

News and Brews II

Deep Dive Topics

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Topic #1: Sponge Rollers

Instructions:

Phase 1: Find your group members and a place to sit. You will have 45 minutes to discuss the scenario below. Meeting facilitators will give a 10 and 5 minute warning.

- Review the scenario and any additional photos or resources which were provided to you.
- Discuss the questions presented, and resources that might be used to address the questions. Some “tips” are included as bonus questions to help you develop the response.
- Draft a consensus response to the scenario. Review critique elements in Phase 2 to help as you formulate your responses.

Phase 2: A second group will be asked to spend 20 minutes evaluating your written response to the scenario. Criteria for the evaluation include:

- Does the response answer the questions?
- Is the answer understandable to someone less familiar with the regulatory language?
- Does the answer clearly distinguish between regulatory requirements and best practices based on experience and data-based understanding?
- Is all of the information presented in the answer accurate?
- Are supporting resources provided or referenced including citations to the PSR (as necessary and appropriate ☺)?

The second group will present your response with critique (both successes and room for improvement) during report out. Assign one team member as your group’s spokesperson for the report out.

Scenario Group Member Names:

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Review Group Member Names:

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Scenario Responses:

What is the Real Problem in this scenario?

What Provisions of the PSR 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.

Scenario:

Cab Calloway Farms grows tomatoes, bell peppers, and squash for commercial sale. Their sales volume is about \$300K per year, and they sell wholesale. The farm manager, Jamerson Calloway, describes the following during Module 6 discussion of sanitary design.

In their packinghouse, they use a Best Cleaning Solution (BCS) brand washer/packer with latex sponge drying rollers. These sponges absorb water, and cannot be easily removed for routine cleaning and sanitation. They are replaced when visibly dirty, or when they start to degrade from use. The sponges are moist when not in use, including overnight and on the weekends, until they air dry. The sponge unit is periodically used to dry field-moist produce, independent from the washer unit. Jamerson Calloway is the produce safety manager at Cab Calloway Farms and seeks input from you prior to a scheduled Produce Safety Rule inspection.

Discussion/Questions

Write out a response for Cab Calloway Farms addressing Jamerson's question:

- Are latex sponge drying rollers acceptable for use in contact with produce, such as in this pack shed?

To help develop your response and fully meet the informational needs of Cab Calloway Farms, consider how, or whether, to address these Bonus questions.

- Is the latex sponge drying roller a food contact surface?
- What aspects of the Produce Safety Rule can Jamerson expect to be asked about during the part of the inspection when the BCS washer/packer is evaluated?
- What are the risks, and would you make any suggestions to help Cab Calloway Farms reduce their risks when using this drying unit?
 - What information would you share about what makes materials more appropriate, or less appropriate, for use as food contact surfaces?
 - What measures might help reduce the probability that the foam rollers will become contaminated?
- If the rollers are not well maintained, would you share information about "egregious" conditions considering prior outbreaks?
 - Consider the Jensen Farms outbreak in particular.
 - Is that information relevant to this scenario? Are inspectors sensitized to these issues because of this historic outbreak?

Supporting Information

Basic information about foam rubbers, including latex sponges:

https://en.wikipedia.org/wiki/Foam_rubber

One example of a real fruit and vegetable washer/packer using latex sponge drying material is the [Tew unit](#):

**PACKAGING
MACHINERY**
And Replacement Parts

**QUALITY LATEX
SPONGE DRYING
DONUTS**
#1 DRYING DONUT IN THE WORLD

PACKING LINES FOR:

- Apples
- Tomatoes
- Peppers
- Squash
- Cucumbers
- Pickles
- Cherry Tomatoes
- Egg Plant
- Gourds
- Potatoes
- Pears
- Citrus Fruit
- Mini Pumpkins
- Peaches
- And Others




**FACTORY DIRECT
PRICES**

TEW MANUFACTURING CORPORATION

WATER ABSORBER

To remove excess water from the produce as it leaves the washer and permit continuous processing, the Tew water absorber uses seven donut-style rolls. It is powered by washer.

WATER ABSORBER SPECIFICATIONS	Series 1650	Series 2450
Inside Width	16 ¹ / ₂ "	24 ¹ / ₂ "
Outside Width, Frame	26"	34"
Overall length	37 ¹ / ₈ "	37 ¹ / ₈ "
Height w/legs at min. setting	36 ¹ / ₄ "	36 ¹ / ₄ "
Intake ht. minimum	32 ¹ / ₄ "	32 ¹ / ₄ "
Discharge ht. minimum	30 ³ / ₄ "	30 ³ / ₄ "
Standard adj. up	8"	8"
Shipping wt. crated, approx.	225#	275#



ABSORBER PRICES
Series 1650\$2055.00
Series 2450\$2445.00
Crate charge if shipped- \$60.00

PRICE SUBJECT TO CHANGE WITHOUT PRIOR NOTICE

5

Additional information about “egregious conditions” that is not especially easy to find

An egregious condition is one in which an imminent public health hazard is posed if a corrective action is not taken immediately per [On-Farm Readiness Reviews](#) by MN Department of Ag

NASDA, the States, and FDA agreed on this definition of an egregious condition starting page 121 of the *On Farm Readiness Review Manual* version May 2018 (selected passages reproduced in italics below)

Conditions as outlined below would trigger a regulatory response, even if observed during a nonregulatory farm visit (e.g., during an On-Farm Readiness Review or initial inspection). In general, however, if an egregious condition on a farm is corrected immediately and no affected product is in commerce, no regulatory response is required.

