



# Food Safety Modernization Act (FSMA)

## Frequently Asked Questions for Fresh Fruit and Vegetable Producers

### What is the Food Safety Modernization Act?

The Food Safety Modernization Act, also known as FSMA (often pronounced "FIZZ mah"), was signed into law by President Barack Obama in 2011. FSMA is designed to help protect public health by preventing food contamination before it causes human illness rather than responding to foodborne illness outbreaks after people have already gotten sick. The seven major rules of FSMA address the critical points of the global supply chain for both animal and human food (Table 1). The U.S. Food and Drug Administration (FDA) is the enforcing agency of FSMA.

for human consumption. These activities are defined as "covered" activities and are subject to requirements set forth in the PSR.

**Additional rules and requirements may also apply** if a) your business meets the definition of a "farm" versus "mixed-type facility" and/or b) if you are performing activities (besides growing, harvesting, packing, and holding) that may be considered manufacturing/processing\*. Certain aspects of the "farm" definition are very fact-specific, and therefore the FDA is not issuing guidance focused on these topics at this time but is instead addressing them on a case-by-case basis.

*\*Examples of manufacturing/processing activities of a mixed-type facility may include but are not limited to baking, boiling, bottling, canning, cooking, cooling, cutting (ex., any cuts after removal of the harvestable portion from the mother plant), distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing.*

**Table 1.** The Seven Rules of the Food Safety Modernization Act

Title/Rule	Commonly Referred to as
<b>Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption</b>	<b>Produce Safety Rule</b>
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food	Preventive Controls for Human Food Rule
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals	Foreign Supplier Verification Rule
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications	Third-Party Accreditation and Certification Rule
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	Preventive Controls for Food for Animals
Focused Mitigation Strategies to Protect Food Against Intentional Adulteration	Intentional Adulteration
Sanitary Transportation of Human and Animal Food	Sanitary Transport Rule

### What rule(s) under FSMA affect fresh fruit and vegetable farms?

The Produce Safety Rule (PSR) establishes for the first time the science-based, minimum food safety standards for activities such as growing, harvesting, packing, and holding fruits, vegetables, mushrooms, and sprouts intended

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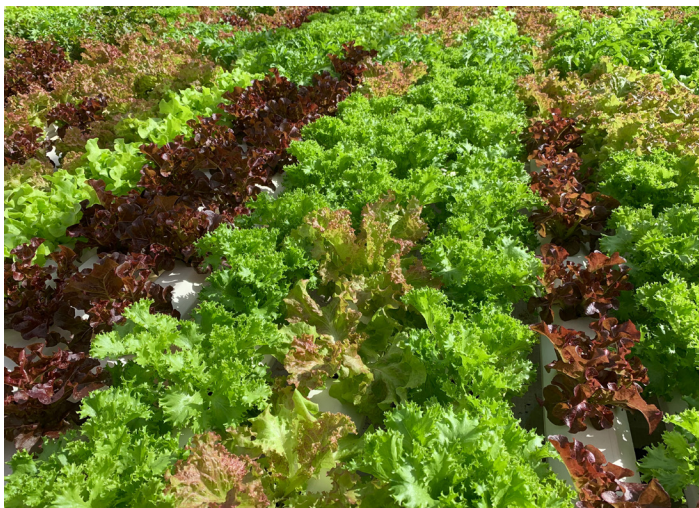
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Determining whether the activities you perform are solely within the “farm” definition (only growing, harvesting, packing, and holding) versus being a farm that also conducts “mixed-type facility” activities is critical to determining whether your business is exempt from registration as a food facility with FDA and the requirements of the Preventive Controls for Human Foods Rule. Farms and farm activities are not subject to these requirements.

For more information, visit the FDA’s websites on FSMA:

- Food Safety Modernization Act (FSMA), <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma>
- Coverage and Exemptions Flowchart, <https://www.fda.gov/media/94332/download>
- FSMA Final Rule on Produce Safety, <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>
- Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industries (Draft Guidance for Industry), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-classification-activities-harvesting-packing-holding-or>



**Figure 1.** Lettuce is a covered crop under the FSMA Produce Safety Rule.

## What types of produce and farm activities are covered under the Produce Safety Rule?

Fruits and vegetables that are regularly consumed raw, sprouts, and mushrooms are covered under (subject to) the Rule. There are exemptions, including farms with average annual produce sales of no more than \$25,000 calculated over the previous three years of production and adjusted for inflation.

