

Part 1 — Introduction to FSMA

Introduction to the FDA Food Safety Modernization Act

Learning Objectives

By the end of this section, you should be able to:

- Explain what **FSMA** is and why it was introduced.
 - Understand the difference between **FDA, FSMA, Rules, and Regulations**.
 - Understand the basic position of **PCHF** within the FSMA framework.
 - Explain the shift from a reactive to a preventive approach to food safety.
 - Understand the concept of **Applicability** when determining FSMA requirements.
 - Recognize the relationship between FSMA and other food safety systems such as **HACCP, ISO 22000, FSSC 22000, and BRCGS**.
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1. Why Was FSMA Introduced?

Food safety systems traditionally relied heavily on detecting problems after they occurred.

A reactive approach can be summarized as:

Problem Happens

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Detection / Investigation

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Corrective Action / Recall

FSMA strengthened a different philosophy:

Prevention Before Reaction

The focus is to identify potential hazards before they cause a food safety problem and establish appropriate controls.

A simplified preventive approach is:

Identify Hazards

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Assess Risk

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Prevent / Control



Monitor



Verify

The objective is not to eliminate testing, corrective actions, or recalls. Instead, the goal is to prevent food safety problems whenever they can reasonably be prevented or controlled.

2. What Is FSMA?

FSMA

Food Safety Modernization Act

FSMA is a U.S. federal law enacted in **2011**.

One of its major impacts was strengthening the U.S. food safety system around a more:

- **Preventive**
- **Risk-Based**
- **Science-Based**

approach to food safety.

⚠ Important

FSMA is **NOT**:

- A certification
- An ISO standard
- A single food safety rule
- A certification scheme
- A certificate that a facility obtains to become "FSMA Certified"

Instead, FSMA is a broad legislative framework that resulted in the development of multiple rules and programs addressing different areas of the food supply chain.

3. FDA vs. FSMA

One of the most important concepts to understand from the beginning is that:

FDA ≠ FSMA

FDA

U.S. Food and Drug Administration

FDA is the U.S. regulatory agency responsible for important areas of food safety regulation and oversight.

FSMA

Food Safety Modernization Act

FSMA is the law that significantly changed and expanded the U.S. food safety framework.

A simplified regulatory sequence is:

Law



FSMA



FDA Rules



Regulations



Facility Requirements



Compliance

The important question for a food safety professional is therefore not simply:

"What does FSMA say?"

but:

"What requirement applies to my operation, and where does that requirement come from?"

4. FSMA Is Not One Single Rule

FSMA resulted in several rules and programs addressing different activities and risks throughout the food supply chain.

Examples include:

PCHF

Preventive Controls for Human Food

Preventive Controls for Animal Food

Requirements related to animal food.

Produce Safety Rule

Requirements associated with certain activities involving produce.

FSVP

Foreign Supplier Verification Program

Primarily related to responsibilities of U.S. importers regarding foreign suppliers.

Sanitary Transportation

Requirements related to maintaining food safety during transportation.

Intentional Adulteration

Requirements addressing intentional acts intended to cause widespread harm, commonly associated with **Food Defense**.

Food Traceability

Additional traceability requirements for certain foods covered by the applicable traceability rule.

5. The Importance of Applicability

A critical principle throughout FSMA compliance is:

What applies to my operation?

Not every FSMA rule applies to every food facility.

Applicability can depend on factors such as:

Product

+

Activity

+

Facility

+

Role in the Supply Chain

Then we determine:

- Which rule applies?
- Is the facility within the scope?
- Is there an applicable exemption?

- Are modified requirements applicable?
- Are there additional requirements?

Only after determining applicability should we begin evaluating compliance.

Remember:

First determine applicability. Then determine compliance.

6. Where Does PCHF Fit?

For applicable human food operations, one of the most important areas we will study is:

PCHF

Preventive Controls for Human Food

PCHF is closely associated with the requirements in:

21 CFR Part 117

These requirements address areas including:

CGMPs

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Hazard Analysis

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Risk-Based Preventive Controls

for human food.

A simplified picture is:

FSMA

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FDA Rules

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21 CFR Part 117

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PCHF Requirements

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Food Safety System in Practice

This relationship will become much clearer throughout the following sections of the course.

7. FSMA and Other Food Safety Systems

If you already have experience with:

- **HACCP**
- **ISO 22000**
- **FSSC 22000**
- **BRCGS**

you will recognize several concepts that are also important in FSMA/PCHF, such as:

- Hazard Analysis
- Risk-Based Thinking
- Preventive Measures / Controls
- Monitoring
- Verification
- Corrective Actions
- Documentation

However, these systems are **not identical**.

They can differ in:

- Regulatory framework
- Terminology
- Scope
- Specific requirements
- Implementation approach

Therefore, having a HACCP, ISO 22000, FSSC 22000, or BRCGS system does not automatically mean that a facility is compliant with every applicable FDA/FSMA requirement.

8. A Practical Example

Imagine a food factory in Egypt producing food for export to the United States.

Instead of immediately asking:

"What is the FSMA checklist?"

A food safety professional should first ask:

Step 1

What product are we producing?

Step 2

What activities are we performing?

Step 3

What is our role in the supply chain?

Step 4

Which FDA/FSMA rules apply?

Step 5

Are there any applicable exemptions or modified requirements?

Step 6

What specific requirements must we comply with?

This is the beginning of a proper **FSMA Applicability & Compliance Assessment**.

9. Reactive vs. Preventive Food Safety

Reactive Thinking

Problem

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Detection

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Investigation

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Corrective Action

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Recall if necessary

Preventive Thinking

Hazard Identification

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Risk Assessment



Preventive Control



Monitoring



Verification

The preventive approach does not mean that corrective actions or recalls are unnecessary.

Instead, it means that the food safety system should be designed to **prevent problems whenever possible**, rather than relying primarily on detecting problems after they occur.

10. Key Takeaways

Before moving to the next section, make sure you understand these points:

1. FSMA = Food Safety Modernization Act

2. FSMA is a U.S. federal law enacted in **2011**.

3. FSMA is **not a certification**.

4. **FDA and FSMA are not the same thing.**

5. FSMA is a broad framework that resulted in multiple rules and programs.

6. Not every FSMA rule applies to every food facility.

7. **Applicability must be determined before compliance requirements are assessed.**

8. **PCHF — Preventive Controls for Human Food** is a major component for applicable human food operations.

9. **21 CFR Part 117** is a key regulatory reference for human food requirements.

10. FSMA shares several concepts with HACCP and other food safety systems, but the systems are not identical.



Self-Check Questions

Try to answer these questions without looking back at the guide:

1. What does **FSMA** stand for?
2. When was FSMA enacted?
3. Is FSMA a certification?

4. What is the difference between **FDA** and **FSMA**?
5. Why is FSMA not considered a single food safety rule?
6. What does **Applicability** mean in the context of FSMA?
7. Why should applicability be determined before conducting a compliance assessment?
8. What does **PCHF** stand for?
9. What is the role of **21 CFR Part 117** in the human food framework?
10. How is a preventive food safety approach different from a reactive approach?
11. Name two food safety systems that share some concepts with FSMA/PCHF.
12. Explain the following sequence in your own words:

FSMA → Applicable Rules → Requirements → Implementation → Compliance

★ Remember

The most important mindset from this section is:

FSMA compliance does not start with a checklist. It starts with understanding what applies to your operation.

And the key question to carry with you throughout this course is:

What applies to my operation — and why?

Once you can answer that question, you can move from simply **knowing about FSMA** to actually **applying FSMA requirements in a food facility**.