Definition: A practice, condition, or situation on a farm or in a packing house that is reasonably likely to lead to:

- Serious adverse health consequences or death from the consumption of or exposure to covered produce;*
- An imminent public health hazard is posed if corrective action is not taken immediately (example: edible portions of produce contacting a potential source of contamination).*

Factors to consider in determining whether a practice, condition, or situation may be an egregious condition

Note: These factors are not intended to be stand-alone, but should be considered together in determining the impact of the findings on the produce.

The examples listed below are intended to be examples only, and should not be considered to be a final determination that the situation is or is not egregious.

Source of contamination

- 1. Type of contamination*
Examples: biological (microbial, virus, parasite) vs. chemical vs. physical
- 2. Extent of contamination source: widespread vs. limited or contained (i.e., contamination covers large amount of product vs. contamination limited to a small amount of product)*
 - contaminated water source used for overhead irrigation vs. grey water on small corner of a field*
 - rampant animal fecal contamination vs. limited animal intrusion*
- 3. Potential for farm practice, condition or situation to increase contamination risk*
 - dump tank with dead rats floating*
 - visibly filthy harvesting bins or trailer beds that cannot be adequately cleaned in direct contact with covered produce*
- 4. One-time event vs on-going practice or condition*
 - one cow got loose and contaminated one small area of a field vs allowing cattle to roam through the field regularly*
 - birds roosting in a packing house vs. occasional bird flying through a packing house*

Information about the importance of an egregious condition finding are summarized in the [NASDA Model Produce Safety Implementation Framework](#) document, page 57-59

Expectations Topic #1

What is the Real Problem in this scenario?

- Because they are vulnerable to contamination, wet for prolonged periods, and never cleaned the sponges might allow bacterial pathogens such as *Listeria* to regrow

What Provisions of the PSR address the real problem?

- § 112.123(a) use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained
- § 112.123(d) inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces
- Subpart A: Coverage and Exemptions, Exclusions

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

- Coverage status (probably not eligible for qualified exemption due to market)
- The latex sponges are a food contact surface, would you put your lunch on them?
- Examples, such as Jensen Farms, in which inappropriate materials rendered food contact surfaces difficult or impossible to clean, contributing to outbreak
- Information that might be available about closed-cell versus open cell materials
- Information that might be available about whether latex foam can support the growth of bacterial pathogens
- The PSR does not require washing of produce

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

Are latex sponge drying rollers acceptable for use in contact with produce, such as in this pack shed?

- The answer to this question is not obvious. We can discuss some risk factors and ways to reduce the risk. Ultimately it is a regulatory question and up to the inspector.
 - As a Small Farm, not exempt, you can expect educational inspection in 2020
- To get an answer from the regulatory agency, consider submitting a question to the TAN
 - You could also offer to ask the regulatory agency in your state, or put Jamerson in contact with the inspectional unit if appropriate to the relationship
- Our main goal is to reduce risks to produce; some ways to do this are:
 - Do not dry 'dirty' produce on the foam rollers
 - Use sanitizer in water used to wash the produce to reduce the risk of cross-contamination from produce onto the rollers
- Be aware that if the rollers are wet, dirty, degraded, and otherwise appear to be contaminated a visitor with regulatory authority might view the condition to be "egregious" based on the history of outbreaks such as Jensen Farms. We do not know if this is the case, but it is one more reason to maintain clean and sanitary sponges.

- Consider whether it is necessary to wash your produce; it may be just as easy, and less of a risk, to use a dry brush process or spot-wipe produce with a clean cloth (so long as you maintain cleanliness of the cloths)

Topic #2: Postharvest Water

Instructions:

Phase 1: Find your group members and a place to sit. You will have 45 minutes to discuss the scenario below. Meeting facilitators will give a 10 and 5 minute warning.

- Review the scenario and any additional photos or resources which were provided to you.
- Discuss the questions presented, and resources that might be used to address the questions. Some “tips” are included as bonus questions to help you develop the response.
- Draft a consensus response to the scenario. Review critique elements in Phase 2 to help as you formulate your responses.

Phase 2: A second group will be asked to spend 20 minutes evaluating your written response to the scenario. Criteria for the evaluation include:

- Does the response answer the questions?
- Is the answer understandable to someone less familiar with the regulatory language?
- Does the answer clearly distinguish between regulatory requirements and best practices based on experience and data-based understanding?
- Is all of the information presented in the answer accurate?
- Are supporting resources provided or referenced including citations to the PSR (as necessary and appropriate ☺)?