Crops that are commonly eaten raw, including but not limited to vegetables, such as lettuce, spinach, cucumbers, tomatoes, herbs, and most fruits, are considered covered. Tea, vanilla, and edible flowers as raw agricultural commodities are technically covered unless roasted or otherwise processed. Turmeric is covered, yet ginger is not (see below).

Sprouts and microgreens are covered under the PSR, but are regulated differently due to the differentiating amount of risk. Sprouts (young plants harvested when the cotyledons are still un- or underdeveloped and whose true leaves have not yet begun to emerge) have their own section under the PSR and must undergo strict microbial testing beyond what a normal farmer must conduct. Microgreens (small plants that are harvested after the emergence of their “true” leaves) are treated as any other covered produce under the Rule.

Aquaponics and hydroponic operations are currently regulated the same as other farms with an increased water risk. At the time of this publication, these operations do not have a special section like sprouts. For specialized information, please see the Northeast Center to Advance Food Safety’s Produce Safety in Hydroponic and Aquaponic Operations website.

## What are some situations in which I would not be allowed to harvest or sell my crops under FSMA?

You must not harvest produce where the harvestable portion of the crop has been contaminated by floodwaters, where the floodwater was knowingly contaminated (e.g., from a chicken manure pile on your property), or at risk of contamination (ex., floodwater that came from beyond your property and may have been contaminated by trash, chemical contamination, sewer wastewater, etc.). Water pooled in your fields that only derived from the rain and did not come from an off-property source may be examined for risk on a case-by-case basis. This is a more significant hazard to low-growing crops (e.g., strawberries) than orchards (e.g., lychee). For more information, please see FDA’s Guidance for Industry: Evaluating the Safety of Flood-affected Food Crops for Human Consumption.

You must also not sell “dropped produce” or produce harvested from a plant and then accidentally or intentionally dropped or placed directly in contact with the ground where this action is not part of the industry standard for harvesting. For example, harvesting bananas and then putting them in the dirt at the base of the tree makes them contaminated as multiple sources of pathogens (wild animal feces, spilling of chicken manure as you transport it through the orchard, your pet dog peeing on the tree) may have been in the dirt or grass that now touches the bananas. To avoid this and keep your bananas sellable,



perhaps place them on a tarp or directly into your truck. For more information, please see this FDA Fact Sheet: [Dropped Covered Produce](#)

### What types of crops and farm activities are NOT covered under the Produce Safety Rule?

- Fruits and vegetables that are not sold commercially and grown only for personal or on-farm consumption are not covered under the Rule.
- Crops that are not commonly eaten raw (per the FDA as an exhaustive list "Rarely Eaten Raw")
- Asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.
- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed)
- Honey is not covered under the PSR but rather under the Preventative Controls for Human Food.
- For more information, please see the FDA Fact Sheet: [Rarely Consumed Raw Produce](#)

### What are the key requirements of the Produce Safety Rule (PSR)?

The key requirements of the Rule, intended to prevent contamination of produce during production, harvest, and after harvesting, fall into the following categories:

- Worker Health, Hygiene, and Training (21 CFR Part 112, Subpart D)
- Agricultural Water for Pre- and Postharvest Uses Water (21 CFR Part 112, Subpart E)
- Biological Soil Amendments of Animal Origin (21 CFR Part 112, Subpart F)
- Domesticated and Wild Animals (21 CFR Part 112, Subpart I)
- Equipment, Tools, Buildings, and Sanitation (21 CFR Part 112, Subpart L)
- Sprouts (21 CFR Part 112, Subpart M)
- Records (21 CFR Part 112, Subpart O)



**Figure 2.** Produce grown for personal consumption is not covered under the FSMA Produce Safety Rule

### How long do I have to get in compliance? When is the compliance deadline?

Compliance dates for covered farms have already passed. This means that all covered farms must be in compliance with the standards and requirements of the PSR, excluding the agricultural water-related requirements, which have extended deadlines of January 26, 2022, 2023, and 2024, based on business size.

