

REGULATIONS FOR FOOD PROCESSING FAQ ON THE FOOD SAFETY MODERNIZATION ACT



Farms and food businesses need to comply with rules and requirements of the federal Food Safety Modernization Act (FSMA). Answers to these Frequently Asked Questions about FSMA provide a baseline of information.

This factsheet includes information on:

- The Food Safety Modernization Act.
- The Produce Safety Rule.
- Modernized Good Manufacturing Practices and the Preventive Controls for Human Food Rule.
- Compliance Timeline and Enforcement.

The Food Safety Modernization Act

What is “FSMA”?

The Food Safety Modernization Act (FSMA) was signed into law in 2011. This sweeping law is the first comprehensive update to federal food safety laws since 1938. It sets new standards for food handling across the entire food chain, with rules for businesses ranging from farms and food processors to food shippers, importers, retailers, and others. It is the first federal food safety law that includes specific rules for produce farms.

What is the intent of FSMA?

FSMA represents a change in the Food and Drug Administration’s (FDA) approach to ensuring a safe U.S. food supply. Rather than reacting to instances of food borne illness or contaminated products as they occur, FSMA shifts the focus toward preventing contamination in food.

What are the key areas of FSMA?

The law includes several different rules that apply to different sectors of the food system including farms, food processors, food transporters, etc. The sections of the law that are most relevant for most people using this fact sheet are the Produce Safety Rule and the Preventive Controls for Human Food Rule, which modernizes Good Manufacturing Practices (GMPs) for processing facilities.

Does FSMA apply to me?



Do you have a produce farm?

If you operate a farm that grows, harvests, packs, or holds produce, ***the Produce Safety Rule likely applies to you.***

Do you process a food product?

If you operate a business that processes, packs, manufactures, or holds food, the modernized ***Good Manufacturing Practices (GMP) and Preventive Controls for Human Foods rules likely apply to you.***

If you grow *and* process food you may be covered by both rules.

Are you a food hub or farmer cooperative that deals with produce?

For the purposes of the FSMA Produce Safety Rule, FDA has written a specific definition of a “farm.” A food hub or cooperative may also be considered a “farm” depending on their ownership structure and sourcing model. Food hubs and cooperatives that don’t fit the FSMA definition of a farm, may instead need to meet the requirements of the FSMA Sanitary Transportation Rule.

The following resources can help you determine which rules apply to you:

- “FSMA Flowchart for Farms and Food Businesses.” Search for it by name on the National Sustainable Agriculture Coalition (NSAC) website, sustainableagriculture.net.
- Coverage and Exemptions/Exclusions for Farms chart. Search for “Standards for Produce Safety” on the FDA website, fda.gov.

What's the difference between FSMA and "GAPs"?

FSMA is a law, and the rules are mandatory for farmers and food businesses to follow, with some exemptions that are explained below.

Good Agricultural Practices (GAP) and Good Handling Practices (GHP) are sets of best practices for reducing food safety hazards for produce on the farm. GAP/GHP are voluntary, market-driven standards. Many farms become GAP/GHP audited at the request of their buyers. A GAP/GHP audit is a way that farms can provide customers with a third-party assurance of their on-farm food safety practices.

Many of the basic principles for reducing food safety risks are similar between GAP and FSMA. Farms that are familiar with GAP/GHP will be well prepared to comply with FSMA.

I've been hearing about FSMA for years. What's the status now?

After the law passed in 2011, FDA developed initial drafts of the rules, which it released in 2013. Over the next two years, FDA solicited input from farmers, food processors, and food system advocates throughout the country. You may have submitted comments yourself during this period. After several rounds of comment and revisions, the rules were finalized in 2015 and 2016. The good news is that FDA heard many of the concerns from small farms that are reflected in the final rules. Now the final rules are being implemented. See below for specifics on the deadlines for compliance.

The Produce Safety Rule

Aren't some farms exempt from the Produce Safety Rule?