The second group will present your response with critique (both successes and room for improvement) during report out. Assign one team member as your group’s spokesperson for the report out.

Scenario Group Member Names:

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Review Group Member Names:

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Scenario Responses:

What is the Real Problem in this scenario?

What Provisions of the PSR 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.

Scenario:

Phillip Toccus is a Plain (e.g., Amish or Mennonite) farmer. He and his family operate a horse-powered farm with about 5 acres in tomato, sweet corn, beans, onions, squash, eggplant, and a variety of other commodities. The produce is sold as lots at the [local auction house](#), and the auction manager is encouraging its farmer community to be GAP audited. Phil decides he'd rather not share his farm's sales figures with you.

Phil approaches you at a PSA Grower Training and says his farm uses a [spring box](#) as its main water source, that feeds into a holding tank. Water from the tank is used to wash produce, and to mix pesticides and other foliar applications. Water from the tank is also used for household drinking water. The water has never been tested.

Phil is also considering the example of his neighbor, because sometimes his spring box does not yield enough water to meet the combined needs of the farm and the family house. This neighbor uses a separate water tank at the packing shed to hold municipal water that he pays to have trucked in as needed.

In both households, compressed air is used to provide water pressure in an air-over-water pressure tank. The [Ordnung](#) under which Phil and his family live does not include use of technology or operating motorized vehicles, but does include use of internal-combustion machinery for specific, necessary, tasks such as pumping water and cutting pond ice. Consider the specific cultural requirements of this farmer as you formulate your response.

Discussion/Questions

Write out a response for Phil in response to his questions:

- What test, at what frequency, would you recommend for the water?
- What if the source of the water changed to the municipal water source scenario?

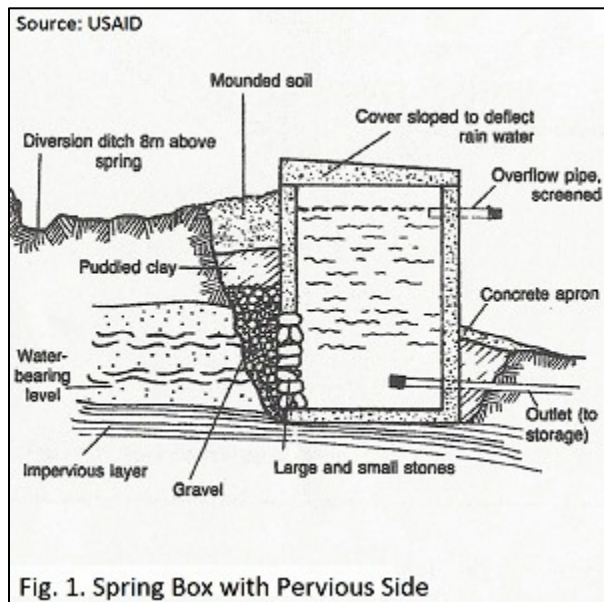
Remember that Phil is considering sending water for testing to maintain produce safety, improve market access and meet legal requirements. To help develop your response and fully address the question, consider how, or whether, to address these Bonus questions.

- What are some potential sources of contamination for the water source?
- What is the status of water-related requirements under the Produce Safety Rule?
 - How do you communicate this information? What would the requirements be if Subpart E were in effect, as currently written?
 - Can you provide other information about water testing, such as for drinking water use, with appropriate context?
- Is the water from the spring box surface water or ground water?
- Is use of sanitizer required, or advised, for any of the stated uses?
- Would the farm ever be required to clean the water tank(s)? How often?

