

The FSMA Produce Safety Rule Inspection Process: What to Expect



Background on the Produce Safety Rule

Congress passed the Food Safety Modernization Act (FSMA) in response to outbreaks of dangerous foodborne illnesses and called on the Food and Drug Administration (FDA) to implement new rules. The FSMA rules provide a hands-on approach to preventing illness and food recalls by focusing on food safety at all points in the food system. These rules cover seven areas, one of which is produce safety. The Produce Safety Rule (PSR) sets minimum standards for the safe growing, harvesting, packing, and holding of produce for human consumption. Between 2018 and 2020, the PSR requirements are being implemented across the country. The Minnesota Department of Agriculture (MDA) Produce Safety Program is responsible for implementing the rule in Minnesota.

Why Inspections?

On-farm inspections are required to encourage compliance with the FSMA Produce Safety Rule (PSR). The goal of inspections is to help farms improve their food safety program and maintain a safe and healthy food supply. The MDA may inspect your produce operation, including routine or follow-up inspections, for a variety of reasons. Initial inspections will be education-focused. However, a practice, condition, or situation that poses an imminent public health hazard may require immediate corrective action. Inspections in future years will enforce all levels of violations. There is no cost to the farmer for routine inspections.

Is your farm excluded or eligible for a qualified exemption?

An inspector may review records to confirm this status. On-farm practices will generally not be inspected for farms determined to be excluded or qualified exempt. See the FSMA Coverage and Exemptions/Exclusions Flowchart (available on the FDA's website) to understand how the PSR applies to your farm.

Types of Inspections

In Minnesota, most inspections will be announced, but there may be circumstances in which unannounced inspections happen such as:

1. In response to a complaint, recall, or foodborne illness outbreak investigation
2. If your farm has had produce safety issues in the past and the issue has not been corrected
3. If a follow-up inspection is needed and an unannounced inspection may work best to observe the necessary changes being made
4. If your farm does not respond to multiple contact attempts.



Online Resources

- [The FSMA Produce Safety Rule \(PSR\)](#)
- [The Produce Safety Alliance Required Records Fact Sheet](#)
- [MDA Produce Safety Program](#)
- [UMN Extension – The GAPs Education Program](#)

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651-201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.

March 2019

Funding for this statement, publication, press release, etc. was made possible, in part, by the Food and Drug Administration through grant PAR-16-137. The views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.”

The process for announced routine inspections includes:



1 Pre-Inspection Planning Call

The inspector will call in advance to confirm information and learn about your farm. The person in charge of produce safety at your farm should talk to the inspector on the phone and be with the inspector during the inspection. The inspector will:

- Ask about produce grown, harvested, packed or held by your operation and your farm's average annual food sales, and
- Make a preliminary determination about how the PSR applies to your farm.

If your farm is covered under the PSR, the inspector will explain:

- The general flow of the inspection
- What the inspection will include, and
- Records that may be reviewed.

You and the inspector will decide on an inspection date that works for both of you, typically within the next five business days. At least one of these activities – harvesting, packing or holding – must be underway during the inspection.

The length of the inspection will depend on the type of inspection, farm activities, size of the farm, and what the inspector observes onsite. Plan to have a representative from your farm knowledgeable in the growing, harvesting, packing, and holding activities escort the inspector around your farm.

During this call, provide important details such as biosecurity practices, safety protocols, parking instructions, or other visitor requirements.

- Agricultural Water
- Biological Soil Amendments of Animal Origin
- Domesticated and Wild Animals
- Growing, Harvesting, Packing, and Holding Activities
- Equipment, Tools, Buildings, and Sanitation

The inspector may:

- Take notes, pictures or collect samples
- Ask questions about farming practices and operations that are not observable during the inspection
- Review and copy records for the following:
 1. Personnel Training
 2. Biological Soil Amendments of Animal Origin
 3. Equipment and Tool Cleaning and Sanitizing
 4. Agricultural Water source(s) and testing

If there are any regulatory concerns, the inspector will explain the reason(s) for concern and the related public health significance. If corrections are needed and you are able to make these changes during the inspection, the inspector will document the corrections you made. If a problem cannot be corrected during the inspection, the inspector will work with you to determine a timeframe to make changes. If observed, a serious condition that could be an imminent public health hazard will be immediately addressed. Possible actions taken to address serious conditions could include seizure, embargo, voluntary destruction or recall of products.

2 Day of the Inspection

Upon arriving at your farm, the inspector will:

- Provide official MDA identification
- Explain the reason for the visit
- Issue a written Notice of Inspection
- Ask about the covered activities taking place on the farm that day, and
- Explain the scope of the inspection.

Farm Walk-Through: The inspector will observe your farm operation, working with you to match inspection activities with farm operations. For example, if the harvest crew is not working in the morning but will work in the afternoon, the inspection might begin in the packing and holding areas and move to where harvesting is taking place later in the day, or vice versa.

Throughout the inspection, the inspector will explain what is being looked at and why it is related to the PSR topics, including:

- Personnel Training
- Health and Hygiene

Closing Meeting and Inspection Report

The inspector will summarize observations, provide information on resources and technical assistance, and give you a copy of the Inspection Report. The inspector will review with you any orders written and the timeline for corrective actions.

Questions?

For more information about the Produce Safety Rule and the Minnesota Department of Agriculture Produce Safety Program, visit www.mda.state.mn.us/food-feed/produce-safety-program.

If you have questions about what to expect at an inspection, contact the

Produce Safety Team at 651-539-3648 or ProduceSafety.MDA@state.mn.us.