



P.1 FOOD SAFETY MODERNIZATION ACT AND COVERED PRODUCE

PURPOSE OF THIS FACT SHEET

This fact sheet is to make you aware of the basic requirements of the Food Safety Modernization Act (FSMA) including which types of agricultural operations are covered and which are exempt, and the requirements for demonstrating an exemption. It is your duty to be aware of, and in compliance with any laws that apply to you. The penalty for failure to comply with the law is usually an order to come into compliance, and a fine. This area of law is called “regulatory law.” Unlike criminal law, a government official does not necessarily need a search warrant or an arrest warrant to come on your property to see if you are in compliance with a regulation, however just like with criminal law you always have what are called “due process rights.” This means that you are always entitled to a hearing in which a government official explains their case against you and you have an opportunity to show evidence against their case.

Note that meat and dairy products are regulated separately and are not covered in this fact sheet.

CONCEPTS

The Food Safety Modernization Act (FSMA) directed the Food and Drug Administration (FDA) to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. This directive resulted in two rules: The Produce Safety Rule and the Preventive Controls for Human Food Rule.

Covered Produce: Neither of these rules apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity, including produce that is processed with a “kill step” such as cooking or pasteurizing that adequately reduces the presence of pathogens.

Covered Operations: The Produce Rule applies to farms and their related harvesting, packing and cooling operations as defined by the FDA. Generally the FDA defines “Primary Production Farms” as farms including on site packing and cooling and “Secondary Activities Farms” as harvesting, packing and cooling operations that are majority owned by the farm that grows the majority of the product harvested, packed or held. Any operation that meets the FDA definition of a “Primary Production Farm” or a “Secondary Production Farm” is subject to the Produce Rule. All other operations that handle covered produce are subject to the Preventative Controls for Human Food Rule.

Exempted Operations: Some farms may be exempted from the produce rule, but any operation claiming an exemption must be able to document that they meet the criteria for the exemption.

There are two exemptions:

1) Full exemption: Farms that can demonstrate that for the previous 3 years the average annual gross sales of covered produce was \$25,000 or less are fully exempt.

2) Qualified exemption: Farms that can demonstrate that for the previous 3 years the average annual gross sales of covered produce was \$500,000 or less and also demonstrate that the majority of sales during that period were to “qualified end users” may have a qualified exemption which includes certain labeling or notice requirements. A qualified end user may be either: (1) the consumer of the food or (2) a restaurant or retail food establishment located in the same State or on the same Indian reservation as the farm or not more than 275 miles away.

By January 1, 2020, farms with a qualified exemption are required to include their name and complete business address either on the label of the produce or as a display at the point-of-purchase.

Farms claiming the qualified exemption must also be able to demonstrate that they verified their continued eligibility for the exemption each year.

All other non-exempt farms selling covered produce are required to be in compliance with The Produce Rule by the end of 2017.

The Produce Rule: The rule focuses on five major areas: 1) worker training and health and hygiene, 2) water, 3) animals, 4) equipment, tools and buildings, 5) sprouts. In very general terms all covered farms are required to have at least one person who has received a certificate documenting completion of an FDA approved produce safety training, and must further document that all farm workers who have contact with covered produce have also received appropriate food safety training. Farm worker training may be included with other training and does not have to be delivered through an FDA approved course. In addition to training, covered farms must be able to demonstrate that any water or equipment that comes into contact with covered produce is relatively free of dangerous pathogens, and must ensure that any covered produce that has likely been contaminated by animal feces is not harvested or packed for human consumption. A written food safety plan is not required, but numerous written records are required, and it would be difficult to demonstrate compliance without an organized written plan for doing and documenting all that is required.

The Preventive Controls for Human Food Rule: Covered facilities that are neither “Primary Production Farms” (generally farms including onsite packing and cooling) or “Secondary Production Farms” (generally packing and cooling facilities majority owned by the farm supplying the majority of the product handled) are required to establish and implement a food safety system including a written analysis of hazards and risk-based preventative controls.

Enforcement: In most states the FDA has delegated enforcement to state departments of agriculture. In some states and on Indian Reservations the FDA is still determining how enforcement will be implemented.

In an enforcement action the FDA may issue a warning letter, require a recall or administrative detention of farm product, or seize the farm products and issue an injunction prohibiting further sales.

The FDA may withdraw a qualified exemption (making a farm fully subject to the rule) if there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm. The FDA must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead FDA to withdraw the exemption, provide an opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency. A withdrawn exemption may be reinstated if the FDA determines that the outbreak was not directly linked to the farm, or that the problems have been adequately resolved.

WHAT TO DO IF A GOVERNMENT INSPECTOR COMES TO YOUR PROPERTY

If an inspector comes on your property remember that whatever decision they make is subject to appeal, and that if you cannot find the records you need at the time, if you find them later you may be able to reduce your fines.

If an inspector documents some violation, take a picture of what they were looking at. If an inspector takes a soil, water, or chemical test, take a picture and try to take the same or a similar sample at the same time, or immediately after so you can have the test results independently verified.

If you are issued a notice of violation you should consult an attorney who can help you to navigate the process of appealing the decision and making your case for why the penalties should be reduced.

WHERE TO GET HELP

For information about produce food safety training:

[The Produce Safety Alliance https://producesafetyalliance.cornell.edu/](https://producesafetyalliance.cornell.edu/)

[National Farmers Union Local Food Safety Collaborative https://nfu.org/farmsafety/local-food-safety-collaborative/](https://nfu.org/farmsafety/local-food-safety-collaborative/)

[Initiative for Indigenous Food and Agriculture at the University of Arkansas Law School http://indigenousfoodandag.com/](http://indigenousfoodandag.com/)

ADDITIONAL RESOURCES

[The FDA Food Safety Modernization Act page at www.fda.gov/FSMA](http://www.fda.gov/FSMA)

[Farm Commons https://www.farmcommons.org/food-safety](https://www.farmcommons.org/food-safety)

FARM AND RANCH BUSINESS HEALTH ASSESSMENT

Author: Poppy Davis, October, 2017

This publication is a joint effort of California FarmLink and SAGE (Sustainable Agriculture Education) funded by the United States Department of Agriculture Farm Service Agency.

We would like to thank additional partners: ALBA (Agricultural and Land Based Training Association) for testing and Spanish language translation.

The Business Health Assessment and all related fact sheets are available on the Resources section of the California FarmLink website www.CaliforniaFarmLink.org