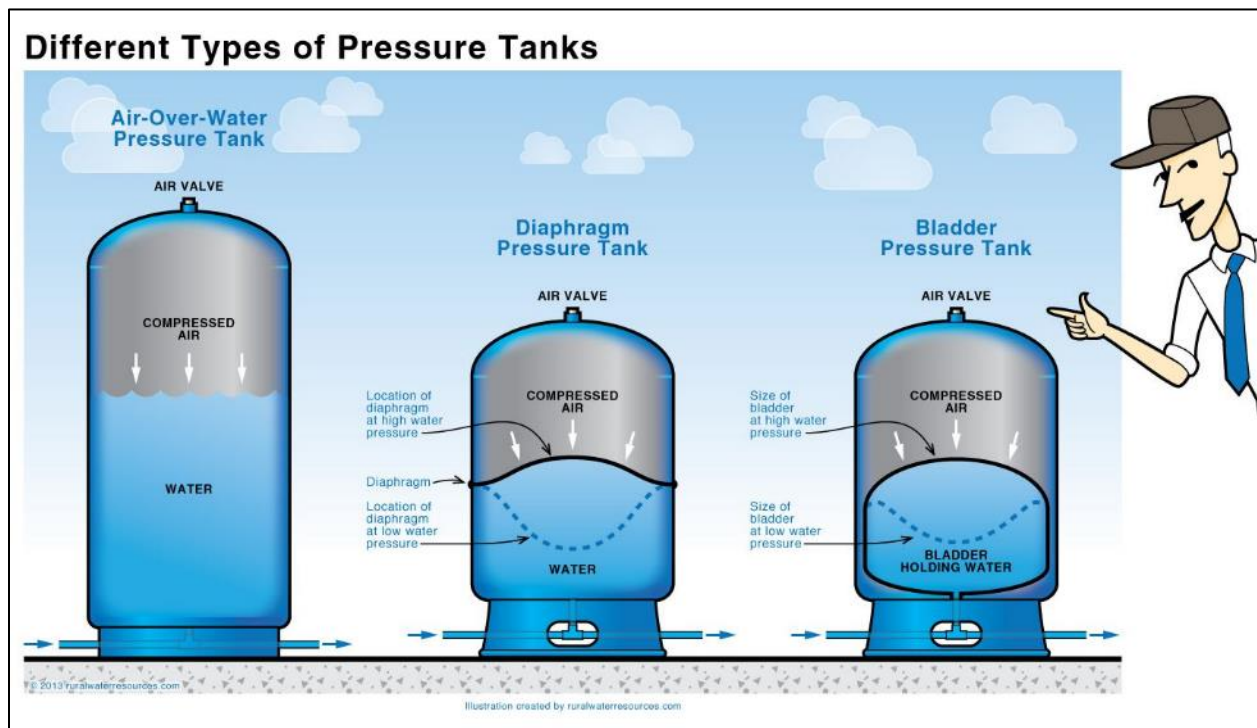
As part of this discussion, you may find yourself formulating questions to ask Phil. If so, formulate the question and also describe how you would respond to some possible responses as part of your discussion (you may assume a particular answer to simplify your responses).

Supporting Information

Diagram of a box spring from a US AID site *A Layman's Guide to Clean Water: [Spring Development May Be a Clean Water Option for Some Communities](#)*



Compressed air pressure tanks diagram from Planet X Town Hall [topic: Water wells and pumps](#)



One form of cistern/water tank, from [National Tank Outlet](#)

5000 GALLON BUSHMAN BLACK RAINWATER COLLECTION STORAGE TANK

also called water storage container, water cistern, rainwater tank, water tank



- ✓ Complies with FDA standards 21 CFR 177.1520 (1) 3.1 and 3.2
- ✓ UV Stabilized Resin to prolong the life of your tank
- ✓ BPA Free Polyethylene Resin
- ✓ 5 Year manufacturer warranty
- ✓ Features 16" Screened Manway, two 1" Outlets, & 3" Overflow

ⓘ Water tanks are designed for water storage only.

ⓘ Images may be inaccurate. See specs table below to ensure accuracy.

Quick Summary	
PART#	MPN: 45567 / Store ID: X6173512
DIMENSIONS	129" Diameter x 96" Height
LIQUID ACCESS	1 Manway / Lid, 3 Outlets, 1 Inlet

OTHER COLOR OPTIONS

- Green - Rainwater Tank
- Mocha - Rainwater Tank

~~\$2,350.00~~ **\$1,999.99**

15% Off MSRP Guaranteed for 9 hours only

Another form of cistern/water tank from [The Homestead Survival](#)



Expectations Topic #2

What is the Real Problem in this scenario?

- The produce safety problem is that the water may be contaminated at the source, in the distribution system, or in the holding tanks. If the water is contaminated, it could contaminate the produce when used in production or postharvest.
- There is a secondary problem that you don't know the specifics of this farm's water system, geology, and equipment and you don't know their coverage status

What Provisions of the PSR address the real problem?

- § 112.3 definition of surface water and ground water
- § 112.41-48 water quality criteria and may not use untreated surface water in postharvest
 - Compliance date extension
- § 112.2, 4-6 definitions of business size class, exemptions and exclusions

Other requirements that might be discussed are

- FD&C Act prohibition on selling adulterated produce (relevant even if not covered by PSR)
- EPA Total Coliform Rule which only applies to public water supplies, but is relevant as a benchmark for safe drinking water

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

- You could spend all day on education, so be careful here. Keep in mind that a typical Plain community stops formal education at 8th grade, though many individuals will be life-long learners. Since this is a lot of information, and you don't know much about his system, suggest a site visit if that fits within your role.
- Talk about pathogens as something that is so small it can't be seen, but can multiply in the body and make a person sick. Even if the water comes out of the ground and tastes sweet, it could have pathogens in it. Those pathogens are an issue for water used for drinking, for pesticide mixes, for irrigation, and for washing.
- Talk about manures and human waste as the main sources of pathogens that make people sick from eating and drinking, usually causing diarrhea (that can be life threatening)
- Once the landscape is established, you can introduce the idea that there is one kind of bacteria, *E. coli*, that is cheap and easy to detect and it is associated with manure or human waste contamination. If you test the water and there's little or no *E. coli*, you can be more confident in using the water.
- By sampling at the TANK, you can know if your whole system is 'clean'. If you have *E. coli* in the tank, then you will want to track down the source of the problem. You'd

sample at the source (box spring) first – if that’s clean, then you should work to find the source of contamination to your distribution system.

