DELAWARE DEPARTMENT OF
AGRICULTURE

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"What to Expect of a Regulatory Inspection" Informational Handout for Farmers

The Delaware Department of Agriculture may conduct an inspection of your farm for a variety of reasons, such as a routine or follow-up inspection. Inspections are one part of our regulatory program related to produce safety, which also includes education, outreach, and technical assistance. This document provides you with an overview of the steps that state or federal inspectors will take when conducting routine Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) inspections, and should address any initial questions you may have. If you have additional questions after reading this document, you should contact: Anna Wicks at anna.wicks@delaware.gov or at (302) 698-4582.

Scheduling the Inspection

Most of the time, the Delaware Department of Agriculture inspector 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 that you designate to be in charge of produce safety should be a part of scheduling the inspection and should accompany the inspectors during the inspection.

During the pre-inspection call, the inspector will ask questions to make a preliminary determination about whether the PSR applies to your farm. Utilize 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 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 farm meets the requirements for the processing exemption.

If your farm is determined to be exempt or qualified exempt, the inspector may perform an inspection to review records that support this status. Please see the Produce Safety Alliance document, "Records Required by the FSMA Produce Safety Rule," for more information about records required under the PSR. Click on the title or navigate to:
https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Records-Required-by-the-FSMA-PSR.pdf

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Announced Inspections

- If the produce grown on your farm is covered by the rule, the inspector will schedule an inspection date that works for both the inspector 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 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 will explain the general flow of the inspection, what the inspection will cover and records that may be reviewed.
- The inspector will ask if your farm has any biosecurity practices, hazards, safety protocols, and other requirements that inspectors 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 is unresponsive (no contact within five (5) business days after reasonable contact attempts have been made) or unwilling to set a date for the inspection;
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; or
4) In response to a complaint, recall, or foodborne outbreak investigation.

Day of the Inspection

When an inspector arrives on your farm, the inspector will ask to speak to the owner or person in charge. The inspector will introduce themselves (name, title, and agency), reason for the visit and are required to provide identification. Depending upon your State regulations or if FDA conducts the inspection, the inspector 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. A person knowledgeable in growing, harvesting, packing and holding activities, preferably the person responsible for produce safety, should plan on accompanying the inspectors during the inspection.

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Initial Interview

The inspector 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 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 will observe your farm operation, working with you to coordinate inspection activities with farm operations. It is helpful for the person in charge or produce safety manager to accompany the inspector during the inspection. An inspector may ask questions about farming practices and operations that they are not able to observe during the inspection. He or she will take notes, and 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 will explain what is being looked at and why. If there are any regulatory concerns, the inspector 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 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 will document the corrections that you implemented. If the deficiency cannot be corrected during the inspection, the inspector will work with you to determine a reasonable time frame to implement preventive measures and corrective actions. During the exit interview, the inspector will also identify preventive produce safety practices and conditions on your farm that align with the requirements of the PSR. The inspector 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.