


Down the Rabbit Hole: What You Asked About

A white rabbit is sitting in a lush green field. To its left is a large, old tree with a thick trunk that has a dark, circular hole at its base. Sunlight filters through the dense green canopy of the tree, creating a bright, hazy glow in the background. The overall scene is peaceful and evokes the classic story of Alice's Adventures.

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PRODUCE SAFETY ALLIANCE

Educator Adventures in FSMA Land

- There is a lot of confusion and the PSR evolves
 - Coming up with a clear response can be a challenge
- But ... usable information is available
 - FDA: Preamble, Draft Guidance, Stakeholder Updates and TAN
 - Outreach: University, Extension, Commodity groups, Farm groups
- As a Death by PowerPoint course, you will not get buy-in
 - Go beyond the standard curriculum
 - Make content engaging and impactful
- Connect FSMA to the real world
 - Link requirements to best practices
 - Help work through decisions



Connecting FSMA to Reality

- Not everyone learns the same way
- Some content is hard to 'get' off the farm
- Inquiry/scenario based learning requires you to be sharp
 - Apply material to a realistic setting



Connecting Your Answers to Reality

- A lot of the PSR language is not actionable
 - “as necessary” ... really?
- Be real, but also be careful about giving advice
 - The grower might listen to you and follow your advice
 - Your interpretation of the Rule might not match the Inspector’s
- Most people want a concrete answer
 - The recommendation for one person might not be appropriate for use by everyone in the room
 - A guiding principle is more likely to be appropriate for everyone
 - FDA language is usually safer than your interpretation



Sifting the FDA's Language

- FDA and others have released literally thousands of pages of information about the PSR
 - ORGANIZE!!! Make a list of helpful links
- A few key resources
 - Preamble to the Produce Safety Rule, 2015 publication
 - PSR Draft Guidance for Industry, 2019 publication
 - Fact Sheets and Stakeholder Updates from FDA PSR web page
 - NECAFS Clearinghouse
 - Outreach materials created by Regional Centers and other stakeholders
 - Volunteer-contributed TAN responses



Introduction to Today's Activity

- Team-based fact finding
 - Realistic scenarios or questions based on your requests
 - Each has regulatory, GAPs, and soft skills components
 - Step 1: Review and discuss scenario in break-out
 - Step 2: Switch with another group and critique
- All break-out group members should participate in the discussion –
 - You may encounter these questions from growers
 - Answer with care regarding technical content and message
- These scenarios are constantly updated
 - Give your feedback for improvement!



Warm Up Scenario: Agritainment & Visitors

- Happy Acres Farm is a medium sized, diversified farming operation
- The farm grows produce on ~30 acres, including both covered and non-covered commodities
 - The farm sells \$150,000 in PRODUCE per year
- Farm includes a seasonal petting zoo along with a U-pick operation and a farm market
 - Farm market sells additional food items totaling \$720,000 FOOD produce and value-added food sales
- Happy Acres plans to start a 50 member CSA this season, with Thursday share pick up at the farm market



Warm Up Scenario: The Question

- The owner of Happy Acres Farm approaches you during a Grower Training course
 - Am I covered by the Produce Safety Rule?
 - Am I doing what needs to be done for my visitors?
 - If I start a CSA, what might change?



Happy Acres Farm Store

Includes men's/women's restrooms
(2 toilets, 2 sinks each)

This is where customers pay for U-Pick, entry to petting zoo.



U-Pick Operation

Each customer receives a clean, plastic bucket with a liner that is removed when weighing for final purchase.

Happy Acres is thinking about adding a sanitizer stand at the entrance to the petting zoo.



Happy Acres Petting Zoo Area
currently has a handwashing station inside the area
but it is rarely used.

Dissecting this Scenario

- **What really matters?**
 - What are the risks to produce and consumer safety
- Petting zoo and produce in one area
- Easy access between animal area and produce area
 - Hand sanitizer is not a replacement for hand washing
- Inconvenient placement of hand washing stations
- Unknown level of communication with visitors

Regulatory Aspects

Relevant requirements of the Produce Safety Rule

What is Happy Acres Farm required to provide to visitors:

- Which people on the farm are visitors?
- Do visitors have to be trained?
- Facilities and harvest containers provided for visitors
- Other 'smart' policy decisions
 - Pets brought with visitors



Regulatory Aspects

- **Legal stuff: What is the definition of a visitor?**
 - § 112.3(c): A visitor is any person (other than personnel) who enters your covered farm with your permission.
- **Legal stuff: What does the PSR require for visitors?**
 - § 112.33 (a) You must make visitors aware of your policies and procedures to protect covered produce and food-contact surfaces from contamination by people, and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures
 - § 112.33 (b) You must make toilet and hand-washing facilities accessible to visitors.