- When it comes to regulatory requirements, you should consider taking privately with your Extension or other trusted resource about status. Give Phil a copy of the Decision Tree for coverage.
 - If Phil feels like he might be covered, discuss compliance dates
- When it comes to market access, explain the difference between an audit and an inspection. Make sure your recommendations to the answer clearly distinguish Drinking Water, Audit Requirement, and PSR Requirement

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

What test, at what frequency, would you recommend for the water?

- Since this water is used for drinking, it’s a good idea to send a sample to the County Health department for potability testing. That test is usually cheap (if not free) and would give you valuable information about generic *E. coli* for wash and spray uses.
- If the potability test is positive for *E. coli*, or if the potability test is just as expensive as a straight quantitative *E. coli* test, get at least one generic *E. coli* test
 - Unless you have reason to believe that the system is open to the environment, in which case recommend 3 or more to satisfy audit for surface water
 - If Phil doesn’t have access to a lab, offer to help him find a lab since he does not have internet access

What if the source of the water changed to the municipal water source scenario?

- For municipal water source, the focus of the response would be more on maintaining integrity of the distribution system since the water from the truck should be clean without fail.

Topic #3: Produce Sold to Processors

Instructions:

Phase 1: Find your group members and a place to sit. You will have 45 minutes to discuss the scenario below. Meeting facilitators will give a 10 and 5 minute warning.

- Review the scenario and any additional photos or resources which were provided to you.
- Discuss the questions presented, and resources that might be used to address the questions. Some “tips” are included as bonus questions to help you develop the response.
- Draft a consensus response to the scenario. Review critique elements in Phase 2 to help as you formulate your responses.

Phase 2: A second group will be asked to spend 20 minutes evaluating your written response to the scenario. Criteria for the evaluation include:

- Does the response answer the questions?
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- Is all of the information presented in the answer accurate?
- Are supporting resources provided or referenced including citations to the PSR (as necessary and appropriate ☺)?

The second group will present your response with critique (both successes and room for improvement) during report out. Assign one team member as your group’s spokesperson for the report out.

Scenario Group Member Names:

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Review Group Member Names:

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Scenario Responses:

What is the Real Problem in this scenario?

What Provisions of the PSR 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.

Scenario:

Angelica Shauber is the food safety manager at Aceto Farms, a cabbage farm in the Finger Lakes region of New York (about \$1 million annual sales). During the PSA Grower Training course, Module 1, Angelica asks questions about her farm's status. Since the questions were specific to Aceto Farms, the training team put her question in the Parking Lot and discussed her specific situation with her during break. Your training team wishes to share appropriate information both with Aceto Farms and with the class as items in the parking lot are retired.

Aceto sells their cabbage into three food chains:

- Kimchi Manufacturers, Ltd, purchases \$500,000 annually, on average, and creates Kimchi products sold unpasteurized in vacuum packs and jars
- Das Flatulente Deutsch, Inc, purchases \$300,000 annually, on average, for processing into sauerkraut, sold fresh (unpasteurized) in vacuum packs
- Local Goodness Grocery Stores, a regional chain covering a 500-mile radius including 8 States and Canada, purchases \$200,000 annually for in-house processing at the deli in various stores (sauerkraut and kimchi) as well as fresh sales in the produce department.

The different sales avenues demand different varieties of cabbage; as such, the produce is grown in three distinct fields. The same equipment and labor teams are used at the three fields. The cabbage is harvested manually, and field packed into retail or wholesale boxes. The green head cabbage destined for sauerkraut is cored in the field during harvest.

All three buyers are also in New York, and Aceto Farms contracts with a hauling company to bring the product to the buyers' warehouses. All three buyers sell their respective products throughout New York and the surrounding region.

Discussion/Questions

Angelica asks you to clarify the coverage status of Aceto Farms, and help her understand the resulting requirements for the farm.

- What can you tell Angelica about the Produce Safety Rule coverage status and associated (general) requirements for Aceto Farms?
- What topical information is appropriate to share with your class?

To help develop your response and fully address the question, consider how, or whether, to address these Bonus questions.

- What is the business size class of Aceto Farms?
- Is Aceto Farms eligible for a qualified exemption?
- Which FSMA Rules should Aceto Farms be aware of? Is Aceto Farms covered by any of the other FSMA Rules?
- What are some major potential sources of contamination to the cabbage?
- How are these risks addressed by Produce Safety Rule requirements?
- Are the processes used for creation of kimchi and sauerkraut 'kill steps'?
 - What is the impact of this on Aceto Farms?