The rule covers produce farms. Some types of produce and several categories of farms are exempt:

- **Farms with annual produce sales**, averaged over the last three years, of **\$25,000 or less**, are exempt.
- **Produce** used only for **personal** or on-farm **consumption** is exempt.
- **Produce that is** defined by FDA as **"rarely consumed raw"** is exempt.

FDA's exhaustive list of those products is: "asparagus; beans, black; beans, great Northern;

beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts."

- **Food grains** such as barley, wheat, quinoa, rapeseed, are exempt.
- Hops, wine grapes, pulse crops and almonds are not exempt, but the Produce Safety Rule will not be enforced for these commodities until more crop-specific guidance is available. Find more information by searching for "Policy for Hops, Wine grapes, Pulse" on the FDA website, [fda.gov](https://www.fda.gov).

Most diversified farms grow and handle a mix of produce, some on the exempt list, others not. You may find it is more practical to grow and handle all your produce crops in compliance with the Produce Safety Rule, rather than using different practices for crops exempt from the rule.

In addition, your farm may be eligible for a "qualified exemption" if **both** apply:

1. Your **total annual food sales** (not just produce sales) averaged **less than \$500,000** over the past three-year period.
2. The **majority of all sales** over the past three-year period **were direct to consumers** or other "qualified end-users," such as restaurants, grocery stores, farmers markets or other retail food establishments located in the same state or Indian reservation as the farm or within 275 miles of the farm.

Qualified exempt farms are exempt from the majority of the rule. *As of January 2020 qualified exempt farms must prominently display the farm name and address on packaging labels or at the point of sale, for example on a sign at a farm stand or on an invoice.*

FDA could withdraw this exemption if there is a foodborne illness investigation or other food safety concern, however qualified exempt farms will not undergo routine produce safety inspections.

To demonstrate that they meet the criteria for any of these exemptions, **all farms must keep sales records, and make them available upon request. Records should cover the most recent three years in operation. This recordkeeping requirement went into effect in January 2016.**



What are the key requirements of the Produce Safety Rule?

The Produce Safety Rule sets standards for farms to meet in seven key areas. The intent is to reduce food safety risks by limiting microbial contamination – and cross contamination – through hygiene, water, soil, animals, and surfaces on your farm.

This is a very brief summary to give you a sense of the key elements of the Produce Safety Rule. Please use the resources at the end of this section to learn specifics about the standards in each section and how they might be achieved on your farm.

1. **Worker Health and Hygiene** sets requirements for reducing food safety risks with good training and appropriate hygiene practices for farmers and employees who are in contact with produce.
2. **Agricultural Water** must meet specific water quality standards, depending on the water source and how it is used on the farm. Post-harvesting handling water (including water used for washing produce, hands and contact surfaces) must meet standards for potable water. Irrigation water must meet specific testing criteria for generic *E.coli*. Required testing frequency depends on your specific water quality, source, and use.
3. **Biological Soil Amendments** section defines how raw manure, stabilized compost, and other inputs of animal origin, may be used so as to minimize the risk of contaminating produce. The current recommendation for raw manure is to follow the National Organic Program Standards.
4. **Domesticated and Wild Animals** section recognizes that animals, whether domestic or wild, are a normal part of farms and requires farmers to monitor crops and have practices to minimize contamination or damage to crops caused by animals.
5. **Equipment, Tools and Buildings** section requires a cleaning and sanitizing schedule for food contact surfaces such as harvest tools, dump tanks, and packaging materials. Buildings, heavy machinery, toilet and handwashing facilities, etc. must be clean and well maintained.
6. **Produce Safety Training** – Each farm must have at least one person who has completed the approved FDA Produce Safety Training.
7. **Recordkeeping** – FDA has included specific recordkeeping criteria intended to increase accountability, traceability, and transparency of practices. Sales records, water testing results, soil amendment treatment, and equipment cleaning schedules are some of the activities that may need documented recordkeeping.

