



FSMA Food Safety Modernization Act

Frequently Asked Questions

FSMA FREQUENTLY ASKED QUESTIONS

The Food & Drug Administration's (FDA) much anticipated Food Safety Modernization Act (FSMA) rules went into effect for large manufacturers on September 19, 2016. It is estimated by the FDA that processed foods covered by this regulation are responsible for approximately nearly a million foodborne illness each year, costing the American public approximately \$2.2 Billion. These new regulations are designed to reduce the risks and mitigate the costs associated with these illnesses.

This White Paper has been developed to help companies prepare for the new FSMA requirements surrounding the handling of Human Food. Frequently asked questions are answered. Questions that companies should be asking as they consider the steps they need to take to become FSMA complaint are also included. For more specific information please refer to the contact at the end of this paper or visit www.fda.gov.

FSMA FREQUENTLY ASKED QUESTIONS

What is FSMA?

The Food Safety Modernization Act (FSMA) was signed into law January 2011 with the intention of ensuring the safety of the food supply in the United States and establishing procedures to execute food recalls when needed. The Act requires mandatory safety standards and preventative controls to be in place for all food processing and distribution facilities.

Five Key Sections

There are five key sections in the FSMA regulations that impact food handling facilities.

Prevention

Facilities must establish and implement a food safety plan that includes an analysis of potential hazards in their facility along with preventive controls. Preventive controls include a food safety plan, documented processes and sanitation measures.

Inspection and Compliance

All food processing and distribution companies will be inspected by the FDA for compliance with FSMA. To comply with the FSMA requirements companies need to establish food safety plans and maintain records that are easily accessible for FDA inspectors. High risk companies will be inspected on a more frequent basis by the FDA. A company is considered to be “high risk” if they process or distribute raw products such as fish, produce, or poultry.

Imports

Importers will be responsible and liable for their suppliers’ compliance with the FSMA regulations. An importer must be



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able to show that the products they are importing comply with FSMA and the associated food safety preventive controls. There are third-party certification programs that can be used for this purpose.

Response

The U.S. Food & Drug Administration is requiring manufactures and distributors to enhance their record keeping for all food products they have had custody of. They recommend that records be accumulated by technology that can capture and maintain product information including lot numbers, expiration dates, manufacturing codes, and temperatures. FSMA requires manufactures and distributors to keep three years of records for all products they have handled in their facility and have the ability to notify all end users of a recall within 24 hours.

Enhanced Partnerships

Enhanced Partnerships allow for the various food safety agencies to work together to implement the FSMA regulations. The cooperation of all Federal agencies working to ensure the safety of the food supply is necessary for the goals of the legislation to be accomplished.

For more information on these key sections please go to:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA>

FSMA FREQUENTLY ASKED QUESTIONS

Who should care about FSMA?

Any company that manufactures, distributes, stores, or transports dry and/or temperature controlled food products is subject to the FSMA requirements.

How soon does my company need to have FSMA compliance in place?

Compliance dates vary based on the size of your business and the requirements of the supply chain program. However, there are many factors including company size and the types of products you handle that affect the compliance date. To confirm the date your company is required to comply please refer to the FDA guidelines.



Key Compliance Dates

Large Business Compliance Period (500 or more employees business-wide)

FSMA Regulation	Effective Date
Preventive Controls for Human Food	8/30/2016
Produce Safety	12/31/2017*

Small Business Compliance Period (less than 500 employees business-wide)

FSMA Regulation	Effective Date
Preventive Controls for Human Food	8/30/2017
Produce Safety	12/31/2018*

Very Small Business Compliance Period (business has annual food sales below the applicable limit)

FSMA Regulation	Limit	Effective Date
Preventive Controls for Human Food	<\$1M	8/30/2018
Produce Safety	<\$250K	12/31/2019*

***All farms have an additional 2 years to comply with certain water-related requirements.**

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Does FSMA apply to me.....

My warehouse only distributes produce?

FSMA has a section dedicated to produce safety. The FDA established minimum standards for the safe harvest of fruits and vegetables. Proper product storage and temperature controls play a big role in ensuring produce does not contain or become exposed to unwanted bacteria, mold, or spoilage. Produce processors and distributors are required to keep temperature logs of products as they move through the supply chain. This data needs to be available for the FDA when they are researching a recall.

For more information on the Produce Safety Rule go to the U.S Food & Drug Administration website: <http://www.fda.gov/food/guidanceregulation/fsma>

My warehouse only distributes refrigerated product?