Supporting Information

Vacuum packed and jar packed Kimchi product, such as [Seoul Kimchi Original](#)



Colorado State University Fact sheet [Understanding and Making Kimchi](#)

Vacuum packed sauerkraut product, such as [Flannagan's Krrrisp Kraut](#)



Colorado State University Fact sheet [Understanding and Making Sauerkraut](#)

Napa cabbage harvesting and packing at [The Produce Nerd](#)



Green head cabbage harvesting and packing at the [Democrat & Chronicle](#)



(Photo: Sherry Griffo, Submitted photo)

[*Sauerkraut leaves Shortsville: What's next for a region steeped in sour stuff*](#)

[*NY agriculture more than a lot of cabbage*](#)

Expectations Topic #3

What is the Real Problem in this scenario?

- Workers and management may have the impression that the cabbage going to processing poses no food safety risk
- Workers and management may be challenged to effectively separate equipment and practices between fresh-sale and process-sale cabbage

What Provisions of the PSR address the real problem?

- Subpart A coverage, exemptions, and exclusions in general
- §112.2 Commercial processing (kill-step) exclusion specifically
- §112.111 Measures to take for grow, harvest, pack or hold both covered and excluded produce
- All other provisions of the PSR, at a minimum for the fields destined for the grocery

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

- Discuss what is a kill step. Rely on FDA's [Food Safety A to Z](#) for guidance-driven information, for example.
 - It says "Most bacteria will not grow in acidic foods with a pH level below 4.6. Microorganisms thrive in a pH range above 4.6. That's why acidic foods, such as vinegar and citrus fruits, are not favorable foods for pathogenic bacteria to grow in. However, bacteria may survive in the food"
- Talk about why the processed items may be considered excluded, while the fresh-sale are not excluded
 - Again, be sure you know they are excluded if you are going to be definitive. Otherwise, provide concepts as your factual information.
- Have a conversation about segregation of covered from excluded produce, and what it means to the farm's operations
- Talk about other Rules. In particular,
 - Decisions made on the farm about when and where to cut the cabbage may cause parts of the farm operation to fall under PC-HF Rule not PSR. Consult [FDA Guidance](#) in support.
 - Decisions made to contract transport versus transport using farm equipment have bearing on [Sanitary Transport Rule](#). Become familiar with the farm exemption to Sanitary Transport to be sure and give accurate recommendations related to transport.

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

What can you tell Angelica about the Produce Safety Rule coverage status and associated (general) requirements for Aceto Farms?

- Business size class is “other” meaning more than \$500K produce sales, and separately not eligible for a qualified exemption (>\$540 food sales). That means the compliance date for most provisions (other than water) was 2018 and as things happened the first (educational) inspections were 2019.
 - Aceto Farms can expect to have a visit from PSR inspectors; in New York, NYSDAM does the inspections.
 - Consider whether to treat the field sold to processing as covered produce or excluded produce. It might be easier to just treat them all the same.
Recommend training course such as the PSA Grower Training to learn more.
- Be aware of [Activities Classification](#). Field coring is considered a part of harvest, but if coring or other pre-processing steps move into the packinghouse then Aceto Farms might be considered a mixed farm type facility

What topical information is appropriate to share with your class?

- Your understanding, gained during side-bar investigation during the course, about what constitutes a kill step for purposes of §112.2 would be useful to share with the class. The specific information about Aceto Farms’ coverage and decisions would be less suitable for sharing.
- Discuss interplay among PSR, PC-HF, and Sanitary Transport Rule in general, if applicable to others in the course.

Topic #4: Controlled environment productions systems

Instructions:

Phase 1: Find your group members and a place to sit. You will have 45 minutes to discuss the scenario below. Meeting facilitators will give a 10 and 5 minute warning.

- Review the scenario and any additional photos or resources which were provided to you.
- Discuss the questions presented, and resources that might be used to address the questions. Some “tips” are included as bonus questions to help you develop the response.
- Draft a consensus response to the scenario. Review critique elements in Phase 2 to help as you formulate your responses.

Phase 2: A second group will be asked to spend 20 minutes evaluating your written response to the scenario. Criteria for the evaluation include:

- Does the response answer the questions?
- Is the answer understandable to someone less familiar with the regulatory language?
- Does the answer clearly distinguish between regulatory requirements and best practices based on experience and data-based understanding?
- Is all of the information presented in the answer accurate?
- Are supporting resources provided or referenced including citations to the PSR (as necessary and appropriate ☺)?

The second group will present your response with critique (both successes and room for improvement) during report out. Assign one team member as your group’s spokesperson for the report out.

Scenario Group Member Names:

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Review Group Member Names:

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Scenario Responses:

What is the Real Problem in this scenario?

What Provisions of the PSR 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.

Scenario:

Johannes Hannanis grows strawberries. During Module 2, he makes a point of telling you that he grows strawberries. Just. Grows. Strawberries. He is not interested in training people on topics other than growing strawberries. He is not interested in writing things down to make inspectors happy. He grows strawberries with the help of two seasonal employees.

The way Johannes grows strawberries is hydroponic, using a tubular PVC system to support plants and circulate water. In part to control pests (e.g., spotted wing drosophila), and in part to extend the season for his day-neutral berries, Johannes grows under glass.

