

Attachment A

Compliance and Enforcement Decision Table Routine/Surveillance Inspection, Follow-up Inspection

Conditions that are technical violations of the PSR and will not likely cause produce contamination

Conditions that may cause produce contamination or continued technical violations of the PSR

Conditions that will cause imminent public health hazard if not corrected or conditions that directly contaminate produce
(Not dependent on previous inspection history)

Background and Context

These tables are a graphic depiction of the inspection processes in the NASDA Framework document and appendices. The key actions outlined in the tables may be beneficial as states work to develop their standard operating procedures. They are not meant to be an exhaustive list of tasks that are required for completion of the inspectional process but should be used to help achieve uniformity and consistency. System Thinking is encouraged as the implications of all observed conditions should be considered. In the following tables:

- Inspection, Compliance, and Enforcement are program functions, not position descriptions.
- References to program management or supervisor indicate administrative functions.
- In certain circumstances, technical observations may be included on the Form 4056 when they are related to the significant findings.
- Technical observations not related to the significant findings should be recorded on the Inspection Report Summary along with farm management's responses.
- In all cases, the final inspection report packet should be assembled by the inspector and then submitted to compliance to be reviewed for completeness.

Compliance and Enforcement Decision Table

Routine/Surveillance Inspection, Follow-up Inspection

Evaluation of Severity of Observed Conditions	Conditions that are technical violations of the PSR and will not likely cause produce contamination	
Regulatory Action	Inspection	<ul style="list-style-type: none"> • Discuss observed conditions with the farmer at the point when they are observed. • Document the details of the observed conditions in the inspection notes for future reference. • Record observations that are "not significant" on the Produce Farm Inspection Report Summary for review with the farmer on the next routine inspection. Include the farm management's response on the Produce Farm Inspection Report Summary. Non-significant observations are discussion items and would not be included on a Form 4056 except when related to significant observations also noted on the farm during the inspection. • Record (on the Produce Farm Inspection Report Summary) the farm's short term and longer term corrective actions and establish a time line for corrections that are not completed.
	Compliance	<ul style="list-style-type: none"> • Review the final inspection report packet. Discuss observations and the farm's responses with the inspector, when appropriate. • Ordinarily, an expedited follow-up inspection would not be warranted. Follow up should happen during the next routine inspection and a regulatory action would not be warranted • Determine inspection classification. • Track that farm's next routine inspection is in the queue to be assigned.
	Enforcement	<ul style="list-style-type: none"> • A regulatory letter or other enforcement action is not typically associated with this type of observed condition. • Voluntary compliance should be encouraged.
Outreach and Education	<p>Provide outreach and education resources:</p> <p>1. Training; 2. Guidance Documents; 3. Technical Assistance Network; 4. On-farm direct technical assistance.</p>	

Compliance and Enforcement Decision Table

Routine/Surveillance Inspection, Follow-up Inspection

Evaluation of Severity of Observed Conditions	Conditions that may cause produce contamination or continued technical violations of the PSR	
Regulatory Action	Inspection	<ul style="list-style-type: none"> • Discuss observed conditions with the farmer at the point when they are observed. • Document the details of the observed conditions in the inspection notes for future reference. • Collect evidence that supports the observations. • Document immediate corrective actions and/or timelines for longer-term corrective actions on the Produce Farm Inspection Report Summary. • Document significant observed conditions on the Inspection Observation Form (4056). • Document the observation and the farm management's response on the Produce Farm Inspection Report Summary. • Document observations that are "not significant" but are important on the Produce Farm Inspection Report Summary.
	Compliance	<ul style="list-style-type: none"> • Review the final inspection report packet and discuss observations and the farm's responses with the inspector and state produce program management, when appropriate. • Determine if a regulatory letter, follow-up inspection or re-inspection within an appropriate time line is warranted. • Determine inspection classification. • Track completion of regulatory actions and any assigned re-inspections.
	Enforcement	<ul style="list-style-type: none"> • If warranted, issue a regulatory letter or other enforcement actions. • Consider progressive enforcement actions if the observation has been previously discussed with the farmer.
Outreach and Education	<p>Provide outreach and education resources:</p> <p>1. Training; 2. Guidance Documents; 3. Technical Assistance Network; 4. On-farm direct technical assistance.</p>	

Compliance and Enforcement Decision Table

Routine/Surveillance Inspection, Follow-up Inspection

Evaluation of Severity of Observed Conditions	Conditions that will cause imminent public health hazard if not corrected or conditions that have directly contaminated produce (Not dependent on previous inspection history)	
Regulatory Action	Inspection	<p>Produce is under control of the farm</p> <ul style="list-style-type: none"> • Discuss observed conditions with the farmer at the point when they are observed. • Document the details of the observed conditions in the inspection notes for future reference. • Collect evidence that supports observations. • Evaluate the need for additional actions such as embargo or stop-sale of affected produce on the farm. • Contact supervisor for discussion of the details of the observed conditions and additional actions that may be warranted. • Document significant observed conditions on the Inspection Observation Form (4056). Document the observations on the Produce Farm Inspection Report Summary as well as farm management's responses. • Record the farmer's immediate corrective actions and/or a time line for longer-term corrective actions.
	Inspection	<p>Produce has left the farm</p> <p>If suspect produce has left the farm or is not otherwise under the control of the farmer, consider the following additional actions:</p> <ul style="list-style-type: none"> • Initiate actions to prevent additional produce from entering commerce (e.g., stop-sale or embargo). • Discuss the inspection with the state produce program's management and consider additional actions that may be warranted including a recall. • Discuss, with the farmer, actions needed to remove shipped produce from commerce. • Notify the FDA about the observed conditions.
	Compliance	<p>During the inspection:</p> <ul style="list-style-type: none"> • The inspector should discuss with Compliance (FDA or state, as appropriate) the observations and possible immediate corrective actions required. In addition, discuss the need for collecting samples and/or other evidentiary documentation to support the actions being taken (e.g., embargo/stop sale). <p>If the suspect produce has left the farm and is not under the control of the farmer, consider the following additional actions:</p> <ul style="list-style-type: none"> • Work with the inspector and state produce program's management to gather all information needed to support the regulatory actions. • Discuss with the farmer, the need for, and parameters of, a recall of the affected produce. • Communicate actions to the FDA. <p>When the inspection is complete and the final inspection report packet has been submitted for review:</p> <ul style="list-style-type: none"> • Discuss the final inspection report packet and the farm's responses, if any, with the state produce program's management and the FDA to determine the adequacy of short and longer-term corrective actions. • Determine if an expedited follow-up inspection, re-inspection, regulatory letter or other enforcement actions are warranted. • Determine inspection classification. • Track completion of regulatory actions and any assigned re-inspections.
	Enforcement	<ul style="list-style-type: none"> • Assign an expedited follow-up inspection or re-inspection within an appropriate time line to determine progress on corrective actions. • Issue an appropriate regulatory letter detailing the violations and consider if additional enforcement/legal action is warranted.
Outreach and Education	<p style="text-align: center;">Provide outreach and education resources:</p> <p style="text-align: center;">1. Training; 2. Guidance Documents; 3. Technical Assistance Network; 4. On-farm direct technical assistance.</p>	