Strategies to Promote Consistency in the Implementation of the Produce Safety Rule

Background:

This program was designed to establish a level of consistency, not based on forms or paperwork but through a basic understanding of the Produce Safety Rule (PSR) for implementation. This project aims to ensure that a covered farm in one state has the equivalent expectations to meet the minimum requirements of the PSR as a covered farm in another. Separate from individual inspection styles and techniques, there should be no differences in the interpretation and implementation of the PSR from farm to farm, state to state.

The development of this program was conceived out of the need for state-to-state partners to openly discuss and clarify aspects and/or intent of the PRS for a more depth understanding and development of critical thinking. This format is not intended to be used as a platform to debate or challenge the PRS's intent and does not supersede an individual State program's goals regarding implementation.

The content and material of this program are primarily FDA resources already created and accessible to everyone. The use of these materials can also be used to educate inspectors in conjunction with the PSR to communicate the PSR expectations effectively. Utilizing already developed and available materials use by both FDA and States will also assist with maintaining consistency from federal to state agencies alike.

The program packet also allows for the use of State program-specific resources that can support the understanding of the PSR, so long as it is in keeping with the program's objective and utilized to promote active discussion and participation. Included in this program are documents that may assist your consistency program. Two scenarios have also been provided for potential use; however, ideally, the host states should ask the participants to develop scenarios so that they are relevant regionally and helps to engage participants. The suggested format is intended as a platform for sharing ideas, information, and materials again as long as it is in keeping with the program's overall objective.

This program was designed to fit seamlessly within most program's current training plans. It is not intended to be a stand-alone course but to work in conjunction with already established programs, and required educational curricula, preferably after personnel have completed the PSA grower training, FD226, and OFRR Train the Trainer course

This program can be used by individual States, delivered by a host State within a region, and adapted to be used in a web-based remote platform. Generally, a regional platform promotes communication between states and aids in maintaining consistency.

By furthering consistency and knowledge of the PSR, this program will provide those who conduct inspection activity another opportunity for education regarding the PSR before going through the FDA Calibration as a development tool within the state.

The objective is that this will not be a one-time event as there will always be a need for an education platform to discuss the PSR and its interpretation in keeping with current federal agency thinking and future implementation guidance.

Continuing education, communication, and collaboration will promote a robust Produce Safety Program within states, regions, and nationally.

Purpose:

This activity is intended to augment training for States doing inspections to enhance consistent implementation of the PSR across the nation. Understandably, every inspector will have their unique approach to conducting inspections; however, the interpretation of the Rule should be consistent. In other words, the outcome should be the same regardless of the method of the inspectional process. Working together as a part of a multi-state training will help ensure consistency for farmers covered by the PSR.

This program is specific to state personnel conducting inspection activities; however, having a representative from the FDA is essential and strongly suggested to assist when the intent and interpretation of the Rule is under question. FDA presence can also provide clarity for any other Agency-specific information or programs as it applies to implementing the PSR.

Other than state inspectors and FDA personnel, the inclusion of other participants can provide benefit to the group. However, if you choose to have additional guests, firm boundaries for participation should be discussed and put in place. Rule discussion should be between state inspectors regarding the application of the rules and not be an open forum of debate, criticism, or personal sentiments that could otherwise undermine the focus on applying the rules or derail the purpose of the training. Other guests can help to moderate, take notes, and actively participate in Option 1.

NOTE: It should be clear that the purpose of this program is to promote the consistent implementation of the PSR and is not how to do inspections.

Goals:

1. Provide a framework for active collaboration among state inspectors to supplement administrative mechanisms that enhance consistency.

2. Provide a training resource for states in a region and their CFSAN-PSN representative.

3. Promote consistency so that farms are subject to the same interpretation of the PSR in each state.

Objectives:

1. Identify the role and purpose of the terminology used in Standard.

2. Learn how to read the Standard.

3. Based upon the Standard, determine at-risk behavior/activity.

4. Based on the Standard, determine hazards of at-risk behavior/activity.

5. Determine if the condition represents an observation that would be recorded on the inspection report as a violation of the PSR regulatory requirements.