This year was not a great year for Johannes; his farm suffered a series of production setbacks. Total sales in 2019 (the first year of production) were \$20,000. He plans to have a great year in 2020, though, in part because of his plans to open up the production area to You-Pick customers (Johannes LOVES the idea of having You-Pick customers walking around tasting the berries and learning about his operation).

As you talk with Johannes, he gets more friendly and starts to share more. You learn that the berries are his retirement plan. He spent most of his life growing row crops. He still sells \$1.5M per year of corn and soybean and hopes to sell off that part of the farm in 10 years to focus on his true passion, growing strawberries. He thinks it will go nicely with the You-Pick pumpkin patch that he co-manages with his wife on the same property, bringing in \$30,000 per year.

Discussion/Questions

Following the training, Johannes participates in an OFRR. He contacts you because the OFRR people told him, to his surprise, that he was covered by the Produce Safety Rule and that he would need to start training his two employees who help with the berries.

- Is Johannes covered by the PSR?
- What elements should be in his training plan (in particular, related to “the standards established by FDA in subparts C through O that are applicable ...”)?

To help develop your response and fully address the question, consider how, or whether, to address these Bonus questions.

- Are all of Johannes’ products being sold under the same farm business?
- What are the major produce safety risks that you anticipate for the strawberries?
- How are those risks related to specific requirements in the Produce Safety Rule?
- What training elements would help to reduce those risks, as related to subparts C through O?
 - Would his training geared toward subparts C through O be different if the berries were grown outdoors, rather than in a controlled environment?
- If Johannes opens his operation to visitors, how might that change his training plan?
- How does the attitude Johannes showed at the beginning of the training impact how you communicate your information to him?

Supporting Information

One example of a PVC hydroponic system is the INTUBUYING system shown for sale on [eBay](#)


INTBUYING Hydroponic 6 Pipes Grow Kit Pump - 141118

★★★★★ Be the first to [write a review](#) | [About this product](#)

Your pick
\$118.00

Brand new
\$87.46

Make an offer:
brand new







Your pick
\$99.00
+ \$19.00 Shipping

or Best Offer

Get it by **Tue, Oct 15 - Tue, Oct 29** from Scarborough.

- New condition
- 30 day returns - Buyer pays return shipping



3+

Example of a glass-covered growing area for hydroponic strawberries (image borrowed with gratitude from [Farmtario](#))



A typical visitor that Johannes hopes to attract during You-Pick season, viewed at a different farm (image from [Inquisitive Wanderlust](#)).



Expectations Topic #4

What is the Real Problem in this scenario?

- Johannes and developing a culture of food safety at his farm. He is unaware of the Produce Safety Rule and appears resistant to the knowledge.

What Provisions of the PSR address the real problem?

- The PSR does not address this cultural problem but it does affect your discussions with Johannes.
- Definition of a Farm. If all three income streams are under the same farm, then the inclusion of strawberries to current sales of pumpkin and grains will trigger a shift in coverage status (e.g., now the farm is selling covered produce).
- Subpart C, training, is the crucial regulatory aspect but all parts of C through O are relevant to the strawberry operation.

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

- Understand the status of the three operations as one farm, or distinct businesses. This is crucial to understanding the status of the farm from a regulatory perspective. Johannes should probably seek legal advice on this topic.
- Regardless of coverage status, understand that fresh strawberries are different from pumpkins and grain crops when it comes to produce safety. Encourage Johannes to seek additional GAPs or other produce safety training
 - Talk through the main sources of risk in a typical confined operation: workers (hygiene and illness), pests (birds and rodents), general sanitation (which they generally have covered by combatting plant disease)
- Look at the Draft Guidance document for information about estimating produce sales amounts during transition or start-up periods

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

Is Johannes covered by the PSR?

- Probably, if the entire business is considered one farm. The education person should avoid saying anything definitively because this is really important and we really don't know. Do not give advice on legal matters.
 - More than \$27,500 produce, more than \$540,000 food
- Even though Johannes has only one year of fresh produce sales, at less than \$20K, the 'farm' may have a history of \$30K-plus in produce (pumpkin) sales.

What elements should be in his training plan (in particular, related to "the standards established by FDA in subparts C through O that are applicable ...")?

- Encourage Johannes to pay close attention to worker illness, worker hygiene, pest control, and general sanitation in his policies, SOPs, and worker training. This is a subset of the whole spectrum, because (in general) the confined agriculture operation has less risk due to BSAAO, wildlife, water (if well managed) compared with an outdoor operation that uses direct-contact irrigation.
- Be particularly supportive and convincing and fact-based because of the resistance shown during early conversation.

Topic #5: Flooding

Instructions:

Phase 1: Find your group members and a place to sit. You will have 45 minutes to discuss the scenario below. Meeting facilitators will give a 10 and 5 minute warning.

