

## **FSMA Preventive Controls Rule for Human Food**

The Food Safety Modernization Act (FSMA) broadens the oversight of the US Food and Drug Administration (FDA) over small food processing businesses. FSMA is a preventive, proactive approach to food safety. FDA is a federal-level food safety regulatory agency.

The Preventive Controls Rule for Human Food is the specific component of FSMA that affects small processors. FDA finalized the Preventive Controls Rule in September 2015.

Congress passed FSMA in 2010, and the President signed it in 2011, significantly overhauling US food law. Since then, FDA has proposed, revised, and revised again the rules that determine how FSMA affects farmers and food processors. In all, FSMA includes seven rules: Produce Safety, Preventive Controls for Human Food, Preventive Controls for Animal Food, Sanitary Transportation of Foods, Foreign Supplier Verification Programs, Accredited Third-Party Certification, and Focused Mitigation Strategies to Protect Food against Intentional Adulteration.

This introductory overview familiarizes small processors with when and how FSMA may affect their operations, and it suggests further resources.

### **Does This Section Apply to Me?**

You should be familiar with FSMA requirements whether or not you operate a licensed facility.

FSMA applies to different processors in different ways. Some processors are required to follow some provisions but are exempt from others. Please review all of this section.

### **What to Expect: Your Compliance Dates**

Depending on scale of operation, processors may have extra time to comply.

#### **Small Business**

- September 18, 2017
- A business with fewer than 500 full-time equivalent employees

#### **Very Small Business**

- September 17, 2018
- Averaged less than \$1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, during the preceding 3-year period.

## **What to Expect: Key Changes for Small Processors**

### **Facility registration**

FSMA requires processing facilities to register with FDA.

“Facility” is defined and registration procedures are described in this section of the regulations.

Some facilities are exempt from registration. See below.

### **Food safety system**

FSMA requires processors to establish and implement a food safety system. This includes:

1. HARPC (“HARP-see”), a hazard analysis and risk-based preventive controls plan including:
  - a written food safety plan
  - hazard analysis
  - measures to establish preventive controls
  - a recall plan
  - and other requirements
2. A supply-chain program. Approved suppliers must be used for ingredients and raw materials that present an identified hazard, and supplier activities must be verified.

Some facilities are exempt from some of these requirements or may qualify for modified requirements. See below.

### **Current good manufacturing practice**

FSMA modifies and expands [current good manufacturing practice](#) (CGMP) requirements. In particular, it adds provisions to prevent allergen cross-contamination. It also changes wording so that some activities that were previously recommended are now required.

### **Training and recordkeeping**

FSMA adds [training](#) and [recordkeeping](#) requirements, even for exempt businesses.

### **Facility Registration: Exemptions**

Private residences of individuals (such as [Pickle Bill](#) processors), retail food establishments, and some farms are among facilities that don’t have to register.

See FDA's [guide](#) for small entities on facility registration. A full list of exemptions appears in the guide under "These Facilities DON'T Have to Register."

## **Food Safety System: Exemptions and Modified Requirements**

### **Exemptions**

Some facilities are exempt from HARPC and supply-chain program requirements.

Exempt facilities are still bound to [facility registration](#), [good manufacturing practice](#), [recordkeeping](#), and [training](#) requirements.

Exempt facilities include:

- Small or very small *on-farm* facilities:
- that *pack or hold* specified low-risk foods (listed [in 21 CFR 117.5\(g\)\(3\)](#))
- that *process* specified low-risk foods (listed [in 21 CFR 117.5\(h\)\(3\)](#))
- Facilities that manufacture products already covered by separate regulations:
- Juice and seafood products, which are already covered by HACCP<sup>†</sup> requirements
- Low-acid canned foods. However, this exemption only covers microbiological hazards. Physical, chemical, and other hazards still require a HARPC plan under FSMA.
- Alcoholic beverages

Exemptions are detailed in [21 CFR 117.5](#).

### **Modified requirements**

Other facilities may qualify for *modified* HARPC requirements. FSMA refers to these as "qualified facilities."

Facilities that qualify for modified requirements are still bound to [facility registration](#), [good manufacturing practice](#), [recordkeeping](#), and [training](#) requirements.