FSMA has a section that addresses temperature sensitive products. FSMA requires product temperatures and lots to be captured and recorded at time of receiving, and monitored as products move through the supply chain to the end user. Item temperatures and lots should be recorded for products at key touch points including receiving, picking, loading and delivery. These procedures are intended to document that products have been stored properly and were not subject to spoilage or contamination.

My warehouse only distributes non-refrigerated product?

FSMA requires track and trace capabilities for all companies that handle food items that can be subject to a recall. This includes dry products that contain ingredients such as nuts, cocoa, or eggs because they have the potential to be recalled. FSMA requires all companies to have the ability to recall products they have handled, if needed.

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How will the FDA know if my building is FSMA compliant?

FSMA requires annual inspections of all food processing and distributing facilities. FDA inspectors will be inspecting facilities to confirm FSMA compliance measures are in place. FSMA gives the FDA access to all food safety records in all food facilities at any time. Expected documents include a food safety plan, recall plans, and product track and trace capabilities.

What role does technology play in FSMA?

Technology can :

- ◆ Enable distributors to automate processes including receiving, picking, replenishment and delivery
- ◆ Eliminate the need for paper records
- ◆ Capture and store product information including lot numbers and expiration dates
- ◆ Provide information and reporting to support recall requirements
- ◆ Provide information and reporting about products that are in a building
- ◆ Provide information and reporting about products that have been delivered over the past three years



Will a technology company make me FSMA compliant?

There are many technology companies operating in the United States today. Simply having technology in your warehouse is not enough to make you FSMA compliant. Distributors and processors need to work with a technology company that has a full understanding of FSMA requirements and a track record of successful implementations. Knowledgeable technology companies can help distributors and processors to become FSMA compliant by assisting with the selection and implementation of appropriate technology solutions for FSMA compliance.

FSMA FREQUENTLY ASKED QUESTIONS

When is the next phase of FSMA being released?

The next phase of FSMA will be released in the Spring of 2017. This phase will require temperature tracking of products as they move through the facility.

What type of record keeping do I need to have?

Companies that are subject to FSMA need to maintain three years of records on all shipments for recall purposes. FSMA authorizes the FDA to have access to all company food safety records including food safety plans and product track and trace records. FDA inspectors will have authority to review all track and trace records which will explain how products were stored. This will be of particular interest to an inspector if they suspect food has been compromised in a facility.



What about imported foods? Do they have to be tracked differently?

Under the new FSMA requirements, importers will need to verify that the foreign food facilities where imported products are purchased from comply with U.S. food safety standards. Importers are required to track Country of Origin information for each product received as part of their FSMA compliance obligations.

FSMA FREQUENTLY ASKED QUESTIONS

Additional questions that companies who process or distribute food should ask when considering FSMA.

1. Do we need to comply with FSMA?
 - a. See answers above
 - b. Do we understand the difference between HACCP and FSMA?
2. What products are we distributing that have risk?
 - a. Produce, fresh meats, seafood, chicken, milk, eggs, etc.?
3. Do we understand what we need to do to be FSMA compliant?
 - a. Which of our current processes need to be changed or enhanced?
 - b. What documentation needs to be created?
 - c. How will our product records be stored so they can be easily retrieved when needed?
 - d. How will our activity documentation be stored so it can be easily retrieved when needed?
4. Do we have resources internally who can write and implement a Food Safety plan?
 - a. What training do we need to give them?
 - b. Should we recruit a person for this project?
 - c. Do we have a designated PCQI, (Preventative Controls Quality Individual) ?
5. What options or outside companies are available to help with these new legal requirements?
 - a. Consulting firms, trade association resources, buying groups resources, etc?
 - b. What should we expect from an outside resource?

Who can I contact for more information about complying with FSMA requirements?

<http://www.fda.gov/Food/GuidanceRegulation/FSMA>

Who can I contact for more information about technology solutions that can help me comply with FSMA requirements?

Erin Inman

ProCat Distribution Technologies

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About ProCat Distribution Technologies:

ProCat Distribution Technologies provides barcode scanning solutions to distribution centers throughout North America. ProCat supports over 150 buildings across the country with its suite of solutions from its offices in Southern New Jersey, learn more about ProCat solutions at www.procatdt.com.

Disclaimer: This document is provided for informational purposes only and does not constitute legal advice.

Consult the U.S. Food and Drug Administration to confirm your interpretation of the information.