Qualified exempt farms are exempt from all requirements listed here (1 – 7 above), including recordkeeping.

Sprouts have special requirements in the FSMA Produce Safety Rule because of their susceptibility to contamination. Please see the *Selling Sprouts and Microgreens* fact sheet.

Where can I find key information for farmers to help me understand the Produce Safety Rule?

The Produce Safety Rule sets the standards, but does not always define the specific actions a farm must take. This is to allow flexibility for farms to meet the standards in ways that work for their particular operation. WSDA, Washington State University (WSU) Extension, and many other organizations provide trainings, publications, and other resources to help Washington farms implement the Produce Safety Rule standards.

- **WSDA Produce Safety Program** is federally funded to help farmers understand and comply with the Produce Safety Rule and to implement a consistent inspection program. Search for it on agr.wa.gov, or contact producesafety@agr.wa.gov, or 360-902-1848
- **WSDA's Regional Markets Program** offers on-farm food safety guidance for small-scale and diversified farms, including the "Bridging the GAPs Farm Guide" publication, which provides an overview of the FSMA Produce Safety Rule and information about specific practices farms can use to meet FSMA requirements. Look for it on agr.wa.gov, or contact smallfarms@agr.wa.gov, or 206-256-6157.

REGULATIONS FOR FOOD PROCESSING

- **National Sustainable Agriculture Coalition (NSAC)** wrote a summary of the Produce Safety Rule, “Understanding FDA’s FSMA Rule for Produce Farms” to help farms understand how specific requirements apply to small farms. Find it on NSAC’s website, sustainableagriculture.net
- **FDA’s “Key Requirements: Final Rule on Produce Safety”** fact sheet can be found at fda.gov
- **The Produce Safety Alliance**, a collaboration among Cornell University, FDA and USDA, developed the official FDA-approved Produce Safety Training program and offers extensive resources on their website, producesafetyalliance.cornell.edu.

Modernized Good Manufacturing Practices (GMP) and the Preventive Controls for Human Food Rule

What is the Preventive Controls for Human Food Rule and how does it relate to Good Manufacturing Practices (GMP)?

FSMA updates GMP by adding “Hazard Analysis and Risk-based Preventive Controls for Human Food” requirements. With FSMA, products that are considered higher risk (due to a presence of allergens or likelihood of pathogens) fall under the new preventive controls regulation. Allergen and pathogenic bacteria control is more prescriptive, and more monitoring and recordkeeping are required when food safety risks are considered high.

Businesses with higher risk products now must implement a preventive control program that includes a hazard analysis of their ingredients, process, and products to determine the potential points where risks of contamination exist. Then they must create a Food Safety Plan that outlines the steps, or “preventive controls,” they will use to reduce the risks of contamination.

Training is now required for all employees and must be documented. Training needs to be in writing and specific for the work you and your employees are doing to assure sanitation, food safety, and personal hygiene.

The new requirements for preventive controls were integrated into WSDA Food Processor License requirements over a timeframe of several years and are now in effect for even the smallest processors of food and dairy.

Are there any exemptions to the preventive controls requirements?

Under the FDA Preventive Controls for Human Food Rule, there are some modified requirements for small businesses and exemptions for certain low-risk agricultural processing activities done by farms.

A “qualified facility” is subject to modified requirements under FSMA. To determine if your business can be considered a qualified facility, you’ll need to file an attestation with the FDA. Qualified facilities will still have to follow updated Good Manufacturing Practices under the Preventive Controls for Human Food Rule, but the attestation reduces some of the documentation required by FSMA. FDA or WSDA can withdraw the exemption if a facility fails to maintain compliance with public health requirements. Keep a copy of the submission to show state and federal inspectors if requested.

I already have a WSDA Food Processor License. Do GMP and the Preventive Controls for Human Food Rule apply to me?