Compliance dates for qualified exempt farms have also passed, meaning these farms must be in compliance with the labeling and recordkeeping requirements (Table 2.)

### Are there any exemptions to the Produce Safety Rule?

Farms with an average annual value of produce sold during the previous three-year period of \$25,000 or less (adjusted for inflation) are not covered under the Rule.

Stores and restaurants (that do not grow produce to

**Table 2. FSMA Produce Safety Rule Compliance Dates (Source: Cornell Produce Safety Alliance & Southern Center for Training Education, Extension, Outreach, and Technical Assistance to Enhance Produce Safety, Rev. 3/19/19)**

Business Size	Compliance Dates for Sprouts	Compliance Dates For Most Produce	Water Related Compliance Dates <sup>1</sup>	Compliance Date for Qualified Exemption Labeling Requirement <sup>2</sup>	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>\$500K)	1/26/17	1/26/18	1/26/22	1/1/2020	1/26/16
Small businesses (>\$250K-500K) <sup>3</sup>	1/26/18	1/28/19	1/26/23		
Very small businesses (>\$25K-250K) <sup>4</sup>	1/28/19	1/27/20	1/26/24		
<sup>1</sup> According to the Final Rule issued 3/18/19, compliance dates for Subpart E, Agricultural Water, allow an additional four years. <sup>2</sup> A farm eligible for a qualified exemption must notify consumers as to the complete business address of the farm where the food is grown, harvested, packed, and held. <sup>3</sup> A farm is a small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$500,000. <sup>4</sup> A farm is a very small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$250,000.					

be sold to the public on the business property) are not covered under the Rule. However, they may be covered under other state or local regulations, such as the Hawai'i Department of Health, Food Safety Code.

Farms that sell less than an average of \$500,000 in food sales over the previous three years (adjusted for inflation) may be eligible for a qualified exemption and must comply with modified requirements. To be eligible for a qualified exemption, more than 50% of the average annual food sales must be to qualified end-users (QEU). QEU are consumers who purchase the food directly from the farmer and some local retail establishments (farmers markets, restaurants, grocery stores) that are located in Hawai'i or not more than 275 miles away. Selling directly to the mainland, to a wholesale company that will ship your produce to the mainland, or to a broker (ex. middleman), are entities not considered QEU. For more information, refer to [Publication FST-67 on Qualified Exemptions to the FSMA PSR](#).

The FDA can withdraw a qualified exemption status in the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm, or if they "determine [withdrawal] is necessary to protect the

public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety" of the covered produce your farm is growing, harvesting, packing, and holding. Visit the FDA for more information.

Another exemption is the processing exemption. Covered produce processed by a method validated to eliminate harmful microorganisms of public health significance (including spore-forming microorganisms) is eligible for an exemption and must only comply with limited requirements. Validated methods include but are not limited to boiling/steaming/roasting/cooking, canning, pasteurizing, acidifying/pickling, juicing with a Hazard Analysis and Critical Control Points (HACCP) plan, refining, distilling, or manufacturing into sugars, oils, spirits, wine, beer, or similar products.

For example, a tomato crop destined for a commercial cannery would be eligible for this exemption. The other crops on the farm not destined for that commercial cannery or other

commercial processing would not be eligible and would be considered covered produce. However, it is possible that the qualified exemption could apply.

## Who determines if a farm is exempt?

Each farm is responsible for determining its eligibility for any of the exemptions. However, the Hawai'i Department of Agriculture, Hawai'i Produce Safety Program and the enforcement agency (FDA) may request information and documentation to confirm the exemption status. Therefore, farms must maintain the necessary documentation to support their exemption status as the FDA is currently conducting routine inspections of all covered non-exempt farms.

## How do I determine if my farm is eligible for a qualified exemption?

A qualified exemption is based on total food sales from the previous three years and sales to qualified end-users. For more information and a worksheet to determine your eligibility, refer to Extension Publication [FST-67: Qualified Exemptions to the FSMA PSR](#).





**Figure 3.** Taro is a covered crop under the FSMA Produce Safety Rule. However, with proper documentation, growers may obtain an exemption only if the taro is destined to be sold to a commercial processor that will process it using a validated kill step.