Agenda Examples:

A. **Option 1** - Classroom training only (2 1/2 days) Class-only option (for flexibility as an on-farm visit may not always be feasible or wanted)
B. **Option 2** - Classroom training with On-farm visit (3 full days)

A. Option 1 Classroom only

Day 1 – All day:

- Explanation of roles of those in attendance, i.e., FDA, PSA, Extension
- Discuss limitations of this program
- Discuss the overall goal of this program-Understanding to Apply
    - One farm is one farm – this is not black and white as manufacturing
    - Consistency is the key, especially when collaborating with other States
    - Consistency based on understanding the Rule
- Review/discuss resources
- Review Subpart A
    - Coverage criteria-Use FDA flowchart and supporting documentation to discuss coverage criteria
    - Review Vocabulary- "Why does this mean that"?

Suggestions:

1. *Go through Subpart A SEC. 112.3," What definitions apply to this part?" review each term or review most commonly questioned terms. See examples list*
2. *Terms used in Subpart A - At A Glance document or*
3. *Training facilitators/coordinators could survey participants before class to determine which terms need further clarification, discussion, and deep dive.*

Examples:

- *Adequate, reasonably necessary, reasonably foreseeable*
- *Covered Activity*
- *Covered Produce – covered even if the farm only sells a little of a covered product*
- *Primary Production and Secondary Activities farm definitions*
- *Mixed type facility*
- *Food/Produce – calculating sales*
- *Qualified end-user – who verifies? How is this verified? Website, spreadsheet*
- *FD&C requirements related to adulteration*
- *BSAAO – treated soil amendments*
- *Agricultural water – as it relates to the definition in Subpart A*
- *Covered, Not covered, or Qualified exempt (Terms are not interchangeable)*

- Review Subpart B- Why does this Subpart matter? (as time allows)

Day 2 – All day:

- Remaining Subpart (C, D, *F, I, K, L, O) review with scenarios mixed in
- Review enforcement discretion

Day 3 – ½ day:

- Defining the difference between audits, inspections, and investigations
- Techniques
  - Interactive inspectional process
  - Systems thinking - looking at the big picture
- Review and discuss Egregious conditions
- Other additional topics
  - Interstate commerce (Produce farms along state lines)
- Debrief of program

B. Option 2 – Classroom and On-Farm Visit

Day 1 - 4 hours (1/2 day for morning travel)

- Explanation of roles of those in attendance, i.e., FDA, PSA, Extension
- Discuss limitations of this program
- Discuss the overall goal of this program-Understanding to Apply
  - One farm is one farm – this is not black and white as manufacturing
  - Consistency is the key, especially when collaborating with other States
  - Consistency based on understanding the Rule
- Review/discuss resources
- Review Subpart A
  - Coverage criteria-Use FDA flowchart and supporting documentation to discuss coverage criteria
  - Review Vocabulary- "Why does this mean that"?

Suggestions:

4. *Go through Subpart A SEC. 112.3," What definitions apply to this part?" review each term or review most commonly questioned terms. See examples list*
5. *Terms used in Subpart A - At A Glance document or*
6. *Training facilitators/coordinators could survey participants before class to determine which terms need further clarification, discussion, and deep dive.*

Examples:

- *Adequate, reasonably necessary, reasonably foreseeable*
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- *BSAAO – treated soil amendments*
- *Agricultural water – as it relates to the definition in Subpart A*
- *Covered, Not covered, or Qualified exempt (Terms are not interchangeable)*

Day 2 – All day:

- Review Subpart B- Why does this Subpart matter? (as time allows)
- Remaining Subpart (C, D, F, I, K, L, O) review with scenarios mixed in
- Review enforcement discretion

Day 3 – All-day

- Morning – on-farm assessment
- Afternoon – Debrief of on-farm activity
    - Debrief by asking each team to identify their top three concerns/violations.
    - Discuss the concerns, what part of the Rule applies, and why.

Day 4 – ½ day:

- Defining the difference between audits, inspections, and investigations
- Techniques
    - Interactive inspectional process
    - Systems thinking - looking at the big picture
- Review and discuss Egregious conditions
- Other additional topics
    - Interstate commerce (Produce farms along state lines)
    - Optional:
        - Remaining subparts -E and F
            - Subpart E – Agricultural Water (can be time-intensive, plan accordingly)
                - The dates for water testing compliance have been pushed back to begin for large farms in 2022 and are currently not evaluated during inspections.
            - *Subpart F – BSAAO
                - Certain sections still under FDA review. Those farms that choose to use untreated BSAAO's one element of this area (time to harvest after applying untreated BSAAO) are reserved until further scientific studies are completed.
- Debrief of program