Regulatory Aspects

- **Are the individuals on this farm visitors?**
 - U Pick customers
 - Market customers who go to the petting zoo
 - CSA members picking up produce
 - CSA members working for a share
- **Comment 114:** Requirement applicable to all visitors, not just the ones who touch produce.
- **Comment 172:** “For example, a farm could comply with § 112.33(a) by **explaining the importance of health and personal hygiene**, including proper hand-washing procedures and the potential for contamination from ill or infected visitors, to all visitors who are likely to come into contact with covered produce or food-contact surfaces, at the beginning of a visitor's visit. As another example, **a farm could clearly post the rules applicable to visitors where they are likely to be seen and read at the beginning of a visitor's visit**, such as near the entrance or cash register at a “pick-your-own” farm operation.”
- **Comment 157:** Gives more info about ‘Pick Your Own’ operations



Regulatory Aspects

- **Is there any risk in the plan to add a hand sanitizer station to augment the unused hand washing station?**
 - **§ 112.130(d):** Sanitizer is not a substitute
 - **Comment 173:** What is/is not required for visitors versus farm workers
 - **Comment 360:** Use of antiseptic hand sanitizers
- **Is a visitor record log required?**
 - Not a required record
- **How else can the farm protect themselves from exposure linked to visitor access?**
 - Thoughtful policies and placement of facilities (see next slide)



Regulatory Aspects



Legal stuff: Are there any specific requirements for the containers that U Pick & CSA customers will be using?

- §112.116: What measures must I take when using food-packing (including food packaging) material?
 - (a) You must use food-packing material that is adequate for its intended use, which includes being:
 - (1) Cleanable or designed for single use; and
 - (2) Unlikely to support growth or transfer of bacteria.
 - (b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Educational Aspects

- Some things are not required, but smart visitor policies can help to meet Farm requirements
 - Flow of foot traffic
 - Signage to improve compliance
 - Availability of trash cans
 - When possible customers leave pets at home
 - Clear policies about service animals
 - Management of animals/manure



Writing Your Response

Recognize that the farm cannot afford to tick off its You-Pick customers

- Encourage them to
 - Make all signage language friendly
 - Do everything possible to make facilities convenient
- Speak with the farm owner with compassion
- Listen to the farm owner's concerns, and respond with thoughtful suggestions
- Avoid prescriptive recommendations
 - Identify the source and pathway of the hazard
 - Suggest multiple ways to reduce risk from the hazard
- Be Practical and Thoughtful

Example Response

What is the Real Problem in this scenario?

What Provisions of the PSA address the real problem?

What Educational Opportunities can you utilize to help the farm in the scenario maintain produce safety while staying within the PSR?

Outline THE ANSWER to the question you were asked by the farmer in the scenario.

What is the Real Problem

- Petting zoo and produce in one area
 - Animals can carry pathogens
- Easy access between animal area and produce area
 - People can carry the pathogens from petting zoo to produce area
- Inconvenient placement of hand washing stations
 - People can make themselves sick by not washing hands
 - Hand washing stations help prevent contamination to another area
- Unknown level of communication with visitors
 - People won't meet your expectations if you don't make those expectations clear

What Provisions of the PSA

List out the regulatory items

- §112.3 Definition of a visitor
- §112.4-6 Qualified Exemptions information
- §112.33 Requirements related to visitors
- §112.116 Requirements for packing containers
- §112.130 Requirements related to hand washing

What Educational Opportunities

Example policies that we discussed

Information about past outbreaks that can help make the point.

- In a similar scenario, there was an unfortunate incident in Minnesota in which a child became ill after visiting the petting zoo at a U-pick pumpkin
- That business had a multi-million dollar settlement against them
- Message this not as a scare tactic, but rather as an example of outcomes that have happened

Information about reasonable ways to meet the requirements

- How many restrooms might be needed (reference to OSHA)
- How to build a low-cost hand washing station
- Other resources available to understand “as necessary”, “when appropriate” and other flexible language

Keep the discussion data driven, not recommendations

Outline THE ANSWER

Am I covered by the Produce Safety Rule?

- Yes:
 - More than \$27,500 in PRODUCE
 - More than \$500,000 in TOTAL FOOD

Am I doing what needs to be done for my visitors?

- Not everything,
 - Should think hard about better access to hand washing
 - Must advertise policies
- If I start a CSA, what might change?
 - Probably not much, you may have more people to train

- Formulate the response in the context of this farm's realities
 - Congratulate the farm for doing such a good job with the harvest containers

Preview of Scenarios

- Sponge Roller Material
- Postharvest Water Storage
- Produce Sold for Processing
- Controlled Environment Systems
- Natural Flooding



Instructions

- Scenarios might be assigned to more than one group. Afterward, only the in-person group with each scenario will be asked to present and online participants can add additional insights.
 - All five scenarios will be discussed, but only 5 presentations will be made.
- All groups should be prepared to discuss, even if you are not selected to make the main scenario presentation.
- Break out into groups according to your assigned group number.
- Detailed instructions for the scenario response, and for the critique stage, are in your Google Doc

Instructions – Responses

- Each group is provided with a scenario and has 45 minutes to discuss and respond
 - Each scenario has discussion points and questions for your group to consider and work through
 - Groups were chosen to have a diverse set of inputs to each scenario
 - By the end of the 45 minutes, have a written response to the main character introduced in your scenario to share with the critique team

Instructions – Critique

- Each group is provided with the scenario and response and has 20 minutes to discuss
 - Critique criteria are in your instructions
 - Does the response answer the questions?
 - Is the answer understandable?
 - Are regulatory requirements and best practices discussed?
 - Is all of the information presented in the answer accurate?
 - Statements supported, including citations to the PSR?
 - Your feedback helps all of us do a better job
 - By the end of the 20 minutes, select one person to introduce the scenario, summarize the response, and provide the critique

Ready, Set, Down the Rabbit Hole!

- Find your group
- Find a place to sit
- You have **45 minutes** to discuss the scenario, spend your time wisely!
- We will provide 10 and 5 minute warnings
- Critique teams have **20 minutes** to discuss
- Be prepared to present the summary and critique in about **10 minutes** or less