Yes. WSDA’s Food Processor License requirements are designed around the criteria of Good Manufacturing Practices (GMP). This means processors licensed by WSDA, must follow basic GMP for their products. WSDA Food Safety Program has adopted the FSMA Preventive Controls Rule as the current standard for food processing and will be integrating the rule into WSDA Food Safety Program licensing requirements and technical assistance services over time.

This means if you have an existing WSDA Food Processor License, or are interested in becoming licensed, how the new regulations apply to you depends largely on your products and the size of your operation. Contact the WSDA Food Safety Program to get the latest information on the requirements for your particular operation.

Where can I get training on key information for food processors about the Preventive Controls for Human Food Rule?

- The FDA overview of the “FSMA Final Rule Preventive Controls for Human Food” page on the FDA website, [fda.gov](https://www.fda.gov), is a comprehensive resource.
- FDA at-a-glance sheet, “Key Requirements: Final Rule on Preventive Controls for Human Food,” [fda.gov](https://www.fda.gov).
- National Sustainable Agriculture Association (NSAC) has a FSMA resource center on their website with information for small farms and processors, sustainableagriculture.net.

Where can I get training on preventive controls?

- The Food Safety Preventive Controls Alliance (FSPCA) with the Illinois Institute of Technology provides training and information, iit.edu/ifsh/alliance.
- WSU Food Processing Extension and Research offers trainings and resources on preventive controls for food processors,

foodprocessing.wsu.edu, or contact Dr. Girish Ganjyal, girish.ganjyal@wsu.edu, 509-335-5613.

- Food Northwest, (formerly the Northwest Food Processors Association) offers a full education and training schedule, foodnorthwest.org.

Compliance Timeline and Enforcement

When do farms and processors have to comply with FSMA?

Both the Produce Safety Rule and the Preventive Controls for Human Food Rule are being implemented now. The specific timelines for implementation and compliance vary by the different parts of the rules and are based on the business size and type of markets.

Under the Produce Safety Rule, the final compliance date for all farms required to comply is January 2020. However, FDA officially extended compliance dates for agricultural water requirements, because that section is under review.

The tables below provide an overview of key compliance timelines for the Produce Safety Rule and the Preventive Controls Rule.

PRODUCE SAFETY RULE WATER COMPLIANCE DATES

CATEGORY	PRODUCE SAFETY WATER COMPLIANCE DATE
General Compliance (more than \$500,000 in annual produce sales)	January 2022
Small Businesses (between \$250,000 and \$500,000 in annual produce sales)	January 2023
Very Small Businesses (between \$25,000 and \$250,000 in annual produce sales)	January 2024

SUMMARY OF PREVENTIVE CONTROLS FOR HUMAN FOOD RULE COMPLIANCE DEADLINES

CATEGORY	PREVENTIVE CONTROLS COMPLIANCE DEADLINE
Recordkeeping Requirements*	In effect as of January 2016
General Compliance – Large Businesses	In effect as of September 2016
Small Businesses (less than 500 full-time equivalent employees)	In effect as of September 2017
Businesses subject to Pasteurized Milk Ordinance	In effect as of September 2018
Very Small Businesses (Less than \$1 million market value of annual food produced and/or sold)	In effect as of September 2018

*Applies to all businesses.

How will the rules be enforced?

In Washington State, the Good Manufacturing Practices and Preventive Controls for Human Food Rule for food processors are incorporated into the requirements for the WSDA Food Processor License.

Farms that must comply with the Produce Safety Rule will be inspected by the WSDA Produce Safety Program. Farms will be notified 5-7 days in advance of an inspection. Exempt and qualified exempt farms will not undergo routine produce inspections.

Where can I find detailed information about all the FSMA rules?

The FDA has developed web pages for each rule in FSMA that include fact sheets, guidance, and links to the final rule as they were published in the Federal Register. Search for them by name at [fda.gov](https://www.fda.gov):

- Food Safety Modernization Act (FSMA)
- FSMA Final Rule on Produce Safety
- FSMA Final Rule for Preventive Controls for Human Food



22. Good Agricultural Practices

23. WSDA Food Processor License and Facilities