A facility may be qualified if:

- it is a Very Small Business, or

- it averaged less than \$500,000 in annual sales of all food during the preceding 3-year period, AND most sales of food (in monetary value) were to consumers, restaurants, or retail food establishments in the same state or not more than 275 miles from the facility.

**HARPC requirements** may be modified for qualified facilities. Qualified facilities have two options in place of full HARPC requirements:

- Comply with state and local regulations, or
- Submit other documentation to FDA attesting that you are implementing and monitoring preventive controls to address the hazards you have identified.

**Supply-chain program.** Qualified facilities are not required to develop a supply-chain program.

Modified requirements are detailed in [21 CFR 117, Subpart D](#). Qualified facilities are defined in [21 CFR 117.3](#).

## Key Terms

### **Food Safety Modernization Act (FSMA)**

Pron. FIZZ-mah

An act passed by Congress in 2010, the most significant overhaul of US food law since 1906. *FSMA* also refers to the FDA regulations that implement the congressional act.

### **Hazard Analysis and Critical Control Points (HACCP)**

Pron. HASS-ip

A specific type of food safety management system required for facilities that process juice, seafood, and meat. See page **Error! Bookmark not defined..**

### **Hazard Analysis and Risk-Based Preventive Controls (HARPC)**

Pron. HARP-see

A food safety management system introduced by FSMA. It has some similarities to HACCP and that applies to virtually all food processing facilities.

## Resources

### **FDA**

- [FSMA](#) page
- FDA's [fact sheet](#) on the Preventive Controls Rule.
- FSMA [webinars](#) on the Preventive Controls Rule. FDA produced 1-hour webinars in September 2015:

- Final Rules for Preventive Controls for Human and Animal Food: Who is Covered? What Is the Definition of a Farm?
- Final Rule for Preventive Controls for Human Food: Significant Provisions of the Rule
- Watch for the FDA’s Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.
- FDA is developing training and technical assistance for affected food businesses.
- Query [FDA’s FSMA Technical Assistance Network](#) with questions on regulation and policy interpretation.

### **Food Safety Preventive Controls Alliance (FSPCA)**

- [FSPCA](#) is a public-private alliance that FDA created to develop training and outreach for industry on FSMA.
- FSPCA offers food processor training. Watch FSPCA’s site for [trainings](#).
- Query the [FSPCA Technical Assistance Network](#) with scientific and technical questions about FSMA.

### **State and local regulations still apply**

- Contact the Wisconsin Department of Agriculture, Trade and Consumer Protection ([DATCP](#), “DAT-cap”), [datcpdfslicensing@wisconsin.gov](mailto:datcpdfslicensing@wisconsin.gov), 608-224-4682.
- See DATCP’s [Local Food Marketing Guide](#), Chapter 4, “Rules, Regulations, and Other Considerations.”

### **Non-Governmental Resources**

#### [National Sustainable Agriculture Coalition](#) (NSAC, “EN-sack”)

- NSAC is an alliance of grassroots organizations that provides information resources for small farmers and food processors.
- NSAC offers extensive information and discussion on its [FSMA pages](#) and in its [blog](#).
- Exemptions from certain parts of the rule for farm mixed-type facilities and small-scale facilities are discussed [here](#).

## [Jambor Heyman](#)

- A law firm for food businesses in the natural, organic, and specialty sectors, providing workshops and other services.

## [Farm Commons](#)

- A nonprofit that provides legal resources for small producers.
- Audio commentary on FSMA is [here](#).

## **Regulatory References**

### **Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR 117)**

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=aaf4ec84c049c6d734798bf18945bed9&ty=HTML&h=L&mc=true&r=PART&n=pt21.2.117>

### **Registration of Food Facilities (21 CFR 1 Subpart H)**

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=355ba5580208a2c6c1648ad3ce26d93b&h=L&mc=true&n=pt21.1.1&r=PART&ty=HTML#sp21.1.1.h>

### **FSMA Final Rule for Preventive Controls for Human Food | Compliance Dates**

[http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm#Compliance\\_Dates](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm#Compliance_Dates)

## **Credit**

This section originally appeared as a fact sheet produced by Jenifer Buckley for small Wisconsin processors in 2016, “FSMA Preventive Controls Rule for Human Food: Introductory Overview,” <http://jeniferbuckley.com/outreach-instruction/fsma-pc-rule-intro/>.