



Regulations for Food Safety

FAQ on 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’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 choose to have a voluntary GAP/GHP audit at the request of their buyers. A GAP/GHP audit is a way that farms can provide their 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.

What are the key areas of FSMA?

The law itself is broken down into 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 for farms and the Good Manufacturing Practices (GMP)/Preventive Controls Rule for processing facilities.

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

After the law passed in 2011, the FDA developed initial drafts of the rules which it released in 2013. Over the next two years, the 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 the 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.

Does FSMA Apply to Me?

Do you have a produce farm? If you operate a farm business 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 **Good Manufacturing Practices (GMP) and Preventive Controls for Human Foods Rule likely applies to you.**

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

Are you a food hub or farmer cooperative? For the purposes of FSMA, FDA has written a specific definition of a “farm.” Food hubs and cooperatives may also be considered a “farm” depending on their ownership structure and sourcing model.

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

FDA’s Farm Definition: <https://www.federalregister.gov/articles/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human#p-2861>

National Sustainable Agriculture Coalition’s Flowchart for Farms and Food Businesses: http://sustainableagriculture.net/wp-content/uploads/2016/02/2016_2-FSMA-Final-Rule-Flowchart-V3.pdf

FDA Coverage and Exemptions/Exclusions for Farms: <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf>

The Produce Safety Rule for Farms

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

The rule covers produce, but some types of produce and several categories of farms are exempt:

- If your farm’s average annual sales of produce over the last three years are \$25,000 or less, your farm is exempt. To claim this exemption, keep records of your **produce sales.**

- Produce used only for personal or on-farm consumption is exempt
- Produce that is defined by the FDA as “rarely consumed raw” is exempt, such as potatoes. The FDA has developed a specific list of produce that they include in that category, <https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption#p-2005>. Food grains such as barley, wheat, quinoa, rapeseed, etc. are also exempt.

Most diversified farms grow and handle a mix of produce, some on the exempt list, others not. Depending on the specific circumstances of your own farm operations, you may find it is most practical to manage all your produce crops in compliance with the Produce Safety Rule rather than using different practices for crops covered by the rule and those that are exempt.

In addition, your farm may be eligible for a qualified exemption if:

- Your total annual **food sales** averaged less than \$500,000 over the past three-year period;
AND
- The majority of all of your combined sales over the past three-year period were made directly to “qualified end-users.” Qualified end-users are end consumers, restaurants, or retail food establishments located in the same state or Indian reservation as your farm or within 275 miles of your farm.

Farms with qualified exemptions still need to meet modified requirements of the rule, such as prominently displaying the farm name and address on all packaging labels or at the point of sale and complying with the record keeping, compliance, and enforcement provisions of the rule. A farm may lose its qualified exempt status if there is an FDA investigation of a food borne illness or other food safety concern.

To demonstrate that your farm is eligible for the qualified exemption, you must keep good sales records and make them available upon request. 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 six key areas. The intent is to reduce food safety risks by limiting microbial contamination – and cross contamination – from hygiene, water, soil, animals, and surfaces on your farm.

The Produce Safety rule sets the standards but does not always define the specific actions you must take. This is to allow flexibility for farms to meet the standards in ways that work for your particular operation. Over the coming years, WSDA and other organizations will provide trainings, guidance, and other resources to help Washington farms implement the Produce Safety Rule standards.

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 apply to your operation.

- **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.
- **Agricultural Water** must meet specific water quality standards depending on the water source and how it is used on the farm. Irrigation water and post-harvesting handling water (including water used for washing produce, hands and contact surfaces) must meet specific testing criteria for generic *E.coli*. Required testing frequency depends on your specific water quality, source, and use.
- **Biological Soil Amendments** section defines how raw manure and stabilized compost may be used as soil amendments to minimize the risk of contaminating produce. At this time, the recommendation is to follow the National Organic Program Standards for raw manure.
- **Domesticated and Wild Animals** section recognizes that animals are a part of farms but requires farmers to have crop monitoring and corrective action practices to minimize contamination or damage to crops caused by animals.
- **Equipment, Tools and Buildings** section addresses storage, maintenance, and sanitation of surfaces that can come into contact with produce. For example, things to consider include hand washing facilities, packing sheds, tractors and harvesting bins.
- **Record Keeping** – FDA has included specific recordkeeping criteria related to different parts of the rule to increase accountability, traceability, and transparency of practices. Sales records, water-testing results, stabilized compost treatments, and equipment cleaning schedules are some of the activities that may need documented recordkeeping.
- **Sprouts** have special requirements because of their susceptibility to contamination. If you grow sprouts, please see the Sprout Safety Alliance for more details, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm293429.htm>

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

WSDA's Regional Markets Team (Small Farm Direct Marketing and Farm to School Programs) provides trainings and is available to answer questions and give technical assistance about on-farm food safety, including the Produce Safety Rule, smallfarms@agr.wa.gov or 206-256-6151.

