Connect, food companies are achieving end-to-end traceability for their supply chain and acting with confidence when food safety or quality issues arise or they have to issue a stock withdrawal or recall.

See FoodLogiQ Connect in action today!

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