- Review the scenario and any additional photos or resources which were provided to you.
- Discuss the questions presented, and resources that might be used to address the questions. Some “tips” are included as bonus questions to help you develop the response.
- Draft a consensus response to the scenario. Review critique elements in Phase 2 to help as you formulate your responses.

Phase 2: A second group will be asked to spend 20 minutes evaluating your written response to the scenario. Criteria for the evaluation include:

- Does the response answer the questions?
- Is the answer understandable to someone less familiar with the regulatory language?
- Does the answer clearly distinguish between regulatory requirements and best practices based on experience and data-based understanding?
- Is all of the information presented in the answer accurate?
- Are supporting resources provided or referenced including citations to the PSR (as necessary and appropriate 😊)?

The second group will present your response with critique (both successes and room for improvement) during report out. Assign one team member as your group’s spokesperson for the report out.

Scenario Group Member Names:

•

Review Group Member Names:

•

Scenario Responses:

What is the Real Problem in this scenario?

What Provisions of the PSR 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.

Scenario:

Atlantis Farms, in Southern Illinois, grows and sells \$750,000 per year in cantaloupe wholesale. The cantaloupe are grown on plastic-covered mounds and the vines often grow into the furrows between mounds. Just before flowering, the fields flooded causing many of the vines to show signs of stress. However, some of the vines did set fruit and Atlantis Farms was able to harvest about 75% of their normal yield.

During Module 5.1 of the Grower Training course, Annabella Stulzberg asks you whether they were wrong to harvest those cantaloupes and sell them in 2019. She went on to share with you that the farm is downstream from a small city that is known to release sewage (combined sewer overflows, CSO) during unusually wet weather into the river that flooded her fields. The season is already over, and the fruits have been sold, but she is concerned for her customers.

A week after the course, Annabella calls you and tells you that her food safety auditor requires that she test the fields for microbial hazards if she wants to pass the audit in 2020. She does not know what to test for, but she feels that she must accommodate the requirement since her main buyer requires a food safety audit. She asks for your help.

Discussion/Questions

Answer the following questions that Annabella asked.

- Were the melons safe to harvest and sell in 2019?
- What should Annabella do about the affected fields in 2020? How can she do better in the future to plan for flooding situations and respond to them?

To help develop your response and fully address the question, consider how, or whether, to address these Bonus questions.

- Were the cantaloupes adulterated when the plants were flooded in 2019?
- Are there any ramifications in this scenario related to the Produce Safety Rule? In particular, consider whether the 2019 flooding event constitutes a ‘known or reasonably foreseeable hazard’ for crops grown in 2020.
- What testing could you advise, if any, to help Annabella be confident growing produce in the affected fields in 2020?
- What is the impact of not testing on the audit process in 2020? Assume that Atlantis Farms operates under the Harmonized audit standard.

Supporting Information

Cantaloupes growing on black plastic, shared by the [University of Florida](#)



Example of flooding after fruit set, shared by [Purdue University](#)



Expectations Topic #5

What is the Real Problem in this scenario?

- Sewage could carry pathogens with flood water and contaminate the plants, the melons, and the soil.

What Provisions of the PSR address the real problem?

- There is not much directly in the PSR. §112.11 is the catch-all.
 - Take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce
- Consider whether §112.83 applies: required if there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce
- Consider also the definition of [Adulteration](#)
- Food contacted by natural flood water is adulterated; refer to [FDA Guidance to Industry](#)

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

- Talk about the pathogens in sewage, and their longevity in soil
 - There are risks associated with high intensity, high pathogen load application such as land-applied sewage (e.g., [Toranzos](#) 2003)
 - After a year, very low microbe survivorship is expected. It's a matter of initial concentration and how long for the log-removals to bring them down to acceptable levels. Reference [FDA guidance](#) for guiding principles
- Transfer of pathogens from soil to produce
- Discuss the nature of the audit, as a points-based system
- Discuss the variability of soil testing, and the inability to test for every pathogen with detection limits that are relevant to public health
 - Expect highly variable distribution of pathogens, if any, in the soil post-flood so one sample tells you little and may be misleading
 - Generic *E. coli* is a good start for understanding risk of fecal-oral pathogens, especially for fresh contamination, but over time different die-off rates for different organisms makes it less and less relevant
- Know what's in the Harmonized Standard

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

Were the melons safe to harvest and sell in 2019?

- Circumstantial: risk factors would be whether the flood water touched blossoms or fruit, whether the melons grew in contact with soil or plastic that was affected by flood water, and whether other factors like raindrop splash or wind may have transferred pathogens potentially in the soil to the melons.

What should Annabella do about the affected fields in 2020?

- Testing soil for common indicators or pathogens is an option, but be sure to know what you will do with the data if they are detected
- The auditor may reduce points for Harmonized F1.1 The food safety plan shall, initially and at least annually thereafter, evaluate and document the risks associated with land use history and adjacent land use including equipment and structures.
 - Work with the Annabella to find out what tests the auditing body would consider convincing in this regard
 - Discuss whether it is worth losing the points