The National Sustainable Agriculture Coalition has an excellent set of blog posts, recorded interviews, and charts to help farms understand the specific requirements of rules and how they apply to small farms, <http://sustainableagriculture.net/blog/produce-rule-analysis-part-1/>

FDA overview and guidance, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

FDA Produce Safety Rule Key Requirements Fact Sheet, <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf>

The Good Manufacturing Practices (GMP) and Preventive Controls Rule for Processors

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

Yes. How it applies depends on your products. WSDA's Food Processor License requirements are designed around the basic criteria of Good Manufacturing Practices (GMP). This means if you are licensed by WSDA, you are already following GMP for your product.

FSMA updates GMP by adding the Preventive Controls Rule. With the updated GMP, products that are considered to be at a higher risk (due to a presence of allergens or likelihood of pathogens for example) fall under the new regulation. For Preventive Controls, processors must do a hazard analysis of their process to determine the potential points where risks of contamination exist and create a Food Safety Plan that outlines the steps or "preventive controls" they will use to reduce the risks of contamination.

Where can I find key information for food processors about the Preventive Controls Rule?

The FDA Overview of the FSMA Proposed for Preventive Controls for Human Food is an excellent resource, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

FDA Preventive Controls for Human Food Key Requirements Fact Sheet, <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM461834.pdf>

Where can I get training on Preventive Controls?

The Food Safety Preventive Controls Alliance (FSPCA) provides training and information, <http://www.iit.edu/ifsh/alliance/>

WSU Food Processing Extension and Research offers trainings and resources on Preventive Controls for food processors. <http://foodprocessing.wsu.edu/> Dr. Girish Ganjyal, girish.ganjyal@wsu.edu or 509-335-5613.

Northwest Food Processors Association, <http://www.nwfpa.org/nwfpa-events/training>

Are there any exemptions to the Preventive Controls Rule?

Under the Preventive Controls Rule from FDA, there are some exemptions. WSDA is currently reviewing those exemptions as part of the process of identifying exactly how the new FDA FSMA regulations will be implemented in Washington State.

Compliance Timeline and Enforcement

When do farms and processors have to comply with FSMA?

Both the Produce Safety Rule and the Preventive Controls Rule are being implemented now. The specific timelines for implementation and compliance vary by the different parts of the rules and based on the size your business and type of market. The tables below provide an overview of the compliance timelines for the Produce Safety Rule and the Preventive Controls Rule.

TABLE 1. SUMMARY OF PRODUCE SAFETY RULE COMPLIANCE DEADLINES

Category	Produce Safety Compliance Deadline
Record Keeping Requirements for sales of food and produce*	January 2016
General Compliance	January 2017
Small Businesses (between \$250,00 and \$500,00 in annual produce sales)	January 2018
Very Small Businesses (between \$25,000 and \$250,000 in annual produce sales)	January 2019
Water Requirements	All farms have an additional two years from the applicable deadline above, though some testing and recordkeeping prior to this deadline may be advised.
Labeling Requirements*	January 2020

*These deadlines also apply to Qualified Exempt farms.

TABLE 2. SUMMARY OF PREVENTIVE CONTROLS RULE COMPLIANCE DEADLINES

Category	Preventive Controls Compliance Deadline
Record Keeping Requirements*	January 2016
General Compliance	September 2017
Small Businesses (less than 500 full-time equivalent employees)	September 2016
Businesses subject to Pasteurized Milk Ordinance	September 2018
Very Small Businesses (Less than \$1 million market value of annual food produced and/or sold)	January 2019

*Applies to all businesses.

How will the rules be enforced?

The exact way the rules will be enforced is not yet defined. FDA has directed individual states to determine specifically how the new regulations will be adopted and enforced in each state.

WSDA is currently working on how the regulations will be adopted in our state and has begun state rulemaking procedures. WSDA is seeking engagement from stakeholders, including farms and food

processors regarding this rulemaking. You can learn more about rulemaking and track activity, like public hearings, for specific rules on WSDA's website, <http://agr.wa.gov/lawsrules/>.

Where can I find 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.

Complete FSMA, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm>.

Produce Safety Rule, <http://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm>

GMP / Preventive Controls for Human Food Rule,
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

Recommended Fact Sheets

- 18. Good Agricultural Practices (GAPs)
- 19. WSDA Food Processor License and Facilities

For further information, to provide comments, or suggest a resource to add to this fact sheet, please email smallfarms@agr.wa.gov or call (206) 256-6157.