

FDA FACT SHEET

Produce Safety Rule (21 CFR 112)

“What to Expect of a Regulatory Inspection” Informational Handout for Farmers

The U.S. Food and Drug Administration (FDA) or a state regulatory agency may conduct an inspection of your farm for a variety of reasons, such as a routine or follow-up inspection. Inspections are part of our regulatory program related to produce safety, which also includes education, outreach, and technical assistance. This document provides an overview of the steps that state inspectors or federal investigators will take when conducting routine inspections for compliance with the Produce Safety Rule (PSR) established by the FDA Food Safety Modernization Act. If you have questions, please contact the FDA Office of Regulatory Affairs Produce Safety Network (PSN) at: ProduceSafetyNetwork@fda.hhs.gov.

Scheduling the Inspection

Most of the time, the agency inspector or investigator will call the most responsible person on your farm, such as the farm owner, manager, or person in charge, to schedule the inspection. The person you designate to be in charge of produce safety should be a part of scheduling the inspection and should accompany the inspectors or investigators during the inspection.

During the pre-inspection call, the inspector or investigator will ask questions to make a preliminary determination about whether the [PSR](#) applies to your farm. Use the FDA decision tree entitled “[Standards for Produce Safety, Coverage and Exemptions/Exclusions](#)” found at <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf> to assist in this discussion.

The inspector or investigator will discuss:

- Whether your farm grows covered produce (produce regulated by the rule);
- Whether your farm conducts covered activities (growing, harvesting, packing or holding);
- Farm size (produce sales and/or food sales) to determine if your farm is not subject to the rule or meets the requirements for a qualified exemption;
- Whether your produce meets the requirements for the commercial processing exemption.

If your farm is determined to be eligible for a qualified exemption or your produce is determined to be eligible for the commercial processing exemption, the inspector or investigator will review records that support this status.

Announced Inspections

If your farm is covered by the rule, the inspector or investigator will schedule an inspection date that works for both the inspector or investigator and the person in charge. In most cases, the inspection will be scheduled within five (5)

business days of contact with the person in charge. If the person in charge is not the produce safety/quality expert, the inspector or investigator may suggest that individual also be present for the inspection. Plan to have a representative from your farm knowledgeable in the growing, harvesting, packing and holding activities, preferably the person responsible for produce safety, escort the inspection team around your farm. The inspector or investigator will explain the general flow of the inspection, what the inspection will cover, and records that may be reviewed.

The inspector or investigator will ask if your farm has any biosecurity practices, hazards, safety protocols, and other requirements that inspectors and investigators need to be aware of and adhere to before the visit.

Unannounced Inspections

Most inspections will be announced but there are circumstances in which unannounced inspections may be conducted. The following are examples of when an unannounced inspection may occur:

1. If your farm has had produce safety issues in the past and the issues have not been corrected;
2. If a follow-up inspection is needed and an unannounced inspection may work best to observe the necessary changes being made;
3. If your farm is unresponsive (no contact within five (5) business days after reasonable contact attempts have been made) or is unwilling to set a date for the inspection; or
4. In response to a complaint, recall, or foodborne outbreak investigation.

Day of the Inspection

When an inspector or investigator arrives on your farm, he or she will ask to speak to the owner or person in charge. The inspector or investigator will introduce himself or herself (name, title, agency), provide the reason for the inspection, and show identification. Depending upon your state regulations or if FDA conducts the inspection, the inspector or investigator may also issue a written Notice of Inspection or similar form to you. It is preferred that the owner, person in charge, or produce safety manager is onsite for the inspection. As noted earlier, a person knowledgeable in growing, harvesting, packing and holding activities, preferably the person responsible for produce safety, should plan on accompanying the inspector or investigator during the inspection.

Initial Interview

The inspector or investigator will provide you with a brief description of the reason for and scope of the inspection and activities to be conducted during the inspection. The amount of time an inspection will take depends on the type of inspection, farm activities, size of the farm, and what is observed during the inspection. The inspector or investigator will ask you about the activities performed the day(s) of the inspection, such as whether the farm is planting, harvesting, packing or holding, and about the farm's organization.

Walk-Through of the Farm

During the inspection, the inspector or investigator will observe your farm operation, working with you to coordinate inspection activities with farm operations. He or she may ask questions about farming practices and operations that

cannot be observed during the inspection. He or she will take notes, may take pictures, may collect samples, and will review and may copy records, such as training and biological soil amendment records.

Throughout the inspection, the inspector or investigator will explain what is being looked at and why. If there are any regulatory concerns, the inspector or investigator will discuss them with you and explain the reason(s) for each regulatory concern and the public health significance.

Exit Interview

It is preferable if the most responsible person on your farm, such as the farm owner or manager, is available during the exit interview. The inspector or investigator will go over any regulatory concerns and findings and provide you with information on resources and technical assistance. If you are able to make corrections during the inspection, the inspector or investigator will document them. If the deficiency cannot be corrected during the inspection, the inspector or investigator will work with you to determine a reasonable time frame to implement preventive measures and corrective actions. During the exit interview, the inspector or investigator will also identify preventive produce safety practices and conditions on your farm based on the requirements of the PSR. The inspector or investigator will also answer any questions you may have regarding the inspection. He or she will also provide you with an inspection sheet with agency contact information that will document the inspection.

For information on the Produce Safety Rule:

- <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.