### Am I required to attend a training course for the Produce Safety Rule?

If you have determined that your farm and the produce you grow are covered under the Produce Safety Rule and you do not have an exemption for all your produce, there are specific training requirements. At least one supervisor or responsible person on the farm must complete food safety training at least equivalent to that received under a standardized curriculum recognized by FDA (Figure 4.). In association with the FDA, the Cornell Produce Safety Alliance (PSA) designed an approved curriculum to prepare producers to meet the Produce Safety Rule's requirements. This training course must be given by a certified trainer(s) and completed to receive a certificate of completion. For more information, please see this FDA Fact Sheet: [Required Training for Covered Farms](#).

### Do I need a Food Safety Plan?

A written farm food safety plan (FFSP) allows growers of fresh fruits and vegetables to become better organized and focused on produce safety. While not explicitly required by FSMA, it is a helpful tool for complying with FSMA as it becomes a central place for growers to assess risks, outline practices to reduce those risks, record policies and standard operating procedures (SOPs), and keep necessary records. A written farm food safety plan is usually required for third-party GAP audits.

### Are there other food safety regulations besides FSMA that I should be aware of?

Yes, the Federal Food, Drug, and Cosmetic Act (FD&C Act, Title 21).

### Who can I contact for more information about FSMA, the Produce Safety Rule (PSR), and upcoming Produce Safety Alliance (PSA) Grower Training in Hawai'i?

In Hawai'i, growers can contact the University of Hawai'i at Mānoa, College of Tropical Agriculture & Human Resources, [Cooperative Extension](#) for questions about FSMA and the PSR, as well as the PSA Grower Training course. This course is taught by a team of agricultural Extension Agents who are familiar with Hawai'i crops, cropping systems, and farm food safety, and have been trained to deliver this curriculum. For more information on the training and curriculum, please visit:

- <https://cals.cornell.edu/produce-safety-alliance/training/trainings-what-expect-and-how-find-right-one>
- <https://cals.cornell.edu/produce-safety-alliance/psa-curriculum>



**Figure 4.** Papaya growers complete Produce Safety Alliance Grower Training led by the UHM-CTAHR Farm Food Safety Program Extension Agents.

Growers can also contact the Hawai'i Department of Agriculture (HDOA), Produce Safety Program, for information on FSMA, the Produce Safety Rule, and upcoming training: [www.hifarmsafe.org](http://www.hifarmsafe.org).

### **How can I prepare for an inspection?**

#### **What should I expect?**

To prepare for an inspection, farmers must make sure they are in compliance. This includes on-farm practices and having proper documentation and records as required by the Rule. Growers often use the training manual from the Produce Safety Alliance (PSA) Grower Training as a reference tool to guide compliance.

On-Farm Readiness Reviews (OFRR) are confidential and voluntary educational walk-throughs of farms to support farms with FSMA PSR inspection readiness. In Hawai'i, these are conducted by CTAHR Extension Agents and HDOA. Growers can request an OFRR by contacting HDOA's Produce Safety Program or their Extension Agent. Participation in the PSA Grower Training is required before scheduling an OFRR.

For more information, please see this FDA Fact Sheet: [What to Expect of a Regulatory Inspection](#).

### **Who are Extension Agents, and how can they help me with farm food safety?**

Extension Agents are faculty with the University of Hawai'i at Mānoa, College of Tropical Agriculture and Human Resources (CTAHR), who work with farmers in Hawai'i. The CTAHR Farm Food Safety Team consists of agricultural Extension Agents in each county who support commercial farmers with their farm food safety needs. Extension Agents can assist growers with farm food safety through workshops and training, farm walk-throughs, reviewing farm food safety plan documents, and answering your questions related to specific topics. Extension Agents also work closely with partner institutions and agencies who work directly with farm food safety.

### **How is the Hawai'i Department of Agriculture (HDOA) involved in farm food safety and the Produce Safety Rule? What are their role and responsibilities?**

HDOA's Produce Safety Program has a grant from the FDA to provide outreach and education to growers that the FSMA Produce Safety Rule may impact. The HDOA Produce Safety Program also facilitates PSA Grower Training Courses and On-Farm Readiness Reviews for Hawai'i growers in partnership with CTAHR. HDOA's Commodities Branch offers Farm Food Safety Audits using the USDA Schemes. For more information, visit [www.hifarmsafe.org](http://www.hifarmsafe.org).